دستور الأدوية الدولي

The International Pharmacopoeia

الطبعة الثالثة

Third Edition

Volume 3

Quality specifications

المجلد الثالث

مواصفات الجودة

تمت الترجمة في المركز العربي للتعريب والترجمة والتأليف والنشر بدمشق

منظمة الصحة العالمية 1988

World Health Organization 1988

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The International Pharmacopoeia

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Volume 3 ƘǁƒƙǁƐ ɋǂƜƋǁƐ

Quality specifications ƴɋNjƜǁƐ ǀƒƨƬƐNjƋǄ

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World Health Organization 1988

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ǦǤĦǂƨƗ ǿƗǦǦǒ ǾǾǤǦǦǩ *International pharmacopoeia* ƑƩǢƗ ǦǦƩǂǦǩƗ ǿƩǤǦǦ ǦǦƩǂǦǩƗ ǦƩǦǦǒƗ ǦƩǦǦƩƗ ǦƩǦǦƩƗ ǦƩǦǦƩ

ČŁţÅĦöä ČĦUÔöä ČţŢÅŋ ğÅŁòžǩ 3ŋ ȧÀÛöä ŏÅÕQţä Ęžäžţ^Ąş ÛČţŁŸèş ČÛÊĠŋ ČĄÆŁŸÕǩ ČŁąÅŁţŁõ ŇęÀù ČÕäÅÊöä ğÆÕĦţä ȧÀÛöä .[1]ŇÛèžţŋ şÛ ŇK8ò ÅŢŸţ3 ȧÅÛφ ȷžÓΛ UøQöä ČĄşǻȷä ǻǻžDZ ČäÅęø ğäΞQÁţ ČŋàŸöä ğäÆĦţÅä ČÕŸĦQţä Uţţ^Ąş ÛÿÅŋȷä Бŭ UøAùžöä ?žţÊţä ržŸ3 ČĄóžţèǻ KĄÅĦŋ ÈŁèüǩ 3žǻ Ž БşÆöä ČĄşǻȷä óžţèǻ ǯÅţţÛ Æ3ÅÊΛ ČŋÅ3 ŇęÀù БşÆöä ČĄşǻȷä óžţèǻ ďĦĠΛş ÛȷäÆŸĠöä ka 3èäş žU ržŸ3 ČĠÊţÓţţä ğäΞ]äş 3ÅΛöä ğäæ ȯǻÅĠţöä ğÅŁŸţ3 3Ŕơ ǻÆΛÆDZ ğÅDzţΛŋ ržŸ3 Ōä ÛÙÕž ČĄşǻȷä óžţèǻ Ž ČŸţţÎţä ǻäžţä ržŸ3 ÈŁö ĘŁĠÛţŸö ČŸäÅę ȷžÓǩ ȷÛ ďÓţ ÕĦŸĦţţö .ŇŔΛÛ registration ÕŁDzÊǩ ČŁŸţŤö

ğÅĠŸÛţţäş ğäÆĦţäş ȧÀÛöä Ž ČφşÀţä âÅŁÕŋ ržŸDzţΛş ÛŇţţŤŋ Õöæ ȷžÓΛ Åţţ3Ł ğ БşÆöä ČĄşǻȷä óžţèǻ ZŁÓţΛ БşÆöä ČĄşǻȷä óžţèǻ ĆŁţΛ ČŁΛÙžöä KǩÅèÆöä ďŋ ÆΛÆĦöä 3ŋ ČφóÅÕţÅäş ÛΞèäş žU ržŸ3 ŇŁţÅ3 ¢ÕÅţţĦţèä ÕţŢÊǩ UøQöä ğäÆĦţŸö ÕŔžȷä ÿäÆÁţèŕä ďŋ ďÓţ ČŸΛÆä ȧÀÙ ÿäÆÁţèä Ξ3 ÅŢÕŁÕÕŢ Æz UøQöä ğÅĠŸÛţţä 3ŋ ČφşÀţä ďŋ ŇÆΛÂŋ ÿäÆÁţèÅä ĆţţÊǩ monographs ğäşÀžȷä ďŋ ÆΛÆĦöä Ž ČΛţŔţŋ ČŸΛÆä 8äÅĦţèä ȧÀÙ ÆDZžǩş .ğΞ]äş ČŁŸŸĦţöä ȧÀÙ ȷžÓǩş ÛďţţÕöä ČŁöÅď ğÅŢŢDZÛ ǻžDZş U3ÆţÊǩ UøQöä ČŁąÅŁţŁõžΛÅŁÅöä ğäøÅĠţţŋŕä ďŋ ŇŕÆä ČΛÆŁŸÕţöä ČŁŸŸĦţöä ȧÀÛöä ȷąÅţöä ŁÆĦǩ ÕÎöä ȯÅg Ž ďÓöş .ČŋÆÁţÊţä ČΛóžţèÆöä ȧÀÛöä ?Ægţ ÕäÅÕŋ ČÕäÅè ČŁęşÆÕŋ ğäæ ČŸΛÆĠöä ČÊΛÅÕţä ČSÅΣä UŁ БşÆöä ČΛşǻȷä óžţèǻ Ž ržÛĦţä öäÀDZqä Ęžş ÅŢŸŸ3 ȯžÔΣä ĻţΛ UøQöä

žŁ Åţţõş .ÆŸÖä äØŁ Ž ĘŁĠÛţŸö ČŸäÅę ČĦĠÛöä ČØT ČÕäÅÊöä ğäÆŸÖä Ž ČΛţŔţä ÕŸŸĦţţöä ȧÀùş ČŋÅĦöä ğÅŢgŸţä ąÛ UąÅŋŸöä) Ægäş ÕÓÌ ďŋ ÄŷõÛ Ęžş ČŋÆÁţÊţä ǻäžţä Ž ČęŸĦöä ğäæ ȯÅÓÌȷä ğÅĠŸÛţţŋ 3ŁţΘ ?ÀDZ 2 ÆŸÖä Ž ȯÅΣä ȷÅŁä ?ÀDZ ďÓöş ÛgÆŁgş gäşÀžÛ Ž (ȯÅŷţä ÕŁĠè ržŸ3 ÛĻŁÕĦöäş ďÕĦţŸö ÕäÅÕöä Ǩď şÛ Ûhydrated UąÅţţäş anhydrous .U3žφ ÕÓÌ ďÕõ Ž ãžŸÛţţä ÆÊŒ ČŸÔÅţţä ğäøÅĠţţŋŕä

ääžţä ŘĦä Ž ĻţţÓ ğŕÅg ąÅÌǩ ČΛÆŁŸÕţöä ČŁŸŸĦţöä ȧÀÛöä ržŸ3 äÅŁţţ3ŕä Ž ŇÅφÛ ÅŢΛ3 ČžΛţţä ČèÅŁÊöä ďŋ ĻďÀöÅäş БÅ3 ÕąÅÊöä ãäÀÎţèŕä" ÿäÆÁţèÅõ ČŁŸŒ ȧÀù Ξ3 ČŁžÅõ ČφęäÅŋ äžDZş (bleomycins ğÅŁÊŁŋžŁŸĠöä ÕŸŋ) ğÆÕĦţţä ČØŁ ržŸ3 ÆŸÖä äØŁ Ž ğääşÀžȷä ďŋ ÆΛÆĦöä ÕŁţţÅä ÆÕž ÕöØö Ü"High-pressure liquid chromatography Ù8ŔöäğŸΛÆĦţţöä Ž 1 ÆŸÖä Ž ğÅÛĦţţä ČÕΛÀÛöä Ž ÒžţÅ ČĦÅžŋ Version ČDZäÀÅÅÛ ŘĦŕŕş ÕÅäžţţöä ržŸ3 ŇşÅÅğş .ČÕΛÀÛöä ĻÅä ȯÅŁ3 ČŁŸŸĦţöä ğÅĦÛŸÛÕţţä Ž ğÆΛÆŕä ČÕ3ÂφÅöä ţÅČǩŕ ŇÀŢφş .[2]373-387 ğÅĦÅÔöä 2ş 1 ďΛÆŸÖä ržŸ3 ČŁžÅŕqä .''High performance liquid chromatography ÅÅÕqä 3ŁžÅöä ÕąÅÊöä ãäÀÎţèŕä'' ĆĠÔŁÕ ČÕΛÀÛöä ČØŁ âÅŁę) ČŋÆÁţÊţä ČÊΛÅÕţä ČÕΛÀù ȷȷ ŇŁŸČÕţÊŋ ŇĦŁÕÅǩ Praziquantel ÕŁφäžÓΛäÅΞöÅä ČÕŸŸĦţţä gäşÀžȷä ÆŁÛţǩ ĻďóŞ .БşÆöä ČΛşǻȷä óžţèǻ ¢ŁÕ 8ÆŢΛ Åŋ Ęžş ČĠèÅŋ ČÕΛÀù ÆŸǩ B (öäÅţΣä ŘơČŸÌȷä Ž UţÒöä UąžŔöä ZŁÛöä ğÅŁèóÅŢŸĠöä öäå ČĦžÅÓŋ ȷŋÅφÅä Ž ÕŁφäžÓΛäÅΞöÅä ČŁZÛ ȷÅĠÊΣÅä ďΛØÒÛ UŁ ÅţõŞ gäşÀžȷä ÀÎφ øÅÕǩ ÕöäÆ

[1] ČŁţÅĦöä ČĦUÔöä ČţŢÅţ UøAÕφöä ÀÅÅÕφöä ČŸÊŸè 1984 Û704 Ļęó

[2] ČŁäÅĦöä БÛ БşÆöä ČΛşǻȷä óžţèǻ ČPÅǩ ÆΛ3 ČÕäÅÊöä ČĦäóȷä ğäÆŸÖä ržŸ3 ǻÅÌÅŋ ÈŋÅĻä ÆŸÖä ČΛÅŒ ržφφǻ ğŸΛÆĦφöä ÕõŞ ŘŸÌÅäÛ (ȷžPÅφţä)

[illegible] Schistosomiasis [illegible]

[illegible]

[illegible]

specific [illegible] absorbance [illegible] ($A_{1\,cm}^{1\,\%}$) [illegible] extinction [illegible] ($E_{1\,cm}^{1\,\%}$)

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[1] [illegible] 1984 [illegible] 704 [illegible] 49.

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l ƒøĭNjøƤƟDŽǁƐ

ǦƤƱÁÔõã

5 ..... ÁƤƬƢq

7 ..... ÄȮȉ Ǧƭŷõ

10 ..... ǧãǻşÄzǰã

379 ..... ǦƤƭDzΣã ŌƤõÅǂãş øÁǤǫȎȉrã ŌƤõÅȚ ÛƵ ȉãzȮõã Ǧƭəǰę

l ƐǫNjƥƷŬƐ

ǦȺÂƤŷõqã ǦÁÊÁõÅã ǻøş Åȵ ÆÊƜ zƤ ǦƤãÄȦõã ŏÅƵjã ÆƤkÄk

ǦƤƱÁÔõã

47 ..... ȷşàǰŷƤȵÅǤƤǦõã ǧãKõÅz

50 ..... ƱȺÁÆȺKǦƤǦõã

52 ..... ƱȺÁÆȺKǦƤǦõã ÁȺøzŷõşøÁƤƤ

54 ..... kÊƤȵzŷǦõã ÁȺøzŷõşøÁƤƤ

58 ..... kÊƤȵzƤŷǦõã ǧÅÁŷè

63 ..... ȷÅÁŷèzã

64 ..... ȳzƤÊõÅȮõã ǧÅǫzãÄõ

66 ..... ȳzƤÊõÅȮõã ǧÅÆƤõzz

69 ..... kǦȺàÅȵÅãÄȮõã

72 ..... ÅãşÁƤãÄȮõã

74 ..... ŌƤèzǦȵãøzŷȮõã

76 ..... ȯzȮƤÁÆÅȵãøzŷȮõã ǧÅǤƭÅã

78 ..... ƱȺÁƤÊȮŁøzŷȮõã ǧÅǤƤèÛ ƱəÅÅǫ

ǦƤƱÁÔõã

17 ..... ȳzƤÁÆȵzůǰã ÁƤƤÊõşøÁƤƤ

19 ..... kèÅȮƤȵǰã

20 ..... kèÅȮƤȵǰã ǧÅÁŷè

23 ..... ÁȺøzŷƤȵǰã ÁȺøzŷõşøÁƤƤ

25 ..... kõÅȺǻzȵÛ

27 ..... B kÊȺKǰzÅȵÛ

30 ..... ǦŘÅõã ǧãÄǫp

32 ..... ƱȺÄãzƤǫãÄÛ

34 ..... kèãÄǫƤèÅã

37 ..... ŌǫÂõã kèãÄǫƤèÅã

39 ..... ȳzȺøÅǦõã ǧÅÁŷè

41 ..... ȷşàÅǫƤȵzŷȮǦõã ǧÅǫzƤãşÄã ƱəÅÅǫ

44 ..... kǫãÂøȺǦõã kŷÊȺã ŌȺÂøȺã

140 ..... ƙÊŁŋşÀŽȚóqą̈ ğÅŁÊÒè ÕŁŽȚÚ
142 ..... ƙÊŁŋşÀŽȚóqą̈ ğąóÅŁQè
145 ..... óŁÁŁğ̈ Ƙǫ̈ j̈ą̈
147 ..... ÆŁŋÅǫzŽȚÚ
149 ..... àşÆȚÆΣą̈ ğąóÅŋȚzȚ
151 ..... ƀȚóàzǫŁèzŸȚ
154 ..... JşÂŁƙózõşóÅzŸÅóą̈ ğÅǫŁèÙ
156 ..... ƙÅÊȚózŸÅóą̈ ȳzȚÅzò
160 ..... ÕŁèąózȚşózŸȚ
163 ..... ƙŋŗÅ8óą̈ ÆȚÅzŁŽȚÀƙ
165 ..... ƙÊŁŋÅǫȚąą̈ ğÅÅŸè
167 ..... ÆŁŋŸÒȚǤŁŸdŋ
169 ..... ƙąşÀƙÅŋzTą̈ ÆŁŋÀąşóÆŁŁ
171 ..... ƀȚàŗąóÆŁTą̈ ÆȚózŸõşóÆŁŁ
173 ....JşÂŁƙózõşóÆŁTą̈ ȳzȚÅzò ğÅŁÊÒè
176 ..... ƙŋŗÅązõzÊõşóÆŁŁ
179 ..... ƙŋŗÅą̈ zõzÊõşóÆŁTą̈ ÆȚózŸõ
179 ..... ƙŋŗÅązõzÊõşóÆŁTą̈ ğÅÅŸè
183 ..... ÆŁŁÓóą̈ ȧÀȝ
186 ..... ȳzŁèÅƙzGóą̈ ğąÀǫŁè
188 .....ÕȚÀǫÊŁDZ ózǫzÅŁõ
190 ..... ƙÊõşƙǫzÅŁŸóą̈ ȳzȚÅzò
193 ..... ÆŁŋąƙązŸóą̈ ÆȚózŸõşóÆŁŁ
195 ..... ȳzȚÂŁÅ8ţą̈ ÆŁÊõşóÆŁŁ
197 ..... ȳzȚÂøÅ8ţą̈ ÆŁÊõÙ
200 ..... òşàąÆÆǤŁŋ
80 .....ƀȚÆŁÊÒŁzŸÒóą̈ ÆȚózŸõşóÆŁŁ ȤąÅǫ
83 ..... ƙŸÒŁèąÀǫƙzŸÒóą̈ ÆȚózŸõşóÆŁŁ
86 ..... ƀȚÆŁǫŁtŁÊóą̈
89 ..... ƙȚàÅzzŸÒóą̈
91 .....ƀÅŁŋzŸÒóą̈ ğąÀǫŁè
93 .....ƙÊŁÎózÒóą̈
96 ..... ÆŁŋÅÅÊŁzŸÒŁÊóą̈
98 ..... ƙąąóÅǫŁÊóą̈
100 .....ƙŋÅÊõşƙÅȚÆóą̈ ğŸŁÊŋ
102 ..... ƙÆŁȚşóÆŁTȚÆóą̈ ÆȚózŸõşóÆŁŁ ȤąÅǫ
104 ..... JşàÅŽŁŋÅÊÒȚÆóą̈ ȳzȚÅzò ğÅÅÊŋ
107 .....JÅzózŽŁŋşÀǫÊÒȚÆóą̈ ÆŁŋÀąşóÆŁŁ
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112 ..... ÆŁǫÅÊõzŸȚÆóą̈ ğąşózz
114 ..... òşÀąÅõƙȚÅ
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265 ..... ƙŸȮƛèȧȦǫǩ ƱÊõşɟȧ ÁΛǿzŸõşǿÁƛƛ
269 ..... ȯzŋȦǫƛèȧǿȦȧ
271 ..... ƙÊƛŋzŋşǿȦǿȧ ğȦȦŸè
273 ..... ƙŋŸƛÊȦǿȧ
275 ..... ȡΛÁƛŋȦǫȦǿȧ ğȦǫzƛǫΛÂΛŬ
277 ..... ȡΛÁƛŋȦǫȦǿȧ ğŸƛÊƛŋ
279 ..... ȡΛÁƛǫƛǿȧ ÁΛǿzŸõşǿÁƛƛ
281 ..... ɟzΛǡȦÁƛŋzǫƛz
284 ..... ȷƱȦȦǿȧ ɟȧÀÛę
284 ..... ȮƛǫȧzȮΛèȧÀȧ
286 ..... ɟzȯşÂƛφǡÀȧ ğȦǫƛèŬ
289 ..... ÁƛÊƛÁƛȧşƎǿȧ
291 ..... ƙŸÊȦȧ ȮΛÂøȦȧ ƙΛȦõşÀȧ
293 ..... ȡΛèȦȧǿȦõşƎǿȧ ÁΛǿzŸõşǿÁƛƛ
295 ..... ȡΛèȦŸƛŋşƎǿȧ ÁΛǿzŸõşǿÁƛƛ
296 ..... ÁƛŋȦǫzƛƙşƎǿȧ
299 ..... ȮƛǫȧKǿȧ ğȦǫzǿŬ
302 ..... ÁƛŋȦΛèȧKȧ
304 ..... ƙŋȦŸƛzKǿȧ
305 ..... ȡΛÁƛÁƛȮǿȧ ğȦȦŸè
308 ..... ƙȦƛȮǿȧ ğȦȦŸÊƛȧ
311 ..... ƙȦƛȮǿȧ ÁΛǿzŸõşǿÁƛƛ ƱəȦǡǫ
313 ..... ƙÊƛǿŋȦȦΛǿ
316 ..... ȯzŋȦƙzǿȦÊǿȧ
202 ..... ğȦÊõÀƙzŸƛŋ
204 ..... ȳzƛǫzƛǫ ȮƛŸƛŋȧ ÁΛǿzŸõ
207 ..... ÁƛŋȦȧzŸõzǫƛŋȧ ÁΛǿzŸõşǿÁƛƛ
209 ..... ğȦǫzȦΛÀǫƛŋ
211 ..... ȯşÀȦǫzȮƛŋȧ ğȦÀǫφ
213 ..... ɟzÊõzȮȦǿȧ ÁΛǿzŸõşǿÁƛƛ
216 ..... ȳzΛǡzÔǿȧ ȳzƛÊȮȦõ ğȦǫΛÁΛŬ
218 ..... ȳzΛǡzÔǿȧ ğȦÀǫè
220 ..... ȳzΛǡzÔǿȧ ğȦȮƛŸdzŋşÀõ
223 ..... ȳzΛǡzÔǿȧ ÁΛǿzŸz
224 ..... ȳzΛǡzÔǿȧ ƙΛÀǫφ
226 ..... ȳzΛǡzÔǿȧ ÁƛèşȦȧşÀǫφ
288 ..... ȳzΛǡzÔǿȧ ğȦǫzõzŸdzƛǫè
230 ..... ȳzΛǡzÔǿȧ ğȦȦŸè
233 ..... ƛȧŋŸǿȧ ȳzΛǡzÔǿȧ ğȦȦŸè
235 ..... ȳzΛǡzÔǿȧ ğȦȦŸèzƛǫ
237 ..... ȳzΛǡzÔǿȧ ğȧşƎȮȦz
240 ..... ƙÊΛȦŋzƛȦǿȧ ğȦȦŸè
242 ..... ƙȶ8ǫèzƛȦǿȧ ğȦȦŸè Ȯƛǫƛŋ
245 ..... ÈõzȶƛƙǿzȦƛȦǿȧ
246 ..... ȯşÀȧÁΛƙȦǿȧ
249 ..... ȳȦƛΛȧÀǫȦǿȧ
251 ..... ȡΛzǫφǿzzşÀǫȦǿȧ
254 ..... ƙȦȮèzȦǿȧ
256 ..... ƙȦȮèzȦǿȧ ÁΛǿzŸõşǿÁƛƛ
258 ..... ƙƙȦǫÊȦǿȧ

348 ..... ȳȚŁǫȚǮŁŋȦÊȮȦÊöä ÁΛǫȚŶȮ
350 ..... ɟȘǨǫèȚǫÊǫöä ǧȦǫǫȦȦΛÙ
353 ..... ƙəȦȮöäÀǫǫöä ÁΛǫȚŶȮȘǫÁŁŁŁ
355 ..... ƙŋȦŁǮöä ÁŁŋȘÀäȘǫÁŁŁŁ
357 ..... ƙŋȦŁǮöä ÁΛǫȚŶȮȘǫÁŁŁŁ
359 ..... ƙŋȦŁǮöä ǧäÀǫǫ ÞȦȦǵÙ
360 ..... ɟȘàȦǫŁèÙȚŁǮöä
362 ..... ȯȘàäÁÁäȦŁǫöä
364 ..... ÕΛÁŁȦȦŁÊȮȮTΛÀǫöä ÁΛǫȚŶȮȘǫÁŁŁŁ
366 ..... ƀΛǫäǫȚȮȚäȚǫöä ÁΛǫȚŶȮ
368 ..... ÕŁŋȦääKȦöä ÁΛǫȚŶȮȘǫÁŁŁŁ
370 ..... ƙǫÊΛÀȮȦÀöä ǧȦÀŶè
372 ..... ȳȚΛȦȚÔöä ƀΛǫȦȚǫäȘ
375 ..... ÕǫÂöä ÁŁÊȮÙ
318 ..... ȯȚŋȦȦȚǫöÀÊöä ǧȦÀŶè
320 ..... (ŦȮŋȦÀÊöä) ȦÀÊöä ǦęǫȘ
322 ..... (ŦȮŋȦÀÊöä) ȦÀÊöä ǦTȮȦȚ
324 ..... ƙÊŁŋȚÀŁǫȮǦè ÁΛǫȚŶȮȘǫÁŁŁŁ
327 ..... ɟȚǫȮŦȚǫȘǦè
329 ..... ɟȚŁŁǫǫɟä ȳȚΛȦȚò ǧäÀùÀù
331 ..... ÁŁŋȦǫŁèȦÀŶè
333 ..... ȳȚΛȦȚÔöä ÁŁŋȦǫŁèȦÀŶè
336 ..... ƀΛÁŁȚȦȦŶÊöä
338 ..... ȳȚΛȦȚÔöä ƀΛÁŁȚȦȦŶè
340 ..... ƙÊȮȘȦȦŶè
342 ..... ƀΛàŦȦèȦÀŶè
345 ..... ȳȚΛȦȚÔöä ƙŋȦǫȚè

MONOGRAPHS l ε¶Nj β ø ʒŬε

ALUMINII HYDROXIDUM

Aluminium hydroxide !Njĭıŭĭ̈DŽNj‖ŬЄ ǫĭ ƨ |Njβǫĭlj

Al(OH)$_3$:**Molecular formula** ĞŁĂΛÂƨä Ğ8ŁÔöä

78.00 :**Relative molecular mass** ĞŁGÊΛöä ĞŁĂΛÂƨä ĞŸǫÒöä

Aluminium hydroxide CAS Reg. No. 21645-51-2 :**Chemical name** ЧэĂŁŧŁÒöä ĮèŕĂ

.ĞHЧэäÀöä CÆ3 ÛĮ3Ăφ ÛJƨŸöä ŘŁäÜ Û(ÐǿƨŸä ŕ) ÕÒÎöä CÆ3 ȧƨHЧÊη :**Description** Ƨòƨöä

ÕΛǿƨŸõşǿÆŁTä Ŕβ Ž ā äşä ÜΛŁŸŧ3 TS (ȯ/ħ750~) ȯƨφĂŽΛqäş öĂŧä Ž ā äşä Ƙd :**Solubility** ĞŁφĂäşØöä

.TS (ȯ/ħ80~) ȳƨΛåƨÔöä ÆŁÊõşǿÆŁŁ ȯƨŸŢ Žş TS (ȯ/ħ70~)

.Ğŕƨŧ∑ä åĂŘη :**Category** ĞĂÀöä

.ȳĂÒǵüä ĞÕŸ8η ĞΛşĂǵ Ž ȳƨŁÆηƨȯĵä ÆŁÊõşǿÆŁŁ ŞĂǵ Æƨ :**Storage** ȼΛÂÅǫöä

REQUIREMENTS ƘĠhωĬƵkdž!f

ȼ3 ÆΛÂΛ ŕş %71.9 ȼ3 ÕÕΛ ŕ Ăη ƨŸ3 ȳƨŁÆηƨȯĵä ÆŁÊõşǿÆŁŁ Ƀƨǫƶ :**General requirement** ȳĂĬöä ÆŸÛǫŧä

.Al(OH)$_3$ ȼη %94.9

.TS (ȯ/ħ80~) ȳƨΛåƨÔöä ÆŁÊõşǿÆŁŁ ȯƨŸŢ ȼη Õη 5 Ž ƙÅÊǫöĂä ħ0.10 ā äØł :**Identity test** ĞΛƨTä ǿĂĞǫnä

.ŏĂŘŁä ĞŁηŸŁ ĞäĂèǿ JǫΛΛ ÛR ȳƨŁǫƨηĵä ÆΛǿƨŸõ ħ0.5 ŽĂÔöä ȯƨŸ‡ä Ƃŭ ȣĂŘΛ

Õη 5 Ž ÛƙÅÊǫöä 3η ÛĬħ0.5 ā äØΛ ǿĂǫnŕä ȯƨŸŢ ƘŘƠ ȣÆŏ :**Heavy metals** ĞŸŁÕŽöä (ğäÂŸÀöä) JåĂĬŧä

Û4-3 ƨǿǫǵ ĞǵĂìÀöä (pH) ŏĂŁĂä ȯŁÉĬΛ .ĞηÀŁş ÛŏĂŧĂä Õη 10 ƨǿǫǵ ƷĂƨ ÛTS (ȯ/ħ300~)ÕŁǫŁèĵä Ŕβ ȼη

ǿĂǫnŕä" JƨƨΛ3 ŘƠ ȣƨòƨη ƨŁ Ăŧõ ĞŸŁÕŽöä (ğäÂŸÀöä) JåĂĬŧä ƨŸǫŢ ȼŁΛ .ƷÂƨş ÛŏĂŧĂä Õη 40 ƨǿǫǵ ƷĂƨ

ŕ Ü(129 ĞHЧÁÔöä Û1 ÆŸŎä) A ĞÕΛÀÛöä ÆÊШ "Limit test for heavy metals ĞŸŁÕŽöä (ğäÂŸÀöä) JåĂĬŧη ÕDZĵ ƂÆΣä

.ħ/ȳäÀdşÀÒη 60 ȼ3 ÆΛÂΛ

ȼη Õη 35ş TS (ȯ/ħ100~) ÕΛǿƨÀŸÊöä Ŕβ ȼη Õη 20 Ž ħ3.3 ÂŁõÀǫä ȯƨŸŢ ȳÆÅǫÊΛ :**Arsenic** ÑŁφǿÂöä

"Limit test for arsenic ÑŁφǿÂöä ÕDZĵ ƂÆΣä ǿĂǫnŕä" JƨƨΛ3 ŘƠ ȣƨòƨη ƨŁĂη ÆÊШ ÕŧĬħöä ÕŧÒǫÊΛş ÛŏĂŧĂä

.ħ/ȳäÀdşÀÒη 5 ȼη ÀŽõÜ ÑŁφǿÂöä ƨƨŸǫŢ JƨÒΛ ŕ JÜ Æƨ Ü(130 ĞHЧÁÔöä Û1 ÆŸŎä)

ȯȚ ȡ Ď 25 **:Ammonium salts** ȚȡȚ Ď 5.0 ȡ Ď 100 ȡ Ď 200Ș TS (ȯ/ȟ200~) ȚȡȚ Ď 25.0 VS (ȯ/ȯȚ 0.1) ȚȡȚ Ď 22.5 ȡ Ď 2 Ž ȟ0.10 **:Chlorides** ȚȡȚ Ď 10 ȟ/ȚȚ 10 ȡ Ď (129 Ž ȟ0.10 **:Sulfates** ȚȡȚ Ď 5 ȟ/ȚȚ 5 ȡ Ď (125 Ž ȟ0.50 **:Neutralizing capacity** ȚȡȚ Ď 37 Ž ȟ 0.05) (ȟ/ȚȚ 3.0Ș 2.3Ș 1.8 ȡ Ď 20Ș 15Ș 10 ȯȚ 37 Ž ȟ 0.5) ȚȡȚ Ď 10 .4.0 ȡ Ď (ȯ/ȯȚ 0.1) ȚȡȚ Ď 200 Ž ȟ 0.04 (pH) **:Alkalin impurities** ȚȡȚ Ď 10.0 ȡ Ď

Ž ȟ/ȚȚ 3.900 VS (ȯ/ȯȚ 0.5) ȚȡȚ Ď

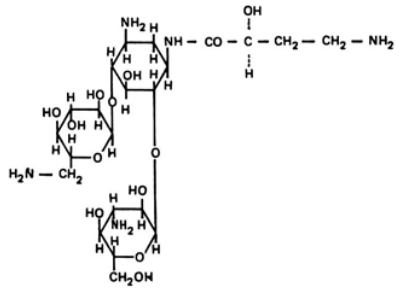
AMIKACINUM

Amikacin – DžĭƨƑłĭDŽŬɛ

:Molecular formula ǦɛĬʌÂƨä Ǧ8ɛÔöä $C_{22}H_{43}N_5O_{13}$

:Relative molecular mass ǦɛǦÊʌöä ǦɛĬʌÂƨä ǦŸǫȮöä 585.6

:Graphic formula ǦɛǫĬʌɛǦţä Ǧ8ɛÔöä



:Chemical name ŬəĬɛţɛȮöä ȷèɾä

***O*-3-Amino-3-deoxy-*α*-D-glucopyranosyl-(1→4)-*O*-[6-amino-6-deoxy-*α*-D-glucopyranosyl-(1→6)]-*N*³-(4-amino-L-2-hydroxybutyryl)-2-deoxy-L-streptamine; (*S*)-*O*-3-amino-3-deoxy-*α*-D-glucopyranosyl-(1→6)-*O*-[6-amino-6-deoxy-*α*-D-glucopyranosyl-(1→4)]-*N*¹-(4-amino-2-hydroxyoxobutyl)-2-deoxy-D-streptamine; CAS Reg. No. 37517-28-5.**

:Description Ƶòƶöä .ĬǦʌÀÖǩ ǦHɄəäÀöä CÆȝ ÛɄƶŸäæ ŘĬæÛ ƀøƶŸæ ȧƶHɄÊŋ

:Solubility ǦɛǫĬæşØöä ÔɛŸę .ǒĬţä Ž ɄĬæşØöä

:Category ǦĬÀöä .ȷɛǫäÀƨä ǎĬŘŋ ǒäşǎ

:Storage ȣʌÂǍǫöä .ÿĬȮǵüæ ǦÖŸ8ŋ ǦʌşĬǵ Ž ƙèĬȮɛŋȷä ŞĬǵ Æz

REQUIREMENTS ƚǦȣʌƵȣkdž!ƒ

:General requirement ÿĬĦöä ÆŸÛǫţä ȣŋ ÿäÀd ŞÀȮŋ 900 ȣȝ ÔÖʌ ɾ Ĭŋ ƨŸȝ ƙèĬȮɛŋȷä ƀƶǫƵ .ǦɛƨĬŋŸöä ǵǎĬţä Ƀŭ ţƶDŽÀöĬæ ÛŋŸŋ 1 Ôõ Ž $C_{22}H_{43}N_5O_{13}$

:Identity testes hŭŇjNJlIɛ ɩɛƀƑǦĦƷɛ

:A ŻÛƵÂƨŞ TS (ȯ/ȟ80 ~) ÿƶʌǎƶÔöä ÆɛÊõşóÆɛŁ ȯƶŸŢ ȣŋ Ôŋ 1 ȣĬŘʌ ÛŏĬţä ȣŋ Ôŋ 1 Ž ŋŸŋ 10 ā ǎØʌ .ŬDzÊĬæ ɄƶȯŬ ǰǫʌ ÜTS (ȯ/ȟ 10) (II) ǨöĬæƶȮöä ǵäÀǫǫ ȯƶŸŢ ȣŋ Ôŋ 2 ȣĬŘʌ

:B ŬDzÊĬæ ɄƶȯŬ ÔȮÎǫʌ Ü(Anthrone TS) TS ɄşÀƵǫɾä ȯƶŸŢ ȣŋ Ôŋ 4 ȣĬŘʌş ǒĬŋ Ôŋ 3 Ž ȟ 0.05 ā ǎØʌ

.ȧǿȁȷǎ Ƃǔ ǎǿǎȉȓ

Ƃǔ ţȚDZȂǿǎǽ ǼÊȜȘ Ȍȝ/ȝȲȝ 20 ǼǼõȂǿǽ ȯȚȲȚ ȳǼǼǾÊȂ **:Specific optical rotation** ȜȚȚǿǎ ƀȂÔǾǎ ȂȂȘǼǾǿǎ

.$[a]_D^{20°C} = 97$ to $+105°$:ǾǼǽȉȝȲǎ ǾǼǽȉȝȲǎ ǾǼǽȉȝȲǎ

1000~) ȌȂȂǾǿǎ Ȓƥ ȣȝ Ȍȝ 2 ǿǎǼȌȝ ǾǾǽȚȚǾǎ ǼȚȚȚǾǎ (ǼǼȝȂǾǎ) ȯȉȈǾȚȚȚǽ ǼȈǽ :**Sulfated ash** ȈȉȲȊȚǾǎ ǽȉȝȂǾǎ

.ȟ/ȝȲȝ 10 ȣȚ ǼȂȂȂ ȚȚ ȚǔȚ ǼȚ ȜTS (ȯ/ȟ 1760 ~) ȌȂǿȚȉȲȊǾǎ Ȓƥ ȣȝ Ȍȝ 2.0 ǾǾǽȂǽȘ TS (ȯ/ȟ

Determination of water ȂÎǼȚ ȯǿȉȌǾ ǾȌȂȂÛǽ ǾȉǾǎ ȚǼȈȟ" ȚǽȚȚ ȈȜ ȚȚǾȚȚȚ ȣǼȈȂ : **Water** ǾȉǾǎ

ǼȂȂȂ Ț ÜǾȉȉǾǎ ȣȝ ȟ2.0 ǾǾǽȂǽ ȳǼǼȉȌǾǾȂǽ Ȗ(145 ǾȜȚȉÔǾǎ Ȗ1 ǼȲǾǎ) A ǾȌȂȂÛǾǎ Ȗ" by the karl Fischer method

.ȟ/ȝȲȝ 85 ȣȚ ǾȉǾǎ ȚǽȚȚ

.11.5-9.5 ȚǽǽȂǾǾǎ ǼǼÊȌǾǾ ȜǾȉȂȚ ȣȝ ƀȉȚǾǎ ǾȉǾǎ Ž Ȍȝ/Ȝȝ10 ǼǼȌȂǾǾǽ ȯǿȲȚǎ ǾȉȚȉȂǽ ȝȲȚȂ :**pH Value** ǾȉȚȉȂǾǾǎ ǾȚǼǽ

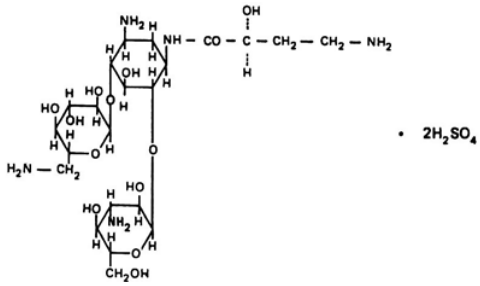
ȂȚǽǼΣǎ ȝǎǼȉȂȚȚȚǾ ǾǼǾȚǽȯǿǽǼȚǾȂȂǾǾǎ ǾÊȂȉȉǾǾǎ" ȚǽȚȚ ȈȜ Ȝǿȯǿȝ ǿȚ ȉȝ ǼÊȂȂ ǾÊȂȉȉǾǾǎ ÊǾÛǾ :**Assay**ÊǾÊȂȉȉǾǾǎ

Bacillus ǾȌǼǽȚǾǾǎ ǾȚǿÔȚǾǾǎ (*a*) ȉȝǾ ȳǼǼȂǾǾǽ Ȗ(155 ǾȜȚȉÔǾǎ Ȗ1 ǼȲǾǎ) "Microbiological assay of antibiotics

ȝȉȉÊǽ ǾǼǾǾǎ Ȗ6.7-6.5 ȣȝ ȜǼȉǾ (pH) ǾȉȚȉǽ Ƀǽ Cml ţǾǾ ȜǾǾȚ ȂǾȉǾǾȝȝȝǾǾǾǾ ȣȝ ȯǿȲȚ ȂTS3 ȚȚ TS2 ȚȚ TS1 (pH) 6.0 ǾȉȚȉǽ ȝǾǾ ǾȚǼȌȝ

ATCC) *Staphylococcus aureus* ǾǼǾȚȌǾǾ ǾȂǽȌȌȉǾǾǾ (*b*) ȚȚ Ȗ°ȳ 35-32 ȚǾ ǾȉǾȂȝ ǾȌǾǾǽǾǾ ȣǼȂȂȂȚȚȚ Ȗ(ȌȝȚȉȂȚȚȚ

Graphic formula ĞĦęĀĦĠţā Ğ8ĦÔöā:



Chemical name ŦəĀĦŧĦÒöā ţèŕā:

O-3-Amino-3-deoxy-α-D-glucopyranosyl-(1→4)-*O*-[6-amino-6-deoxy-*α*-D-glucopyranosyl-(1→6)]-N^3-(4-amino-L-2-hydroxybutyryl)-2-deoxy-L-streptamine sulfate (1:2) (salt); (*S*)-*O*-3-amino-3-deoxy-α-D-glucopyranosyl-(1→6)-*O*-[6-amino-6-deoxy-α-D-glucopyranosyl-(1→4)]-N^1-(4-amino-2-hydroxy-1-oxobutyl)-2-deoxy-D-streptamine sulfate (1:2) (salt); CAS Reg. No. 39831-55-5.

Description Ƶòƶöā:ňĞĀÀÕĭ ĞĦəāÀöā CÆ3 ÜÀĀòQţ ā øĀŕ ŘĦāŬ Бŭ ɟƶŸöā ŘĦāŬ ÛBƿƶŸā ȧƶHəÊŋ.

Solubility ĞĦęĀāşØöā:Ž ňĦŸŧ3 ā āşá Ćd Üŏāţā Ž ňÆDZ ā āşá.R ÿøƶƶşøƶŸÒöā

Category ĞĀĀöā:ţĦęāÀƨā āĀŘŋ öāşā.

Storage dbÂĀĀęöā:ÿĀÒǵüā ĞÕŸ8ŋ ĞĀşĀǵ Ž ƙèĀÒĦŋɟā ǧĀĀŸè ŞĀǵ Æz.

Labelling ţĦèƶęöā:ĞĦƶĀŕqā ǧĀĠŸÛęţā Бŭ ÆĦDzęÊĭ gāĀţā ɟŭ Бŭ ĞŧĦÕĦöā ƙèĀÒĦŋɟā ǧĀĀŸè ĞĦŧÊęöā ĆÎĭ.ʔĀnɟā ĞŧĦÕĦöā ǧĀÕĦĠÛęöā Ž şŭ ňĀÕǵ öĀÛ3qā Ž ÕŧĦęÊł ɟŭ dbÒƨş ĞŧĦÕĦöā ƙèĀÒĦŋɟā ǧĀĀŸÊö

REQUIREMENTS ĆĞnňŽƦkdž!ƒ

General requirement ÿĀĦöā ÆŸÛęţā:Õõ Ž ĞĦöşā gÆǵş 650 db3 ÕÕĀ ŕĀŋ ƨŸ3 ƙèĀÒĦŋɟā ǧĀĀŸè ƿƶęƠ.ĞĦəĀŋŸöā gāĀţā Бŭ ţƶDZĀöĀā ĞāƶÊŢ ÛŋŸŋ 1

Identification tests:ĥŭŸNjNJJIĦ ŀ ɛƥƑĞĦGIJɛ

A:Ż ÛƷÂƨş TS (ȯ/ĥ 80~) ÿƶĀāƶÔöā ÆĦÊõşøÆĦŁ ȯƶŸŢ db ŌŋĀ 1 ȣĀŘĀ ÛŏĀŋ ŌŋĀ 1 Ž ŋŸŋ10 āāØĀ.ŦDzÊĀĀā ɟƶȯ ǰęĀĀ Û(ȯ/ĥ10) (II) ĶöĀāƶÒöā ǧāĀęę ȯƶŸŢ db ŌŋĀ 2 ȣĀŘĀ

B:Бŭ āøĀŕ ŦDzÊĀĀā ɟƶȯ ǰęĀĀ ÛAnthron TS ɟşĀƷęŕā db ŌŋĀ 4 ȣĀŘĀş öĀŋ ŌŋĀ 3 Ž ĥ0.05 āāØĀ

.ȧǿȁȁ ȷȁ

General ǦȵȦȨȨȁȁ ȸȁȁȨǾȅȅȁ ǧȁǿȦǾȁȁ" ȷȁȥȦȝ ǨƠ ȸȥȍȥȵȁ A ȪȝȦȦǾȁȁ ȬȪȨȦ ȪȵȲȵ 20 ȦȅȪȪȦǾȅ ȍȥȲ‡ȁ :C .(123 ǦȬȦȦȪȁȁ Ȳ1 ȦȲȪȁ) ǧȦȦȲȦȲȲȁ ȦȁȥȵȪȝȪ "identification tests

ȤȪ ȵȥDZȦȁȦȦ ȦȦȦȝȘ ȪȵȲȵ10 ȦȅȪȦǾȅ ȍȥȲȴ ȲȦȦȵȦȦ :**Specific optical rotation** ȬȝȥȦȁȁ ȤȦȪȪǦȁȁ ȦȦȘȦǾȁȁ .$[a]_D^{20°C}$ = +69 to79° ȲȪǦȦȦȵȲȁȁ ǧȦȦȵȁȁ

(ȍ/ȥ1000~) ȪȦǾȦȁȁ Ȑβ ȥȵ ȪȵȲ 2 ǦȦȦȦȥȅ ȦȦȦȦ (ȦȦȵȦǾȁȁ) ȍȦȦǾȦȦȅ ȦȦȦ :**Sulfated ash** ȲȦȲȦȵȁȁ ȦȦȵȦȁȁ .ȥ/ȥȵ10 ȥȝ ȦȦȦ ȅ ȲTS (1760~) ȪȦȦȥȦȲȦȁȁ Ȑβ ȥȵ ȦȦȦȦȦȲ ȪȵȲ 0.2 ȦȅȘ TS

Determination of water by ȦȦȦȥ ȍȦȦȪ ǦȪȦȦȦȁ ȍȦȦȁ ȦȦȦȦ" ȷȁȥȦȝ ǨƠ ȸȥȍȥȵ ȥȦ ȦȥȪ ȥȦȦȦ :**Water** ȍȦȦȁ ȤȥȥȦ ȦȦȦ ȅ ȲȦȦȦȦȁ ȥȵ ȥȵ0.2 ǦȦȦȦȦ ȲȦȦȦȦȦ ȍȦȦȦȦ Ȳ(145 ǦȬȦȦȪȁȁ Ȳ1 ȦȲȪȁȁ) A ǦȪȦȦȪȁȁ "the Karl Fischer method .ȥ/ȥȵ 50 ȥȝ ȍȦȦȁ

.7.5-6.0 ȲȷȥȦȦȪȁȁ ȦȦȦȦȪȁȁ ȬȍȦȦȦ ȥȵ ȤȦȦȦ ȍȦȦȁ Ȥ ȪȵȲȵ 10 ȦȅȪȪȦǾȅ ȍȥȲȴ ȍȦȦȦȦ ȵȲGȦ :**pH Value** ȍȦȦȦGȁȁ ǦȦȦȦ Microbiological ǦȦȥȦȦȦ ǧȦȦȦȦȦ

.membran filtration ŏÅÎ8ŏÅæ ÓŒÌÀQŏä øÅGQòä ğäŏäÀDZŬ ĘŒGÛQæ Û(162 ŘHÅÔŏä Û1 ÆŸŎä) "antibiotics

Ĭøœ‰ΘΙΙΕ üƒDŽyƭƨúΙΙ ΥφyDŽΙΙΕ DžĭƨƒΙĭDŽŬΕ lƒ2ǂƨ üΜŬ hŭĭƷFŢä lƒGǂUƬDŽ

Additional requirements for Amikacin sulfate for parenteral use

.(56 ŘHÅÔŏä Û4 ÆŸŎä ÀŢφä) "ŘŒÅÔΣä ğäÀŘHÅQÊţä" øæ ŘòÅ‚ä gåşÀƨğä БÚ ÆŒDzQÊĭ

ŐDZj øÅGQòŕä" jäƨÅ3 ŘƠ 8ƨòƨţä øÅGQòŕä ĘGÛł :**Bacterial endotoxins** ŘŒƨƨÀƨä ŘŒŸòäÆŏä ğÅφÅÅΛØŏä

ЬƨƠ ŕ Û(ŘΛÂŒŸŏqä ŘŘGÛŏä Ž 30 ŘHÅÔŏä Û5 ÆŸŎä) "Test for bacferial endotoxins ŘŒƨƨÀƨä ŘŒŸòäÆŏä ğÅφÅÅΛØŏä

.ŕèÅÒŒƨjä dbƨ ŋŸƨ1 Ŏõ Ž RS ЧŸòäÆŏä jÅÅΛØŏä dbƨ ŘŒŏşå gÆgş 0.33 dbƨ ÀŸõŬ

!ĭŝyΙΙΕ üƒDŽyƭƨúΙΙ ΥφyDŽΙΙΕ DžĭƨƒΙĭDŽŬΕ lƒ2ǂƨ üΜŬ hŭĭƷFŢä lƒGǂUƬDŽ

Additional requirements for Amikacin sulfate for sterile use

Test for sterility of non- dbŐHŬŸŏ ŘŸäÅÔŏä Ŕd ğäÀŘHÅQÊţä ŘnÅŐ3 ŐDZj øÅGQòŕä" jäƨÅ3 ŘƠ åøş Åţ ÆŒDzQÊĭ

.(ŘΛÂŒŸŏqä ŘŘGÛŏä Ž 32 ŘHÅÔŏä Û5 ÆŸŎä) "injectable preparations

ØØØØØ

AMILORIDI HYDROCHLORIDUM

Amiloride hydrochloride φĭƥNj‡ĭDŽŬΕ φĭƥNj‡ΙNjƥφĭlj

anhydrous ĬəƒDŽúΙΙΕ ÛφĭƥNj‡ĭDŽŬΕ φĭƥNj‡ΙNjƥφĭlj

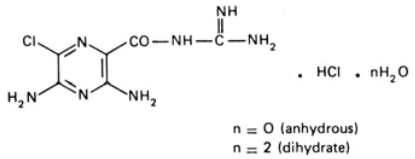
dihydrate lεƥφĭΝJΙΙΕ ĬəƒØŏk φĭƥNj‡ĭDŽŬΕ φĭƥNj‡ΙNjƥφĭlj

ЧəÅÅô) $C_6H_8ClN_7O,HC1,2H_2O$ Ü(ЧəÅ‚ ŕ) $C_6H_8ClN_7O$, HCl :**Molecular formula** ŘŒÅΛÂƨä Ř8ŒÔŏä

.(ğäøÆŒTä

.(ğäøÆŒTä ЧəÅÅô) 302.1 Ü(ЧəÅ‚ ŕ) 2661.1 :**Relative molecular mass** ŘŒGÊΛŏä ŘŒÅΛÂƨä ŘŸQÒŏä

:**Graphic formula** ŘŒφÅŒGţä Ř8ŒÔŏä



:**Chemical name** ƱəÀĖŧĖÓöä ţèŕä

N-Amidino-3,5-diamino-6-chloropyrazinecarboxamide monohydrochloride; 3,5-diamino-*N*-(aminoiminomethyl)-6-chloropyrazinecarboxamide monohydrochloride; 3,5-diamino-6-chloro-*N*-(diaminomethylene)pyrazinecarboxamide monohydrochloride; CAS Reg. No. 2016-88-8 (anhydrous). *N*-Amidino-3,5-diamino-6-chloropyrazinecarboxamide monohydrochloride dihydrate; 3,5-diamino-*N*-(aminoiminomethyl)-6-chloropyrazinecarboxamide monohydrochloride dihydrate; 3,5-diamino-6-chloro-*N*-(diaminomethylene)-pyrazinecarboxamide monohydrochloride dihydrate; CAS Reg. No. 17440-83-4 (dihydrate).

ĞHƱəäÀöä CÆ3 ŞÙ ĞHƱəäÀöä CÆ3 ÜÀŘnQţ ãóÀŕ ÀÀòÙ БÙ ŘŁÀæ ÀÀòÙ ɹzŸæ ȧzHƱÊŋ :**Description** Ƶòzöä .ÑGÀÀÕŘ

Ž ŕŞ R ȳózzşózŸÓöä Ž ãäşáé Ґd ÛTS (ȯ/ȟ750~) ȯzφÀŽÀqäş ŏÀţä Ž ɹÀäşØöä ҐĖHƱì :**Solubility** ĞĖφÀäşØöä .ÑĖŸŧ3 R Ґţ̀ä

.ȯzGöä óÆŋ :**Category** ĞÀÀöä

.ŏzŘöä ƱŋĞŧŤ ÛÑÆĖDZ ĞÕŸ8ŋ ĞÀşÀǵ Ž ÆÀózŸĖŋɹä ÆÀózŸõşóÆĖŁ ŞÀǵ Æz :**Storage** ƱÀÂÁQöä

RQUIREMENTS ҐGƱÑõkdž!ƒ

ÆÀÂÀ ŕŞ %98.0 ƱƷ ÕÕÀ ŕ Àŋ ɔŸ3 ÆÀózŸĖŋɹä ÆÀózŸõşóÆĖŁ ƲzQƵ :**General requirement** ȳÀŘöä ÆŸÛQţä .ĞÀÀÑÖä gáÀţä БÙ ţzDZÀöÀæ ĞæzÊŢ ÛC$_6$H$_8$ClN$_7$O,HCl ƱŋƱ 101.0 ƱƷ

:**Identity tests** hƱŘNjNJÑЄ lЄƥƑĞŦQţЄ

.CŞ B ƱÀóÀĞQnŕä ŞÙ CŞ A ƱÀóÀĞQnŕä ĘĖGÛŘ ƱÓƷ

öäÀŧΣä ŘƠ ĞŘìɹä ĞÕÛÀŋ Ž ƱəzŘöä ZĖÛöä âÀĖę" ɹäzÀ3 ŘƠ áóş Àţ ÑÕzş ÒHƱÀöä ĘGÛÀ :A .(43 Û1 ÆŸŎä) "Spectrophotometry in the infrared region

ŞÙ RS ÆÀózŸĖŋɹä ÆÀózŸõşóÆĖŁ ƱŋĞŸ3 ÕÔHƱQÊţä ZĖÛöä 3ŋ öäÀŧΣä ŘƠ ĞŘìɹä Ž î ÀÔQŋŕä ZĖù ĘäÀÛQÀ .ÆÀózŸĖŋɹä ÆÀózŸõşóÆĖT *reference spectrum* ƱŘDZÀţä ZĖÛöä 3ŋ

ÀŋÆÀ3 ÛVS (ȯ/ȯzŋ 0.1) ÕÀózŸõşóÆĖTä Ŕþ Ž Õŋ/ȳäÀdşÀÒŋ 5.0 ÂĖõÀQæ ȯzŸŢ î ÀÔQŋä ZĖù ƲÆĞł :B ÀQŋzφÀφ 285 ĞDZzţä ȯzÛæ ĞQĖŧŤ3Ù î ÀÔQŋä ƱøŘşóæ ÛÀQŋzφÀφ 380ş ÀQŋzφÀφ 230 ƱøQDZzŋ ȯzù Ґæ ŞǵŸł ĞDZzţäş ÀQŋzφÀφ 285 ƱŧŤ3ɹä ĞDZzţä ȯzÛäş ţè 1 ĞφÀÁǰæ ĞÕĞù ȯŸŋ ƱŋîÀŧQöä ɹzÒÀş ÛÀQŋzφÀφ 361 ĞDZzţäş .Бäzöä ɔŸ3 Û0.31ş 0.28 ĞääÀę ÀQŋzφÀφ 361

General ĞŋÀŘöä ƱäÀŘQèŕä ǵäóÀĞQnä" ɹäzÀ3 ŘƠ Ʊzòzţä A Õ3ÀÀQöä Õŋ/ŋŸŋ 5 ÂĖõÀQæ ȯzŸŧä ƱÛŘÀ :C

.(121 ČHUÁÔöä Û1ÁŸŎä) ğäÁÄóźŸÒŸö Âßtłą Ŏ3ÅÁQõ "identification tests

.ŋŸą 0.1 ďƷ ÁÄÂÄ ŕ :**Sulfated ash** ŘÁŸÊţä ǻÅąÀöä

Determination of water ÄÎŁź ȯóÅõ ǦÕÄÀÛä ŏÅţä ĸŁĦŘ" ɟäźÅƷ ŘƠ ȣźòźą źŁ Åą ÆÊŦ ďłłŘł :**Water** ŏÅţä ǴŸŧŸö ǦǦÊÁöÅä Ûgǻţä ďą ħ0.2 ǦääÀę ÿäÁÁQèÅä Û(145 ČHUÁÔöä Û1 ÁŸŎä) A ǦÕÄÀÛöä Û"by Karl Fischer method .ħ/ŋŸą 130 ďƷ ÁÄÂÄŕş ħ/ŋŸą 110 ďƷ ŏÅţä ƤźQŢ ÕÕÄ ŕ ɟÙ Æź ğäøÁŁTä ŬaÅÅQ

ÁŁÊõşøÁŁŁ ȯźŸHąŋ ÀÄÅŘłş ÛŏÅą Ŏą 50ş R ȯźφÅŽŁą Ŏą 50 ďą ǰÄÂą Ž ħ 1.0 ãäØÄ :**Free acid** ÀΣä ŘŧΣä .Ŏą 0.3 ďą ÀŽõÙ ÿÂŸÄ ŕ ÜPotentiometrically ÁŤƨä âÅŁÕą Ŏ3ÅÁQöä ǦÄÅŒ ǦÛÕφ ĸŁŘQä VS (ȯ/ȯźą 0.1) ÿźÄǻźÔöä

Thin- ǦÕǦęÀöä ǦÕǦÛöä ãäÀÎQèä" ɟäźÅƷ ŘƠ ȣźòźţä øÅǦQnŕä ĘǦÛÄ :**Related substances** ǦŏÅÎţä ǻäźţä ďą ǰÄÂąş ǦŸ8ą ǻǻÅŧõ Silica gel R1 ÅÒŁŸŁÊöä ǦąŸŁ ÿäÁÁQèÅä Û(84 ČHUÁÔöä Û1ÁŸŎä) "layer chromatography ƨŸƷ ŧŸÔÅÄą ĘǦÛÄş .õÀHUQą ózÛõ TS (ȯ/ħ 50~) ÅŁφźąɟä ďą ŁDźǵ 2ş R ɟäózź şøÁŁŁäÀQQöä ďą ŧłłDźǵ 15 ȯźŸ‡ä ÛR ÿózźózŸÒöä ďą ŁDźǵ 1ş R ȯźφÅŽŁţä ďą ÿźDźǵ 4 ǰÄÂą ďą ĸÅöúą ĸöźŸŢ ďą ÀQöşÀÒą 5 ČHUŁÅÔöä .Ŏą 1 Ŏõ Ž øÅǦQnŕä ǻÅąą ďą ÿäÀdşÀÒą 4.0 ÞźƵ :B ȯźŸ‡ä ÛŎą 1 Ŏõ Ž øÅǦQnŕä ǻÅąą ďą ŋŸą 0.4 ÞźƵ :A ȧźź ČĦÌɟÅä ãäÀÎQèŕä ÒHUÅłş öäźTä Ž ZΘ ƨøQǵ õÀQł ÛääÀÎQèŕä ǵKDźǵ ďą ČHUŁÅÔöä ţÂφ ÁĦäş ČΘÅöä ÕŸk ďą ǵÁÌ ÀŽõÙ ÛČŁÊŁąÀöä ČĦÕǦöä ŏÅŽQèÅä ÛA ȯźŸ‡ä ďą ǰQÅk ČĦÕä ǦÄÙ ɟźÒk ŕ .(ÀQŋźφÅφ 365) ČŁDźÊÅÁǦöä .B ȯźŸ‡ä ďą

Ŏą 15 ÛR1 ÕŁQŁèɟä ŘÞ ďą Ŏą 100 ďą ǰÄÂą Ž ÛČŁùźǦŘŋ Ǧφşàźŋ ÛĦ 0.45 ǦääÀę ääØł :**Assay** ǦÊÄÅÒţä 0.1) ÕÄóźŸõKǦöä Řŧłłł ÀÄÅĦÄş ÛTS ÕŁQŁèɟä ŘÞ/ĘǦąÂöä ǵÅQŁèÙ ȯźŸŢ ďą Ŏą 10ş ÛR ɟÅÊõźÄÁöä ďą ŬaÅąŸöä Ùèźöä Ž gÄÅÅĦţä" ɟäźÅƷ ŘƠ ȣźòźą źŁ Åłõ ÁŤƨä âÅŁÕą Ŏ3ÅÁQöä ǦÄÅŒ ǦÛÕφ ĸŁĦŘş VS (ȯ/ȯźą (ȯ/ȯźą 0.1) ÕÄóźŸõşKǦöä ŘÞ ďą Ŏą 1 Ŏõ .(142 ČHUÁÔöä Û1 ÁŸŎä) A ǦÕÄÀÛöä Û"Non-aqueous titration .$C_6H_8ClN_7O,HCl$ ďą ŋŸą 26.61 ùźÅÒÄ VS

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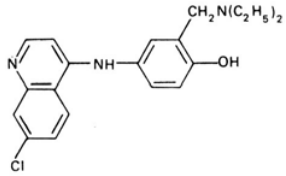
AMODIAQUINUM

Amodiaquine DžĭǀƑĭǫNjDŽć

$C_{20}H_{22}C1N_3O$:**Molecular formula** ǦŁÅÄÂƨä Ǧ8ŁÔöä

355.9:**Relative molecular mass** ǦŁǦÊÅöä ǦŁÅÄÂƨä ǦŸQÒöä

:Graphic formula ČĦąÀĦGţä Č8ĦÔöä



:Chemical name ŲəÀĦŧĦÒöä ţèŗä

4-[(7-Chloro-4-quinolyl)amino]-*a*-(diethylamino)-*o*-cresol; 4-[(7-chloro-4-quinolinyl)amino]-2-[(diethylamino)methyl]phenol; CAS Reg. No. 86-42-0.

:Description Ζòζöä .ČHυəäÀöä CÁƷ ÛÀÀòÛ ɟζŸä ЬóζŸä äζHυÊŋ.

:Solubility ČĦąÀäŞØöä .R ÿóζζŞóζŸÒöä Ž ā äŞäé ÛĦĦŸŧƷ ŏÀţä Ž ā äŞäé Ƙd.

:Category ČÀÀöä .ÀΛóŸţä äÀŘŋ öäŞä.

:Storage dΛÂÁąöä . ÿÀÒǵüæ ČÔŸ8ŋ ČΛŞÀǵ Ž ƙõÀΛäζŋţä ŞÀǵ Æz.

REQUIREMENTS ƘĜυΛΖƠƙdž!ƒ

:General requirement ÿÀĦöä ÆŸÛąţä % 103.0 dƷ ÁΛÂΛ ŗŞ %97.0 dƷ ÕÕΛ ŗ Àŋ ɔŸƷ ƙõÀΛäζŋţä Ьζąζ.
.ČĦəÀŋŸöä gäÀţä Ьǔ ţζDZÀöÀæ ČæζÊŢ ÛC20H22C1N3O dŋ

:Identity test hυŸNjNJΛΙΕ l εƥƑĜĦGţε

• .CŞ B dΛøÀĜąÒnŗä ŞǔÀ A øÀĜąÒnŗä ÀŋǔÀ ĘĦĜÛŸ dÒζ.

:A Spectrophotometry in öäÀŧΣä ŘƠ ČÕÛÀŋ Ž ŲəζŘöä ΖĦÛöä âÀĦę" ɟäζÁƷ ŘƠ 8ζòζţä øÀĜąÒnŗä ĘĜÛł .(43 ČHυÀÔöä Û1ÁŸÖä) "the infrared region

:B free base ÀΣä âÀèɟä dŋ ¢ĦŸƷ ÕÔHυąÊţä ΖĦÛöä Ƶŋ öäÀŧΣä ŘƠ ČĦÌɟä Ž î ÀÔąŋŗä ΖĦù ĘäÀÛąΛ .ƙõÀΛäζŋąţ *reference spectrum* ŲĦDZÀţä ΖĦÛöä Ƶŋ ǔŞ RS ƙõÀΛäζŋţä ÁΛóζŸõŞóÁĦT

:C ÜTS (II) ŘöÀäζÒöä ğäÀąφ/ÿζĦφζŋţä ğÀφÀĦèζĦą òζŸţ dŋ Õŋ 0.5 8ÀŘłŞ öÀŋ Õŋ 0.1 Ž ŋŸŋ 20 āäØł .öäÀŘŋ ČäÀèĦ ɟąÀŘ

A òζŸŧä dŋ ČΘÀΛöä ČĦÕĜöä ĘäÀÛąŘ ."Substances Related ČöÀÎţä ääζţä" ɟäζÁƷ ŘƠ 8ζòζţä øÀĜąÒnŗä ÀŢąä .B òζŸŧä dŋ ČΘÀΛöä ÕŸŘ Ƶŋ gÁÎöäŞ ÀΖŢţäŞ Ƶęζţäæ .ħ/ŋŸŋ 2.0 dŋ dƷ ÁΛÂΛ ŗ **:Sulfated ash** ŘŸÀÊţä äÀŋÀöä

:Water öÀţä Determination of water by ÀÎĦζ òøÀõ ČÕΛÀÛä öÀţä ƙĦĦŘ" ɟäζÁƷ ŘƠ 8ζòζŋ ζŁ Àŧõ dĦĦł

ŏÅţã ʔʒǫŢ ÆΛÂΛ ŕ ÜgǻÅţã ďŋ Ň 0.8 ȳãÆÅǫèÅæ Û(145 ǦHuÅÔõãÛ1 ÆŸŎã) A ǦÕΛÀÛõã Û"the Karl Fischer method .ň/ŋŸŋ 5.0 ďʒ

ǦÕǦÛõã ããÀÎǫèã" ɹãʒʌʒ ŘƠ ȣʒòʒŋ ʒŁ Åŋ ÆÊШ óÅǦǫnŕã ĘǦÛŁ :**Related substances** ǦŏÅÎţã ǻãʒţã ÅÆǫʒŋɹÅæ ʒǻÎŋ ȳóʒʒşóʒŸÒõã ďŋ ȯʒŸŢ ÀÆŘHuŁ .(84 ǦHuÅÔõã Û1 ÆŸŎã) "Thin-layer chromatography ǦÕÆęÀõã .ȳóʒʒşóʒŸÒõã ǦÕǦù ÕÔÅŁş TS (ȯ/ň260~) ÅÆǫʒŋɹã ʒŋ R ȳóʒʒóʒŸÒõã ŘŃ Õõæş

19 ÛÅÆǫʒŋɹÅæ ʒǻÎŋ ÛȳóʒʒşóʒŸÒõã ďŋ ȳʒDzǵ 9 ďŋ ɹΛÂŋş ǦŸǻ8ŋ ǻÅţõ Silica gel R2 ÅÒÆŸÆÊõã ǦŋŸŁ ȳÆÅǫÊŁ ÆÆę ŏÅţã ďŋ Ň 0.15 ããØŁ óÅǦǫnŕã ȯʒŸŢ ƙŘHuǫõş .õÀHuǫŋ óʒÛõ dehydrated ŏÅţã ţşÂøΛŋ ȯʒǫÅŽΛqã ďŋ ÅţDzǵ ŋŸŋ 40 ÕÕŁ reference ǦÆŘDZÀţã ÕÆõÅ+ã ƙŘHuǫõş .(A ȯʒŸŢ) ÅÆǫʒŋɹÅæ ʒǦÎţã ȳóʒʒşóʒŸÒõã ďŋ Õŋ 10 Ž ÒHuÅõã ʒǦÎţã ȳóʒʒşóʒŸÒõã ďŋ Õŋ 2.0 ȣÅŘŁ ÛǻãÆè Ьæ ÜDZÅDZà óÅǦǫnã ãʒǫǫÛ БÛ RS ƙõÅΛǻʒŋɹã ÆΛóʒŸõşóÆÆŁ ďŋ .(B ȯʒŸŢ) ɹÅǫ óÅǦǫnã ãʒǫǫÛ БÛ ȯʒŸ+ã ɹÅǦŁş ÛÀÕǫÊǫõ ǦǦŸÔõã ȳÅÊDZɹã õÀǫk .ǦÕÆęǻ 2 ǻÆŋ ǻÆÎæ ŋŘƧş ÛÅÆǫʒŋɹÅæ 10 ǦHuÆÅÔõã ʔŸʒ ŸÔÅΛŋ ĘǦÛΛ .(C ȯʒŸŢ) ÅÆǫʒŋɹÅæ ʒǦÎţã ȳóʒʒşóʒŸÒõÅæ Õŋ 200 БÛ B ȯʒŸ+ã ďŋ Õŋ 1.0 ƧÅƧ ÒHuÅŁ Ż ŏãʒTã Ž Ƨθ Ŭõ õÀǫŁ ÛããÀÎǫèŕã ǻƙDzǵ ďŋ ǦHuÆÅÔõã ţÂφ ÆŘæ .CŞ BŞ A ÕÆõÅ+ã ďŋ ÀǫõşÀÒŋ ďŋ ÅΛÆŸʒ ÕÔHuǫÊŁ ǦŘÕæ ǦΛÛ ɹʒÒk ŕ .(ÀǫŋʒǫÅφ 254) ǦÆDzÊÅΛǦõã ȧʒʒ ǦŘÌɹÅæ chromatogram ããÀÎǫèŕã ÙÛƯ .C ȯʒŸ+ã ďŋ ÅΛÆŸʒ ÕÔHuǫÊΛ ŬøǫõÃ ÕŸk ďŋ ǻÆÌ ÀŽõÛ ÛǦÆÊÆɹÀõã ǦŘÕǦõã ŏÅΛǫèÅæ ÛA ȯʒŸ+ã

(ȯ/ȯʒŋ 0.1) ÕΛóʒŸõşóÆÆTã Ŕβ ďŋ ǦÆʒÅõ ǦÆţõ Ž ÛǦÆùʒǦŘŋ Ǧǫşàʒŋ ÛŇ 0.3 ǦããÀę ããØŁ :**Assay** ǦÊΛÅÔţã ŬŘDZÀŋ ȯʒŸŢ ÀÆŸÔÅΛŋ ÀŘHuŁ .¢ÊÅφ Ùèʒõæ Õŋ 1000 БÛ ȯʒŸ+ã ãØŁ ďŋ Õŋ 10.0 ƧÅŁ ÜÕŋ 200 ŬÛŘÆõ VS 0.1) ÕΛóʒŸõşóÆÆTã Ŕβ ďŋ Õŋ 1 Õõ Ž RS ƙõÅΛǻʒŋɹã ÆΛóʒŸõşóÆÆŁ ďŋ ȳÀdşÀÒŋ 15 ʔŸʒ ƁʒǫƷ ÕãÅÕŋ ÀǫŋʒǫÅφ 342 ǦããÀę ŬţŢʒŬ ǦDZʒŋ ȯʒÛã ƙȯʒŸ+ã ŸÒõ ɻè1 ǦǫÅǻʒã ǦÕǦù ȯŸn ďŋ î Åţǫõã ãÅØŁ .VS(ȯ/ȯʒŋ ȳãÀd ŬŸÆţÅæ ÛǦÆţÒõã ÆÊÆŁ .VS (ȯ/ȯʒŋ 0.1) ÕΛóʒŸõşóÆÆTã Ŕβ ƁʒƠ ŬøǫõÃ Solvent cell ÆΛØţã ǻƙDzǵ 355.9 ɹŬ Û(355.9/428.8)(20*C*)(A_uIA_s) ǦȣÔõã ȳãÆÅǫèÅæ ÒHuÅõã ÆÆę ǻÅţã Ž $C_{20}H_{22}C1N_3O$ øŸõ Û(ŋŸŋ) ŬŁ C ÛƁãʒǫõã ʔŸʒ ÛŬəÅŋŸõã ƙõÅΛǻʒŋɹã ÆΛóʒŸõşóÆÆTş ƙõÅΛǻʒŋǫõ ƙǫÆǦÊÅõã ƙǫÆÅΛÂʔã ƙǫŸǫÒõã ÅƵ 428.8ş RS ƙõÅΛǻʒŋɹã ÆΛóʒŸõşóÆÆT anhydrous ǦÆəÅŋŸõã ǻÅţã БÛ ţʒDZÀõÅæ ǦãʒÊŢ ÛÕŋ 1 Õõ Ž ȳãÀdşÀÒţÅæ ÛÂÆõÀǫõã .Ɓãʒǫõã ʔŸʒ ÛŬŘDZÀţã ȯʒŸHuŁŸõş ÒHuÅõã ÆÆę ǻÅţã ȯʒŸ+ ɹÅÒÅŁǫõã ÅƵ A_sş A_uş ÛŬŘDZÀţã ȯʒŸ+ã Ž

AMPHOTERICNUM B

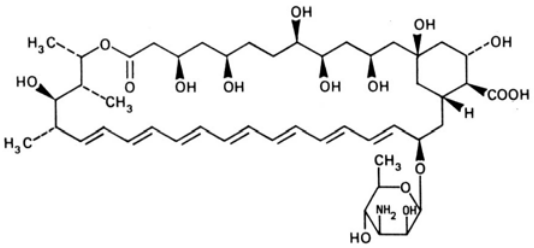
(Amphotericine B) B Dzĭƨĭƥĭ‡Nj2DŽƈ

parenteral Ĭøđŝ9ℓℓ üƒDŽy‡ƨÚε üℓℓŬ **B** Dzĭƨĭƥĭ‡Nj2DŽƈ

$C_{47}H_{73}NO_{17}$:**Molecular formula** ǦÆΛÂƨã ǦȣÔõã

924.1 :**Relative molecular mass** ČĒGÊÁõä ČĒÅÅÂƨä ČŸQÒõä

:**Graphic formula** ČĒφÅĒGţä Č8ĒÔõä



:**Chemical name** ŬəÅĒŧĒÒõä ţèŕä

(1*R*,3*S*,5*R*,6*R*,9*R*,11*R*,15*S*,16*R*,17*R*,18*S*,19*E*,21*E*,23*E*,25*E*, 27*E*,29*E*,31*E*,33*R*,35*S*,36*R*,37*S*)-33-[(3-Amino-3,6-dideoxy-*β*-D-mannopyranosyl)-oxy]-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxa-bicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid; [1*R*-(1*R**,3*S**,5*R**,6*R**,9*R**,11*R**,15*S**,16*R**,17*R**,18*S**,19*E*,21*E*,23*E*, 25*E*,27*E*,29*E*,31*E*,33*R**,35*S**,36*R**,37*S**)]-33-[(3-amino-3,6-dideoxy-*β*-D-mannopyranosyl)oxy]-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid; (3*R*,5*R*,8*R*,9*R*,11*S*,13*R*,15*S*,16*R*,17*S*,19*R*,34*S*,35*R*,36*R*,37*S*)-19-(3-amino-3,6-dideoxy-*β*-D-mannopyranosyloxy)-16-carboxy-3,5,8,9,11,13,15, 35-octahydroxy-34,36-dimethyl-13,17-epoxyoctatriaconta-20,22,24,26,28,30, 32-heptaen-37-olide; CAS Reg. No. 1397-89-3.

.ÅĒGÅÅÕĬk ČĒHuəäÅÅõä CÁÆʒ ÜĒÅÕĬkÅä ĒŬ ÅÅòŬ ɹƨŸä ȧƨHuÊŋ :**Description** Ƨòƨõä

Ž ā ąśá ÜR Ƙõɟąś R ďÅƨõƨQõäś TS (ȯ/ȟ 750~) ȯƨφÅŸÅqąś ŏÅţä Ž ÅĒŸŧʒ ā ąśá Ƙď :**Solubility** ČĒφÅąśØõä

.R ȯƨφÅŸĒţä Ž ɹÅąśØõä ĆĒHuì ÛR ÆĒÊõƨÁŸè ÕĒŸĒŋ ŬəÅÅõ ďŋ ŏõÂDZ 20 Žś R ÆĒŋÅŋøƨƨ ÕĒŸĒŋ ŬəÅÅõ ďŋ ŏÂDZ 200

.ğÅÅÅÛÅõä ąÅŘŋ ŏąśą :**Category** ČÅÅõä

gøäÅg ČDZøÆä ČφÂŬś ÛŏƨŘõä ďŋ ČĒŧŢ ÛŷÅÒgüä ČÕŸ8ŋ ČÅśÅg Ž B ƙÊÅKƙƨÅŋɟä ŞÅg Æz :**Storage** ďÅÂÁQõä

.°ȳ 8ś 2 ƙä

ğÅGŸÛQţä ĒŬ ÆĒDzQÊk gąÅţä ɹŬ ĒŬ ŬøÅÕΣä ȯÅŧĒHQèŕä ÕDZɟ B ƙèKƙƨÅŋŬ ČĒŧÊQõä KÎk :**Labelling** ţĒèƨQõä

.ÅÅÕg ŏÅÛʒqä Ž ÕŧĒHQÊk ɹŬ ďȮƨś B ƙÊÅKƙƨÅŋɟä ÕDZɟ ČĒƨÅŕqąś ČõąĒHţä

ÆÁʒ ɟÅøÆQõÅä ÛŏƨŘõä ā ÅĒd Ž ƨøQg ÛB ƙÊÅKƙƨÅŋɟä ÕØÆQÅ :**Additional information** ČĒƨÅŕŬ ğÅŋƨŸĒŋ

ŏƨŘŸõ âÅÊg ƨŤƨ ČÅÅÅţä ÕĒõÅŧä Žś .ČĒHÅKÅţä gøäÅΣä ğÅDZøä Ž ţÅèŬ ÕÒÅQõä ĆGÔÅś Ûƨƨä ČäƨùÅõ ô ÅĒHQõä

.(pH) ŏÅŧÅGõä ďŋ ČŘÅÁÅţä ţĒÕõä ÆÁʒ ¢ŸĒƨ ÕÛĒHQÅś

Ŏõ Ž ȳäÀdşsÀÒŋ 750 ȣȝ ŎŎΛ ŕÅŋ ɔŸȝ B ƚkÊΛKŽzÀŋĵä ƀzƢȝ :**General requirement** ȳÅĦŏä ÆŸÛƢĵä .ČÁȡÕä ǵÅţä БŬ ţzDZÀŏÅä ČäzÊŢ ÛŋŸŋ1

:**Identity tests** hŭŦNjNJЛЄ l ɛƥƑĠĦƢ]ɛ

øÆŎä ŦŧDzǵ ŦÛĦŏ R ȯzφÅŽŧä ȣŋ ČŧzÅõ Čŧŧõ ȣÅŘΛ ÛR ÆŧÊõzÁŸè ŎŧŽŧŋ ŦəÅÅǫ ȣŋ Ŏŋ 5 Ž ŋŸŋ 25 ā äØΛ :A ȯäzùüä ŞǵŸΛ ÅŋÆÁȝ ÛĵŽÅÁóä ȯzŸHŧŸŏ î ÅÔǫŋŕä ZÅüù ƀÆǴł .R ȯzφÅŽŧÅä Ŏŋ 200 БŬ ¢Aŋ Ŏŋ 2.0 ZȡƢŞ ÛŎŋ 50 ÛÀǫŋzφÅφ 381 ÛÀǫŋzφÅφ 362 ČääÀę ȣŋ ŽäzŋŬ ȯäzùüä ČŧŧŢȝŬ ƤØää ǫŸǫ ÛÀǫŋzφÅφ 450ş ÀǫŋzφÅφ 300 ƚkä Žäzŋĵä ÀǫŋzφÅφ 381 ČDZzŧä ȯzÛä î Åŧǫää БŬ ÀǫŋzφÅφ 362 ČDZzŧä ȯzÛä ĻÈ 1 ČφÅŽä ČŎGÛŏ ŋî Åŧǫää ČGÊφ ȷŬş .ÀǫŋzφÅφ405 .0.9 ČääÀę ŦŁ ÀǫŋzφÅφ 405 ČDZzŧä ȯzÛä ŋî Åŧǫää БŬ ÀǫŋzφÅφ 381 ČDZzŧä ȯzÛä ŋî Åŧǫää ČGÊφ Ü0.6 ČääÀę ŦŁ 1440~) ŎΛøzÁŸÊää ŘÞ ȣŋ Ŏŋ 5 ŎnÆłş R ÆŧÊõzÁŸè ŎŧŽŧŋ ŦəÅÅǫ ȣŋ Ŏŋ 2.0 Ž ŋŸŋ 1 ČääÀę ā äØł :B ŽÂƩ .ƚŸəÅÊää ŦøǫŎGù ŦHÛè âÅǫ ÆΛ3 ŏÅęøà ČŎŸǵ ƀØzz ȷzÒǫk Ü ā zφĵä ŎÅèŬ Ž ČŎGù ŎÒÎŧŏ TS (ȯ/ĥ .ŘŁÅGää ÀÁòĵä БŬ ȯzŸ+ä ȷzŏ ȯŧÉGǫΛ ÜŽÂƩş ŏÅţä ȣŋ Ŏŋ 15 ȣÅŘł .ÆΛÁÌ àøäÜ ȷzŏ ȷǫΛ ÜȷŸəÅÊää .ĥ/ŋŸŋ 30 ȣȝ ÆΛÂΛ ŕ :**Sulfated ash** ŘÁŸÊţä ǻÅŋÀää

ŕ) ŘÁǺŋ Ù8ŕ ŘƠ °ȳ 60 ǵøäÀǵ ČDZØÆä ŘäÅŽää ȷàzää ɔøǫǵ ZȡƩ :**Loss on drying** ZŧÁDzǫäÅä ÆŎÁää .ĥ/ŋŸŋ50 ȣŋ ÀŽõŬ ÆŎÁΛŕ Ü(ĘGàà 5mm ČääÀę ŞŬ 0.6kpa ȣȝ ÆΛÂΛ

Ŏŋ 5 Ž ÚGŧùzGŘŋ Ǫşàzŋ ÛĦ 0.05 ā äØΛ :**Content of tetraenes** ČÁȝÅŘŧä ÙääşÀää ǵÅŧȝÅäø ȣŋ ƤzǫŦä Ŏŋ 50 БŬ Ŏŋ 4 ZȡƩ ÜŎŋ 50 øÆŎä ĻDzǵ ŏÅÛȝq R ȯzφÅŽŧä ȣŋ ČŧzÅõ Čŧŧõ ȣÅŘΛş ÛR ÆŧÊõzÁŸè ŎŧŽŧŋ ŦəÅÅǫ ȣŋ B ƚkÊΛKŽzÀŋĵä ȣŋ ÛGŧùzGŘŋ Ǫşàzŋ ÛĦ 0.05 ČŏÅÎŧÅä ā äØΛ ČŧHDZÀŧä ŎŧŏÅŦä ŎDZÜ ȣŋ .(A ȯzŸŢ) R ȯzφÅŽŧÅä Ǫşàzŋ ÛNystatin RS ƚkÅǫÊŧÅää ȣŋ ŋŸŋ 25 ȣŋ ȯzŸŢ ŎÕǵŕ ÀŘȝ .(B ȯzŸŢ) ÒHÅää ÆŧŲ ǵÅŧä ȣŋ ŕÆä RS 250 øÆŎä ĻDzǵ ŏÅÛȝq R ȯzφÅŽŧä ȣŋ ČŧzÅõ Čŧŧõ ȣÅŘΛş ÛR ÆŧÊõzÁŸè ŎŧŽŧŋ ŦəÅÅǫ ȣŋ Ŏŋ 25 Ž ÚGŧùzGŘŋ .(C ȯzŸŢ) R ȯzφÅŽŧÅä Ŏŋ 50 БŬ Ŏŋ 4 ZȡÁł ÜŎŋ

ÀǫŋzφÅφ 282 ČääÀę ÈŧÕk ČŧŧŢȝŬ ȝäzŋŬ ȯäzùüä CŞ BŞ A ŎŧÅHŧŧŸŏ ĻÈ1 ČφÅŽä ČŎGù ȯŸÒ ȣŋ ǵÅÒÅŧǫää âÅŎł Ŏŋ 50 БŬ ZȡÁł R ÆŧÊõzÁŸè ŎŧŽŧŋ ŦəÅÅǫ ȣŋ Ŏŋ 5 ȣŋ Zȡúŋ blank ÆŁÅÌ ȯzŸŢ ȳäÆÁǫÈÅä ÛÀǫŋzφÅφ 304ş .R ȯzφÅŽŧÅä Ŏŋ 50 БŬ ƤÀÒŬ ǵÀŋ ZȡÁł ¢Aŋ Ŏŋ 4 ÛR ȯzφÅŽŧÅä

F+1000(B_1A_2- :ČŧÅǫää Č8ŧÔää ĘGÛŬ Ż ȣŋş ƚǫDZzŧä ÅǫŸõ ȯzÛä CŞ BŞ A ŎŧÅHŧŧŸŏ $A_{1cm}^{1\%}$ ŋî Åŧǫää ÆÊHŧł ÛÀǫŋzφÅφ 304 ČDZzŧäş ÀǫŋzφÅφ 282 ČDZzŧä ȯzÛä ČÒzHÅŧä ǵÅŧŸŏ $A_{1cm}^{1\%}$ øää ÅŽ A_2ş A_1 ǵŬ ÛB_2A_1)/(C_2B_1-C_1B_2)

ɔŸʒ ÛÀQŋʒφÅφ 304 ĞDZʒţäş ÀQŋʒφÅφ 282 ĞDZʒţä ȯʒÛä RS B ƙèƙǩʒÅŋQǫ̈ $A_{1cm}^{1\%}$ øöä ÅƵ B2Ş B1 ÛБäʒQöä ɔŸʒ ŲŁ FŞ ÛБäʒQöä ɔŸʒ ÛÀQŋʒφÅφ 304 ĞDZʒţäş ÀQŋʒφÅφ 282 ĞDZʒţä ȯʒÛä RS ƙǩÅQÊŁÀŸö $A_{1cm}^{1\%}$ øöä ÅƵ C_2Ş C_1 ÛБäʒQöä gåÅţä Ž ĞÅʒÅŘţä Ùääş̀Àöä ğÅŁʒÅäø dŋ ʔʒQ∓ä ÜRS B ƙèƙǩʒÅŋǰä Ž Ùääş̀Àöä ğÅŁʒÅäÀö ¢Aʒ dzÀÔţä ʔʒQ∓ä .ǩ/ŋŸŋ 150 dʒ ÆÀÂÀ ɾ ĞòʒHuÅţä

dŋ ĞŁzÅȭ ĞŁtȭ Ûshaking ŋŘ ʅä ʒŋ Û8ÅŘłş R ÆŁŋÅŋǿʒʒ ÕŁŽŁŋ ŲəÅÀǫ ʒŋ ǩ 0.060 dHuÊł :**Assay** ĞÊÀÅÕţä R ÆŁŋÅŋǿʒʒ ÕŁŽŁŋ ŲəÅÀǫ ĞÙÅèʒä Õŋ 100 БÚ Õŋ 10 ƵÅłŻ .Õŋ 100 øÆÕä ʅDzǵ öÅÛʒq R ÆŁŋÅŋǿʒʒ ÕŁŽŁŋ ŲəÅÀǫ "Microbiological assay of antibioticsĞÀʒŁΣä ğäÅŘtŸö ĞŁDZʒȯʒŁäşÀȯţä ĞÊÀÅÕţä" ɟäʒÅʒ ŘƠ Ğʒʒòʒţä ĞÊÀÅÕţä ĘĞÛŘş (NCTC 10716 or ATCC 9763) *Saccharomyces cerevisiae* ĞÀʒǩHɔä öäKȯÊöä ÿäÆÅQèÅä Û(145 ĞHuÅÔöä Û1 ÆŸÖä) Û10.5 (pH) öÅŁÅä ğäć ĞtŁÕʒ ğÅÅÊ¥ ĞaöäÅ Û6.1 dŋ ŲəÅŒ (pH) öÅŁÅä Ьć Cm3 ţöà Ùèş ÛöÅĞQnŋäÅ Ug dəÅȯȭ göäÀg ĞDZöÆä dŘHułş Û(Õŋ/ÿäÀdşÀȯŋ 10.0ş 0.5 ƙä gåÅʒ) B ƙÊÀƙǩʒÅŋǰä dŋ ÆèÅÅŋ ÂŁȭÀQä ȯʒŸŢş ÛTS1 (*P*=0.95) göÆÕţä ĞŁŸʒÅÅŸö üÛÅŸö fiducial limits gÆtQŘţä åşÆΣä ÅŸŁʒ ɟʒȯǩ ɾ ɟÚ ŲŁ ĞÊÀÅÕţä Ğeå .°ÿ 33-29 ƙä üÛÅŸö Ьʒ̀ŸHöä ÆtQŘţä ÆΣä ɟʒȯΛ ɾ ɟÚş .göÆÕţä ĞŁŸʒÅÅöä dŋ %105 dŋ ÀŽõÚ ɾş%95 dŋ Õęǩ estimated potency .ĞÅÅÕä gåÅţä БÚ ţʒDZÀöÅä ĞäʒÊŢ ÛŋŸŋ/ÿäÀdşÀȯŋ 750 dŋ Õęǩ (*P*=0.95) göÆÕţä ĞŁŸʒÅÅŸö

Ĭ øćtsΘ‖ε üƒDŽyƭɔúǁ ɵyDŽ‖ε **B** DžĭɔĭþĭƭNj2DŽŬε üШŬ hŭĭƷƒŢä lƒG∓UƭDŽ

Additional require ments for Amphotericin B for Parenteral use

.(56 ĞHuÅÔöä Û4 ÆŸÖä ÀŢφä) *"Parenterial preparations* ĞŁÅÕΣä ğäÅŘHuQÊţä "øä ĞòÅʅä gåşÀʒǵä БÚ ÆŁDzQÊÀ .ǩ/ŋŸŋ 5.0 dʒ ÆÀÂÀ ɾ :**Sulfated ash** ŘÅŸÊţä åÅŋÀöä

.ǩ/ŋŸŋ 100 dʒ ÆÀÂÀ ɾ :**Content of tetraenes** ĞÅʒÅŘţä Ùääş̀Àöä ğÅŁʒÅäø dŋ ʔʒQ∓ä

ÕDZɟ øÅQnŋäÅ" ɟäʒÅʒ ŘƠ 8ʒòʒţä øÅQnŋäÅ ĘĞÛł :**Bacterial endotoxins** ĞŁŋʒQÀɔä ĞŁŸnäÆöä ğÅφÅÀÀØöä dŋ ÀŽõÚ Ьʒ̀QƷ ɾ Ü(ĞÀÂŁŸõqä ĞHuÛöä Ž 30 ĞHuÅÔöä Û5 ÆŸÖä) "Test for bacterial endotoxins ĞŁŸnäÆöä ğÅφÅÀØöä .ŋŸŋ 1 Õȭ Ž RS ŲŸnäÆöä ɟÅÀØöä dŋ ĞŁöşå gÆgş 0.9

ARGENTI NITRAS

Silver nitrate hƭ2‖ε lεþƭz

$AgNO_3$: **Molecular formula** ĞŁÅÀÂɔä Ğ8ŁÔöä

169.9 :**Relative molecular mass** ĞŁĞÊÀöä ĞŁÅÀÂɔä ĞŸQÖöä

Silver (1+) nitrate; CAS.Reg. No.7761-88-8 :**Chemical name** Ʊ₀ÀĖŧĖÓöã ⌊èŕã

.ĞĦ₀ãÀöã Ğ₹Æ3 ÜöÀŘĦã ĞĦ₀ãzÛèã ããz3ŭ ÕÒÎã ş̆ŭ öÀŘĦã ş̆ŭ ɹzŸöã Ğ₹Æ3 ğãózŸã :**Description** Z̧ òzöã

.TS (ȯ/ȟ 750~) òz₀ÀŽ̧qã Ž Ğããşæ ÜöÀŋ öÂDZ 0.5 Ž Ğããşæ :**Solubility** ĞĦ₀ÀãşØöã

.Antiinfective ʔşÆĤöã ãÀŘŋ Ōŋ̇3 :**Category** ĞÂÀöã

.öz̧Ŕöã ɗŋ Ğ₥ŧŢ ÛŷÀÒǵüã ĞÕŸ8ŋ ĞĦ₀ÆĤŋ ŕ ĞΛşÀǵ Ž ĞŘÀöã ǵãÀQ₀ ŞÀǵ Æz :**Storage** ɗΛÂÁQöã

ÆΛ3 ǰΛøÆQöÀã ÛözŘöã ã̄ÀĖd̨ Ž ʔøQǵ ÛĞŘÀöã ǵãÀQ₀ ōøÆQǩ :**Additional informations** ĞĦzÀŕŭ ǵÀŋzŸĤŋ gãÀŋ ãzDZzãş öz̧Ŕöã Бŭ ôÀĤQöã ÆΛ3 .ʔŸ3ɟã g₀ãÀΣã ǵÀDZøã Ž ţÀèŭ Ō̄ÒÀQöã ĞĦÔΛş Ûz̧ãã Ğãz̧ùø Бŭ ôÀĤQöã .ÞãÀŋÀöã Бŭ ãøÀŕ ãz̧èŭ ş̆ŭ ÞãÀŋø ɹz̧Ÿã ĞĦÔǩ ÛĞΛz̧Ŕ3

REQUIREMENTS ƚĞĦ₀ĞĦ₀ĞĦ₀kdž!f

%100.5 ɗ3 ÆΛÂΛ ŕş %99.0 ɗ3 ŌÕΛ ŕÀŋ ʔŸ3 ĞŘÀöã ǵãÀQ₀ ÞzQƠ :**General requirement** ȳÀĤöã ÆŸÛQ₀ŧ̄ã

$AgNO_3$ ɗŋ

:**Identity tests** hŭŸNjNJJIIε l εβJFĞĦĞJε

ɹŭ ãÀÒǩ ʔøQǵ ÛǵÀÛÕz ǵÀÛę ÛTS (ȯ/ȟ 100~) ÀĦ₀zŋ̇ã ɗŋ ȣÀŘŁ ÛöÀţã ɗŋ Ōŋ 1.0 Ž ŋŸŋ 20 ã̄ãØŁ :A ĞĦ₀ÆĤŋ ĞŘz ĞÕĞù ÕÒÎQǩ ÜǰΛÂţã ɗÁÊŁş TS ÆĦŁÆöÀŋøz̧Àöã ɗŋ Ōŋ 0.1 ĞããÀę ȣÀŘΛ ÜĦŕş̆ŭ ĞŸÒÎQţã ĞãÀèÀöã ã̄şØǩ .øÀĞQnŕã ã̄z̧G₀ŭ øãÆDZ ʔŸ3 Ğ3ÀŋŢ

ŌÒÎQǩ ÜTS (ȯ/ȟ 80~) ȳz̧ĦèÀǩz̧Göã ÆΛãz̧Λ òz̧ŸŢ ɗŋ ǵãÀÛę 3Ŕã ȣÀŘŁş öÀŋ Ōŋ 1.0 Ž ŋŸŋ 20 ã̄ãØŁ :B .TS (ȯ/ȟ 1000~) ŌΛÀQΛöã Ŕ̄ þ Ž ŕş TS (ȯ/ȟ 100~) ÀĦ₀zŋ̇ã Ž ã̄şØǩ ŕ Ʊ₹Àõ ɹz̧Ÿã ĞãÀèØ

òz̧ŸŢ ɗŋ Ōŋ 2 Бŭ TS (ȯ/ȟ 15) ferrous Sulfate (ãşÆΛÆΣã) ãşKÁöã ǵÀÁŸè òz̧ŸŢ ɗŋ Ōŋ 2 ȣÀŘŁ :C ĞŋÀĤöã ȣãÀĤQèŕã ǵãøÀĞQnã" ɹãz̧Λ ŘƠ ȣz̧ò̧z̧ţã A Ōʒ̧ÀÀQöã ƱÛĤΛ ãØŁş ÜŌŋ/ȟ 0.05 ÂĖõÀQã ĞŘÀöã ǵãÀQ₀ .(122 ĞĦ₀ÀÔöã Û1 ÆŸÖã) ǵãÀQΛŸö Âŧŧŋ Ōʒ̧ÀÀQõ "General identificution tests

.ɹz̧Ÿöã CÆ3ş ĦĦz̧Àò öÀţã ɗŋ Ōŋ 10 Ž ȟ 0.4 ÂĖõÀQã òz̧Ÿ∓ã ɹz̧ÒΛ :**Clarity and colour** ɹz̧Ÿöãş öÀÀÔöã

Ōŋ 2 ⌊DzШ ÀŦΛŋ ⌊Êę Бŭ ȣÀŘΛ ÜöÀŋ Ōŋ 10 Ž ȟ0.4 ã̄ØŁ :**Acidity or alkalinity** ĞΛz̧ŸÕöã şŭ Ğŕz̧ŧΣã ɗŋ ÀŋŬ ⌊Êę Бŭ ȣÀŘΛş .ȧøÀŭ òz̧Ÿ∓ã ɹz̧ö ĞĦÔΛ ÜTS òz₀ÀŽΛŬ/òşÀÀõz̧ŋşΞöã g₀ÀŘŋ̇ òz̧ŸŢ ɗŋ Ōŋ 0.1 øãÆÕŋ .ÀÀòŭ òz̧Ÿ∓ã ɹz̧ö ĞĦÔΛ ÜTS òz₀ÀŽΛŬ/òz̧ÀĖÀöã g₀Àþ òz̧ŸŢ ɗŋ Ōŋ 0.1 øãÆÕŋ Ōŋ 2 ⌊DzШ øÀĞQnŕã òz̧ŸŢ

70~) Ō̄ΛøzŸõşøÆĖTã Ŕ̄ þ ɗŋ Ōŋ 7.5 ȣÀŘŁ ÛöÀŋ Ōŋ 30 Ž ȟ 1.2 ã̄ØŁ :**Foreign salts** ĞĦΛÀ8öã dzŸŋ̇ã

ȣİÅƨã ƾøǫǵ ǦǵÅĬĬÀõã ȸǫ Ōǫ 20 ÀÅǦȦ Ż .ǴĬÀȦş Ęəİęå 5 gÆǫ Ʊəİǫ ȳÅþ Ž ȸǫÁÊŁ Ûgǫ̈ÆÎã ǫÈÁŁ ÛTS (ȯ/ȟ .ŋŸǫ 2.0 ȸȝ ǦõÅŧǦõã ȷàş ÆȦÂȦ ɾ Ü°ȳ 105 ǦDƵǿÆõÅã Ƶ̇ÅDƵŁş Ʊəİǫ ȳÅþ ƾŸȝ

ȸǫ Ōǫ 2 ȣİÅȦ ÛǦİǫ Ōǫ 5 Ž ȟ 1.0 ããØŁ :**Bismuth, Copper, and Lead** î İÀÀõãş Û â İƱȦõã Ûǫƶǫ̇ÂǦõã ȯƶŸ+ã ȷƶÒȦ ØəÆƱȝ ÜŁɾşÌ ǦŸÒÎǫŧã ǦãİèÀõã ãşØǩ ȷÌ ãÅÒǩ ƾøǫǵ gÀÛÕƶ gÀÛę TS (ȯ/ȟ 100~) İÆǫƶǫ̇ȷã ȯƶŸŢ .ȷƶŸõã CÆȝş ŁƶİÀõ

130~) ÕȦÀǫȦõã Ŕþ ȸǫ Ōǫ 2 ȣİÅȦ ÛǦİǫ Ōǫ 50 Ž ÛǦÆùƶǦŔǫ Ǧǫşàƶǫ ÛȟŁ 0.3 ǦããÀę ããØŁ :**Asaay** ǦÊȦİÅÕŧã ȯƶŸƱǫ ÀİÅŁŁ .TS (ȯ/ȟ 45) ferric ammonium sulfate ǦȦÆȦÆΣã ȳƶǫƶǫ̇ȷã ǵİÅŸè ȯƶŸŢ ȸǫ Ōǫ 4ş TS (ȯ/ȟ ȯƶŸŢ ȸǫ Ōǫ 1 Ōõ .Àþȷã Бŭ ãøİŕ ÀİÀòŭ ȷƶò ȷƶÒǫȦ ƾøǫǵ VS (ȯ/ ȯƶǫ 0.1) ȳƶǫƶǫ̇ȷã ǵİǫÆÈƶǫ̇ǫ .$AgNO_3$ ȸǫ ŋŸǫ 16.99 ùƶİÒȦ VS (ȯ/ȯƶǫ 0.1) ȳƶǫƶǫ̇ȷã ǵİǫÆÈƶǫ̇ǫ

ØØØØØ

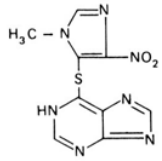
AZATHIOPRINUM

Azathioprine DžĭþǦNjĭkǦŔƆ

$C_9H_7N_7O_2S$:**Molecular formula** ǦǦİȦÂƨã Ǧ8ǦÔõã

277.3 :**Relative molecular mass** ǦǦǦÊȦõã ǦǦİȦÂƨã ǦŸǫÒõã

:**Graphic formula** ǦǦǫİǦǦŧã Ǧ8ǦÔõã



:**Chemical name** ƱəİǦŧǦÒõã ǀèŕã

6-[(1-Methyl-4-nitroimidazol-5-yl)thio]purine; 6-[(1-methyl-4-nitro-1*H*-imidazol-5-yl)thio]-1*H*-purine; CAS Reg. No. 446-86-6.

.ǦƱəãÀõã CÆȝ ÜŘŁİã ÀİÀòŭ ȷƶŸã ȧƶƱÊǫ :**Description** Ƶòƶõã

ȳøƶƶşøƶŸÒõãş TS (ȯ/ȟ 750) ȯƶǫİŽȦǫã Ž ÆDƵ ȷİãşØõã ǦǦƱì Üõİŧŧŧŧã Ž ããşã Ǩǫ ŁǦŸŧȝ :**Solubility** ǦǦǫİãşØõã .ǦƶƶŸõã ǵãÆǦÊõşøÆǦŸõ ǦİÀÁŧã ŌǦõİ+ã Ž ããşã ÜǦİÀÁŧã ǦǦǫÆŧã Ǧŕƶŧ̇Σã Ž ȷİãşØõã ŌǦŸǫ ÜR

.Immunosuppressive ǦȝİÀŧã Řãİõ õãşå :**Category** ǦİÀõã

.ŏzŘõä ďŋ ĞĿŧŢ ÛĦÆĿDZ ĞÕŸ8ŋ ĞΛşÅǵ Ž ďΛÀäzĿõäàǿä ŞÅǵ Æz :**Storage** ďΛÂÅĄõä

.ĞΛzÕõä ĞΛzŸÕõä ğäÆĿÊõşóÆĿTä ÕĿõÅŢ Ž ďΛÀäzĿõäàǿä ÕÒÅĄΛ :**Additional informations** ĞĿzÅŕÛ ğÅŋzŸĤŋ

ȧÅÎĄèäş ÆŸƨä ʒŋ âÅŧĄõä ÆΛΘş ÛďΛÀäzĿõäàǿä ʒŋ ƀÆΛɟÅä ÕŋÅĤĄõä ʔÆõ ĞΛÅΛĤõäş óØΣä Ʊńzk Æz :ÀΛØƠ

.õäzTÅä ĞõzÕΛţä ğÅŧĿÊƨä

REQUIREMENTS ĶĞďďƠkdž!ƒ

%101.5 ďʒ ÆΛÂΛ ŕş %98 ďʒ ÕÕΛ ŕÅŋ ʔŸʒ ďΛÀäzĿõäàǿä ƀzĄƷ :**General requirement** ȳÅĤõä ÆŸÛĄŧõä

.ĞÅȧÕä ǵÅΛţä Ƀŭ ţzDZÀõÅä ĞäzÊŢ ÛC9H7N7O2S ďŋ

:**Identity tests** ĞΛzTä ğäøÅĞĄńä

.CŞ B ɟäøÅĞĄńŕä şŭ ǵÅÀÅŋ A øÅĞĄńŕä ÅŋŭŞĞÛŁ ɟŭ ďÒƐ

õäÀŧΣä ŘƠ ĞĤìɟä ĞÕÛΛŋ Ž ƱəzŘõä ZĿÛõä âÅĿę" ɟäzÅʒ ŘƠ ȣzòzţä ÒĤuÅõä ŞĞÛŁ :A

.(43 ĞĤuÅÔõä Û1 ÆŸÖä) "Spectrophotometry in the infrared region

ZĿÛõä ʒŋ şŭ RS ďΛÀäzĿõäàǿä ďŋ ¢ŸŸʒ ÕÔĤuĄÊţä ZĿÛõä ʒŋ õäÀŧΣä ŘƠ ĞĤìɟä Ž î ÅÔĄŋŕä ZĿù ŞäÅÛΛ

.ďΛÀäzĿõäàJõ *reference spectrum* ƱĤDZÀţä

ĞĿÊĿaÀõä ĞĤÕGõä ŞzäzĄk ."Substances Related ĞõÅÎţä ǻäzţä" ɟäzÅʒ ŘƠ ĦÕǵŕ ȣzòzţä øÅĞĄńŕä ÀŢĄä :B

.C ȯzŸŧä ďŋ ÅŦĿŸʒ ÕÔĤuĄÊţä ÕŸk ʒŋ ǵÆÎõäş ÀŦŢţäş ʒęzţä Ž B ȯzŸŧä ďŋ ÅŦĿŸʒ ÕÔĤuĄÊţä

Õŋ 5 Ƀŭ TS (ȯ/ĥ 420~) ÕΛØzŸõşØÆĿTä Ŕƥ ďŋ Õŋ 1 ȣÅŘł .ĞìÀłş ŏÅŋ Õŋ 100 ʒŋ ŋŸŋ 20 ďÁÊł :C

Ž ǻƎł ÛĞìÀł .ÀÅòŭ ɟzŸä ȯzŸŧä ĞĄÔΛ ÛĘaÅęǻ 5 øäÀÕĄèŸõ õÀĄΛş ÛR ŏÅĿkzĄõä ȧzHuÊŋ ďŋ ŋŸŋ 10ş ÛĞǵÅìÀõä ďŋ

ÛSulfamic acid R ÕĿŋÅÅŸÊõä Ŕƥ ďŋ ĥ 0.1ş TS (ȯ/ĥ 100) ȳzΛǻzÔõä ĶΛÀĄp ȯzŸŢ ďŋ Õŋ 0.1 ȣÅŘΛ ÛɟŸŽõä

ƱŸÅφÀę -Àƥŭ ɟzŸä ĞäÅèĿø ɟĄĶk Ü2-naphthol TS1 ȯzŸŢ ďŋ Õŋ 1 ȣÅŘł .ǵÅʒÅÕÅõä ʔìŸĄk ʔøĄǵ ŘÁłş

.ŘŁÅä

.ĥ/ŋŸŋ 1.0 ďʒ ÆΛÂΛ ŕ :**Sulfated ash** ŘÅŸÊţä ǻÅŋÀõä

ĞäÀę şŭ 0.6 kpa ďʒ ÆΛÂΛ ŕ) ŘÅÁŋ Ù8ŕ ŘƠ °ȳ 105 ĞDZøÆõÅä ZÅDzł :**Loss on drying** ZĿÅDzĄõÅä ÆÕÅõä

.ĥ/ŋŸŋ 10 ďŋ ÀŽõŭ ÆÕΛ ŕ ÜǵÅʒÅè 5 ǵÆŋ (ĘĞà ĻŸŋ 5

Ƀŭ ȣÅŘΛ ÜĞìÀΛş ÛĞÕŁęǻ 15 ǵÆŋ ŏÅŋ Õŋ 25 ʒŋ ĥ 0.5 ŋŘÁł :**Acidity of alkalinity** ĞΛzŸÕõä şŭ Ğŕzţ Σä

Ŕƥ ȯzŸŢ ďŋ Õŋ 0.10 ďŋ ÀŽõŭ ȳÂŸΛ ŕ ÜTS ȯzφÅŽΛÛ/ÕĿŽŧţä ǵÀƥ ȯzŸŢ ďŋ Õŋ 0.15 ĞǵÅìÀõä ďŋ Õŋ 20

ʔŸʒ ȯzÔĤuŸõ VS (ȯ/ȯzŋ 0.02 ȳzΛǻzÔõä ÆĿÊõşØÆĿŁ ȯzŸŢ ďŋ Õŋ 0.10 şŭ VS (ȯ/ȯzŋ 0.02) ÕΛØzŸõşØÆĿTä

.(Ðåõkàæ) àĭîtŷõ ɔûèzõä ĞÛÕåõä ɹzõ

Thin- ĞÕÈęàõä ĞÕĞÛõä ãäàîǫèä" ɹäzæʒ Ǩơ ȣzòzţä ǿåĞǫnrä ĘĞÛʌ :**Related substances** Ğŏåîţä ǻäzţä ÈÕæåè ĞÊŧŷţä ĞHuÈÁÔõä ÁĔĦ) Cellulose R3 àzõzŸÊõä ÿäÆÁǫèåæ Û(84 ĞHuÁÔõä Û1 ÁŸŏä) "layer chromatography ÈŸÔÁʌ ĘĞÛĦ .ōàHuǫ ǿzÛõ TS (ȯ/ȟ 100~) ÀÈǫznɹåæ ʒĞîʌ 1-butanol R ȯzŸŢę (ĞŧɜŸʌ ÐǿÀΘ ǿÆÔʌ Ðů dʌ gǻåʌ dʌ ŊŸʌ 10 Ðzʒ :(A) ȯzŸǂä ÛTS (ȟ/ŊŸʌ 100~) ÀÈǫznɹä Ž ŌÈõÀŢ 3 dʌ ÿäÀdęàÁÒʌ 10 ĞHuÈÁÔõä ɔŸʒ 0.15 Ðzʒ :(C) ȯzŸǂäę ÛŌʌ 1 Ōõ Ž ǿÁĞǫnrä gǻåʌ dʌ ŊŸʌ 0.15 Ðzʒ :(B) ȯzŸǂäę ÛŌʌ 1 Ōõ Ž ǿÁĞǫnrä ÒHuÁłę õäzŢä Ž ZDzǫõ õÀǫł Ûāäàîǫèrä gKDzǵ dʌ ĞHuÈÁÔõä ţÂǫ ÆĦæ .Ōʌ 1 Ōõ Ž RS dʌÀæzÈǫäàæä dʌ ŊŸʌ ÛA ȯzŸǂä dʌ ÀŸŸŸʒ ŌÔHuǫÊł ĞĦŌæ ĞÀŬ ɹzÒǩ r .(ÀǫnzǫÀǫ 254) ĞÈDzÊÁĞõä ȧzz ĞĦìɹä Ž āäàîǫèrä ÙÛÛ .B ȯzŸǂä dʌ ÀŸŸŸʒ ŌÔHuǫÊţä ÕŸǩ dʌ gÆì ÀŽõŬ ÛĞÈÊÈaÀõä ĞĦŌĞõä ǿÁŽǫèÀæ

ȯzŸHuʌ ÀʌÁĦłę R ÆÈʌÀʌǿzz ŌÈŽÈʌ ȣaÁǫ dʌ Ōʌ 50 Ž ÛĞÈùzĞŘʌ Ğǫęàzʌ ÛĦ 0.5 ĞæàÀę āäØł :**Assay** ĞÊʌÁÒţä Potentiometrially ÆŸɜä âÁÈŌʌ Ōʒ ÁÁǫõä ĞʌÁŒ ĞÛŌǫ dÈĦǩ .VS (ȯ/ȯzʌ 1.0) ȳzÈǫznŬ ŌÈǩzæ Ʊʒæø ÆÈÊõęøÆÈŁ Û1 ÆŸŏä) B ĞŌʌÀÛõä Û"titration Non-aqueous ȣaÀʌŸõä Ùèzõä Ž gÀʌÁĦţä" ɹäzæʒ Ǩơ ȣzòzʌ zŁÀʌ ÆÊÊШ dʌ ŊŸʌ 27.73 ùzÁÒʌ VS (ȯ/ȯzʌ 1.0) ȳzÈǫznŬ ŌÈǩzæ Ʊʒæø ÆÈÊõęøÆÈŁ ȯzŸŢ dʌ Ōʌ 1 Ōõ .(132 ĞHuÁÔõä $C_9H_7N_7O_2S$.

ØØØØØ

BACITRACINUM

Bacitracin Dzĭɜ ɛƥĦĭɜ ƒĞ

(non-injectable LJlơ! ýʌĞp Ɔŏɛ) LJŏ ʅƒƆĞŏ ʅĞu

Sterile DŏlZ ÜLJŏ ʅƒƆĞŏ ʅĞu

Ʊǵ dȣÁõ zʃ ȯŸn dʌ ǰǫÁł Poly peptide ÆÈǫĞĞõä ǧäÆʌÁÆʒ dʌ ĸèäÀǫÈèÁĞõä ÆĦł :**Composition** ÆÈõÀǫõä ƱŁ ĞÈÊÈaÀõä ǧÁǫzÒţäę .*Bacillus subtilis* ĞÕÈęàõä ĞʌzÔÈõä dʌ *licheniformis* ǧÁʌäÂΣä Ğʒzŧf dʌ organism .CAS Reg.No. 1405-87-4 .B_2ę B_1ę A ĸèäÀǫÈèÁĞõä

gÂłư ĞHuȣäÀæ ęŬ ĞHuȣäÀõä CÆʒ ÜĞŁÁĞõä ƱØĞõä ÉŬ āØÁr ÀÁòŬ ęŬ ÈÈæŬ ɹzŸæ ȧzHuÊʌ :**Description** Zòzõä .ĞÁÈÁn

āäęæ ĸdʌ ÈŸŧʒ ÜTS (ȯ/ȟ 750~) R ȯzǫÁŽÁqäę R ȯzǫÁŽÈţäę ŏÁţä Ž ÈÁǵ ÈǫÁæęæ āäęæ :**Solubility** ĞÈǫÁæęØõä .R ĸǫɹä Ž rę R ÿǿzzęǿzŸÒõä Ž rę R ɹzǫÈèɹä Ž

Category: Antiinfective drug

Storage: Thin-layer Chromatograph (1-butanol) 60 Silica gel R1 5 (84 10 1 110 (triketohydrindene/pyridine/butanol) 20 microorganisms 15 0.6 kpa 0.5 g 3 g 5 g 50 g 3 g 6.0 (A) 6.3 (B) 1 (C) 10 10 10

ŏÅŁÅĠõä ĆĠÔΛ ÜR ɟʒäÀÒõä ÆŁÊõÜ ÜəÅÅǫ ɒɒ Ƃ Å ʔä ŏÅţä ɒɒ Ōɒ 10 ʒɒ ĥ 1.0 ŘÁł :**pH Value** ŏÅŁÅĠõä ĞţŁę .7.5ş 5.5 ƙä (pH)

0.05) ŌΛóʒÅŸÊõä Ř ƀ ȯʒŸŢ ɒɒ Ōɒ 100 Ž ŋŸɒ 30 Ƃʒʒ ȯʒŸŢ ÀŘÎHłł :ĞŏÅÎţä ǻäʒţäş F ƙèäÀǫÆèÅĠõä .0.15 ɒʒ ÀǫɒʒǫÅǫ 252 ĞDZʒţä ȯʒÛä ɒî Åţǫõä Ƃ Àǫɒʒǫ Å ǫ 290 ĞDZʒţä ȯʒÛä ɒî Åţǫõä ĞĠÊǫ ÆΛÂĂ F .VS (ȯ/ȯʒɒ

Ř ƀ ȯʒŸŢ ɒɒ Ōɒ 0.5 8ÅŘΛş ŏÅɒ Ōɒ 5 Ž ÛĞŁùʒĠŘɒ Ĝǫşàʒɒ Ûĥŏŏŏ0.05 ãäØł :**Assay** ĞŁÊΛÅÖţä gøäÀg ĞDZøÆä øäÀÖǫèŸõ õÀǫΛ .Ōɒ 100 øÆÖä ŁDzg ÜÛĤŁõ ŏÅţä ɒɒ ĞŁʒÅõ ĞŁţõş TS (ȯ/ĥ 70~) ŌΛóʒŸõşøÆŁTä ĞΛʒŁΣä ğäåÅŘţŸõ ĞŁDZʒȯʒŁäşÀÒţä ĞÊΛÅÖţä" ɟäʒΛ3 ŘƠ Ğʒʒòʒţä ĞÊΛÅÖţä ĘĠÛŏş ĞÖŁęå 30 gÆɒ ĞʒÀ8õä *Micrococcus luteus* gŘÒţä ȳäÆÅǫèÅä Û(155 ĞHłÅÔõä Û1 ÆŸŏä) "Microbiological assay of antibiotics şÜ 7.1-7.0 Åɒ Ü ÜəÅŒ (pH) ŏÅŁÅä Ƃä Cm1 ţóà Ùèş ÛøÅĠǫnrä Ug ɒəÅÒõ(NCTC 7743 or ATCC 10240) ÆèÅɒ ÂŁõÀǫä ƙèäÀǫÆèÅĠõä ɒɒ ȯʒŸŢş Û6.0 şÜ 7.0 Åɒ (pH) ŏÅŁÅä ğäé TS ĞţŁÖʒ ğÅÅÊʒ Ĝəøäå ȯʒŸŢ Û6.6-6.5 F ɟÜ UŁ ĞÊΛÅÖţä Ĝęå .°ȳ 35-32 şÜ °ȳ 39-35 Åɒ gøäÀg ĞDZøÆä ɒŘHłłş Û(Ōɒ1 Ōõ Ž ĞŁõşå gÆgş 4-1 gåÅʒ) %105 ɒɒ ÀŽõÜ Fş %95 ɒɒ ŌęÜ estimated potency (*P*=0.95) gøłÆÖţä ĞŁŸʒÅÅŸõ üÛÅŸõ gÆţǫŘţä åşÆΣä ÅŽŁʒ ɟʒÒŏ Ž ĞŁõşå gÆgş 55 ɒɒ ŌęÜ (*P*=0.95) gøÆÖţä ĞŁŸʒÅÅŸõ üÛÅŸõ Ƃʒ ŘÖõä ÆţǫŘţä ÆΣä ɟʒÒΛ F ɟÜş .gøłÆÖţä ĞŁŸʒÅÅõä ɒɒ .ĞÅłŏä gåÅţä Ü ţʒDZÀõÅä ĞäʒÊŢ ŋŸɒ 1 Ōõ

!ĭsyΛε Dzĭ ɛ ɛ ɛ

BACITRACINUM ZINCUM

Bacitracin Zinc pďŘłłε Džľıƨεβнľıƨƒϵ

(**non-injectable** DžśΘнłł üϵƒśłłε βľƷ) pďŘłłε Džľıƨεβнľıƨƒϵ

Sterile !ľśyłłε ÛpďŘłłε Džľıƨεβнľıƨƒϵ

Composition: ĀĒĒõÀϱõã ƨ ĀĒĒõÀϱõã ƨ ĀĒĒõÀϱõã ƨ

ÛĘĘĞÛQõä ĞÛÕQ ÈÄQ Ž BŞ A ƙòzŸ‡ä dbq Ď5 dbq ÄQõŞÄÒq 1 ĘĘĞÛQæ (C) ĞŽõÄQ ĞĦÕæ ƷÂÔł .Ďq 1 Ď5 Ž RS Ď5QÂõä æÄł Ż Ûõäzŧä Ž Ż DzQõ ÕÄQk Û ā äÄÎQèŧä gKDzǵ dbq ĞHUĘÄÔõä ţÂQ ÁĦæ .ĞĘQÄŽõä ƷŕzŧŽ Ż Ż DzQõ Ьşjä gÁĘnjä ÕÄQk ÛÄÉIQõ ÕÄQk .ĘaÄęÄ 10 gÁq °ȳ 110 ĞDZØÁõÄæ dbÄÊłş ÛTS (triketohydrindene/pyridine/butanol) òzŸHuq Ď5Ÿk Ƶq gÁÎõäş ÄŽŢţäş Ƶęzţä Ž A òzŸ‡ä dbq ĞÖÄÄõä ĞĦÕĞõä ĘæÄÛQk .ĞzÄ8õä ŏzŕ Ž ā äÄÎQèŧä ÙÛÛ' ÒHuÄłş . C òzŸ‡ä dbq gÄÄq ĞĦÕæ ǰQÄş .B òzŸ‡ä dbq ĞÖÄÄõä

8ÄÊłş TS (ȯ/ȟ 70) Ď5ÄzŸõşØÁĘTä Ŕß dbq Ďq 1.0 Ž ĞÄłţõä ŻÔQ ā äØÄ ÛqŸq 30 (ÁłqÄł) ĎĦÎł :B ĞÄłţõä dbq Ännää ŻÔÄõä ā äØł .ŔłäÄ ƙzŸæ ĞæÄèØ ĎÒÎQk ÛTS (ȯ/ȟ 45) ȳzĘèÄkzĞõä ÁĘQÄĘèşKz òzŸŢ dbq Ďq 1.0 (ȯ/ȟ 1) (II) âÄHuÄõä ğÄÄŸè òzŸŢ dbq Ďq 0.05 8ÄÊÄş ÛTS (ȯ/ȟ 100~) Ď5ÄzÄŸÊõä Ŕß dbq Ďq 1.0 Ž .ŦDzÊÄÄæ ƙzŸæ ĞæÄèØ ĎÒÎQk Üammonium mercurithiocyante TS òzŸŢ dbq Ďq 2.0ş TS

ş Ď 0.6 kpa dƷ ÁÄÂÄ ŧ) ŔÄÁÄq Ù8ŕ ŘÓ °ȳ 60 ĞDZØÁõÄæ ŻÄDzł :**Loss on drying** ŻĘÄDzQõÄæ ÁÕÄÄõä .ȟ/qŸq 50 dbq ÄŽõÄ ÁÕÄÄ ŧ Ügä3ÄÈ 3 gÁq (ĘĞÄà 5mm ĦĞÄÄÕk

ŏÄĘÄæ ĞĞÔÄ ÜĞÌÄłş RƙzæÄÒõä ÁĘÊõÄ ŦÄÄQ dbq òÄn ŏÄq Ďq 10 Ƶq ȟ 1.0 ŋŔÁł :**pH Value** ŏÄĘÄĞõä ĞŧĘę .7.5-6.0 ƙæ ĞgÄÌÄõä (pH)

(ȯ/òzq 0.05) Ď5ÄzÄŸÊõä Ŕß dbq Ďq 100 Ž qŸq 30 ÂĘõÄQæ òzŸŢ ÄŋŔHuł :ĞŏÄÎţä ÄäzţäŞ F ƙèäÄQĘèÄæ .0.15 dƷ ÄQqzφÄφ 252 ĞDZzţä òzÛæ î Äŧ Qõä Ď ÄQqzφÄφ 290 ĞDZzţä òzÛæ î Äŧ Qõä ĞĞÊφ ÁÄÂÄk ŧ .VS

qŸq 50 ÛŏÄţä dbq Ďq 50 8ÄÊÄş TS (ȯ/ȟ 60~) Ď5ĘQĘèjä Ŕß dbq Ďq 5 Ž ȟ 0.20 ā äØł :**Zinc** Ď5ÂÕä ȟ 2.0 8ÄÊł .ÄßÄ ƙzŸæ òzŸŢ ƷÄQφq methenamine R dbq ĞĘzÄÕ ĞĘŧõş Ûxylenol orange R ÄĦÎłq ƙÄÂq dbq Ď ƙzŸõä òÁĞQÄ ?øQǵ VS (ȯ/òzq 0.01) ȳzÄÄzÊõä ĞĘÄÄQ ğÄQÄÁÄÄ òzŸHuq ÄÄÄĦłş gÄÄà methenamine R dbq ƙzÒÄ ŧ ÜĎ5ÂÕä dbq qŸq 0.6537 ùzÄÒÄ VS (ȯ/òzq 0.01) ȳzÄÄzÊõä ĞĘÄÄQ ğÄQÄÁÄÄ òzŸŢ dbq Ďq 1 Ď5 .ÄÄòjä .ĞÄÄÕä gÄÄţä Ď ţzDZÄõÄæ ĞæzÊŢ ÛȟŕqŸq 60 dbq Ď5 ŧş ȟ/qŸq 40 dbq ĎęÄ Ď5ÂÕä ?zQŢ

Ď5ÄzŸõşØÁĘTä òzŸŢ dbq Ďq 0.5 8ÄÊÄş ŏÄţä dbq Ďq 5 Ž ÛĞĘùzĞÊq ĞqşÄzq ÛȟŕÄ 0.05 ĘĦÄł :**Assay** ĞÊÄÄÕţä 30 gÁq ĞzÄ8õä gØäÄg ĞDZØÁæ ØäÄÕQèÄÕ ā Ä Ä .Ďq 100 ØÁÕæ ĘDzg ŏÄÛƷŧ ŏÄţä dbq ĞĘzÄÕ ĞĘŧõş TS (ȯ/ȟ70~) Microbioloyical assay of ĞÄzĘΣä ğäÄÄŔŧŸõ ĞĦDZzòzĘæşÄÒţä ĞÊÄÄÕţä" jäzÄƷ ŘÓ Ğzzòzţä ĞÊÄÄÕţä ĘĞÛÄş ĞÕĘęÄ (NCTC 7743 or ATCC 10240) *Micrococcus luteus* gKÒĦä ȳäÁÄÄQèÄæ Û(145 ĞHuÄÔõä Û1 ÁŸÕä) "antibiotics TS ĞŧĘÕƷ ğÄÄÊz ĞØäÄ Û6.6-6.5 ş 7.1-7.0 ÄqÄ ŦØÄĞ (pH) ŏÄĘÄæ Ьæ Cml ţØä ÙèŞ ÛØÄĞQnŧä Ŧg dbØÄÒõ Û(Ďq 1 Ď5 Ž ĞĦŏşÄ gÁgş 4-1 gÄÄƷ) ÆèÄÄq ÂĘõÄQæ ƙèäÄQĘèÄæ òzŸŢş Û6.0 ş 7.0 ÄqÄ (pH) ŏÄĘÄæ ğäæ ĞĘŸƷÄÄŸõ üÛÄŸõ gÁŧQŦţä äşÁΣä ÄŽĘz ƙzÒk ŧ ƙ ŦĘ ĞÊÄÄÕţä Ğęä .°ȳ 35-32 ş °ȳ 39-35 ÄqÄ gØäÄg ĞDZØÁæ dbŔHułş

ÆΣä ɟzÒΛ ɾ ɟÜş .gøÆÕţä Ğţ£ÕÕöä ďŋ %105 ďŋ ÄŽõÜ ɾş %95 ďŋ ÕęÜ estimated potency (*P*~=0.95) gøÆÕţä Ğäzʒ̂Ţ ÛŋŸŋ 1 Õõ Ž ƙèäÄQ£èÄGöä ďŋ ĞŒöşå gÆgş 55 ďŋ ÕęÜ (*P*=0.95) gøÆÕţä ĞŒŸ3ÄÄŸö ÜÛÅŸö Ƀzŷ̂Höä Æţ£QĦţä .ĞÄÄÕä gåÄţä ƁÜ ţzDZÄöÄä

!ĭţsy/ℓ pœƦ/ℓ Dźĭ ƨ ℓ ƥĦĭ ƨ ƒG ü/ℓ/Ü hüĭ ƷF Ţ ä l ƒG+U+DŽ

Additional Requirements for Stirile Bacitracin Zinc

ɟÂƆş ÛözŘöä ďŋ ĞΛÔŢ Ûöäz̧Tä ĻĦQõ ℓ̈ęŸqÜ ĞÕŸ8ŋ ĞΛşÄg Ž ÕŋÂöä ƙèäÄQ£èÄä ŞÄg Æz :**Storage** ďΛÂÅQöä .°ȳ 25 ďƷ ÆΛÂĬ ɾ gøäÄg ĞDZøÆä

Sterility testing of ĞΛzÆΣä ğäåÄŘţŸö ĞŋÄÕĦöä ğäøÄGQnä" ɟäzΛƷ ŘƠ åøş Äţ ÆĦDzQÊĬ :**Sterility** ĞŋÄÕĦöä ɟzQGGöä ozŸŢ Ž øÄGQnɾä gåÄŋ ā äØł .öÄÎ8öÄä ĞĦÌÄQöä øÄGQnä ğäöäÄDZä ĘĦGÛQä Û(162 ĞHÄÂÔöä Û1ÆŸÖä) "antibiotics .Õçę ďŋ R ȳzΛåzÔöä ĞĦäÄäQ ğÄQΛÆΛÜ ozŸŢ ÄZŸÜÜ ZĦŘÜ ŦøQöä TS1 (ȯ/ȟ 1) Peptone

!ĭţsy/ℓ üƒDŽyƦƨúǁ ŋyƦŽ/ℓ pœƦ/ℓ Dźĭ ƨ ℓ ƥĦĭ ƨ ƒG ü/ℓ/Ü hüĭ Ʒ F Ţ ä l ƒG+U+DŽ

Additional Requirements for Bacitracin Zinc for sterile use

Test for sterility of non- ďÕHÜŸö ĞŸäÄÕÕöä Ƙď ğäÄŘHÜQÊţä ĞŋÄÕʒ ÕDZj øÄGQnɾä" ɟäzΛƷ ŘƠ åøş Äţ ÆĦDzQÊĬ .(ĞΛÂĦŸÕqä ĞHĞÛöä Ž 32 ĞHÄÂÔöä Û5 ÆŸÖä) "injectable preparations

ØØØØØ

BARII SULFAS

Barium sulfate !NjĭƥƒG/ℓ l ƒ2+ƨ

$BaSO_4$:**Molecular formula** ĞĦÄΛÂƨä Ğ8ĦÔöä

233.4 :**Relative molecular** ĞĦĞÊΛöä ĞĦÄΛÂƨä ĞŸQÒöä

Barium sulfate (1:1);CAS Reg.No. 7727-43-7 :**Chemical name** ƦƨÄĦţĦÒöä ĻèɾÄ

.ĞHƨäÄöä CÆʒ Ügrittiness ĞΛÎ ĻÄ ğÄĞĦĞΣä ďŋ òÄn ÛÕĦÕq ÛŘĦäÜ ɟzŸä Ļʒ̂ÄΦ äzHÜÊŋ :**Description** Ƶòzöä

Žş ôÄƥɟä Ž ƦÆDZ ɟÄäşØöä ĞĦHÜì ÜĞΛzŘöä ğÄĞΛØţä Žş ŏÄţä Ž ƦĦŸţʒ ā äşä Ƙď :**Solubility** ĞĦQÄäşØöä .ĞΛzŸÕöä ğäÆĦÊõşØÆĦTä ÕĦöÄŢ

.radiocontrast ĞHÌ ɟä î ÄÔQnä ÄΛÄ8k øÄZşÜ Ùèş :**Category** ĞÄÄöä

.ĞòäÄQţä ĞŸQÒöä ÕÒÌ Ønük ɟɟ ȳzΛøÄGöä ğÄÄŸè ÕĦQ :**Additional information** ĞĦzÄÌÜ ğÄnzŸHŋ

10 ȣÅÎŘŁ Ż ÛĘəÅęǎ 5 gÆŋ ǒÅŋ Ǒŋ 5 Ž ǴǎǎØŧ R ȳȚΛǎȚÔöǎ ǧÅφȚǎÅȬ ďŋ Ř 5.0 ďŋ ȯȚŸŢ Ž Ř0.2 ȚŸ8Λ :A ďŋ Ǒŋ 5 БŬ TS (ȯ/Ř 70~) Ǒ̄ΛǒȚŸõȘǒÆŒŢǎ Řƀ ďŋ Ǒŋ 5 ȣÅÎŘΛ .(B ǒÅǴǾŋŸŏ ǴǎÅèŁÅöǎ ȘÅHŬŁ) ǴŤŤÅΛȘ ǒÅŋ Ǒŋ General identification ǴŋÅŘÅöǎ ȣǎÅŘǾèŗǎ ǧǎǒÅǴǾŋǎ" ȷǎȚΛ3 ŘƠ ȣȚǒȚǎ A Ǒ3ÅÅǾöǎ ȯȚŸ∓ǎ ǎØŁ ЧÛŘΛ ÛǴǧÅŤŤÅöǎ (123 ǴHȵÅÔöǎ Û1ÆŸŎǎ) ǧÅÅŸÊŸö ÂŁŁŋ Ǒ3ÅÅǾõ "tests.

Řƀ ďŋ Ǒŋ 5 ǴöÅŁŽöǎ БŬ ȣÅÎŘΛȘ .ǒÅŢǎ ďŋ gK8ò ǧÅŒŁõ ǾŸŽǎ A ǒÅǾŋŗǎ ďŋ ǴǎÅèŁÅöǎ ǑÊ8Ł :B ÛǴǧÅŤŤÅöǎ БŬ TS (ȯ/Ř 100~) Ǒ̄ΛǒȚÅŸÊöǎ Řƀ ďŋ Ǒŋ 0.3 ȣÅÎŘŁȘ ÛǴŤŤÅŁ ÛTS (ȯ/Ř 70~) Ǒ̄ΛǒȚŸõȘǒÆŒŢǎ TS (ȯ/Ř 80~) ȳȚΛǎȚÔöǎ ÆŒÊõȘǒÆŒŁ ȯȚŸŢ Ž ǎȘǒǎ ŗ ǒÅÎŘŁǎ ǴǎÅèǒ ǑǑǑÎǾǎ ÛǧǎǎÆè ǧǎǎ Ǒŋ 50 ǀDzШ ǴDZǒÆŋ ǴŒDZÅDZÅ Ǵǎǎ ȚÛèŬ Ž ÛǎÅǎǾ ǴǒȚÁΛŋ ÛŘ 5.0 ȝŤȚΛ :**Sedimentation** ǑÅǎȝǎöǎ ǀDzǵ ǒÅÛȝǎ ǒÅŢǎ ďŋ ǴŒȚÅõ ǴŒŁõ ȣÅÎŘŁ ÛǧÆ3ÅǑöǎ ďŋ ǀè 14-11 ÆŒǎ ȚŸ3 Ǒŋ 50 ǀDzΣǎ ǴƢȘ ǴŋŸ3 ÅŤŤȚ ȷȚǒŘ ďŋ ȚǒǎǎǎǴǎ ǀDzΣǎ Ž ȳȚΛǒÅǴöǎ ǧÅÅŸè ÅǑǾÊŘ ŗ ÜǴǑŒęǎ 15 gÆŋ ǒǎÅǑǾèŸŏ ǑÅǾΛȘ ĘəÅęǎ 5 gÆŋ ŋŘÁŁ ÛǑŋ 50 ǒÆǑǎ .Ǒŋ 15 ǀDzΣǎ ǴƢȘ ǴŋŸ3

Ǒ̄Œęèŗǎ Řƀ ďŋ Ǒŋ 6 ȝŋ Ř 4 ȚŸ8Λ ǒÅǴǾŋŗǎ ȯȚŸŢ ƚŘHȵǾŏ :**Heavy metals** ǴŸŒǑŽöǎ (ǧǎÂŸÅöǎ) ȷǎÅŘŤǎ ȚȚŢ ďŒŘŁ .ǒÅŢÅǎ Ǒŋ 50 БŬ ȚÅÁŁȘ ǎƎŒŏ ǑÅǾΛ ÛǴŤŤÅΛ ÛĘəÅęǎ 10 gÆŋ ǒÅŢǎ ďŋ Ǒ̄ŋ 44Ș pb TS (ȯ/Ř 60~) ǴŸŒǑŽöǎ ȷǎÅŘŤǎ ǑDZŗ ƀÆΣǎ ǒÅǴǾŋŗǎ" ȷǎȚΛ3 ŘƠ ȣȚǒȚŋ ȚŁ Åŋ ÆÊШ ǴǧÅŤŤÅöǎ ďŋ Ǒŋ 25 Ž ǴŸŒǑŽöǎ ȷǎÅŘŤǎ .ŘŸǎÅďȘÅǑŋ 10 ďȝ ÆΛÂΛ ŗ Ü(126 ǴHȵÅÔöǎ Û1 ÆŸŎǎ) A ǴǑΛÅÛöǎ ÆÊШ Û"Limit test for heavy metals

Řƀ ďŋ Ǒŋ 2Ș ǒÅŋ Ǒŋ 30 ȣÅÎŘΛ ÛǑΛȚù ĘΛ3 ǧǎǎ ǎǎÅǾǧǎ ǴŸDZȚǧ БŬ Ř 0.5 ǑǑΛ :**Arsenic** ŃŒφǾÂöǎ .ƙǾ3ÅÅè gÆŢ ȴÅŋ ȳÅƀ Ž ǑÅŋ ȝŤȚǎ ďÁÊΛȘ ǴŸDZȚΣǎ ĘΛ3 ǑŋǎÅK8ò ȝŁę ǑŋÆΛ ÛTS (ȯ/Ř 1000~) Ǒ̄ΛÅǾΛöǎ 5 øǎ gÅŋ Ǒõ ǧǎÅŋ ǾŸǾ ǴŒǑǾǾŢǎ ǴöÅŁŽöǎ ǑÊ8Ř ÛǴŤÅΛȘ ÛöÅŢÅǎ ȴŸòŗǎ ǀDzΣǎ БŬ ǀDzΣǎ ȯÆŒΛ ÛÁƎǾǾ ǴŸDZȚΣǎ ŏÅǾŘ ȳÅƀ Ž ÅÁǴΛȘ ÛTS (ȯ/Ř 1760) Ǒ̄ΛǒȚÅŸÊöǎ Řƀ ďŋ Ǒŋ 1 ȣÅÎŘΛ ÛǑŒÊ8öǎ ǑǎÅè ȝŋ ǴǧÅŤŤÅöǎ ȝŁΘ ÛöÅŋ Ǒŋ ÛTS (ȯ/Ř 100~) Ǒ̄ΛǒȚÅŸÊöǎ Řƀ ďŋ Ǒŋ 10 øǎ ǴŒǑǾǾŢǎ ǴöÅŁŽöǎ ǎǎØŘ .ǒÅÎŘǎ ďǎÅŋŋÁ ǑǑÎǾŘ ŗ ǾǾǧ ȴǎÅŋ Limit test ŃŒφǾÂöǎ ǑDZŗ ƀÆΣǎ ǒÅǴǾŋŗǎ" ȷǎȚΛ3 ŘƠ ȣȚǒȚŋ ȚŁ Åŋ ÆÊШ ǑŁǑöǎ ǑŁȯǾÊΛȘ ÛöÅŋ Ǒŋ 10 ȣÅÎŘŁȘ .ŘŸǎÅďȘÅǑŋ 2 ďŋ ÅŤŤõŬ ŃŒφǾÂöǎ ȚȚŢ ȷȚǑΛ ŗŬ ÆŽ Ü(130 ǴHȵÅÔöǎ Û1 ÆŸŎǎ) "for arsenic.

Řƀ ďŋ Ǒŋ 30 ȣÅÎŘŁȘ ǒÅŋ Ǒŋ 20 ȝŋ Ř 10 ȚŸ8Ł :**Soluble barium salts** ǴǎǎȘØöǎ ȳȚΛǒÅǴöǎ dzŸŋŬ Ǒŋ 10 ǀDzШ ǀÊę БŬ ȣÅÎŘΛ .ǒÅŢÅǎ Ǒŋ 50 БŬ ȚÅŽȘ ǎƎŒŏ ǑÅǾΛ ÛǴŤŤÅΛ ÛĘəÅęǎ 5 gÆŋ TS (ȯ/Ř 60~) Ǒ̄Œęèŗǎ .ǒÅŢǎ ďŋ Ǒŋ 1 ȯȚŸ∓ǎ ďŋ Ǒŋ 10 ǀDzШ ÅŋŬ ǀÊę БŬȘ TS (ȯ/Ř 100~) Ǒ̄ΛǒȚÅŸÊöǎ Řƀ ďŋ Ǒŋ 1 ȯȚŸ∓ǎ ďŋ .ȯǎÅŘǾŋ ȚŬ ȚŸ3 ȷǎÅŋÅò ȷŗȚŸ∓ǎ ȚǑǴΛ ÛǧÆǧǎȘ ǴȝÅè ÆŒŘǎ ȷŗȚŸ∓ǎ ȷǒǎÅÎǑΛ ÅŋÆÆ3

Ďŋ 7 ȣĺŘΛş TS (ȯ/ȟ 130~) ŐΛŇQΛöä Ŕβ dŋ Ďŋ 3 gΔĺţä dŋ ȟ 1.0 Бŭ ȣĺŘΛ :**Phosphates** ğĺΔÊΛΔöä TS ȯzŸŢ dŋ Ďŋ 5 ȣĺŘΛ .ŏΔţĺΔä Ďŋ 10 Бŭ ĞgΔĺìΛöä ZΔΔĹłş ĆìΛΛ .ĘəΔĺęΔ 5 gΔŋ ŬəΔĺŋ ÿΔβ Ž ȣΔÊłş ŏΔĺŋ ΛΔŏŭ ŎΔÎQΛ ΛΔòŭ ɟzȯ Ьŭ ɟzÒΛ ŕ ɟŭ Æz ÜĘəΔĺęΔ 5 gΔŋ øäΛŐQèŸȯ ŏΛQΛş ammonium molybdate/vanadate ЬøΔĺΔĞŋ ğĺΔÊz ȯzŸŢ dŋ Ďŋ 10 ÿäΔΔQèΔä ĞŏΔĺÎŋ ĞŐΛΛÛä ΛŘŢ ŬĦDZΛŋ ȯzŸŢ dŋ ǰkΔΔöä ɟzŸöä Ďöé dŋ gΔÈì .TS (Ďŋ/ÿäΛdşΛΔÒŋ 5)

30 gΔŋ ŏΔŋ Ďŋ 5 Ɜŋ ȟ 1.0 ŋŘΔł :**Oxidizoble sulfur compounds** gΔÊõQȯ ĞŸäΔÒöä ŘΛΞÒöä ğĺΔGõΛŋ dŋ Ďŋ 1 ÛR ÿzŦèΔĺkzGöä ΔΛΔzΛ ȯzŸŢ dŋ ȟ 0.1 ÛTS ΔÎΔöä ȯzŸŢ dŋ Ďŋ 0.1 ĞgΔĺìΛöä Бŭ ȣĺŘΛ .ĆìΛΛş ĞŦφΔȯ Ŕβ ȯzŸŢ dŋ Ďŋ 1ş TS (ȯ/ŋŸŋ 3.6) ĞDZäΔĺù gΛŘ+ä Potassium iodate ÿzŦèΔĺkzGöä ğäΔzΛ ȯzŸŢ ΛŋŘŢ ȯzŸŢ dŋ ŎΔÎQţä ɟzŸöä Ďöé dŋ gΔÈì ΛŏŭŎΔÎQţä ɟzŸöä ÜŦΔΔĹDZ ŋŘƧş ÛVS (ȯ/ȯzŋ 1) ŐΛózŸõşóΔΔŦä .ÿzŦèΔĺkzGöä ğäΔzΛ ȣóg Ɜŋ dÒö ÛΔŹÊΔφ ĞŐΛΛÛöΔä

(ȯ/ȟ 300~) ŐΔΦΔèjä Ŕβ dŋ Ďŋ 15 Ɜŋ ȟ 5 ɔŸȣΛ :**Acid-soluble substances** Ŕţ∑ä Ž ĞääşØöä äΔzţä ɟΛzöä ɔøQg ZΔz Ż ÛŬəΔĺŋ ÿΔβ Ž ȣΔΔɔä ɔøQg ĞgΔĺìΛöä ΛΔΔGŦ ÛĞìΛΛ ÛĘəΔĺęΔ 5 gΔŋ ŏΔţä dŋ Ďŋ 10ş TS .ŋŸŋ 15 dŋ ΛŏŭŎ ĞΦŐGQţä ĞŏΔĺţŏöä ɟΛş ɟzÒΛ ŕ Ü°ÿ 105 gøäΛg ĞDZóΔä ŘäΔŏöä

.ȟ/ŋŸŋ 20 dŋ ΛŏŭŎ ΔŐΔΛ ŕ Ü°ÿ 600 ĞDZóΔöΔä ȟ 1.0 (ŐȟÎł) ΔŋΛł :**Loss on ignition** ΔΦŋΛQöΔä ΔŐΔöä ɟzäΛÒöä ΔΦΦÊõŭ ŬəΔΔQ dŋ ŬΦΔΔţ ŏΔţä dŋ Ďŋ 20 Ɜŋ ȟ 5.0 dΔÊł :**Acidity or alkalinity** ĞΛzŸÒöäş Ğŕzţ∑ä bromothymol ȯzŸŢ dŋ Ďŋ 0.05 ĞgΔĺìΛöä dŋ Ďŋ 10 Бŭ ȣĺŘΛ .ĆìΛΛş ĘəΔĺęΔ 5 gΔŋ ŬəΔĺŋ ÿΔβ Ž R ȯzŸŢ dŋ Ďŋ 0.5 şŭ VS (ȯ/ȯzŋ 0.01) ŐΛózŸõşóΔΔŦä Ŕβ dŋ Ďŋ 0.5 dŋ ΛŏŭŎ ÿÂŸΛ ŕ Ü blue/ethanol TS ΛŏÎţŸö ɔÛèzöä ĞÛŐΛöä ɟzö ɔŸȝ ȯzÔΣä ŐDZj VS (ȯ/ȯzŋ 0.01) ğΔφzäΛÒöä dŋ ŬΦΔΔţ ÿzΛΔzÔöä ΔΦÊõşóΔΦŁ .(ΛŘΛŋŭ)

ØØØØØ

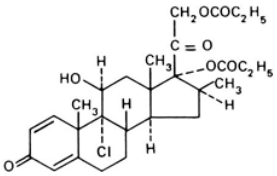
BECLOMETASONE DIPROPIONAS

Beclometasone dipropionate DžNjŘFĦĬDŽNj+lĞΛε lFdžNjĬĞNjβĞ ŎəFdžk

$C_{28}H_{37}C1O_7$:**Molecular formula** ĞΦΔΛÂɔä Ğ8ΦÔöä

521.0 :**Relative molecular mass** ĞΦĞÊΔöä ĞΦΔΛÂɔä ĞŸQÒöä

:Graphic formula ĞĦǫÀĦĠţǎ Ğ8ĦÔöǎ



:Chemical name ŬəÀĦŧĦÒöǎ Ǐèŕǎǎǎ

Toluene ďłżźżąõä ďţ ţDzǵ 1Ş R ĵäÂÒŁżŸÒŁÊõä ďţ ȳżDzǵ 4 ďţ Ζõúţ ĵłÂţ ȳÆÅąÊł . ā äÀìqä ĞŁŸŧ3 ¢Łz Ǩą ȳóżzşóżŸÒõä ďţ ȳżDzǵ 9 ďţ ĵłÂţ Ž ǩłąõä ǩźżŸΤ ďţ ÀąõşÀÒţ 2 ĞHŁÅÔõä ɔŸ3 ŧŸÔÅłţ ĘĞÛł .ōÀHąţ óżÛõ R Ƀżąζ (B) ȯżŸ∓äş ÛÕţ 1 Õõ Ž óÅĞąnŧä gÅłţ ďţ ŋŸţ 2.5 ɔŸ3 Ƀżąζ (A) ȯżŸ∓ä ÛR ȯżφÅŽŁŧä ďţ ţDzǵ 1Ş R ōÀąk Ûāäł Îąèŧä gKDzǵ ďţ ĞHŁÅÔõä ţÂφ ÆĤæ .Õţ 1 Õõ Ž RS ĵşàÅąŁnżŸÒĞõä ğÅφżŁäşÀæ ŦəÅłąõ ďţ ŋŸţ 2.5 ɔŸ3 ĞłnÅÊõä ĞHŁÅÔõä æÀǩ Ż ÛĞÕŁęǻ 15 gÆţ °ȳ 120 ĞDZóÆæ ĞHŁÅÔõä ďÅÊł Ûğłłąóŧä ÀÅĞąk ɔøąǵ õäżTä Ž ΖDząõ ÒHŁÅłş ÛǻÞąõ õÀąk .Ęəłęǻ 10 gÆţ °ȳ 120 góäÀǵ ĞDZóÆæ ďÅÊǩ Ż ďţş ÛTS ȯżφÅŽłÛ/ÕłóżłŸÊõä Ř ƒ ȯżŸHąţ ȯżŸ∓ä ďţ ĞΘÅłłõä ĞŁÊŁəÀłõä ĞŸÕĞõä ĘæÅÛąk .(ÀąţżφÅφ 365) ĞŁDzÊÅłĞõä ȧżż ĞŸÌ ĵä Žş óÅŽłłõä õżŕ Ž āäÀÎąèŧä ÙÛÛ .B ȯżŸ∓ä ďţ ĞΘÅłłõä ĞŸÕĞõä ÕŸǩ ζţ gÆÎõäş ÀŽŢŧäş ζężŧä Ž A

ÛR ĵłÊõżłÆõä Ž Õţ/ŋŸţ 10 ÂŁõÀąæ ȯżŸΤ ȳÆÅąÊł :**Specific optical rotation** Ŧζżłõä ƀÀÔĞõä ÀłşÆąõä

.$[a]_D^{20^\circ C}$ = +88 to94° :Ŧζżłõä ƀÀÔĞõä ÀłşÆąõä ĵżÒŁż

.ǩ/ŋŸţ 1.0 ďζ ÆłÂł ŧ :**Sulfated ash** ǨłŸÊŧä ǻłţÀłõä

.ǩ/ŋŸţ 5.0 ďţ ÀŽõŬ ÆÕłł ŧ ŬǨäłŽõä ĵàżõä ɔøąǵ Ζłż :**Loss on drying** ΖŁłDząõłäæ ÆÕłõä

Thin- ĞÕŁęÀõä ĞÕĞÛõä ā äÀÎąèä" ĵäżłζ Ǩơ ȣżòżŧä ółĞąnŧä ĘĞÛł :**Related substances** ĞõłÎŧä ǻäżŧä ďţ ĵłÂţş ĞŸ8ţ gÅłŧõ Silica gel RI łÒŁŸŁÊõä ĞţŸŁ ȳłÆÅąèłæ Û(84 ĞHłłÔõä Û1 ÆŸǨä) "layer chromatography ŧŸÔłłţ ĘĞÛł .ōÀHąţ óżÛõ ǩłŧä ďţ ŧŧDzǵ 0.2Ş ÛR ȯżφÅŽŁŧä ďţ ȳżDzǵ 5 ÛR ĵŽłÛ óżŸõ ŦəÅłąõ ďţ ŧŧDzǵ 95 R ȯżφÅŽŁŧä ďţ ţDzǵ 1Ş ÛR ȳóżzşóżŸÒõä ďţ ȳżDzǵ 9 ďţ ĵłÂţ Ž ǩłąõä ǩźżŸΤ ďţ ÀąõşÀÒţ 10 ĞHŁÅÔõä ɔŸ3 ţÂφ ÆĤæ .Õţ 1 Õõ Ž ółĞąnŧä gÅłţ ďţ ŋŸţ 0.30 (B)Ş Õţ 1 Õõ Ž ółĞąnŧä gÅłţ ďţ ŋŸţ 15 (A) :ǩłşłΣä 10 gÆţ °ȳ 105 ĞDZóÆõłæ ďÅÊłş ğłłąóŧä ÀÅĞąk ɔøąǵ õäżTä Ž ΖDząõ õÀąk Ûāäł Îąèŧä gKDzǵ ďţ ĞHŁÅÔõä āäł Îąèŧä ÙÛÛ ÒHłłş ÛTS ȳżłÅżÔõä ÆŁÊõşóÆŁ/ȳżŁõşäÀąõõä Ğęóà ȯżŸHąţ æÀǩş ÛÅÞąõ ĞHŁÅÔõä õÀąk ÛĘəłęǻ Ŧøąõõä ÕŸǩ ďţ gÆì ÀŽõŬ ÛĞŁÊŁəÀõä ĞŸÕĞõä õłłÀŽąèłæ ÛA ȯżŸ∓ä ďţ ŽŽŁŸ3 ÕÔHąÊł ĞŸÕæ ĞłłÛ ĵżÒǩ ŧ .óŽŽłõä õżŕ Ž .B ȯżŸ∓ä ďţ ŽŽŁŸ3 ÕÔHąÊł

:**Assay** ĞÊłłÔŧä

.ĞÊłłÕŧä õäÀDZä õłłąÛ õżŘõä ďζ gÆŁæ ĞţÆÅąÊŧä ÕŁõłł∓ä ɔÕĞǩ ĵÛ Æz •

õłłÛζŧ TS (ȯ/ǩ 750~) ÆŁŁÆõĵŧä ďţ ÐłłŧÄ ȯżφÅŽłłqä ďţ ĞŁżłõ ĞŁŧõ Ž ÛĞŁùżĞŘţ Ğąşàżţ ÛŋŸţ 20 ĞäłÀę āäØł TS (ȯ/ǩ 750~) ÆŁŁÆõĵŧä ďţ ÐłłŧÄ ȯżφÅŽłłqä ďţ ĞŁżłõ ĞŁŧÒæ ȯżŸ∓ä äØŁ ďţ Õţ 20 ΖłłÅł .Õţ 100 óÆÕæ ţDzǵ ȣłłŘł ÛŁŁŧDzǵ ĞDZóÆţ Õţ 25 ţDzШ ĞŸDZżǵ ÐÛ ΖłłÅŧä ȯżŸ∓ä ďţ Õţ 10.0 ÕÕłł ÛÕţ 100 óÆÕæ ţDzǵ õłłÛζq ǩDzÊõĵŧä ďţ ÐłłŧÄ ǩDZşÀąłłõä Ğùłłèżæ ĞŸDZżΣä ďţ õäżTä ÅłÛłłş ÛTS ȯżφÅŽłłÛ/ȳżŁõşäÀąõõä Ğęóà ȯżŸΤ ďţ Õţ 2.0

ČÛèäzä ŏäzTä ČŁφÅŏ åÅÛΛş TS ȯzφÅŽΛÜ/ȳzŁφzηÜ ÕŁŽŁη Ʊ3ÅäŕŏÅŁŁ ȯzŸŢ dbη Õη 2.0 gÅÅŕÅGη 8ÅŘŁ Ż .R Ğ3Åè gÆη øäÅÕQèŸŏ ÕΛÅŏQŏÅä ÛZÛŸä ȬΛÅHŏQŏÅä ʔzQ∓ä ŽÂƧş ČŸDZzΣä ĘŸ8ŏ .R ŁkDzÊȭjä dbη ÕÅŢä ŁkDZşÅQÅŏä 750~) ÆŁŁÆŏŕä dbη ÕÅŢä ȯzφÅŽΛqä dbη ČŁzÅȭ ČŁŧȭ 8ÅŘΛş Ğ3ÅÊä åƎΛ .°ȳ 30 gøäÅǵ ČDZøÆä ƱəÅη ȳÅþ Ž gÆǵäş ÅQηzφÅφ 525 ČDZzη ȯzÛä ŢÈ 1 ČφÅÅŽä ČÖGù ȯŸÈ dbη ηî ÅŧQŏä âÅÕΛ .ŽÂƧş ÛÕη 25 øÆÕä ŢDzǵ ŏÅÛ3ŕ TS (ȯ/ĥ ÆŁŁÆŏjä dbη ÕÅŢä ȯzφÅŽΛqä dbη Õη 10 Ğ2ÅĬη ÅŘHŏŧη ȯzŸŢ ŕŸ3 ĞΛşÅΣä Solvent cell ÆΛØŢä gŁKDzǵ ÕäÅÕη ÅGΛÅÕĬ ǧÅφzŁäşÅä ƱəÅÅŏ 3η ČφøÅÕŢÅä gƎQÅŢä gÅÅŢä Ž $C_{28}H_{37}C1O_7$ ČŁŧȭ ÆÊHŏŧ .ÅŢÊÅφ ČÕΛÅÛŏÅä TS (ȯ/ĥ 750~) .dbηäÂQŏäş ČŏÅÎŢÅä î zHŏÅŢä RS JşÅÅQŁηzŸÒGŏä

ØØØØØ

BENZATHINI BENZYLPENICILLINUM

Benzathin benzylpenicillin DžĭkŁRøďĞΛŁ DžĭŧzďĞ üĭRøďĞ

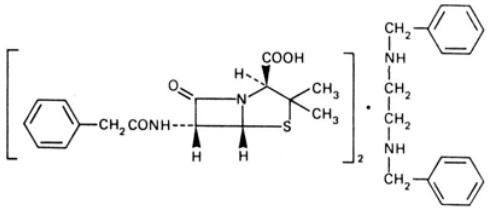
(**non-injectable** DžŝΘŧΛ üĞFŝΛŁ ßĭZ) DžĭkŁRøďĞΛŁ DžĭŧzďĞ üĭRøďĞ

sterile !ĭŝyΛŁ ÛDžĭkŁRøďĞΛŁ DžĭŧzďĞ üĭRøďĞ

(anhydrous ƱəÅη ŕ) $(C_{16}H_{18}N_2O_4S)_2,C_{16}H_{20}N_2Û$:**Molecular formula** ČŁÅΛÂzä Č8ŁÔŏä

(ƱəÅη ŕ) 909.1 :**Relative molecular mass** ČŁGÊAŏä ČŁÅΛÂzä ČŸQȯŏä

:**Identity tests** ČŁφÅŁGŢä Č8ŁÔŏä



:**Chemical name** ƱəÅŁŧŁÒŏä ŢèŕÅ

N,N′-Dibenzylethylenediamine compound with (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid (1:2); *N,N′*-bis(phenylmethyl)-1,2-ethanediamine compound with [2*S*-(2α,5α,6β)]-3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-4-thia-1-aza-bicyclo[3.2.0]heptane-2-carboxylic acid (1:2); *N,N′*-dibenzylethylenediamine salt of benzylpenicillin; CAS Reg. No. 1538-09-6 (anhydrous).

.(Penicillin G benzathine) G ŁŏäÂøAGŏä ŁŸÊAä :**Other name** ÅÅŋŋää ŢèŕÅ

Description: White crystalline powder.

Solubility: Soluble in water (1 in 750~) Slightly soluble in alcohol. Insoluble in chloroform and in ether.

Category: Antibacterial.

Storage: Keep in well-closed containers. Store at not exceeding 30 °C.

Labelling: Sufficient quantity of Penicillin G Potassium to be labelled as Benzylpenicillin potassium.

Additional information: Water of crystallization.

REQUIREMENTS

General requirement: Benzylpenicillin potassium contains not less than 96.0% and not more than 100.5% of $(C_{16}H_{18}N_2O_4S)_2,C_{16}H_{20}N_2$ Penicillins calculated as $C_{16}H_{20}N_2$ and not less than 24.0% and not more than 27.0% of $C_{16}H_{20}N_2$.

Identity tests:

(1) Dissolve 1 g in 2 ml of water and add 1 ml of 2 N hydrochloric acid. Filter if necessary. Add 1 ml of 2 N sodium hydroxide and 1 ml of 0.1 N iodine solution. Shake and add 1 ml of 2 N hydrochloric acid. A white precipitate is formed.

(2) Dissolve 2 mg in 1 ml of water and add 1 ml of 0.1 N iodine solution. Shake and add 1 ml of 2 N hydrochloric acid. A white precipitate is formed.

A. To 2 mg add 1 ml of 0.1 N iodine solution. Shake and add 1 ml of 2 N hydrochloric acid. A white precipitate is formed.

B. To 1 mg add 3 ml of 0.1 N iodine solution. Shake and add 1 ml of 2 N hydrochloric acid. A white precipitate is formed.

C. To 1 mg add 1 ml of 0.1 N iodine solution. Shake and add 1 ml of 2 N hydrochloric acid. A white precipitate is formed.

D. To 1 mg add 1 ml of 0.1 N iodine solution. Shake and add 1 ml of 2 N hydrochloric acid. A white precipitate is formed.

Water: Not more than 1.0% (Method 2, Method 3).

Bacterial endotoxins: Not more than 0.1 EU/mg.

Sterility: Sterile.

Pyrogen: Not more than 0.1 EU/mg.

Crystallinity: Not less than 90% (Method 1).

Picrate: Not more than 214 mg/g (Picrate).

Determination of water ÄÎŁź òóÅȭ ČȬÅÄÛä ŏÅţä ĸŁĦĬĸ" ɟäźÅ3 ŘƠ 8ź òźŋ źŁÅŋ ÆÊШ ďŁĦĬÅ :**Water** ŏÅţä ŏÅţä ƤźŲŢ ɟźÒÅ ŧ Ügǻţä ďŋ ĭ 0.5 ÿäÆÁŲèÅä Û(145 ČĦÅÔää Û1 ÆŸŎä) A ČȬÅÄÛää Û"by Karl Fischer method .ĭ/ŋŸŋ 80 ďŋ ÄŽȭŮ ŧş ĭ/ŋŸŋ 50 ďŋ Ō̄ęŮ

ÐÅŲä ŏÅţä ďŋ Ō̄ŋ 10 Ž ĭ0.05 ČääÄęź ƤŸ3 Ðşź̄Σä 3ÊÎţä òźŸ∓ä (pH) ŏÅŁÅäź ČŧŁęź ŋŸČĭ :**pH Value** ŏÅŁÅČäää ČŧŁęź .7.5-5.0 ÛR ɟźäÄÒää ÆŁÊȭŮ ÜəÅÄŲ ďŋ

:**Assay** ČÊÅÅÕţä

ďŋ Ō̄ŋ 10 Ž ÛČŁùźÊŘŋ ČŲşäźŋ ÛĭĬ 0.065 ČääÄęź ā äØÅ :*For total penicillins ČŁŸÓää ğÅÆŸÊÆźŸõ ČÊÆÅäź* :A ÅŧŦÅŋ Ō̄ȭ ɟÅŲÅää ɟÅŲŋÅÊęź Ō̄Ō̄Å .Ō̄ŋ 1000 øÆÕź ŲDźǵ ŏÅÛ3ŧ ŏÅţä ďŋ ČŁźÅȭ ČŁŧÒź Ƶźź̄Ş R ÆŁŋźŋóźźź ŌŁŽŁŋ ÜəÅÄŲ ďŋ Ō̄ŋ 10.0 ĸźźŲŲţä ÆǵŮ ÐŮ 8ÅŘÅ .gǻäÆÊź ÅŧŦÅŋ Ō̄ȭ ǻşÅŋ ĸŸÔÅÅŋ ĸÅää ĸźźŲŲ ÐŮ ôźŸ∓ä äØŁ ďŋ Ō̄ŋ 2.0 25 gÆŋ °ȳ 60 ČDźØÆäÅź ÜəÅŋ ȳÅþ Ž 3ŕźÅş ā źŲţä ĘŸ8Å ÛŽÅƐ ÛTS ĘŲəÅää ÆÅØźŸȭ/imidazol ôşääÆŁƐä ôźŸŢ ŽÅƐş ŏÅŋ Ō̄ŋ 10.0 ÜØŲÅŽää ā źŲţä ÐŮ 8ÅŘÅ .(A ôźŸ∓ä) °ȳ 20 ČDźØÆää ÐŮ Ğ3ÄÊź ā źŲţä ǻÆÅ .ÙŲŘäÅź ČȬęǻ (B ôźŸ∓ä).

gKDźǵ Ō̄źÅȬŋ ÄŲŋźŲÅŲ 325 ČääÄęź ÜŧŢ3Ů ČDźźŋ ôźÛź ŲÈ 1 ČŲÅÁŽź ČȬĞù ôŸÈ ďŋ ŋî ÅŧŲää âÅȬł KÈüĭk ɟşǻş A ôźŸHŧŸõ ČŲÊÆäÅź TS ĘŲəÅää ÆÅØźŸȭ/ôşääÆŁƐä ôźŸŢ ďŋ Ō̄ŋ 10.0ş ŏÅŋ Ō̄ŋ 2.0 ďŋ ĭÅŋ ƤŸ3 ČÅşÅΣä ÆÅØţä .B ôźŸHŧŸõ ČŲÊÆäÅź ŏÅţä ƤŸ3ş

gǻÅţä Ž $(C_{16}H_{18}N_2O_4S)_2,C_{16}H_{20}N_2$ øäÆȬŋ ÆÊHŧł B ôźŸ∓ä ŋÈÒÅŲş A ôźŸ∓ä ŋÈÒÅŲ ĸź ÀÄÅää ôŸÈ ďŋşş Øòɟä 3ŋ ÛďŋäÅŲäÅź ČŏÅÎţÅź î źHÅţä RS ÿźÅǻźÔää ĸŸÊź ÕÅØźź ďŋ ĭ 0.050 3ŋ ŲØÅȬţä ôŸÈ ďŋ gƎŲÁţä ďŋ ŋŸŋ 1.275 ùźÅÒÅ $(C_{16}H_{17}N_2O_4S)$ RS ÿźÅǻźÔää ĸŸÊź ÕÅØźź ďŋ ŋŸŋ 1 Ō̄ȭ ɟŮ ÐŮ ɟÅÊΣÅź øäÆȬŋ ÛČÅÅÅÒź ÄÆĬĬţä ÜəźŘää ŽŁÛää âÅÆȬŋ Ž ÛÜĬDźÄţä ôźŸ∓ä ŋî ÅŲ ɟźÒÅ ɟŮ Æź .$(C_{16}H_{18}N_2O_4S)_2,C_{16}H_{20}N_2$ .0.03 ± 0.62

400) ÿźÅǻźÔää ÆÅØźŸȭ ôźŸŢ ďŋ Ō̄ŋ 30 ÚČŁùźÊŘŋ ČŲşäźŋ ÛĭĬ 1 ČääÄęź ÐŮ 8ÅŘÅ :$C_{16}H_{20}N_2$ øŸȭ ČÊÆäÅź :B Ûğ Åŧŧȭ 3äøüź ÒŸÁŲÊÅş ÛĭĬÆÆDź ŋŘŞ ÛTS (ò/ĭ 150~) ÿźÅǻźÔää ÆŁÊȭşøÆŁŁ ôźŸŢ ďŋ Ō̄ŋ 10ş TS (ò/ĭ ÛŏÅţä ďŋ Ō̄ŋ 10 ŲDźÜÜ ÅŦŦÅŋ Ō̄ŋ Ō̄ŋ Ûğ Åŧŧȭ ŲŸźź ğÅòŸŲä ɟÅŋ ŌÊ8ł .R Ğŋɟä ďŋ Ō̄ŋ 50 ŲDźÜÜ ÅŦŦÅŋ Ō̄ŋ Ğŋɟä ôźŸŢ ÄÁĠł .ÚÊŁźÄää Ğŋɟä ôźŸŢ ÐŮ ĞòŸŲä 8ÅŘŏş ÛĞŋɟä ďŋ Ō̄ŋ 25 øź ğŧÅÊ8ää ɟÅŋ ÒŸÁŲÊł ÄÁĠş R (ĘŸÛţä) dehydrated ŏÅţä ţşÅøźŋ ôźŲźÅŲä ďŋ Ō̄ŋ 2 8ÅŘÅş ÛŲDźǵ ŘÅòŮ ÐŮ ôźòźää ƤøŲǵ ÕŲźŸõĞää Ř ôźŸHŋ ÄÅÄĬłş R ÜDźŸźää Ō̄ÆŲèɟä Ř ôźŸHŋ ďŋ Ō̄ŋ 50 ČŁȬŲŲţä ČäÅŧźää ÐŮ 8ÅŘÅ .8ÅÄƨä ƤøŲǵ ÜČòźHÅţä gǻÅţä ɟşǻ ČÆŸŧĬäää ǻÅĬĬł .1-naphtholbenzein/acetic acid TS ÄĬĬÎţä ÿäÆÁŲèÅä ÛVS (ò/ôźŋ 0.1)

[illegible] .liberated base [illegible] $C_{16}H_{20}N_2$ [illegible] 12.02 [illegible] VS (ò/ò[illegible] 0.1) [illegible]

[illegible]

Additional Requirements for Sterile Benzathin Benzylpenicillin

[illegible] **Storage** [illegible] .°ÿ 30 [illegible]

Sterility testing of [illegible] **Sterility** [illegible] Penicillinase TS [illegible] (162 [illegible] Û1 [illegible]) "antibiotics [illegible]

[illegible]

Additional requirements for Benzathine benzylpenicillin for parenteral use

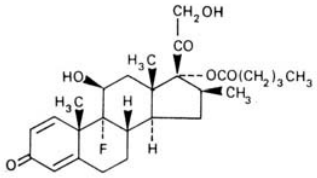
(56 [illegible] Û4 [illegible]) "*Parenteral preparations* [illegible] **Bacterial endotoxins** [illegible] [illegible] Ü([illegible] [illegible] Ž 30 [illegible] Û5 [illegible]) "Test for bacterial endotoxins [illegible] [illegible] [illegible] 1 [illegible] Ž RS [illegible] [illegible] 0.01 [illegible]

[illegible]

Additional requirements for Benzathin benzylpenicillin for Sterile use

Test for Sterility of non- [illegible] [illegible] [illegible]

:Graphic formula ČĦąÅĦĠţä Ğ8ĦÔöä



:Chemical name ŬəÅĦţĦÒöä ţèřä

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate; 9-fluoro-11β,21-dihydroxy-16β-methyl-17-[(1-oxopentyl)oxyl]pregna-1,4-diene-3,20-dione; CAS Reg. No. 2152-44-5.

:Description Ζòζöä ÒĦąäÅöä CÆȝ ÜŬζÅõ ŘĦäÜ БÜ ŘĦäÜ ţζŸä ȧζĦŬÊą.

:Solubility ĞĦąÅäşØöä ţζQĦèţä Ž ţÅäşØöä Ăǵ ÜTS (ȯ/ĥ 750~) ȯζąÅŽΛąä Ž ā äşä ÜÅĦŸţȝ ŏÅţä Ž ā äşä Ƙą.

:Category ĞÅÅöä .Antiinflammatory ā ÅŽQŏŸŏ åÅŘą ŏäşå.

:Storage ąĊΛÂÅQöä .ŏζŘöä ĊĦţŢ ŬŷÅÒǵüä ĞÕŸ8ą ĞΛşÅǵ Ž ţşàÅŽĦąÅQĦĠöä ğäƘŏÅζ ŞÅǵ Æz.

REQUIREMENTS ƘĞĦüŽƠƙdž!ƒ

:General requirement ŷÅĬöä ÆŸÛQţä ĊȝÂÂΛ řş %96.0 ĊȝÕÕΛ řÅą ƨŸȝ ţşàÅŽĦąÅQĦĠöä ğäƘŏÅζ ƁζQƠ. ĞÅäÒä gåÅţä БÜ ţζDZÅöÅä ĞäζÊŢ ÛC27H37FO6 ĊĦą %104.0.

:Identification tests hŭŇjNJŇŒ lεβƒĞĤĢŋε

• ĘŞ CŞ D ğäøÅĞQònřä şÜ BŞ A ţäøÅĞQònřä ĘĠÛΛ ţÜ ĊȯÒε.

:A ŏäÅţΣä ŘƠ ĞĤìţä ĞÕÛΛą Ž ŬəζÊöä ΖĦÛöä âÅĦę" ţäζΛȝ ŘƠ ȯζòζą ζŁÅą ÆÊŒ ÒĦȯÅöä ĘĠÛΛ ŘƠ ĞĤìţä Ž î ÅÔQąřä ΖĦù ĘäÅÛQΛ .(43 ĞĦȯÅÔöä Û1 ÆŸŎä) "Spectrophotometry in the infrared region ğäƘŏÅÅŏ *reference spectrum* ŬĤDZÅţä ΖĦÛöä ȝą şÜ RS ţşàÅŽĦąÅQĦĠöä ğäƘŏÅζ ĊĦą ǰŏÅÅöä ΖĦÛöä ȝą ŏäÅţΣä .ţşàÅŽĦąÅQĦĠöä

:B БÜ ȯÅŘΛ .¢ÊÅφ ÆΛØţÅä ÕĦą 20 БÜ ÕĦą 2 ΖÅÅłş TS (ȯ/ĥ750~) ȯζąÅŽΛąä ĊĦą ÕĦą 20 Ž ŋŸĦą 20 ā äØΛ Ŗβ/ĊΛäöÆĦŁ ÕĦÆζ ȯζŸŢ ĊĦą ÕĦą 10 øäÆÕĦą gåäÆè Ƃé øÅĞQònä ā ζąÜ Ž ţζřζţä ȯζŸ+ä äØŁ ĊĦą ÕĦą 2 ĊĦą ąî Åţöä ţζÒΛ ř .ÅØζζ åƎΛş ÛĞÕĦęå 20 gÆą °ȳ 60 gøäÅǵ ĞDZØÆä ŬəÅą ȳÅβ Ž ĊÅÊΛ ÛŽÂζ ÛTS ÕΛØζÅŸÊöä .0.25 ĊĦą ÅŽõÜ 423 nm ĞäÅę ŬţŢȝÜ ĞDZζą ȯζù ÆÅȝ ţè 1 ĞąÅÅŽä ĞÕĠù ȯŸn

ĞŁÊŁəÀõä ƷÕĢõä ĘżżÀÛŢǩ ."Related steroids ĞŏÅÎţä ğäÆÄŞÀŢŁÊõä" ɹżÄƷ ŘƠ ȣȚȍȚţä øÀĢŢnŕä ƁÚ ÀŢţä :C
ɗŋ ĞΘÀÄõä ĞŁÊŁəÀõä ĞĦÕĢõä ĘżżÀÛŢǩ ÛÕõØõ ĞȚÄŕÚ .B ȍȚŸǂä ɗŋ ĞΘÀÄõä ÕŸǩ Ƹŋ ƷȚȚţä Ž CŞ A ǩȍȚŸǂä ɗŋ ĞΘÀÄõä
.B ȍȚŸǂä ɗŋ ĞΘÀÄõä ÕŸǩ Ƹŋ gÆÎõäŞ ÀŤŢţä Ž A ȍȚŸǂä
Û1 ÆŸŎä) "Oxygen flask method ǩDzÊõɟä ĞŸDZȚg ĞÕÄÀù" ɹżÄƷ ŘƠ ȣȚȍȚţä ȧäÀŢǵŕä ĘĢÛÄ :D
0.01) ȳȚÄźȚÔõä ÆŁÊõŞøÆŁŁ ȍȚŸŢ ɗŋ Ōŋ 0.5 ɗŋ ǰÄŋŞ øÀĢŢnŕä gÅÄŋ ɗŋ ŋŸŋ 7 ȳäÆÅŢèÀä Û(132 ĞHŁÄÔõä
Ōŋ 0.1 ɗŋ ǰÄŋ ɗŋ Ōŋ 0.1 ȣÄŘÄ ÛĞŁŸŁHõä ŌŁŢȮǩ ÄŋÆÄƷ .absorbing ÎÄŢ ŌəÄÊõ ŏÄţä Ōŋ 20Ş VS (ȯ/ȍȚŋ
ÜZirconyl nitrate TS ȍȚŸŢ ɗŋ Ōŋ 0.1Ş ŇDZäÄù ÀŘŢ TS (ȯ/ȟ1) Sodium alizarin sulfonate ȍȚŸŢ ɗŋ
.ÀÄòɟä ɹȚŸõä ƁÚ Àþɟä ȍȚŸǂä ɹȚõ ȯÆĢŢÄ
ÛåƎÄ .ĘəÄęå 5 gÆŋ ƲəÄŋ ȳÄþ Ž TS1 ȍȚŢÄŽÄqä/ȳȚŁèÄǩȚõä ÆŁÊõŞøÆŁŁ ȍȚŸŢ ɗŋ Ōŋ 2.0 Ƹŋ 0.05 ɗÅÊł :E
ŌŁŽÄqä ğäKõÄȚ ĞHŁəäø ĘŸÛÄǩ ÜĞŌŁęå 1 gÆţ ȚÛŸä ȚŸ8ÄŞ ÛTS (ȯ/ȟ100~) ÕÄøȚÄŸÊõä Ř þ ɗŋ Ōŋ 2.0 ȣÄŘÄŞ
.ĻŋÎõÄä ÕäøåŘõ ĞŸäÄÕõä/ĞÄŁÛŸõä
ÜɹÄÊõȚÄÆõä Ž Ōŋ/ŋŸŋ 10 ÂŁõÀĢä ȍȚŸŢ ȳÆÅĢÊÄ :**Specific optical rotation** ƲƷȚÄõä ƁÀÔĢõä ÀÄŞÆĢõä
.$[a]_D^{20°C} = +75 \text{ to} + 81°$

.ȟ/ŋŸŋ 2.0 ɗƷ ÆÄÂÄ ŕ ÜǩǩŸĢõä ɗŋ ĞÕǩȚä Ž (ȧÀHł) ÆŋÀłŞ ȟ0.1 ɹàȚÄ :**Sulfated ash** ŘÄŸÊţä åÄŋÀõä
.ȟ/ŋŸŋ 5.0 ɗŋ ÀŽõÚ ÆÕÄÄ ŕ Ü°ȳ 105 ĞDZøÆõÄä ŘäÄŽõä ɹàȚõä ȚøĢǵ ȚÄz :**Loss on drying** ȚŁÄDzĢõÄä ÆÕÄõä
Thin- ĞÕŁęÀõä ĞÕĢÛõä ãäÀÎĢèä" ɹżÄƷ ŘƠ ȣȚȍȚţä øÀĢŢnŕä ĘĢÛł :**Related steroids** ĞŏÅÎţä ğäÆÄŞKĢÊõä
ɗŋ ǰÄŋŞ ĞŸ8ŋ gÅłõ Silica gel R1 ÅÒŁŸŁÊõä ĞŋŸŁ ȳäÆÅĢèÄä Û(84 ĞHŁÄÔõä Û1 ÆŸŎä) "layer chromatography
ŇŸÔÄÄŋ ĘĢÛÄ .õÀHĢŋ øȚÛõ ŏÄţä ɗŋ ŇłDzǵ 0.2Ş ÛR ȍȚŢÄŽŁţä ɗŋ ȳȚDzǵ 5 ÛR ɹÄŽÄÚ øȚŸõ ȣÄÄĢ ɗŋ ŇłDzǵ 95
ȍȚŸǂä ÛR ȍȚŢÄŽŁţä ɗŋ ŇłDzǵ 1Ş R ȳøȚȚŞøȚŸõ ȳȚDzǵ 9 ɗŋ ǰÄŋ Ž ǩÄĢä ǩȍȚŸŢ ɗŋ ÀĢõŞ ÀÕŋ 1 ĞHŁÄÔõä ȚŸƷ
Ōõ Ž RS ɹŞàÄŽŁŋÄĢŁĢõä ğäKõÄȚ ɗŋ ŋŸŋ 15 ƁȚƵ :(B) ȍȚŸǂäŞ Ōŋ 1 Ōõ Ž øÀĢŢnŕä gÅÄŋ ɗŋ ŋŸŋ 15 ƁȚƵ :(A)
A ȍȚŸǂä ɗŋ ǩõÅÄŘĢŋ ǩłDzǵ ǰÄŋ ɗŋ ɹȚÕŋ (C) ǴõÄĢ ȍȚŸŢ ɗŋ ÀĢõŞ ÀÕŋ 2 ĞHŁÄÔõä ȚŸƷ ŇŘÄÚ ĘĢÛÄ ÜÕŋ 1
¢ÊÄφ ÆÄØţä ɗŋ Ōŋ 1 Ōõ Ž øÀĢŢnŕä gÅÄŋ ɗŋ ŋŸŋ 0.15 ȚŸƷ ƁȚǴ (D) Ƹäø ȍȚŸŢ ɗŋ ÀĢõŞÀÕŋ 1Ş BŞ
ÀÄĢǩ ȚøĢǵ õäȚTä Ž ȚDzĢõ õÀĢǩ ÛäÀÎĢèŕä gKDzǵ ɗŋ ĞHŁÄÔõä ţÂφ ÆŸäŞ .BŞ A ǩȍȚŸHłŁŸõ ȳÆÅĢÊţä
ÆŁÊõŞøÆŁŁ/ȳŁõŞääÀĢĢõä Ğęøà ȍȚŸHŋ æÀÄŞ ÛÅƎĢõ õÀĢǩŞ ÛĘəÄęå 10 gÆŋ °ȳ 105 ĞDZøÆõÄä ĞHŁÄÔõä ɗÅÊł Ż .ğÄGØţä
ĞHŇĞõä õÄÄŽĢèÄä ÛA ȍȚŸǂä ɗŋ ǰĢǩ ĞŇÕä ĞÄÚ ɹȚÕǩ ŕ .øÄŤÄõä õȚŕ Ž ãäÀÎĢèŕä ÙÛÙ ÒHŁÄŞ ÛTS ȳȚÄźȚÔõä
.D ȍȚŸǂä ɗŋ ĞΘÀÄõä ÕŸǩ ɗŋ gÆì ÀŽõÚ ÛĞŁÊŁəÀõä

Assay ǦÊΛÌÕţä :

• ǦÊΛÌÕţä gÆŋ ȯŸȵ ȯzŘöä ȵŋ ÕŒöÌ∓ä ɔtHŭ ɟÙ Æz.

ȯÌÛȝq TS (ȯ/ȟ750~) ÆŒŁÆöɟä ȵŋ БÌ ţä ȯzφÌŽΛqä ȵŋ ǦŒzÌõ ǦŒtõ Ž ÛǦŒùzǦŘŋ ǦφŞàzŋ ÛŋŸŋ 20 ǦäÀę ā äØΛ TS (ȯ/ȟ750~) ÆŒŁÆöɟä ȵŋ БÌ ţä ȯzφÌŽΛqä ȵŋ ǦŒzÌõ ǦŒtȮä ȯzŸ∓ä äØŁ ȵŋ Õŋ 20 ZÌƩ .Õŋ 100 øÆÕä ţDzǵ ȣÌŘΛŞ ÛŒŒtDzǵ ǦDZØÆŋ Õŋ 25 ţDzШ ǦŸDZzΣä БÙ ZÌÁţä ȯzŸ∓ä ȵŋ Õŋ 10.0 ÕÕΛ .Õŋ 100 øÆÕä ţDzǵ ȯÌÛȝq .R ƙDzÊõɟä ȵŋ БÌ ţä ƙDZŞÀφΛÌä ǦŸDZzΣä ȵŋ ȯäzTä ÅÀÛΛŞ ÛTS ȯzφÌŽΛqä/ȳzŒöŞàäÀφφÕä Ǧęøà ȯzŸŢ ȵŋ Õŋ 2.0 ǦŸDZzΣä ȵŋ ǦŒφÌφ ȯäzTä ÅÀÛΛŞ TS ȯzφÌŽΛqä/ȳzŒφzŋÙ ÕŒŽŒŋÌÀφφÕä ÆŒÊõŞøÆŒŁ ȯzŸŢ ȵŋ Õŋ 0.2 gÀÌÌÁǦŋ ȣÌŘΛŞ Ǧ3Ìè 1 gÆŋ øäÀÕφèŸȯ õÀφƙŞ ÛZÛŸä ÕΛÀHφφÌä ǧÌΛzφ∓ä ȝÂφ ÛǦŸDZzΣä ĘŸȣƙ .R ƙDzÊõɟä ȵŋ БÌ ţä ƙDZŞÀφΛÌä TS (ȯ/ȟ750~) ÆŒŁÆöɟä ȵŋ БÌ ţä ȯzφÌŽΛqä ȵŋ ǦŒzÌõ ǦŒtõ ȣÌŘΛŞ ÛǦ3ÀÊä åƎΛ .°ȳ 30 ǦDZØÆä ŬÌŋ ȳÌþ Ž 525 ǦäÀę ŬtŢ3Ù ǦDZzŋ ȯzÛä ţè 1 ǦφÌÁŽä ǦÕǦù ȯŸȵ ȵŋ î ÌtφÕä âÌÕΛ .ȝÂƩŞ ÛÕŋ 25 øÆÕä ţDzǵ ȯÌÛȝq (ȯ/ȟ750~) ƙDzÊõɟä ȵŋ БÌ ţä ȯzφÌŽΛqä ȵŋ Õŋ 10 Ǧ∂ÌŘŋ ÀŘŢ ȯzŸŢ ɔŸ3 ǦΛŞÌΣä ÆΛØţä gKDzǵ ÕäÌÕŋ ÀφzφÌφ ǦȯzHŭÌţä RS ɟŞÀÌŽŋ ÌφŒǦÕä ǧäKÕÌz ȝŋ ǦφØÌÕţÌä ǦȯzHŭÌţä gÅÌţä Ž $C_{27}H_{37}FO_6$ ǦŒtõ ÆÊHŭ .ÌZÊÌφ ǦÕΛÀÛÕÌä .ȵŋäÂφÕäŞ ǦŏÌÎţÌä

ØØØØØ

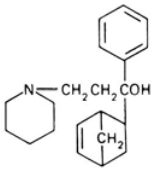
BIPERIDENUM

Biperiden البيبيريدين

Molecular formula ǦŒÌΛÂ∂ä Ǧ8ŒÔÕä: $C_{21}H_{29}NO$

Relative molecular mass ǦŒǦÊΛÕä ǦŒÌΛÂ∂ä ǦŸφÒÕä: 311.5

Graphic formula ǦŒφÌŒǦţä Ǧ8ŒÔÕä:



Chemical name ŬφÌŒtŒÒÕä ţèrä:

α-5-Norbornen-2-yl-α-phenyl-1-piperidinepropanol; α-bicyclo[2.2.1]hept-5-en-2-yl-α-phenyl-1-piperidinepropanol; CAS Reg. No. 514-65-8.

.ǦĦʊǎǎÀÀõǎ CǦÆʒ ÜǦǦǦÀÀÔǩ ŘŘĦǎǎǔ ǩǔ ŘŘĦǎǎǔ ɟʒŸǎ ƀØʒŸǎ ȧʒĦʊÊǩ :**Description** Ʒ ȯʒõǎ

ǦĦʊì ÜR Ǩǫɟǎ Ž ǎǎǩǎ ÜR ȳØʒʒǩØʒŸÒõǎ Ž ɟǎǎǩØõǎ Àǧ ÜǦĦŸŧʒ ȯǎŧǎ Ž ǎǎǩǎ Ǩɖ :**Solubility** ǦĦǫǎǎǩØõǎ

.TS (ȯ/ȟ750~) ȯʒǫǎŽʌǫǎ Ž ɟǎǎǩØõǎ

.Antiparkinsonism ǦĦǫʒÊʌõØǎǦõǎ ǎǎŘǩ ȯǎǩǎ :**Category** ǦǎǎÀõǎ

.ȯʒŘõǎ ȯǩ ǦĦŧŢ ÜȳǎÒǧüǎ ǦÕŸ8ǩ Ǧʌǩǎǧ Ž ȯʌÆʌǩǦĦǦõǎ Şǎǧ Æz :**Storage**ǫȯʌÂǎǫõǎ

REQUIREMENTS ǨǦȯʌƵǨȯ!ƒ

ȯǩ %101.0 ȯʒ ÆʌÂʌ ŗǩ %98.0 ȯʒ ÕÕʌ ŗǎǩ ʔŸʒ ȯʌÆʌǩǦĦǦõǎ ƀʒǫƷ :**General requirement** ȳǎŘõǎ ÆŸÛǫŧǎ

.ǦǎǎÕǎ gǎŧǎ Бǔ ţʒDZÀõǎǎ ǦǎʒÊŢ Ûc$_{21}$H$_{29}$NO

:**Identification tests** hƀŸNjNJЛЄ l ɛƥƒǦĦǦ|ɛ

.Dǩ Cǩ B ǧǎǎǎǦǫŋŗǎ ǩǔ ǦǎǎÀǎǩ A ǎǎǦǫŋŗǎ ǎǩǔ ĘǦÛʌ ɟǔ ȯÒɛ •

õǎÀŧΣǎ ŘƠ ǦŘŸì ɟǎ ǦÕÛʌǩ Ž ƀʒʒŘõǎ ʒĦÛõǎ ǎǎĦę" ɟǎʒʌʒ ŘƠ ȯʒȯõʒǩ ʒŧǎǩ ÆÊШ ÒĦʊǎõǎ ĘǦÛʌ :A

ŘƠ ǦŘŸì ɟǎ Ž î ǎÔǫǩŗǎ ʒĦù ĘǎǎÛǫʌ .(43 ǦĦʊǎÔõǎ Û1 ÆŸŎõǎ) "Spectrophotometry in the infrared region

.ȯʌÆʌǩǦĦǦŸõ *reference spectrum* ƀŘDZÀŧǎ ʒĦõǎ ʒǩ ǩǔ RS ȯʌÆʌǩǦĦǦõǎ ȯǩ ɟǩǎÀõǎ ʒĦõǎ ʒǩ õǎÀŧΣǎ

.ÀŘǩǔ ɟʒȯ ɟǫʌ ÜõǎÀÕǫÈŸȯ õÀǫʌǩ TS (ȯ/ȟ1440~) ÕʌØʒǎÊʌõǎ Ŗβ ȯǩ Ōǩ 5 Ž ŋŸǩ 20 ǎǎØʌ :B

ʔøǫǧ ȯǎÊʌǩ ÛTS (ȯ/ȟ70~) ÕʌØʒŸõǩØÆĦŢǎ Ŗβ Ōǩ 0.5 Ûŏǎǩ Ōǩ 80 øǎÆÕǩ ȟ0.20 Бǔ ƀǎŘʌ :C

õǎÀǎò ǦǎǎÈǩ ÕÒÎǫǩ ÜgÀÛÕʒ gÀÛę bromine TS1 ȳǩƎõǎ ȯʒŸŢ ȯǩ ȯʒŸ+ǎ ǎØŁ ȯǩ Ōǩ 5 Бǔ ƀǎŘʌǩ ǎƎʌ .ɟǎǎǩØõǎ

.ǦʒÆǫÊǩ ǦǎǎÈǩ ŘŸÒÎǩ ǎŧŸõ TS1 ȳǩƎõǎ ȯʒŸŢ ʒĦŗŴ ǎŧŸõǩ .ÕʌÀĦʊǫõǎ Æǎʒǎǩǩ ɟʒŸõǎ

.°ȳ 114 ǦǎǎÀę ÛØǎŦÔǫŗǎ ǦDZØǎ :D

.ȟ/ŋŸǩ 1.0 ȯʒ ÆʌÂʌ ŗ :**Sulfated ash** ŘǎŸÊŧǎ ǎǎǩÀõǎ

.ȟ/ŋŸǩ 10 ȯǩ ÀŽõǔ ÆÕǎʌ ŗ Ü°ȳ 105 ǦDZØÆǎ ǧǎʒǎÈʒ gÆŧ ʒǎz :**Loss on drying** ʒĦǎDzǫõǎ ÆÕǎõǎ

Thin- ǦÕĦęÀõǎ ǦÕǦÛõǎ ǎǎÀÎǫÈǎ" ɟǎʒʌʒ ŘƠ ƀʒȯõʒŧǎ ØǎǦǫŋŗǎ ęǦÛʌ :**Related substances** ǦõǎÎŧǎ ǎǎʒŧǎ

Silica gel R1 ǎÒĦŸĦÊõǎ ǦǩŸŁ ęŸŘǫÊǩ ǦÊĦŸǩ ǦHʊĦǎÀò ȳǎÆǎǫÈǎǎ Û(84 ǦĦʊǎÔõǎ Û1ÆŸŎõǎ) "layer chromatography

Toluene ȯʌʒȯʒǫõǎ ȯǩ ǩŧDzǧ 96.5 ȯǩ ɟʌǎǩ õÀĦʊǫǩ ØʒÛõǩ ÛVS (ȯ/ȯʒǩ 0.5) ȳʒʌǎʒÔõǎ ÆĦÊõǩØÆŁ ȯʒŸŢ Ž

ȯʒŸ+ǎ ÛR ȳØʒʒǩØʒŸÒõǎ Ž ƙǎǫõǎ ƙȯʒŸŢ ȯǩ Àǫõǩ ÀÒǩ 5 ǦĦʊǎÔõǎ ʔŸʒ ǩŸÔǎǎǩ ęǦÛʌ .R ȯʒǫǎŽĦõǎ ȯǩ ǩŧDzǧ 3.5ǩ R

.Ōǩ 1 Ōõ Ž ØǎǦǫŋŗǎ gǎǎǩ ȯǩ ŋŸǩ 0.20 ƀʒƷ :(B) ȯʒŸ+ǎǩ Ōǩ 1 Ōõ Ž ØǎǦǫŋŗǎ gǎǎǩ ȯǩ ŋŸǩ 40 ƀʒƷ :(A)

Potassium idobismuthate ȯzŸHŋ ǦHȣÅÔöä æÀǩ ÛöäzTä Ž Ζ DzQȯ ȫÀQǩ Û ä äÀÎQèŕä ǥKDzǵ ȯbŋ ǦHȣÅÔöä ţÂǫ ÆĦäş ÛǦȣÊȣƷÀöä ǦĦÕǦöä ȯÅÅŽQèÅä ÛA ȯzŸǂä ȯbŋ ǰQǩ ǦĦÕä ǦÀÛ ȣzÒǩ ŕ .øÅŽÀöä ȯzŕ Ž ä äÀÎQèŕä ÙÛÛƯ ÒHȣÅÅş ÛTS2 .B ȯzŸǂä ȯbŋ ǦȮÅÅöä ÕŸǩ ȯbŋ ǥÆì ÀŽȫÛ

0.15 ȣÅÎÅ ÛR1 ŦDzŸŽöä ÕĦQȣèǰä Ŕβ ȯbŋ Ôŋ 30 Ž ÛǦȣùzǦÎŋ Ǧǫşàzŋ ÛĦ0.4 ǦääÀę ä äØÅ :**Assay** ǦÊÅÅÔţä ÛVS (ȯ/ȯzŋ 0.1) ÕÅØzŸȫǦöä Ŕβ ȯzŸHŋ ÀÅÅĦşÀĦÎŧȫ 1-naphtholbenzein/acetic acid TS ȯzŸŢ ȯbŋ Ôŋ ÆŸÖä) A ǦÕÅÀÛöä ÆÊŦ Ú"Non-aqueous titration ŦəÅŋŸöä Ùèzöä Ž ǥÀÅÅĦţä" ȷäzÅ3 ǨƠ ȣzòzŋ zŁÅŋ ÆÊŦ .$C_{21}H_{29}NO$ ȯbŋ ŋŸŋ 31.5 ùzÅÒÅ VS (ȯ/ȯzŋ 0.1) ÕÅØzŸȫǦöä Ŕβ ȯbŋ Ôŋ 1 Ôȫ .(142 ǦHȣÅÔöä Û1

Ǐøüsθ℠ üƒDŽyƭzúǁ ǫyDŽ℠ DžǐǫǐƥǐǦǐǦ℠ üŦŬ ǏƷƬä ƒƭƯƭDŽ

Additional requirement for Biperiden for parenteral use

.(56 ǦHȣÅÔöä Û4 ÆŸÖä ÀŢǫä) "*Parenteral preparations* ǦÆÅÕΣä ǥäÀŘHȣQÊţä" øä ǦòÅǏä ǥǵşÀzǵǥä БÛ ÆÆDzQÊÅ

ØØØØØ

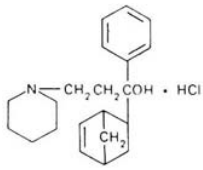
BIPERIDENI HYDROCHLORIDUM

Biperiden hydrochloride DžǐǫǐƥǐǦǐǦ℠ ǫǐƥNj‡lNjƥǫǐlj

$C_{21}H_{29}NO,HCl$:**Molecular formula** ǦÆÅÅÂƨä Ǧ8ÆÔöä

347.9 :**Relative molecular mass** ǦÆǦÊÅöä ǦÆÅÅÂƨä ǦŸQÒöä

:**Graphic formula** ǦÆǫÅÆǦţä Ǧ8ÆÔöä



:**Chemical name** ŦəÅÆŧÆÒöä ǰèŕä

α-5-Norbornen-2-yl-α-phenyl-1-piperidinepropanol hydrochloride; α-bicyclo[2.2.1]hept-5-en-2-yl-α-phenyl-1-piperidinepropanol hydrochloride; CAS Reg. No. 1235-82-1.

.ǦHȣäÀöä CÆ3 ÜŔÆäÛ ȷzŸä ȣózŸä ȧzHȣÊŋ :**Description** Ζòzöä

ÕÆŸę ÜR ǨǫǰäŞ TS (ȯ/Ĥ750~) ȯzǫÅŽÅqäŞ R ȳózzŞózŸÒöäŞ ȫÅţä Ž ȷÅäŞÓöä ǦÆHÙì :**Solubility** ǦÆǫÅäŞÓöä .R ȯzǫÅŽÆţä Ž ȷÅäŞÓöä

.Antiparkinsonism ǦĒǫʒÊʌõǒÁǦŸõ ǎǎŘŋ ǒǎşǎ :**Category** ǦǎÁǎõǎ

.ǒʒŘõǎ ɗŋ ǦĒŧŢ ÛȳÁÒǵüǎ ǦÕŸ8ŋ ǦʌşÁǵ Ž ɗʌÆʌKǦĒǦõǎ ÆʌǒʒŸõşǒÆĒŁ ŞÁǵ Æz :**Storage** ɗʌÂÁǫõǎ

REQUIREMENTS ƙǦĥʌŸƱkdž!ƒ

ɗʒ ÆʌÂʌ ŕş %98.0 ɗʒ ÕÕʌ ŕÁŋ ɔŸʒ ɗʌÆʌKǦĒǦõǎ ÆʌǒʒŸõşǒÆĒŁ Ƀʒǫʒ :**General requirement** ȳÁĤõǎ ÆŸÛǫţǎ .ǦÁÁǒǎ ǵǎŤǎ Ƃǔ ţʒDZÀõÁǎ ǦǎʒÊŢ ÛC$_{21}$H$_{29}$NO,HCl ɗŋ %101.0

:**Identification tests** hŭŸNjNJЛЄ l ɛƀƑǦĤƊ|ɛ

.Dş Cş B ǧǎǒÁǦǫnŕǎ şǔ Dş A ɗʌǒÁǦǫnŕǎ ĘǦÛʌ ɟǔ ɗÒʒ •

õǎÀŧΣǎ ǨƠ ǦĤŸìɟǎ ǦÕÛʌŋ Ž ƱəʒŘõǎ ZĒÛõǎ âÁĒę" ɟǎʒʌ3 ǨƠ ȣʒòʒŋ ʒŁÁŋ ÆÊЦ ǒÁǦǫnŕǎ ĘǦÛʌ A ǨƠ ǦĤŸìɟǎ Ž î ÁÔǫŋŕǎ ZĒù ĘǎÁÛǫʌ .(43 ǦHɅÁÔõǎ Û1 ÆŸǒǎ) "Spectrophotometry in the infrared region *reference spectrum* ƱĤDZÀŧǎ ZĒÛõǎ Ʒŋ şǔ RS ɗʌÆʌKǦĒǦõǎ ÆʌǒʒŸõşǒÆĒŁ ɗŋ ǰǨʌõǎ ZĒÛõǎ Ʒŋ õǎÀŧΣǎ .ɗʌÆʌKǦĒǦõǎ ÆʌǒʒŸõşǒÆĒT

.ÀŘnǔ ɟʒŏ ǰǫʌ ÜǒǎÀÕǫèŸŏ õÀǫʌş TS (ȯ/ȟ 1440~) ÕʌǒʒÁÊʌõǎ Ř ƀ ɗŋ Õŋ 5 Ž ŋŸŋ 20 ǎǎØʌ B

ÜgÀÛÕʒ gÀÛę bromine TS1 ȳşƎõǎ ȯʒŸŢ ɗŋ ȯʒŸǂǎ ǎØŁ ɗŋ Õŋ 5 Ƃǔ ȣÁŘʌş ǒÁŋ Õŋ 50 Ž ȟ0.10 ǎǎØʌ C

.ǦƩǫÊŋ ǦǎÁèǿ ǰǫʌǩ TS1 ȳşƎõǎ ȯʒŸŢ ɗŋ ǧǎʌà ǦʒÁŕǔ ÆʌʒŞ .ÕʌÀHɅǫõǎ ÆʌʒǎşØǩ ɟʒŸõǎ ǒǎÀÁǒ ǦǎÁèǿ ǰǫʌǩ

General ǦŋÁĤõǎ ȣǎÀĤǫèŕǎ ǧǎǒÁǦǫnǎ" ɟǎʒʌ3 ǨƠ ȣʒòʒŋǎ BÕʒÁÁǫõǎ Õŋ/ŋŸŋ20 ÂŁõÀǫǎ ȯʒŸǂǎ ƱÛĤʌ D

.(121 ǦHɅÁÔõǎ Û1 ÆŸǒǎ) chlorides ǧǎÆʌǒʒŸÒŸŏ ÂŁŧŋ ÕʒÁÁǫõ"identification tests

.ȟ/ŋŸŋ 1.0 ɗʒ ÆʌÂʌ ŕ :**Sulfated ash** ǨÁŸÊŋǎ ǎÁŋÀõǎ

.ȟ/ŋŸŋ 5 ɗŋ Àǰõŭ ÆÕÁʌ ŕ Ü°ȳ 105 ǦDZǒÆǎ ǧÁʒÁè 3 gÆŋ ZÁz :**Loss on drying** ZĒÁDzǫõÁǎ ÆÕÁõǎ

ǦÕĒęÀõǎ ǦÕǦÛõǎ ǎǎÀÎǫèǎ" ɟǎʒʌ3 ǨƠ ȣʒòʒŋ ʒŁ ÁŧõŞ ǒÁǫnŕǎ ĘǦÛʌ :**Related substances** ǦǒÁÎŋǎ ǎǎʒŋǎ

Silica ÁÒĒŸĒÊõǎ ǦŋŸŁ ĘŸĤǫÊŋ ǦÊĒŸŋ ǦHɅÁÒ ȳǎÆÁǫèÁǎ Û(84 ǦHɅÁÔõǎ Û1 ÆŸǒǎ) "Thin-layer chromatography ɗʌzȯzǫõǎ ɗŋ ŧŧDzǵ 96.5 ɗŋ ǰʌÂŋ ŞÀHɅǫŋ ǒʒÛŞ ÛVS (ȯ/ȯʒŋ 0.5) ȳʒʌǎʒÔõǎ ÆĒÊõşǒÆĒŁ ȯʒŸŢ Ʊøʒ gel R1 :(A) ȯʒŸǂǎ ÛR ȯʒφÁǰĒŋǎ Ž ƙÁǫõǎ ƙȯʒŸŢ ɗŋ ÀǫõŞ ÀÒŋ 10 ǦHɅÁÔõǎ ɔŸʒ ŧŧÔÁʌŋ ĘǦÛʌ .R ȯʒφÁǰĒŋǎ ɗŋ ŧŧDzǵ 3.5Ş ŋǎ ÆĤǎŞ .Õŋ 1 Õõ Ž ǒÁǫnŕǎ gǎÁŋ ɗŋ ŋŸŋ 0.10 Ƀʒǫ :(B) ȯʒŸǂŞ Õŋ 1 Õõ Ž ǒÁǫnŕǎ gǎÁŋ ɗŋ ŋŸŋ 20 Ƀʒǫ

ÙÛÜ ÒHɅÁʌŞ Ûpotassium iodobismuthate TS2 ȯʒŸHɅŋ æÀǩŞ Ûõǎʒŋŋǎ Ž ZDzǫõ õÀǫǩ ÛgƙDzǵ ɗŋ ǦHɅÁÔõǎ ǦƟÁõǎ ÕŸǩ ɗŋ gÆì Àǰõŭ ÛǦĒÊŁÀõǎ ǦĤÕǦõǎ ǒÁǰǫèÁǎ ÛA ȯʒŸǂǎ ɗŋ ǰǫʌǩ ǦĤÕǎ ǦʌÙ ɟʒȯǩ ŕ .ǒÁǰǫõǎ ǒʒŕ Ž ǎǎÀÎǫèŕǎ .B ȯʒŸǂǎ ɗŋ

ZÛŸǎ ɗÁÊŁŞ ÛR1 ƱDzŸǰõǎ ÕĒǫĒèɟǎ Ř ƀ ɗŋ Õŋ 30 Ž ÛǦĒÙʒǦŘŋ ǦφŞàʒŋ ÛĤ0.4 ǎǎØʌ :**Assay** ǦÊʌÁÕŢǎ

:ÀĤÎŋǎ ȯʒŸŢ ɗŋ Õŋ 0.15Ş TS ÕĒǫĒèɟǎ Ř ƀ/ĘǦǎÂõǎ ǧǎǫĒèÙ ȯʒŸŢ ɗŋ Õŋ 10 ȣÁŘʌş ÛȯʒŸǂǎ ɔŸʒ ȯʒÔHɅŸõ

Ǩƣ ȣȝȍȝŋ ȝŁȦŋ ǼÊШÛvs (ȯ/ȯȝŋ 0.1) ÕȪȍȝŸõşǩGöä ŘŧШ ÀȦȦĤȦ .1-naphtholbenzein/acetic acid TS Ōŋ 1 Ōõ .(142 ǦHȣÀÔöä Û1 ÁŸÖä) A ǦÕȪÀÛöä ǼÊШ Û"Non-aqueous titration ȣȦŋŸöä Ùèȝöä Ž gÀȦĤŧä" ȷäȝȦ3 .$C_{21}H_{29}NO,HCl$ ȡŋ ŋŸŋ 34.79 ùȝȦÒȦ vs (ȯ/ȯȝŋ 0.1) ÕȪȍȝŸõǩGöä Řþ ȡŋ

ØØØØØ

BLEOMYCINI HYDROCHLORIDUM

Bleomycin hydrochloride DžĭƨĭDŽNjĭǂǦǁɛ ǫĭþNjǂǀNjþǫĭlj

(**non-injectable** DžśΘǂǁ üǦƒśǁɛ þĭȝ) DžĭƨĭDŽNjĭǂǦǁɛ ǫĭþNjǂǀNjþǫĭlj

Sterile !ĭśyǁɛ ÛDžĭƨĭDŽNjĭǂǦǁɛ ǫĭþNjǂǀNjþǫĭlj

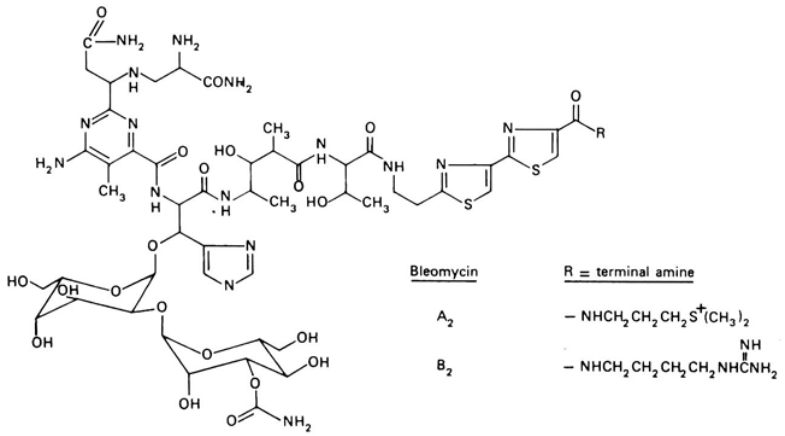
ǦŋÊŸÊǫǂä zy ƎȝǰǫǍǩ ǎäȝŋ ǰȦŧ ÐÁȪȍȝŸõşǫÁÉŁTä ǦŸŧä zŁ ǩÊŁŋȝÉŸǦöä ÁȪȍȝŸõşǫÁÉŁ :**Composition** ÆÉŁõÀǫöä CAS Reg. ÜB$_2$ ǩÊŁŋȝÉŸǦöäş A$_2$ ǩÊŁŋȝÉŸǦöä ÀŹ ǰȦŧŸõ ǰÀÉÊŁƨÀöä ǰÀǫȝÒŧä .*Streptomyces verticillus* ǦŁŋäşÁöä .No. 67763-87-5

.$C_{55}H_{84}N_{17}O_{21}S_3,Cl$:A$_2$ ǩÊŁŋȝÉŸǦöä ÁȪȍȝŸõşǫÁÉŁ :**Molecular formula** ǦŁÀȦÂƨä Ǧ8ŁÔöä

.$C_{55}H_{84}N_{20}O_{21}S_2,HCl$:B$_2$ ǩÊŁŋȝÉŸǦöä ÁȪȍȝŸõşǫÁÉŁ

ÁȪȍȝŸõşǫÁÉŁ Ü1452 :A$_2$ ǩÊŁŋȝÉŸǦöä ÁȪȍȝŸõşǫÁÉŁ :**Relative molecular mass** ǦŁǦÊÀöä ǦŁÀȦÂƨä ǦŸǫÒöä 1461 :B$_2$ ǩÊŁŋȝÉŸǦöä

:**A$_2$/B$_2$ bases** ǩèÀèȷä **B$_2$/A$_2$** ǩÊŁŋȝÉŸǦŸõ ǦŁǫÀŁǦŧä Ǧ8ŁÔöä



:Chemical name ŬəÀĖŧĖÒöä ĻèŕÄ

Bleomycin A_2 hydrochloride: N^1-[3-(Dimethylsulfonio)-propyl]bleomycinamide chloride; [3-[2′-[2-[(2*S*,3*R*)-2-[(2*S*,3*S*,4*R*)-4-[(2*S*,3*R*)-2-[6-amino-2-[(1*S*)-1-[[(2*S*)-2-amino-2-carbamoylethyl]amino]-2-carbamoylethyl]-5-methyl-4-pyrimidinecarboxamido]-3-[[2-*O*-(3-*O*-carbamoyl-α-D-mannopyranosyl)-α-L-gulopyranosyl]oxy]-3-imidazol-4-ylpropionamido]-3-hydroxy-2-methylvaleramido]-3-hydroxybutyramido]ethyl][2,4′-bithiazole]-4-carboxamido]propyl]dimethylsulfonium chloride; CAS Reg. No. 49830-49-1.
Bleomycin B_2 hydrochloride: N^1-(Guanidinobutyl)bleomycinamide hydrochloride; (β*S*)-4-amino-β-[[(2*S*)-2-amino-2-carbamoylethyl]amino]-6-[[(1*S*,2*R*)-2-[[2-*O*-(3-*O*-carbamoyl-α-D-mannopyranosyl)-α-L-gulopyranosyl]oxy]-1-[[(1*R*,2*S*,3*S*)-3-[[(1*S*,2*R*)-1-[[2-[4-[(4-guanidinobutyl)carbamoyl][2,4′-bithiazol]-2′-yl]ethyl]carbamoyl]-2-hydroxypropyl]carbamoyl]-2-hydroxy-1-methylbutyl]carbamoyl]-2-imidazol-4-ylethyl]carbamoyl]-5-methyl-2-pyrimidinepropionamide hydrochloride; N^1-[4-[(aminoiminomethyl)amino]butyl]bleomycinamide hydrochloride; CAS Reg. No. 55658-44-1.

.øäÀÀòQò ãøÀŕ ŘĖäŬ ÉŬ ŘĖäŬ ÞøzŸä ȧzHÞÊŋ :**Description** Z ò z ò ä

Ƙd ÜTS (ȯ/ħ750~) ȯzφÀŽΛqä Ž JÀäŞØöä ĠĖHÞì ÜR ȯzφÀŽΨŧä ŽŞ ŏÀŧä Ž JÀäŞØöä Àǵ :**Solubility** ĞĖφÀäŞØöä

.ĦĖŸŧȝ R Ƙõŧä Ž ŕŞ R JzQĖèŧä Ž ãäŞá

.Cytotoxic ÀΛŸÁŸö ȳÀè öäŞá :**Category** ĞÀÀöä

.ȳÀÒǵüæ ĞÕŸ8ŋ ĞΛŞÀǵ Ž ƙÊĖŋzĖŸGöä ŞÀǵ Æz :**Storage**ąbΛÂÁQöä

ĞĖzÀŕqä ǧÀGŸÛQŧä ŬøGŸƙ gáÀŧä JŬ ÉŬ ĻĖÕĦöä ƙÊĖŋzĖŸGöä ÁΛózŸõŞØÁĖŁ ĞĖŧÊQöä ƙÎƙ :**Labelling** ĻĖèzQöä

.ʔÀnŧä ĞŧĖÕĦöä ǧÀÕĖGÛQöä ÕDZŧ ŞŬ ŬøΛÕΣä ŏÀÛȝRö ÕŧĦQÊΛ JŬ ȯÒƨŞ ĻĖÕĦöä ƙÊĖŋzĖŸGöä ÁΛózŸõŞØÁĖŁ ÕDZŧ ÁŸƨä ȝŋ âÀŧQöä ÆΛΘŞ ÛÞÁΛŧÀä ƙÊĖŋzĖŸGöä ÁΛózŸõŞØÁĖŁ ÕŋÀĦΛ ÀŋÁΛȝ ĞΛÀĦÀÄöäŞ øØΣä Ŭnzƙ Æz :ÀΛØƠ

.öäzTÀä ĞözÕΛŧä ǧÀŧĖÊƨä ȧÀÎΛQëäŞ

REQUIREMENTS ƙĞöΛÄÕƙdž!f

ÛA ĞÊΛÀÕŧä ÆÊШ ÒHÞÀΛ ÀŋÁΛȝ ÛƙÊĖŋzĖŸGöä ÁΛózŸõŞØÁĖŁ ÞzQȝ :**General requirement** ȳÀĦöä ÆŸÛQŧä ÉŬ ŧzDZÀöÀä ĞäzÊŢ ÛŊŸŋ 1 Õõ Ž B_2/A_2 ƙÊĖŋzĖŸGöä ƀŋ ĞĖöŞá gÁǵŞ 2000 ƀȝ ÁΛÂΛ ŕŞ 1500 ƀȝ ÕÕΛ ŕÀŋ ʔŸȝ

.ĞÀÀÒä gáÀŧä

%55.0 ƀȝ ÕÕΛ ŕÀŋ ʔŸȝ ÛB ĞÊΛÀÕŧä ÆÊШ ÒHÞÀΛ ÀŋÁΛȝ ÛƙÊĖŋzĖŸGöä ÁΛózŸõŞØÁĖŁ ÞzQȝ ÛÕöé ƀŋ ÀŽõÛ ŕ ÜB$_2$ ƙÊĖŋzĖŸGöä ƀŋ %32.0 ƀȝ ÁΛÂΛ ŕŞ %25.0 ƀȝ ÕÕΛ ŕ ÀŋŞ ÛA$_2$ ƙÊĖŋzĖŸGöä ƀŋ %70.0 ƀȝ ÁΛÂΛ ŕŞ %7.0 ƀŋ ÀŽõÛ A$_5$ ƙÊĖŋzĖŸGöä ʔzQȚ JzÒΛ ŕŞ .%85 ƀŋ ÕęÛ B$_2$ ƙÊĖŋzĖŸGöäŞ A$_2$ ƙÊĖŋzĖŸGöä ŧzŧf JzÒΛ

.%3.0 ďŋ ÄŽõÜ demethylbleomycin ÕĘŽĘţä ţęÂøÁŋ A_2 ƙÊĘŋzĘŸĠöäę %1.0 ďŋ ÄŽõÜ B_4 ƙÊĘŋzĘŸĠöäę

:**Identification tests** hŭĬNjNJЛЄ l ЄƥƑGĤCJЄ

TS (ȯ/ȟ160) (II) âÅĤUÁÖä ğÅÁŸè ȯzŸŢ ďŋ ÄǫõęÄÒŋ 5 ȣÅŘÄę ÛŏÅŋ Õŋ 10 Ž ŋŸŋ 5 ĞääÄę ā äØÄ A ĞDZzţäę ÄǫŋzφÅφ 242 ĞääÄę ĞDZzţä ȯzÛä ƙĘţŢ3Ü ƙòÅÔǫŋä î ÅÔǫŋŗä ZĘù ÐÆĠÄ ÜÕŋ 100 ɔøǫǵ ŏÅţÅä ZÅƷę .ÄǫŋzφÅφ 268 ĞääÄę ĞDZzţä ȯzÛä ÄÄȣòÜ ÄòÅÔǫŋäę ÛÄǫŋzφÅφ 290 General ĞŋÅĤÖä ȣäÄĤǫèŗä ğäøÅĠǫnä" ɹäzÄ3 ŘƠ ȣzòzţä B Õ3ÅÁǫöä Õŋ/ŋŸŋ 10 ÂĘõÄǫä ȯzŸ‡ä ÜÛĤł B .(121 ĞHuÁÔöä Û1 ÁŸŎä) chlorides ğäÁÄøzŸÒŸö Âßtłŋ Õ3ÅÁǫõ "identification tests

ęÜ ȯÅȮèÅäzŸĘõ 0.6 ďƷ ÁÄÂÄ ŗ) ŘÁÁŋ Ù8ř ŘƠ °ȳ 60 ĞDZøÁä ZÅz :**Loss on drying** ZĘÁDzǫöÅä ÁÕÁöä .ȟ/ŋŸŋ 60 ďŋ ÄŽõÜ ÁÕÁÄ ŗ ÜğÅ3Åè 4 gÁŋ (ĘĠàÄ ŋŸŋ 5 ĞääÄę

.6.0 - 4.5 ÛÕŋ/ŋŸŋ 5.0 ÂĘõÄǫä ȯzŸ‡ä ŏÅŁÅä ŋŸĠÄ :**pH value** ŏÅŁÅĠöä ĞłĘę

10 Ž ā äØŏęę Õŋ 60 ŋDzШ ÕÔz 3łę БÜ ÛĞĘùzĠŘŋ ĞǫęÄzŋ ÛŋŸŋ 75 ÕÕÄÄ :**Copper content** âÅĤUÁÖä ƷzǫŢ ÕÔz 3łę БÜ TS2 ÐóÅĘĤţä âÅĤUÁÖä ȯzŸŢ ďŋ Õŋ 10 ÕÕÄÄ .TS (ȯ/ȯzŋ 0.1) ÕÄȣzŸõęóÄĘŢä Ř ƥ ďŋ Õŋ õÄǫŏ .ĞÕĘęå 1 gÁŋ gÁÎä ŘƷę Zin bis (dibenzyldithiocarbamate)TS ȯzŸŢ ďŋ Õŋ 10 ƙĤłłÕŸö ȣÅŘÄ .ŽÅřÜ .ŏÅţä gåÅÄà ţÂøÅŏ R ĞĘÅŋŸöä ȳzÄåzÔöä ğÅÁŸè ďŋ Ĥ1 Ƶ3 ɔŸÁÊöä ĞÕĠÛöä ĆÌÄĂŏ .ÅłłŢŘĤä ď3 ɹŸÔÁÄǫŏ ɹÅǫÕĠÛöä ÐzŢ ÆÄØŋ gĞKDzǵ ȳäÁÁǫèÅä ÛÄǫŋzφÅφ 435 ĞääÄę ŲłłŢ3Ü ĞDZzŋ ȯzÛä ŋè1 ĞǫÅÁŽä ĞÕĠù ȯŸn ďŋ î ÅłłǫöÄ âÅÕł .R ɹzäÄÒöä ÁÄøzŸõ Ŭ3ÅäØ ÆÄØţä

ÛĞòzHuÅţä gåÅţä ęî ÅǫĞłęę ɔŸ3 *Ao* ȯÁĞęę (*Ao*X15)/(*As*X*W*) Ğ8ĘÔöä ďŋ ȟ/ŋŸţÅä ÄØÁÕŋ âÅĤUÁÖä ƷzǫŢ ÆÊƵ ƷzǫŢ ÁÄÂÄ ŗ ÜĞòzHuÅţä gåÅłłŸö ŋŸţÅä ÄØÁÕŋ ɹäzöä Ğłęę ɔŸ3 *W*ę ÛTS2 ÐóÅĘĤţä âÅĤUÁÖä ȯzŸŢ ęî ÅǫĞłęę ɔŸ3 *As* .ȟ/ŋŸŋ 0.2 ďƷ âÅĤUÁÖä

:**Assay** ĞÊÄÅÕţä

ĞÊÄÅÕţä" ɹäzÄ3 ŘƠ ȣzòzŋ zŁ Åłłõ ĞÊÄÅÕţä ĘĠÛĞę : *Microbiological assay* ĞĘDZzȯzĘäęÄÒţä ĞÊÄÅÕţä **A** ȳäÁÁǫèÅä Û(155 ĞHuÁÔöä Û1 ÁŸŎä) "Microbiological assay of antibiotics ĞÄzĘΣä ğäåÅŘłłŸö ĞĘDZzȯzĘäęÄÒţä ÕÒÎöÅä inoculum ĞHuĘÕÄöä ÄŘHuł .øÅǫnŗä Ŭǵ ďƷÅÒõ *Mycobacterium smegmatis* (ATCC 607) gÄÛÄÄţä .Cm8 ţøÅöä Ùèę ĞÛè ɔŸ3 °ȳ 27 gøäÄǵ ĞDZøÁä Ğ3Åè 48-40 gÁŋ øÅǫnŗä Ŭǵ ďƷÅõ ɔłłÅł :ÐÅǫöä ţøÅöä Ùèę ďŋ Õŋ 100 ÐzŢ ĞŸDZzǵ Õnäå БÜ złłöä ÕÊ8Ä Saline TS UHuŸţä ȯzŸ‡ä ďŋ Õŋ 3 ȳäÁÁǫèÅäę ȳäÁÁǫèÅä ɹäÁöä UÒǫÅÒţä ƷÄöä 3ŋ ȳÄÜ 5 gÁŋ °ȳ 27-25 gøäÄǵ ĞDZøÁä ďŘHułę ÛĞEDZÅDZÄ ğÅĠEĠǵ ďŋ ȟ50ę Cm9

ĞDZóÆä ŞÁƷ ɟŲş ÛĦŋzΛ 14 ȣƷ ÆΛÀǨ ŕ gÆŋ ȯŸƞ ɟǨÁäõä ĘŸĬǾÊţä ÕŧĦǾÊł ɟÙ Æƶ .orbital shaker ŲDzŸĘŸŁÙ ƷÀDZó ĻDzǵ BÙ ŞÙ ĘŸĬǾÊţä ȣŋ Õŋ 0.5 ȳÆÁǾÊΛ inoculated plates ĞHȣÕŸţä ǴƏÀÁÔõä ǴŘƠ ÕDZɟŞ .°ȳ 5 ȣŋ Õęÿ góäÀǵ ŲĬĦDZÀţä ȯzŸǂä ÀŘƷ .°ȳ 27 góäÀǵ ĞDZóÆä Cm8 ţóÂõä Ùèş ğäć óÁǾnŕä ǴƏÀÀò ȳäÆÁǾèÀä ÑÕäÀè ȣĦĬŋ ÆèÀŋ International ŲţÀĬõä ŲĬĦDZÀţä ÀŘHȣǾÊţä ZĘÁÁǾä ÛTS Û7.0 ȯÀŁÀä ğäć ğÀÁÊŸ ĞäóÁ Ž reference solution .(Õŋ 1 Õõ Ž ȳäÀdşÀÒŋ 200Ş 10 ĞäÀƷ) ÆèÀŋ ÂĘõÀĬ BÙ БÙ B2/A2 ĞÊĘŋzĘŸĞŸõ Reference Preparation ȣŋ ÕęÙ estimated potency (*P*= 0.95) góÆÕţä ĞĘŸƷÀÁŸõ ÜÛÁŸõ gÆţǾHţä ÁşÆΣä ÀŦŦz ɟzȮĬ ŕ ÕȮÎä ŲŁ ĞÕΛÀÛõä ĞęÁ Õęÿ (*P*= 0.95) góÆÕţä ĞĘŸƷÀÁŸõ ÜÛÁŸõ ƁzŸĬõä ÆţǾHţä ÆΣä ɟzȮΛ ŕ .góÆÕţä ĞĘŸƷÀÁõä ȣŋ %105 ȣŋ ÀĬõÕÙ ŕŞ %95 1 Õõ Ž B2/A2 ĞÊĘŋzĘŸĞŸõ ĞĘõŞÁ gÆǵŞ 2000 ȣŋ ÀĬõÕÙ ƨøφÁĵä ÆţǾHţä ÆΣä ɟzȮΛ ŕŞ ĞĘõŞÁ gÆǵŞ 1500 ȣŋ .ĞÁÁÒä gÁÀţä БÙ ţzDZÀõÀä ÑäzÊŢ ÛŋŸŋ

ÆÊШ A ÀÕǾÊţä ȯzÛõä ȳÆÁǾÊΛ .*Content of the bleomycin components* ĞÊΛĬŋzĘŸĞõä ğÁφzÓŋ ƲzǾŢ :B .packing material gzÎΣä gÁĬŋ

ɟäzƷ ŘƠ 1 ÆŸÒä ƨŸƷ ĞĘŸĘţÒǾõä ğŸΛÆĬǾõä Ž [1]377-373 ğÀĦȣÁÔõä Ž ȣzòzŋ zŁ Àţõ ÒĦȣÁõä ĘGÛŁ 25 ȯzù Ƀä ÁzţƷ ȳäÆÁǾèÀä Û"High performance liquid chromatography ÀÀõqä ƷĘzÀõä ÕȣÀÊõä ÃäÀÎǾèŕä" ǴÛÊõä ÀŦŦz ȯÆƷ ȣØǾõä ÛÀǾŋŞÀÒŋ 10-5 ÀÛÕõä ğäć ÀÒĘŸĘÊõä ĞŋŸŁ ğÀţĘÊλ zÎŢ ĻŸŋ 4.6 ŲŸÀÁä ÀÛęŞ Ļè linear ŲÛĻä ƷŞóÆţÀä ÕţĦõä ÕDZɟ ÕÀĦȣǾŋ ȯzÛõŞ .octadecyl silyl groups ğÀƷzţƒ Ƶŋ ŕÀĞĞóŕÀä ÑÀÀţĘõ ÛR ȯzφÀŸĘţä ȣŋ ÑţDzǵ 1Ş 1-pentanesulfonic acid TS ȣŋ ȳzDzǵ 9 ȣŋ ɟΛÂŋ ÕţĦõä ÜÆĞΛ Ûgradient development 1-pentane sulfonic acid TS ȣŋ ȳzDzǵ 6 ȣŋ ĞĞĘõÀǾä ÕţĦõä ŕŦÀŞ ÛÑÀφÚ ÀţŦÀŋ õäzTä ÁÀÛŞ ÀĦȣÛĬõ Æę ÀZŸõ ĞĘƏÀŦÀõä ĞĞĘõÀǾõä БÙ ȯzòzõä ĻΛ ǴĘŸ õÀĦȣǾţä ȯzÛõä ȯÆĞǾõ ĞĞèÀŋ ĞĘÛŋ Ğ3ÀÈ ȳäÆÁǾèÀä ÛR ȯzφÀŸĘţä ȣŋ ȳzDzǵ 4Ş ȣŋ Ĭ1.86 :ȯzĞÕŋ ãäÀÎǾèä ŕŸƷ ȯzÔĦȣŸõ õÀĦȣǾţä ȯzÛõä БÙ БÀǾõä ȣÀÊΛ ÛÀŋɟä ȳÂõ äæÙ) .ĞÕĘęÁ 60 gÆŋ ȯŸƞ ĞĘDzÊÀĞõä ȯzz ĞĬĬìɟä Ž ŲƏzŘõä ZĘÛõä âÀĘÕŋ ȳÆÁǾÊΛ detector ȣÀÎÒţõŞ .(ÀǾõ1 Õõ Ž R ȳzΛÁzÔõä ğÀǾΛÆΛÙ 5 ȣÕĦŲł .(ĞţƏŸŋ ÆĬĬł ÀǾõŞÀÒŋ 20-8) ŘÀÁÀŋ ĻDzǵ ğäć ãÀĘÊφä ĞĘŸN ÁŞÂŋ ÛÀǾŋzφÀφ 254 ĞääÀę ĞDZzŋ ȯzÛä ĻΛ .Õŋ 1 Õõ Ž ĞÊĘŋzĘŸĞõä ȣŋ ĞĘõŞÁ ğäÆǵŞ 5 ȯÁÀĬΛ Àŋ ŕŸƷ ƁŞÀΣä ȯÀţä Ž ÁÀǾnŕä ÁÀŋ ȯzŸŢ ȣŋ ÀǾõŞÀÒŋ ĞääÀę ÆŋŋÀφÚ ǵȯzÕÁţä ŕŞÀÎõÀä ÕÀĦȣǾţä ȯzÛõä ɟΛÂŋ ŃŘ Ƶŋ Ûgradient elution ƷŞóÆţŸõ ÀΛÀÊţä ZÛÎõÀä ÕţĦõä .ÕĘŸţä ţŞÂøΛŋ A2 ĞÊĘŋzĘŸĞõä ZÛŘ ĻΛ ŕøǾǵ ŞÙ ĞÕĘęÁ 80 Ûbleomycin acid ŘţΣä ĞÊĘŋzĘŸĞõä Ûvoid ÕÙÀä ĻDzǵ :БÀǾõÀÕ zŁ ĞÊĘŋzĘŸĞõä ğÀφzÒŋ ZÛŘ ÆĘĬÀĬ ɟÙ .ÕĘŸţä ţŞÂøΛŋ A2 ĞÊĘŋzĘŸĞõäŞ ÛB4 ĞÊĘŋzĘŸĞõä ÛA5 ĞÊĘŋzĘŸĞõä ÛB2 ĞÊĘŋzĘŸĞõä ÛA2 ĞÊĘŋzĘŸĞõä

[1] ŕÀĞĞóä ğäÆŸÒä ŕŸƷ gÀŘÀΛŋ ÈŋÀĵä ÆŸÒä ĞÀÀŒ Gǵ ğŸΛÆĬǾõä Õõ ĬŸŋÁÙ .(ɟzPÀǾţä) ĞĘäÀĬõä БÙ БŞÆõä ĞΛŞÁĵä ȯzǾèÁ ĞPÀĬ ÆΛƷ ĞÕäÀÊõä ĞĬäóĵä

ŌȮȯ ȺȦǻǼǯǔ areas ǧȦǵȦǴǵǻ ǼǼȆȄ ǴǹǿȦŌǹ ÛǩÊǼǹǯǼǲǵǻ ǧȦǹǯȮǹ ȯǹ ȷǯȮȹ Ōȯ ʔǯǹǾ ǴȦǯȦȾǵǻ ǴǴÊȦǵǻ ǼÊHǩǩ .ǧȦǼǼÊǼǹǯǼǲǵǻ ŌȮȯ ǴǼǲȮǵǻ ǧȦǵȦǴǵǻ ȝǹ peaks ʔǿØǵǻ

!ǐǯȳǾȄ DžǐǯǐǐDžNjǐǯǾǾȄ ǫǐǐƥNj‡ǀNjƥǫǐǐlj üǾǾǔ hǐǐǯFȚǯ ǀƒǴǯUǯHDž

Additional Requirements for Sterile Bleomycin Hydrochloride

.ǒǯǯȚǲȮ ȽǼǾȯ ǯǔ ǯǲȝ ǴŌȲȲȮ8ȹ ǴȦǯȦǵ Ž ȽǼŌǲǵǻ ǩÊǼǹǯǲǴǵǻ ǼȦǿǯǲŌǯǿǼǼǼȽ ȘȦǵ Æǯ :**Storage** ȺȦÂǴǾǵǻ ǿȦǴǾȦǹǯǯ" ȷǯǯǯȦȝ ǨǾ ȣǯǿǯȹ ǯȽ ȦǯŌ ǿȦǴǾȦǹǯǯ ȘǼǾǾȦ :**Histamine-like substances** ǩȹȦǾÊǼǼǲǲȮ ǴǾǿȦÎǯǻ ǵǵǯǯǻ Ōȹ 1 ȳǻǼǴǾȦèȦǯ Û(167 ǴǼȦȦÔǵǻ Û1 ǼǲǲǾǵ) "Test for histamine-like substances ǩȹȦǾÊǼǼǲǲȮ ǴǾǿȦÎǯǻ ǵǵǯǯǻ ŌDZȷ .Ōȹ 1 Ōŏ Ž ǴǼǾȯǵǵ ǧǼǼǵ 500 ùǯȦȮǨ ǴǼǯŌ ƥǯȝ TS ȣǼȦȲȹ ȯǯȲȚ Ⱥȹ ȘǼǯǯǻ ǴȲǾŌ Ⱥȹ ȹȲŌ 1 ŌȮȯ Sterility testing of ǴȦǯǼΣǻ ǧǵǵȦŘǯǼǼȲ ǴȹȦŌǼǵǻ ǿȦǴǾȦǹǯǯ" ȷǯǯǯȦȝ ǨǾ ǵǵȦ ǼǼǼDzǾÊȦ :**Sterility** ǴȹȦŌǼǵǻ .ǵȦÎǯ8ǵȦǯ ǴǼǼÌǯÀǾǵǻ ǿȦǴǾȦǹǯǯ ǧǵǵÀDZǯ ȘǼǴǾÛǾǯ Û(162 ǴǼȦȦÔǵǻ Û1 ǼǲǲǾǵ) "antibiotics

!ǐǯȳǾȄ üȘDžȳǯǯǯǿǯǯ ǫȳDžǾȄ DžǐǯǐǐDžNjǐǯǾǾȄ ǫǐǐƥNj‡ǀNjƥǫǐǐlj üǾǾǔ hǐǐǯFȚǯ ǀƒǴǯUǯHDž

Additional requirements for Bleomycin hydrochloride for Sterile use

Test for Sterility of non- ȺŌǼȦȲȲȮ ǴȲǯǯȦȦÔǵǻ ǴȹǯǧǵǵÀǼǼȦÊǼǯǻ ǴȹȦŌȝ ŌDZȷ ǿȦǴǾȦǹǯǯ" ȷǯǯǯȦȝ ǨǾ ǵǵȦ ǼǼǼDzǾÊǴ .(ǴȦÂǼǲȲǾǵǯǻ ǴǼǴǾǾǵǻ Ž 32 ǴǼȦȦÔǵǻ Û5 ǼǲǲǾǵ ǵǵǯǯǻ) "injectable preparations

ŌDZȷ ǿȦǴǾȦǹǯǯ" ȷǯǯǯȦȝ ǨǾ ȣǯǿǯȹ ǿȦǴǾȦǹǯǯ ȘǼǾǾȦ :**Bacterial endotoxins** ǴǼǼǹǯǾǵǯǻ ǴǼǲȹǹǯǯǼǼǵǻ ǧȦǵȦǴǾȦǹǯǯ ȣǯǯǯȦȝ ǨǾ ȣǯǿǯȹ ǯȽ ȦǯŌ ǿȦǴǾȦǹǯǯ ǴȦÂǼǲȲǾǵǯǻ ǴǼǴǾǾǵǻ Ž 30 ǴǼȦȦÔǵǻ Û5 ǼǲǲǾǵ)"Test for bacterial endotoxins ǴǼǼǹǯǾǵǯǻ ǴǼǲȹǹǯǯǼǼǵǻ ǧȦǵȦǴǾȦǹǯǯ .ǩÊǼǼǹǯǲǴǵǻ ǿȦǴǾȦǹǯǯ ȘǼǾȹ 1 Ōŏ Ž RS ȣǲȹǹǯǯǼǼǵǻ ȷǯǯǯȦȝ ǨǾ ǴǼǾȯǵǵ ǧǵǵǼǼǵǻ ǿȦǴǾȦǹǯǯ ǯǯǯǯǯ

BLEOMYCINI SULFAS

Bleomycin sulfate DžǐǯǐDžNjǐǯǾǾȄ ǀƒ2‡ǯ

(**non-injectable** DžǯΘ‡ǾǾ hǾ‡ǾƒǯǾȄ ƥǐǐȝ) DžǐǯǐDžNjǐǯǾǾȄ ǀƒ2‡ǯ

Sterile hǾDžǐǯǯǾȄ ÛDžǐǯǐDžNjǐǯǾǾȄ ǀƒ2‡ǯ

ǴǼǼǵǵǯǻǼǼǵǻ ǴȲǼǲȲǾǵǯǻ ǯȳ ȝǯ ǯǵǯǻ ǵǵǯǯǻ ǯȽ ȦǯŌ ǵǵȦǲǼǼǵǻ ǴȲȹ ȣǼ ǩǼǼǹǯǲǴǵǻ ǵǵȦǲȲǼ :**Composition** ǼǼǼȮȦǵǵǻ CAS Reg. No. 9041- :B_2 ǩÊǼǼǹǯǲǴǵǻǵ A_2 ǩÊǼǼǹǯǲǴǵǻ ȦǼ ǯȦÂǯǯǯȦ ǯȦǼÊǼǼǼȦǵǵǻ ǯȦǯȮǯǻ .*Streptomyces verticillus* .93-4

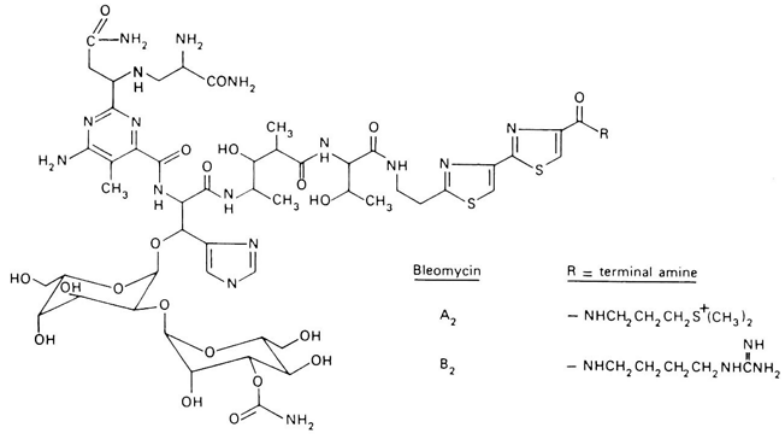
ƙÊŁŋƶŁŸĠõã ğÅÅŸè Ü$C_{55}H_{84}N_{17}O_{21}S_3$,$HSO_4$:A2 ƙÊŁŋƶŁŸĠõã ğÅÅŸè :**Molecular formula** ĞŁÅÅÂƨã ĞȣŁÔõã

.$C_{55}H_{84}N_{20}O_{21}S_2$,HCl :$B_2$

:B_2 ƙÊŁŋƶŁŸĠõã ğÅÅŸè Ü1514 :A_2 ƙÊŁŋƶŁŸĠõã ğÅÅŸè :**Relative molecular mass** ĞŁĠÊÅõã ĞŁÅÅÂƨã ĞŸŲÒõã

.1524

:**A_2/B_2 bases** ƙèÅèɟã **B_2/A_2** ƙÊŁŋƶŁŸĠŸõ ĞŁąÅŁĠţã ĞȣŁÔõã



:**Chemical name** ŲƏÅŁţŁÒõã ĻèŗÅ

Bleomycin A_2 sulfate: N^1-[3-(Dimethylsulfonio)propyl]bleomycinamide hydrogen sulfate; [3-[2′-[2-[(2*S*,3*R*)-2-[(2*S*,3*S*,4*R*)-4-[(2*S*,3*R*)-2-[6-amino-2-[(1*S*)-1-[[(2*S*)-2-amino-2-carbamoylethyl]amino]-2-carbamoylethyl]-5-methyl-4-pyrimidinecarboxamido]-3-[[2-*O*-(3-*O*-carbamoyl-α-D-mannopyranosyl)-α-L-gulopyranosyl]oxy]-3-imidazol-4-ylpropionamido]-3-hydroxy-2-methylvaleramido]-3-hydroxybutyramido]ethyl][2,4′-bithiazole]-4-carboxamido]propyl]dimethylsulfonium hydrogen sulfate.

Bleomycin B_2 sulfate: N^1-(Guanidinobutyl)bleomycinamide; (β*S*)-4-amino-β-[[(2*S*)-2-amino-2-carbamoylethyl]amino]-6-[[(1*S*,2*R*)-2-[[2-*O*-(3-*O*-carbamoyl-α-D-mannopyranosyl)-α-L-gulopyranosyl]oxy]-1-[[(1*R*,2*S*,3*S*)-3-[[(1*S*,2*R*)-1-[[2-[4-[(4-guanidinobutyl)carbamoyl][2,4′-bithiazol]-2′-yl]ethyl]carbamoyl]-2-hydroxypropyl]carbamoyl]-2-hydroxy-1-methylbutyl]carbamoyl]-2-imidazol-4-ylethyl]carbamoyl]-5-methyl-2-pyrimidinepropionamide sulfate (salt); N^1-[4-[(aminoiminomethyl)amino]butyl]bleomycinamide sulfate (salt).

.ŲƷÅÒõÅã ɟƶŸŋ ƽŲ ŘŁãŲ ɟƶŸã ÕÒÎõã CÆȝ ȧƶHŲÊŋ :**Description** Ƶòƶõã

.ŁÆDZ ŏÅţã Ž ããƽá :**Solubility** ĞŁąÅãƽØõã

.Cytotoxic ÅŸŸÅŸõ ȳÅè ŏãƽå :**Category** ĞÅÅõã

.ȳȦȮǵüǽ ČÕŸ8ŋ ČΛȘȦǵ Ž ƙÊŁŋzŁŸĠõã ğȦȦŸè ȘȦǵ Æz :**Storage** ďΛÂÁǫõã

ÕDZɟ ČŁzȦřqã ğȦGŸÛǫţã ȣøGŸǩ gǻȦţã ɟÙ БÙ ČţŁÕŸõã ƙÊŁŋzŁŸĠõã ğȦȦŸè ČŁţÊǫõã ƙÎǩ :**Labelling** ȴŁèzǫõã

.ʔȦnɟã ČţŁÕŸõã ğȦÕŁĠÛǫõã ÕDZɟ ȘÙ ȣøȦÕΣã õȦÛ3Rõ ÕţŸǫÊǩ ɟÙ ďȮƧȘ ČţŁÕŸõã ƙÊŁŋzŁŸĠõã ğȦȦŸè

ȧȦÎȦǫèãȘ ÆŸƨã 3ŋ âȦţǫõã ÆΛΘȘ ƁÆΛɟȦæ ƙÊŁŋzŁŸĠõã ğȦȦŸè ÕŋȦŸŸ ȦŋÆΛ3 ČΛȦȦŸõãȘ ǿØΣã Ȣnzǩ Æz :ΛΛØƠ

.õãzTȦæ ČõzÕΛţã ğȦţŁÊƨã

REQUIREMENTS ƙĜȣŸƵƙdž!ƒ

ʔŸ3 ÛA ČÊΛȦÕţã ÆÊШ ÒHȣȦǩ ȦŋÆΛ3 ÛƙÊŁŋzŁŸĠõã ğȦȦŸè ƁzǫƠ :**General requirement** ȳȦŸõã ÆŸÛǫţã

gǻȦţã БÙ ţzDZÀõȦæ ČæzÊŢ ÛŋŸŋ 1 Õõ Ž B_2/A_2 ƙÊŁŋzŁŸĠõã ďŋ ČŁõȘǻ gÆǵȘ 2000 ďƷ ÆΛÂΛ ƨȘ 1500 ďƷ ÕÕΛ ƨȦŋ

.ČΛȦȦÕã

ÆΛÂΛ ƨȘ %55.0 ďƷ ÕÕΛ ƨȦŋ ʔŸ3 ÛB ČÊΛȦÕţã ÆÊШ ÒHȣȦǩ ȦŋÆΛ3 ÛƙÊŁŋzŁŸĠõã ğȦȦŸè ƁzǫƠ ÛÕõæ ďŋ ÀŽõÙ

ţzŁƒ ɟzȮΛ ƨ ÜB$_2$ ƙÊŁŋzŁŸĠõã ďŋ %32.0 ďƷ ÆΛÂΛ ƨȘ %25.0 ďƷ ÕÕΛ ƨȦŋȘ ÛA$_2$ ƙÊŁŋzŁŸĠõã ďŋ %70.0 ďƷ

B$_4$ ƙÊŁŋzŁŸĠõãȘ Û%7.0 ďŋ ÀŽõÙ A5 ƙÊŁŋzŁŸĠõã ʔzǫŢ ɟzȮΛ ƨȘ .%85 ďŋ ÕęÙ B$_2$ ƙÊŁŋzŁŸĠõãȘ A2 ƙÊŁŋzŁŸĠõã

.%3.0 ďŋ ÀŽõÙ demethylbleomycin ÕŁŽŁţã ţȘÂøȦŋ A$_2$ ƙÊŁŋzŁŸĠõãȘ Û%1.0 ďŋ ÀŽõÙ

:**Identification tests** hƷŸNjNJШЄ l ЄƀƑGŸHƊ|Є

ÛTS (ȯ/ĥ160) (II) âȦHȣȦõã ğȦȦŸè ȯzŸŢ ďŋ ÀǫõȘ ÀȮŋ 5 ȣȦŘΛȘ ÛŏȦŋ Õŋ 10 Ž ŋŸŋ 5 ČæãÀę ããØΛ **A**

ČDZzţã ȯzÛæ ƙŁţŢ3Ù ƙòȦÔǫŋã ČŁDzÊȦΛGõã ȧzz ČĤìɟã Ž î ȦÔǫŋŁã ZŁù ƁÆGΛ ÜÕŋ 100 ʔøǫǵ ŏȦţȦæ ZȦƷȘ

.ÀǫnzǫȦφ 268 ČæãÀę ČDZzţã ȯzÛæ ĦΛÀ8ŏÙ ĦŏȦÔǫŋãȘ ÛÀǫnzǫȦφ 290 ČæãÀę ČDZzţãȘ ÀǫnzǫȦφ 242 ČæãÀę

General ČŋȦĤõã ȣãÀĤǫèŁã ğãøȦGǫnã" ɟãzΛ3 ŘƠ ȣzòzţã A Õ3ȦÁǫõã Õŋ/ŋŸŋ 10 ÂŁõÀǫæ ȯzŸ‡ã ŸÛĤΛ **B**

.(123 ČHȣȦÔõã Û1 ÆŸŎã) ğȦȦŸÊŸõ ÂõŁŋ Õ3ȦÁǫõ "identification tests

ȘÙ ȯȦȮèȦæzŸŁõ 0.6 ďƷ ÆΛÂΛ ƨ) ŘȦÁΛŋ Ù8ŕ ŘƠ °ȳ 60 ČDZøÆæ ZȦæ :**Loss on drying** ZŁȦDzǫõȦæ ÆÕȦõã

.ĥ/ŋŸŋ 60 ďŋ ÀŽõÙ ÆÕΛΛ ƨ ÙğȦ3ȦÈ 4 gÆŋ (ȘĠàÀ ȴŸŋ 5 ČæãÀę

.6.0-4.5 ÛÕŋ/ŋŸŋ 5.0 ÂŁõÀǫæ ȯzŸ‡ã ŏȦŁȦæ ŋŸĠΛ :**pH value** ŏȦŁȦĠõã ČţŁę

10 Ž ããØǩȘ Õŋ 60 ȴDzШ ÕÔz 3ţę БÙ ÛČŁÙzĠŘŋ ĜǫȘàzŋ ÛŋŸŋ 75 ÕÕΛ :**Copper content** âȦHȣõã ʔzǫŢ

ÕÔz 3ţę БÙ TS2 ƁóȦŁĤţã âȦHȣõã ȯzŸŢ ďŋ Õŋ 10 ÕÕΛ .TS (ȯ/ȯzŋ 0.1) ÕΛózŸõȘóÆŁŢã ŘÞ ďŋ Õŋ

.ČÕŁęå 1 gÆŋ gÆÎæ ŘƷȘ Zinc bis (dibenzyldithio carbamate TS ȯzŸŢ ďŋ Õŋ 10 ƙĤţÕŸõ ȣȦŘΛ .ŽȦŕÙ

gǻΛà ţÂøΛõ R ČŁaȦŋŸõã ȳzΛǻzÔõã ğȦȦŸè ďŋ ĥ1 Ǝ3 ʔŸȦÊõã ČÕĠÛõã ĠŕÀĤ .ȦţŤŘĤæ ďƷ ɟŸÔȦΛǫõ ɟȦǫÕĠÛõã ÕÀǫĤ

ÆΛØţã gKDzǵ ÿãÆÅǫèÅæ ÛÄǫŋzφÅφ 435 ǦããÄę Ʊţ.Ţ3Ů ǦDZzŋ ȯzÛã ǰè1 ǦφÅÅǯæ ǦÕǦù ȯŸŋ ȵŋ ŋî Åţǫõã âÅÕΛ .ǎÅţã .R ɹzæÄȮõã ÆΛózŸõ Ʊ3Åæó ÆΛØţã ɔŸ3 ǦΛşÅΣã ÛǦȯzHuÅţã gǻÅţã î ÅǫǦţţę ƱŁ A_o ɹŮ Û$(A_o \times 15)/(A_s \times W)$ Ǧ8ÊÔõã ȵŋ ȟ/ŋŸţÅæ ãóÆÕŋ âÅHuÅõã ƷzǫŢ ÆÊƷ ƷzǫŢ ÆΛÂΛ ŕ ÜǦȯzHuÅţã gǻÅţŸõ ŋŸţÅæ góÆÕŋ ɹàzõã Ǧţţę ƱŁ *W*ş ÛTS2 ƁóÅÊŸţã âÅHuÅõã ȯzŸŢ î ÅǫǦţţę ƱŁ A_s .ȟ/ŋŸŋ 0.2 ȵ3 âÅHuÅõã

:Assay ǦÊΛÅÕţã

ǦÊDZzȯzÊæşÄȮţã ǦÊΛÅÕţã" ɹàzÄ3 ȞƠ Ǧzzȯzţã ǦÊΛÅÕţã ĘǦÛȞ :***Microbiological assay*** ǦÊDZzȯzÊæşÄȮţã ǦÊΛÅÕţã **A** gÄǫÛÄǫţã ÿãÆÅǫèÅæ Û(155 ǦHuÅÔõã Û1 ÆŸȞõã) "Microbiological assay of antibiotics ǦΛzÊΣã ǧãǻÅÊŢţŸõ ɔŁÅŁ :ƁÅǫõã ÕȮÎõÅæ inoculum ǦHuÊÕõõã ÄŘHuŁ .óÅǫǫnŕã Ʊǵ ƁaÅȮõ *Mycobacterium smegmatis* (ATCC 607) ǧÅǦǦΣã ȵŋ ȟ50ş Cm9 ţóÂõã Ùèş ǦÛè ɔŸ3 °ÿ 27 góãÄǵ ǦDZóÆæ Ǧ3Åè 48-40 gÆŋ óÅǫǫnŕã Ʊǵ ƁaÅõ Orbital ƱDzŸÊŸŁã ȝÅÐZó ÿãÆÅǫèÅæ ǰãÆõã ƱȮÊφÅȮÊţã ȝÄõã 3ŋ ÿÅΛŮ 5 gÆŋ °ÿ27-25 góãÄǵ ǦDZóÆæ ȵŘHuŁş ÛǦÊDZÅDZÅõã .°ÿ 5 ȵŋ ÕęŮ góãÄǵ ǦDZóÆæ ŞÅȝ ɹŮş ÛŋzΛ 14 ȵ3 ÆΛÂȞ ŕ gÆŋ ȯŸŋ ǰȞÅõã ĘŸȞǫÊţã ÕŁȞǫÊΛ ɹŮ Æz .shaker ÿãÆÅǫèÅæ ÅÅφŮ ȵÊŁŋ ÆèÅŋ ǰDzǵ ƁŮ şŮ ĘŸȞǫÊţã ÿÆÅǫÊΛ inoculated plaks ǦHuÊÕŸţã ǦaÅÅÔõã ǨŘƠ ÕDZjş Ǧãóǻ Ž reference Solution ƱȞDZÄţã ȯzŸ‡ã ÄŘƷ .°ÿ 27 góãÄǵ ǦDZóÆæ Cm8 ţóÂõã Ùèş ǧãæ óÅǫǫnŕã ǦaÅÅò International Reference Preparation ƱţÅȞõã ƱȞDZÄţã ÄŘHuǫÊţã ZÊÅÅǫæ Û7.0 ǒÅŁÅæ ǧãæ TS ǧÅÅÊŸ ŕ ÕȮÎæ ƱŁ ǦÕΛÄÛõã Ǧęǻ .(Õŋ 1 Õõ Ž ÿãÄdşÄȮŋ 200ş 10 ǩæ gǻÅ3) ÆèÅŋ ÂÊõÄȞ ƁŮ ƁŮ B2/A2 ǩÊÊŋzÊŸǦŸõ ȵŋ ÄƷõŮ ŕş %95 ȵŋ ÕęŮ estimated potency (*P* = 0.95) góÆÕţã ǦÊŸ3ÅÅŸõ ûÛÅŸõ gÆŁǫȞţã ǻşÆΣã ÅZÊz ɹzȮǩ gÆǵş 1500 ȵŋ ÕęŮ (*P* = 0.95) góÆÕţã ǦÊŸ3ÅÅŸõ ûÛÅŸõ ƁzŸȞõã ÆŁǫȞţã ÆΣã ɹzȮΛ ŕ .góÆÕţã ǦÊŸ3ÅÅõã ȵŋ %105 ǦæzÊŢ ÛŋŸŋ 1 Õõ Ž B_2/A_2 ǩÊÊŋzÊŸǦŸõ ǦÊõşǻ gÆǵş 2000 ȵŋ ÄƷõŮ ɔøφǻjã ÆŁǫȞţã ÆΣã ɹzȮΛ ŕş ǦÊõşǻ .ǦÅÅÕã gǻÅţã ƁŮ ţzDZÄõÅæ

ÆÊШ A ÄÕǫÊţã ózÛõã ÿÆÅǫÊΛ *Content of the bleomycin components* *ǩÊÊŋzÊŸǦõã* *ǧÅφzȮŋ* *ƷzǫŢ* :B ɔŸ3 ǧŸΛÆȞǫõã Ž 377-373 ȵŋ ǧÅHuÅÔõã Ž Ʊzȯzŋ zŁ ÅŁõ óÅǫǫnŕã ĘǦÛΛ .packing material gzÎΣã gǻÅŋ ÿãÆÅǫèÅæ Û"High performance liquid chromatography ÄÅõqã 3ÊzÄõã ÕÅÅÊõã ããÄÎǫèã" ɹàzÄ3 ȞƠ 1 ÆŸȞõã Ʊøǫõã ÛÄǫŋşÄȮŋ 10-5 ÄÛÕõã ǧãæ ÅȮÊŸÊõã ǦŋŸŁ ǧÅŁÊÊλ zÎŢ ǰŸŋ 4.6 ƱŸŋãǻ ÄÛęş ǰè 25 ȯzù Ƃæ ǻzŁ3 ȝşóÆţÅæ ÕŁȞõã ÕDZj õÄHuǫŋ ózÛõş .Octadecyl silyl groups ǧÅ3zŁf 3ŋ îÅǦȞórÅæ ÅÊÅÅŁÊõ ǦÛÊõã ÅZÊz ȯęÆ3 ÅŁDzǵ 1ş 1-pentanesulfonic acid TS ȵŋ ÿzDzǵ 9 ȵŋ ɹΛÂŋ ÕŁȞõã ÛÆǦΛ Ûlinear gradient development ƱÛǰã 1- TS ȵŋ ÿzDzǵ 6 ȵŋ ǦǦÊõÄǫæ ÕŁȞõã ƱZΛŁş ÛÅφŮ ÅŁZΛŋ ǒãzTã ǻÄùş ÅHuÄÄÆ ÆÇ ÅZŸõ ÛR ȯzφÅǯÊţã ȵŋ

ĻQΛ ŌĦШ ōÀHυQţä øzÛöä ȯÆGQö ČGèÌÀη ČĦÛη Čʒ̀Àè ÿäÆÅQèÌäæ Ûȯzφ̀ÌŽĦţä dη ÿzDzǵ 4Ş pentanesulfonic acid ɔŸʒ ȯzÔHυŸö ōÀHυQţä øzÛöä Б̀Ů БÅQöä ȣÌÅŘΛ ÛÀηĻJä ÿÂö äæŮ) .ČÕĦęå 60 gÆη ȯŸη ČĦęÌŽΓÁöä ČGĦõÀQöä Б̀Ů ȯzòzöä ZĦÛöä âÌÆÕη ÿÆÅQÊΛ detector ȣÌÎȯtõş .(ÀQö1 Ōõ Ž R ÿzΛåzÔöä ǧÌQΛÆΛŮ dη ň 1.86 :ȯzGÕη ā̀ÀÎQèä ÀȯΗ 20-8) ŘÌÅÅΛη ĻDzǵ ǧäæ ā̀ÌÆÊφä ČĦŸN åţÂĻÛÀQηzφÌφ254 ČääÀę ČDZzη ȯzÛæ ČĦDzÊÌÀΛGöä ȧzz ČĦÌ ĻJä Ž ŲəzŘöä dη ČĦöşå ǧäÆǵş 5 ȯåÌĦΛ Ìη ɔŸʒ ÐşÌΣä ȯÌţä Ž øÌGQnŗä gåÌη ȯzŸΤ dη ÀQöşÀȯη 5 dȯŌʒ .(ČtəŸη ÆĦĦ ÀQöş ōÀHυQţä øzÛöä ĵΛÂη ÑŘ ʒη Ûgradient elution ʒşøÆtŸö ÀΛÌÊţä ZÛÎöÌæ ȯtĦöä ĻQΛ .Ōη1 Ōõ Ž ǩÊĦzĦŸGöä .ȯĦʒĦţä ţşÂøΛη A2 ǩÊĦzĦŸGöä ZÛÌ ĻQΛ ɔøQǵ şŮ ČÕĦęå 80 ČääÀę gÆη ÑÌÅφŮ gøzõØţä îşÀÎöÌæ Ûbleomycin acid ŘtΣä ǩÊĦzĦŸGöä ÛVoid ȯÙÌæ ĻDzǵ :БÌQöÌõ zŁ ǩÊĦzĦŸGöä ǧÌφzȯη ZÛÌ ÆĦĦkÀĬ ĻŮ .ȯĦʒĦţä ţşÂøΛη A2 ǩÊĦzĦŸGöäş ÛB4 ǩÊĦzĦŸGöä ÛA5 ǩÊĦzĦŸGöä ÛB2 ǩÊĦzĦŸGöä ÛA2 ǩÊĦzĦŸGöä ʔøØöä ȯÒö ÑΛåäÀzŮ areas ǧÌǵÌGöä ÆÊę̂ ČφøÌÕη ÛǩÊĦzĦŸGöä ǧÌφzȯη dη ĻzȯΗ Ōõ ʔzQ+ ČΛzÌţä ČGÊÌöä ÆÊȯ .ǧÌÌÊĦzĦŸGöä ȯÒö ČĦŸȯöä ČǵÌGöä ʒη peaks

hυDŽĭŝyΛε DzĭɔĭDŽNjĭ+GΛε lƒ2+ɔ üШŬ hυĭʒFΤd lƒG+UΨDŽ

Additional Requirements for Sterile Bleomycin Sulfate

.ŏäzΓŸö ĻĦQõ zU ɔŸʒ ČÕŸ8η ČΛşÌǵ Ž ČtĦÕĦöä ǩÊĦzĦŸGöä ǧÌÌŸè ŞÌǵ Æz :**Storage** dΛÂÅQöä ĻäzΛʒ ŘƠ ȣzòzη zŁ Ìtõ øÌGQnŗä ĘGÛΛ :**Histamine-like substances** ǩηÌQÊĦΓŸö ČöÌÎţä åäzţä ÿäÆÅQèÌæ (167 ČHυÌÔöä Û1 ÆŸÕä) "Test for histamine-like substances ǩηÌQÊĦΓŸö ČöÌÎţä åäzţä ȯDZĻ øÌGQnŗä" .ȯη 1 Ōõ Ž ČĦöşå gÆǵş 500 ùzÌÒk ČĦtõ ÐzʒTS ŲHυŸη ȯzŸΤ dη ĻÊɔä ČŸQõ dη ĦŸõ 1 ȯÒö ȯη 1 Sterility testing of ČΛzĦΣä ǧäåÌÎÊtŸö ČηÌÕĦöä øÌGQnä" ĻäzΛʒ ŘƠ åøş Ìţ ÆĦDzQÊĭ :**Sterility** ČηÌÕĦöä .öÌÎȣöÌæ ÓĦŸnÀQöä øÌGQnä ǧäöäÀDZŮ ĘĦGÛQæ Û(162 ČHυÌÔöä Û1 ÆŸÕä) "antibiotics

!ĭŝyΛε üFDŽyFɔúΛ YφyDŽΛε DzĭɔĭDŽNjĭ+GΛε lƒ2+ɔ üШŬ hυĭʒFΤd lƒG+UΨDŽ

Additional Requirements for Bleomycin Sulfate for Sterile use

Test for Sterility of non- dȯÕHυŸö ČŸäÌÔöä Ǩq ǧäÀŘHυQÊţä ČηÌÕʒ ȯDZĻ øÌGQnŗä" ĻäzΛʒ ŘƠ åøş Ìţ ÆĦDzQÊĭ .(ČΛÂĦŸȣqä ČĦGÛöä Ž 32 ČHυÌÔöä Û5 ÆŸÕä ÀŢqä) "injectable preparations

ȯDZĻ øÌGQnŗä" ĻäzΛʒ ŘƠ ȣzòzţä øÌGQnŗä ĘGÛΛ :**Bacterial endotoxins** ČĦηzQÀɔä ČĦŸnäÆöä ǧÌφÌÌΛØöä Ðzʒ ŗ Ü(ČΛÂĦŸȣqä ČĦGÛöä Ž 30 ČHυÌÔöä Û5 ÆŸÕä) "Test for bacterial endotoxins ČĦηzQÀɔä ČĦŸnäÆöä ǧÌφÌÌΛØöä .ǩÊĦzĦŸGöä dη ĦŸη 1 Ōõ Ž RS ŲŸnäÆöä ĻÌÌΛØöä dη ČĦöşå ǧäÆǵş 10.0 dη ÀŸõŮ

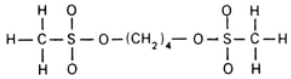
BUSULFANUM

Busulfan DžƒƲƸ NjG

Molecular formula: $C_6H_{14}O_6S_2$

Relative molecular mass: 246.3

Graphic formula:



Chemical name: 1,4-Butanediol dimethanesulfonate; tetramethylene dimethanesulfonate; CAS Reg. No. 55-98-1.

Other name: Myelosanum.

Description: .

Solubility: (ó/ň750~) TS.

Category: Cytotoxic.

Storage: .

Additional information: .

REQUIREMENTS

General requirement: %100.5 %98.5 $C_6H_{14}O_6S_2$.

Identification tests:

A: 0.1 methanesulfonic acid 5 10 .

B: 0.05 .

ŏÂƨã Ř'ŧHŧ .ƀåÅąà ÀŘńÌŭ Бŭ ãKńÌŭş Ûȧóàŭ Бŭ Ż ÛƱDzÊÁAGõã Бŭ ƱøφãzDZóɟã ɟzŸõã ȯzHφΛ ÜTS (ȯ/ȟ10) Ōą 0.05 8ÅŘΛş ÛTS (ȯ/ȟ100~) ÕΛózÅŸÊõã Řβ ϕą Ōą 2 óãÆÕą A óÅGφńŧã Ž ÀŘŧã ȯzŸŧã ϕą ƱøφÅŽõã .ŏÜGã ğÅφÅ8ÅąKGõã ɟzȯ ƨìŸφΛ ÜąŘÁłş TS (ȯ/ȟ10) ȳzÊèÅkzGõã ğÅφÅ8ÅąKã ȯzŸŢ ϕą 0.5ş TS âÅHƱÅõã ğÅφΛÆΛŭ ȯzŸŢ ϕą Ōą 1.0 Ž ĘŸHφÊŧş ÛóÅGφńŧã gåÅą ϕą ȟ0.10 óÅGφńã ãzGφŭ Бŭ ÕÕΛ :C ȯzŸŧã ɟȯzÒΛ ãØŁş ÜTS (ȯ/ȟ60~) ƙDZşóÆÊTã ÆÊÊõşKã ϕą Ōą 0.5 8ÅŘΛ Ż ÛTS (ȯ/ȟ260~) ÅÊφzną̇ã ϕą Ōą 5 gÆą ƱəÅą ȳÅβ Ž ɟÅãzGφǵã ƷŘzΛ .2 ȯzŸŧã ɟzÒΛ ãØŁş ÜóÅGφńŧã gåÅą ɟşå blank ÆŁÅÌ ÀŘƵ ÛĞŏÅÎŧÅãş .1 ȳzΛóÅGõã ÆΛózŸõ ȯzŸŢ ϕą Ōą 4.0ş TS (ȯ/ȟ70~) ÕΛózŸõşóÆÊTã Řβ ϕą Ōą 1.0 8ÅŘΛş åƎΛ ÛĘəÅęå .ĘəÅęå ƷŘã ÆĦã ŏÅŘÊã ĞãÅèɵ Бŭ ȯÆGφk Ʊøφõã Û1 ȯzŸŧã Ž ȳzŧŭ ɟφÅkş ÅÊzÅò 2 ȯzŸŧã ƨÕGΛ ÜTS (ȯ/ȟ50)

.°ȳ 118-115 :**Melting range** óÅŤÔφŧã ȯÅƒ

.ȟ/ηŸą 1.0 ϕƷ ÆΛÂΛ ŧ :**Sulfated ash** ŘÁŸÊţã åÅąÀõã

ÆΛÂΛ ŧ) ŘÁÅąą Ù8ř ŘƠ °ȳ 60 góãÀg ĞDZóÆã ŘãÅžõã ɟàzõã Бŭ ZÅz :**Loss on drying** ZÊÁDzφõÅã ÆÕÅõã .ȟ/ηŸą 20 ϕą Àžõŭ ÆÕÅΛ ŧ Ù(ĘGφà ɟŸą 5 ĞãÀę ęŭ ȯÅÒèÅãzŸÊõ 0.6 ϕƷ

ƱƷzDZÀõã ɟÅΛÀãã ŘƠ ZÛŸã ƨŸ8Λş ŏÅţã ϕą Ōą 25 ĞÊùzGŘą Ğφşàzą ȟ0.25 ĞãÀę Бŭ 8ÅŘΛ :**Assay** ĞÊΛÅÒţã ȳzΛåzÔõã ÆÊÊõşóÆÊŁ ȯzŸHφą ÀΛÅŘΛş ÛåƎΛ ÛŏÅţã ϕą gK8ò ĞÊŧÒã condenser ZÅÒţã ÕÊ8ł .ĞÕÊęå 30 gÆą reflux gåÅţã ɟşå ĞÊŸŧŘõã åÅŘŘ .phenolphthalein/ethanol TS ÀŘÎţã ÿãÆÅφèÅã ÛVS (ȯ/ȯzą 0.1) ğÅφzãÀÒõã ϕą ÐÅ̇ţã 0.1) ğÅφzãÀÒõã ϕą ÐÅ̇ţã ȳzΛåzÔõã ÆÊÊõşóÆÊŁ ȯzŸŢ ϕą Ōą 1 Ōõ .ĞΛóşÀŘ ğÅHƱÊHƱÔŭ ĞΛŭ ÐÀÖş ĞòzHƱÅţã .$C_6H_{14}O_6S_2$ ϕą ηŸą 12.32 ùzÅÒΛ VS (ȯ/ȯzą

ØØØØØ

CALCII CARBONAS

Calcium carbonate !NjĭƨΛFłΛΕ łFõzNjĞβł

$CaCO_3$:**Molecular formula** ĞÊÅΛÂƨã Ğ8ÊÔõã

100.1 :**Relative molecular mass** ĞÊGÊAõã ĞÊÅΛÂƨã ĞŸφÒõã

.Calcium carbonate (1:1); CAS Reg. No. 471-34-1 :**Chemical name** ƱəÅÊŧÊÒõã ɟèŧã

.ĞHƱəãÀõã CÆƷ ÜŘÊãŭ ɟzŸã ÛĞŧƷÅφ ĞÕÊęå ğãózŸã ÕÒÎã ázHƱÊą :**Description** Zòzõã

Řβ Ž ɟãózÅõã Ɜą ãşØΛ .ÅÊŸŧƷ TS (ȯ/ȟ750~) ȯzφÅƵΛqã Ž ŧş ŏÅţã Ž ããşæ Kd :**Solubility** ĞÊφÅãşØõã

.TS (ȯ/ȟ130~) Õ̃ʌÀǫʌõã Ѐ ƥ Žş TS (ȯ/ȟ70~) Õ̃ʌózŸõşóÆÉTã Ѐ ƥ Žş TS (ȯ/ȟ60~) Õ̃ɸǫɛèɟã

.Antacid Ğѐzţ.HʊŸõ ãÌÊŋ ŏãşã :**Category** ĞÌÀõã

.ȳÀÓǵüæ ĞÕŸ8ŋ ĞʌşÌǵ Ž ȳzɸÊõÌÓõã ğÌǫzæÀõ ŞÌǵ Æz :**Storage** ďʌÂÁǫõã

REQUIREMENTS ƚĞʊƵƵkdž!ƒ

ďƷ ÆʌÂʌ ŧş %98.0 ďƷ ÕÕʌ ŧ Ìŋ ɔŸ3 ȳzɸÊõÌÓõã ğÌǫzæÀõ ЬzǫƠ :**General requirement** ȳÀĬõã ÆŸÛǫţã .ĞÀÌÕã gÌţã Бŭ ţzDZÀõÌæ ĞæzÊŢ ÛCaCO₃ ďŋ %100.5

:**Identification tests** hʊŸNjNJЉ l ɛƥƒĞĤǫɛ

ĞǵÌÀÀõã ƱÛĬĬ .ĞÀÀʌş ÛõÌŋ Ōŋ 2ş TS (ȯ/ȟ70~) Õ̃ʌózŸõşóÆÉTã Ѐ ƥ ďŋ Ōŋ 0.3 Ž ŋŸŋ 20 ããØʌ :A gÂƥţŋ ğŸ3ÌÀǫõ̃ "General identification tests ĞŋÌĬõã ȣãÀĬǫèŧã ğãøÌĞǫnã" ɟãzʌ3 ĬƠ Ğzzòzţã ğŸ3ÌÀǫõã .(120 ĞʊÌÂÔõã Û1 ÆŸÓã) ȳzɸÊõÌÓŸõ

CÆ3ş ɟzŸõã CÆ3 ãÌd ózÛǫʌ ÜTS (ȯ/ȟ300~) Õ̃ɸǫèɟã Ѐ ƥ ďŋ Ōŋ 1.0 øãÆÕŋ ȟ0.01 Бŭ ȣÌÂʌ :B .gÀÌÌĞŋ ĞæÌèƥ ÕÓÎǫĭ ÜTS ȳzɸÊõÌÓõã ÆɸÊõşóÆɸŁ òzŸŢ Ž ózÛǫţã ÀÌ8ãã øÀţł .ĞʊæÀõã

ÜTS (ȯ/ȟ60~) Õ̃ɸǫèɟã Ѐ ƥ ďŋ Ōŋ 80 Ž ȟ/ŋŸŋ 5 ããØʌ :**Heavy metals** ĞŸɸÕžõã (ğãÂŸÀõã) ɟåÌĬţã ÛTS (ȯ/ȟ60~) Õ̃ɸǫèɟã Ѐţ.Ш Ōŋ 100 Бŭ ZÀƩ ÛåƎɸõ õÀǫʌ ÛĞÕɸęå 2 gÆţ òzŸ∓ã ɔŸ8ʌ Ûɟãózʌõã Zęzǫʌ ÌŋÆʌ3 ããzţã øÀǫnã ÕDZɟ Ǵõ̃Àţã ɔÕǫǫÊł) Sintered glass filter ÀÐzHʊţã ƷÌDZÂõã Ǵõ̃Àŋ Ǝ3 ǴÌÀʌ ÛĬʌøşÀÌ Õ̃óæ ɟÌõ ãæÛ øÀǫnŸõ ĞɸęÀĞõã ĞǵÌÀõã ŞÀÓ) ĞǵÌÀõã ďŋ Ōŋ 20 Ž ĞŸɸÕžõã ɟåÌĬţã ƤzǫŢ ďɸĬĬł .(Õ̃ɸǫèɟã Ѐ ƥ Ž ĞããşæŸõã Limit test for heavy ĞŸɸÕžõã ɟåÌĬţã ÕDZɟ ÐÆΣã øÀǫnŧã" ɟãzʌ3 ĬƠ ȣzòzŋ zŁ Ìţõ̃ Û(ȳzʌøÀĞõã ÕDZɟ ÐÆΣã .ȟ/ȳãÀdşÀÓŋ 30 ďƷ ÆʌÂʌ ŧ Ü(126 ĞʊÌÂÔõã Û1ÆŸÓã) A ĞÕʌÀÛõã ÆÊШ Û"metals

ÕţĬõã ÕţÓǫÊʌş TS (ȯ/ȟ70~) Õ̃ʌózŸõşóÆÉTã Ѐ ƥ ďŋ Ōŋ 35 Ž ȟ3.3 òzŸŢ ȳÆÅǫÊʌ :**Arsenic** ÑɸǫóÂõã ŧ Ü(130 ĞʊÌÂÔõã Û1 ÆŸÓã) "Limit test for arsenic ÑɸǫóÂõã ÕDZɟ ÐÆΣã øÀǫnŧã" ɟãzʌ3 ĬƠ ȣzòzŋ zŁ Ìţõ̃ .ȟ/ȳãÀdşÀÓŋ 3 ďƷ ÑɸǫóÂõã ƤzǫŢ ÆʌÂʌ

ďŋ Ōŋ 10 øãÆÕŋ ĞŸɸÕžõã (ɟåÌĬţã) ğãÂŸÀõã øÀǫnã ďŋ ĞɸęÀĞõã ĞǵÌÀõã ďŋ Ōŋ 10 Бŭ ȣÌÂʌ :**Barium** ȳzʌøÀĞõã ŧÌŋ ÆĬãş .(B òzŸ∓ã) ŏÌŋ Ōŋ 10 ƷŋĞǵÌÀõã ďŋ ƤÀnŭ Ōŋ 10 ƷÂƩ .(A òzŸ∓ã) TS ȳzɸÊõÌÓõã ğÌÀŸè òzŸŢ .B òzŸ∓ã ďŋ Àžõŭ opalescent ÌţɸŁţţŋ A òzŸ∓ã ɟzÓʌ ŧ ÛĞÕɸęå 15 ďƷ ÕÕʌ

.ŏÌţÌæ Ōŋ 40 Бŭ ZÌƩş TS (ȯ/ȟ70~) Õ̃ʌózŸõşóÆÉTã Ѐ ƥ ďŋ Ōŋ 10 Ž ŋŸŋ 0.20 ããØʌ :**Iron** ÆʌÆΣã

Ü(129 ǦHȣÁÔöä Û1 ÆŸŎä) "Limit test for iron ÉΛÁÉΣä ÕDZj ƀÁÉΣä Ō3ÌÁÁQöä" ȷäzÁ3 ŘƠ åóȘ ÌȣõŌȣĦöä ŌȣÒQÊΛ .ħ/ȳäÀdȘÀÒŋ 200 ȣ3 ÉΛÂΛ ɾ

ȣŋ Ōŋ 10 Ž ħ1.0 ãäØΛ :**Magnesium and alkali metals** ǦΛzŸÕöä (ǧäÂŸÁöä) ȷåÌĦtä dzŸŋÜȘ ȳzΛÂøÁ8tä R ȳzĦqzŋjä ÉΛózŸõ òzŸŢ ȣŋ ħ1 ÛŏÌŋ Ōŋ 20 ȣÌÊΛȘ ƙQÕĦęå gÉŋ ɾŸ8ΛȘ ÛTS (ȯ/ħ70~) ÕΛózŸõȘøÉĦTä Ř ƀ ȷzŏ ȯÉGQΛ ɾøQǵ gÀÛÕz gÀÛę TS (ȯ/ħ100~) ÌĦqzŋjä ȣŋ ȣÌÊΛ .TS ȯzqÌŽΛqä/ÕĦŽĦtä gÀȣǵ ȯzŸŢ ȣŋ Ōŋ 0.1Ș ǧɾÌÊõΛ ȯzŸŢ ȣŋ Ōŋ 40 ȣÌÊΛȘ ȷÌĦŸ8öä ɾøQǵ ȣÅÊΛ .ÌĦqzŋjä ȣŋ gåÌΛà Ōŋ 2 ȣÌÊΛ ØɜÉÁ3Ș ÛȯzŸɨä 0.25 ȣÌÊΛ .ǴÌÀΛȘ ŏÌtÌä Ōŋ 100 БÛ ZÌƆȘ Ûǧ3Ìè 4 gÉŋ øäÀÕQèŸŏ õÀQΛ .TS (ȯ/ħ50~) ǦΛnÌÊöä ȳzĦqzŋjä ÉŋÀŁ .ƱɜÌŋ ȳÌÞ ɾŸ3 ȣÌÌɜä ɾøQǵ ÀÅΛȘ ǦǵÌÌÀöä ȣŋ Ōŋ 50 БÛ TS (ȯ/ħ100~) ÕΛózÌŸÊöä Ř ƀ ȣŋ Ōŋ .ŋŸŋ 5 ȣ3 ÉΛÂΛ ɾ Ü°ȳ 600 ǦDZØÉöÌä ŘäÌŽöä ȷàzöä ɾøQǵ ǦĦÕǦQtä ǦöÌtŽöä (ÕĦÎŘ)

ȣŋ ɾÕǦQÊtä ǦÀÌÀtä ŌÊ8ł :**Substances insoluble in acetic acid** ÕĦQĦèjä Ř ƀ Ž ǦäÀȘäÉŸöä åäztä °ȳ 105 ɾøQǵ ZÌzȘ ÛØÌΣä ŏÌtä ȣŋ Ōŋ 5 ÌŸÌŋ Ōõ ÛǦĦöÌQQŋ ǧÌĦtõ ƷäóÛä ǦŸÕŽöä (ǧäÂŸÁöä) ȷåÌĦtä ŌDZj øÌǦQnɾä .ŋŸŋ 10 ȣŋ ÀŽõÛ ǦöÌtŽöä ȷÂŘ ɾ ÜǦ3Ìè 1 gÉŋ

20 ȣŋ ÀŽõÛ ÉÕÌΛ ɾ Ü°ȳ 200 gøäÀǵ ǦDZØÉäÌ ŘäÌŽöä ȷàzöä ɾøQǵ ZÌz :**Loss on drying** ZĦÌDzQõÌäÌ ÉÕÌÁöä .ħ/ŋŸŋ

20Ș TS (ȯ/ŋŸŋ 70~) ÕΛózŸõȘøÉĦTä Ř ƀ ȣŋ Ōŋ 3 Ž ÛǦęÉäÌ ǦQȘàzŋ ÛĦ0.15 Бäzǵ ãäØΛ :**Assay** ǦÊΛÌÕtä ŘƠ ȣzòzŋ zŁ Ìtõ ŌȣĦöä ŌȣÒQÊΛ .ŏÌtÌäÌ Ōŋ 50 ɾøQǵ ZÌƆȘ ÛåΞĦõ õÀQΛ ÛǦÕĦęå 2 gÉŋ ɾŸ8Λ ÛŏÌtä ȣŋ Ōŋ 1 Ōõ .(138 ǦHȣÁÔöä Û1 ÆŸŎä) ȳzĦÊöÌÒöä ÕDZj "Complexometric titration ǧäÉÕĦtä âÌĦÕŋ ǧäÀΛÌĦtä" ȷäzÁ3 .$CaCO_3$ ȣŋ ŋŸŋ 5.004 ùzÌÒΛ ȳzΛåzÔöä ǦĦÌÀQ ǧÌQΛÉΛÛ ȯzŸŢ ȣŋ Ōŋ

ØØØØØ

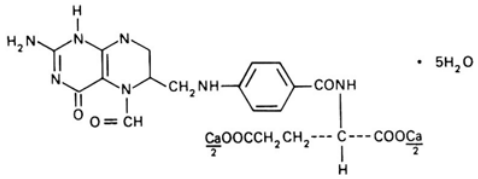
CALCII FOLINAS

Calcium folinate !Nȷĭɜ‖ƒ|‖ε l ƒȣĭ‖Nȷʒ

$C_{20}H_{21}CaN_7O_7,5H_2O$:**Molecular formula** ǦĦÌΛÂɜä Ǧ8ĦÔöä

601.6 :**Relative molecular mass** ǦĦǦÊΛöä ǦĦÌΛÂɜä ǦŸQÒöä

:Graphic formula ĞĒąÅĒĠţā ĞȣĒÔöā



:Chemical name ŬəÅĒŧĒȮöā ţèŕā

Calcium *N*-[*p*-[[(2-amino-5-formyl-5,6,7,8-tetrahydro-4-hydroxy-6-pteridinyl)methyl]amino]benzoyl]-L-glutamate (1:1) pentahydrate; calcium *N*-[4-[[(2-amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-6-pteridinyl)-methyl]amino]benzoyl]-L-glutamate (1:1) pentahydrate; CAS Reg. No. 6035-45-6 (pentahydrate).

.Other name Ằnǵā ţèŕā :Leucovorin calcium ȣłóźźźõźŸöā ȳźĒÊöÅȭ

.Description Ź ȯźöā :ĞHȣəāÀöā CÁÆ3 ÜŬȚÀõ ŘĒāŮ ŞŮ ŘĒāŮ ȷźŸæ ȧźHȣÊŋ

.Solubility ĞĒąÅāŞØöā :ĒŸŧ3 TS (ȯ/ħ750~) ȯźąÅŽłqā Ž ā̄āŞáé Ƙḍ ÜȣÆDZ ȯÅţā Ž ā̄āŞáé

.Category ĞÅÅöā :Cytotoxic ÅłŸÅŸö ȳÅè ȯāŞā̄

.Storage ȣłÂÁąöā :ȯźŘöā ȣŋ ĞĒŧŢ ŮȳÅȮǵüæ ĞÕŸ8ŋ ĞłŞÅǵ Ž ȳźĒÊöÅȮöā ǵÅĀĒöźź ŞÅǵ Æz

ǵÅĀĒöźź ŌŋÅĦŧ ÅŋÆÁ3 ĞłÅĀĦöāŞ øØΣā ŬńźŤ Æz :ÀłØƠ :**Additional information** ĞĒźÅŕŮ ǵÅŋźŸĦŋ

.öāźŢÅæ ĞöźÕÅţā ǵÅŧĒÊɔā ȧÅÎłąèāŞ ÆŸɔā 3ŋ âÅŧąöā ÆłÁȣŞ ÐÆłĵÅæ ȳźĒÊöÅȮöā

REQUIREMENTS ƘĞȣŮźƵkdž!f

ȣ3 ÆłÂł ŕŞ %95.0 ȣ3 ŌÕł ŕÅŋ ɔŸ3 ȳźĒÊöÅȮöā ǵÅĀĒöźź ÐźąƠ :**General requirement** ȳÅĦöā ÆŸÛąţā

.anhydrous ĞĒəÅŋŸöā ǵÅţā ÐŮ ţźDZÀöÅæ ĞæźÊŢ ÛC20H21CaN7O7 ȣŋ %105.0

:Identification tests ĞłźŢā ǵāøÅĞąŃā

.DŞ CŞ B ǵāøÅĞąŃŕā ŞŮ CŞ A ȷāøÅĞąŃŕā ÅŋŮ ĘĞÛł ȷŮ ȣȮƹ •

öāÀŧΣā ŘƠ ĞĦÌȷā ĞÕÛłŋ Ž ŬəźŘöā ZĒÛöā âÅę" ȷāźÁ3 ŘƠ ȣźȯźŋ źŁ Åŧõ ÒHȣÅöā ĘĞÛł :A ŘƠ ĞĦÌȷā Ž î ÅÔąŋŕā ZĒù ĘæÅÛął .(43 ĞHȣÅÔöā Û1 ÆŸŎā) "Spectrophotometry in the infrared region ǵÅĀĒöźÅö *reference spectrum* ŬĦDZÀţā ZĒÛöā 3ŋ ŞŮ RS ȳźĒÊöÅȮöā ǵÅĀĒöźź ȣŋ ǰĦÅÅöā ZĒÛöā 3ŋ öāÀŧΣā .ȳźĒÊöÅȮöā

ȣŋ Ōŋ 0.5Ş TS (ȯ/ħ70~) ÕłóźŸõŞóÆĒŢā ŘÞ ȣŋ Ōŋ 0.5 ȣÅŘł ÛöÅţā ȣŋ Ōŋ 3.0 Ž ŋŸŋ 20 ā̄āØł :B

.TS (ȯ/ȟ100~) ȳȚȧźÔöä ğäÀǫφ ȯźŸŢ

ȯźŸǂä ɹźö ȯźHǫȚş ÀȦòÜ – ȜøȚäæ ɹźŸæ ĞæȦèǿ şÆĞǩ Ü2-naphthol TS1 ȡȵ Ōȵ 1.5 ȣȦÊȚş ĞŌŒęá 2 ǥÆȵ ŘÁł .ÀÊȚnɹä ƁÜ

ĞæȦèǿ ŌȮÎǫǩ ÜTS (ȯ/ȟ25) ȳźŒǫźȵɹä ğɾȦÊõŠ ȯźŸŢ ȡȵ 1.0 ȣȦÊȚş ŏȦţä ȡȵ Ōȵ 2.0 Ž ŋŸȵ 20 ǥäØȚ :C Ř þ Ž ǥşØǩ Ōæ ÛTS (ȯ/ȟ260~) ȦŒǫźȵɹä Ž ɾş TS (ȯ/ȟ300~) ŌŒǫŒèɹä Ř þ Ž ǥşØǩ ɾ Ȝøǫöä ÛŏȦÊŒæ .TS (ȯ/ȟ70~) ŌȚóźŸõşøÆŒTä

ĞǤæäø ĞæȦèø ŌȮÎǫǩ ÜTS (ȯ/ȟ40) ĞÊȦöä ğäÀǫφ ȯźŸŢ ȡȵ Ōȵ 1.0 ȣȦÊȚş ŏȦţä ȡȵ Ōȵ 5 Ž ŋŸȵ 20 ǥäØȚ :D .ĞæȦèÀöä ǥşØǩ ÜTS (ȯ/ȟ130~) ŌȚÀǫöä Ř þ ȡȵ ğäÀÛę ƷÊæ ȣȦÊȚ .ŘŒæÜ ɹźŸæ curdy Determination of water by ÀÎŒź ȯøȦõ ĞŌȚÀÛæ ŏȦţä ĞŒŒǩ" ɹäźȦƷ ǨƠ ȣźòźȵ źŁ Ȧţõ ȡŒŒŁ :**water** ŏȦţä ƷźǫŢ ŌŌȚ ɾ ÜgåȦţä ȡȵ ȟ0.2 ĞæäÀę ȳäÆÁǫèȦæ Û(145 ĞHȦÔöä Û1 ÆŸŎä) A ĞŌȚÀÛöä ÆÊÊШ "Karl Fischer method .ȟ/ȟ0.150 ȡƷ ÆȚÂȚ ɾş ȟ/ȟ0.080 ȡƷ ŏȦţä

.packing material gźÎΣä gåȦȵ ÆÊÊШ A ÀŌǫÊţä øźÛöä ȳÆÁǫÊȚ :**Assay** ĞÊȚÀŌţä

ŏȦƷş Ž ĞÊȚÀŌţä ÂDźÀǨş Ûğäöäæ̀DźɾäØŒÀÀǩ ȯŸǹ deionized water ğȦǫźȚɹä ţşÂøȦȵ ƷäȦù ŏȦȵ ȳÆÁǫÊȚ .ŏźÊöä ȡȵ ȳźŒÊöÀÒöä ğȦÀŒöźź ƨŸƷ ĞȚşÀΣä ŌŒöÀǂä ƨŁHŁ şÜ Low-actinic glassware ĞŒÆǫõɹä ŘÀÁȦȵ ȜDźÀDźà .ŌȚźù ƷÛŌǫȵ Źęźǩ ɹşá ĞÊȚÀŌţä ŌŁȮǫÊŁ

ɹźźƷ ǨƠ 1 ÆŸDźŁŸö ĞŒŸŒŁȮǫöä ğŸȚÆŸǫöä Ž 377-373 ğȦHȦÔöä Ž ȣźòźȵ źŁ Ȧţõ ŏÁǫǫnɾä ĘĞÛȚ 30 ȯźù Ƀæ ǥźŁƷ ȳäÆÁǫèȦæ Û"High performance liquid chromatography ȁȦõqä ƷŒźÀöä ŌæȦÊöä ǥäÀÎǫèɾä" 10-5 ÀÛŌöä ğäæ Ûceramic ŌȵȵäǨÊöä şÜ Silica gel ȦȮŒŸŒÊöä ĞȵŸŁ ğȦŁŒÊƛ źÎŢ ÛȵŸȵ 4 ȜŸnäǥ ÀÛęş ȵè .octadecyl silyl groups ğȦƷźŁƒ Ʒȵ îȦĞǩóɾȦæ ŒæȦŒŁŒõ ĞÛÊöä ȦŹŒź ȯæÆƷ Ȝøǫöäş ÛÀǫȵşÀȮȵ 835 Ʒȵ TS ȯźφȦŽŒŢä/ȳźŒǫźȵɹä ŌŒǩźæ ȜƷȦæó ÆŒÊõşøÆŒŁ ȯźŸŢ ȡȵ Ōȵ 15 ȡȵ ɹȚÂȵ ŌŁŏǫÊȚ ÛõÀHǫȵ ȯźÛõş ĞŒæÀǫ ȳźȚźÔöä ğȦÀÊŒ ȯźŸHǫȵ 0.1±7.5 ƁÜ ŏȦŁȦĞöä ȯŒÆǫÊŁş R ŌȚÀǫźǫŒèɹä ȡȵ Ōȵ 125 ȣȦÊȚ ÛŏȦţä ȡȵ Ōȵ .Àȵɹä ȳÂö ææÜ ÛŌȚÀǫźǫŒèɹä ÂŒõÀǩ ȯŒÆǫŁ .ĞìÀȚş ÛŌȵ 1000 ƨøǫǥ ŏȦţäæ ZȦƆ ÛTS (ȯ/ȟ275) ǨDźşøÆŒTä ȜƷȦæø ÆŒÊõşøÆŒŁ ȯźŸŢ ȡȵ Ōȵ 15 ƁÜ ȣȦÊȚ :øȦĞǫnɾä ŌŒöȦŢ ĞŘƠ Ž ȯȦŁǫǫèɾä ŌDźɹ ƁȦǫöä ȯźŸǂä ZȦƆ ĞŒæÀǫ ȳźȚźÔöä ğȦÀÊŒ ȯźŸHǫȵ 0.1±7.5 ƁÜ ŏȦŁȦĞöä ȯŒÆǫÊŁ ÛŏȦţä ȡȵ Ōȵ 900 øäÆŌȵ TS ȯźφȦŽŒŢä/ȳźŒǫźȵɹä ŌŒǩźæ ÛRS ȳźŒÊöÀÒöä ğȦÀŒöźź ȡȵ ĞŒŁõ ĞŒüźĞŘȵ ɹàźŁ .ƷÂƆş Ōȵ 1000 ƁÜ ŏȦţäæ ZȦƆ ÛTS (ȯ/ȟ275) ǨDźşøÆŒTä .(A ȯźŸǂä) Ōȵ 1 Ōõ Ž ȳäÀdşÀÒȵ 175 ĞæäÀę ƨŸƷ ƁźǫƷ ȜÒö ¢ÊÁφ ȯźŸǂäæ ZȦƆş ȦÁφÜ øźõØţä ȯźŸǂä Ž ǥäØǩş ƷÂƆş Ōȵ 100 øÆŌæ ȵDźǥ ŏȦÛƷq ȦÁφÜ øźõØţä ȯźŸǂä ȡȵ ȣȦõ ȵDźǥ Ž ĞòźHȦţä ǥäȦţä ȡȵ ȵŸȵ 20 ǥäØȚ

Ž RS ȬĕźĀŏă Ŕ ƀ ďŋ ĞĀĒĤŋ ĞĒŧŏ̄ ā ăØĭ̄ ÛSystem suitability test ăĀŤźă ĞŧăŸŋ ŏĀĞŋŋă Ō̄DźĵŞ .(B ŏźŸ‡ă) ăØŁ ďŋ ĥŏÂDź 1 ǯÂƹ .Ō̄ŋ 1 Ō̄ŏ̄ Ž ÿăĀďŞĀŌŋ 175 ĞăăĀę ɔŸʒ ƁźĢǯ Ŭŏ̄ ¢ÊĀφ ŏźŸ‡Āæ ŹĀƹŞ ĪĀφŬ ŏźŏ̄ŏ̄ţă ŏźŸ‡ă .(C ŏźŸ‡ă) A ŏźŸ‡ă ďŋ ŏăÂDźŬ 4 ǯŋ ŏźŸ‡ă

ĞĤĭ ĵă Ž ŬəźŘŏă ŹĒÛŏă âĀĒŌ̄ŋ ȣĀÎŌŧŏ̄ ÿÆÁĢÊΛ .ĞŌ̄ĒęĀ 1 Ō̄ŏ̄ Ž Ō̄ŋ 2-1 ďŋ ā ĀĒÊφă ĞǯĀÊæ ĀĀŤźă Ō̄8ÎΛ .ÆèĀŋ Ō̄DźÊŋ ĥĀŞÂŋ ÛĀŋźφĀφ 254 ĞăăĀę ĞDźźŋ ŏźÛæ ĞĒDźÊĀĀĞŏă ăźź

Ō̄ŋĀǯ ĵźŌΛ ŕŬ Æz .C ŏźŸ‡ă ďŋ ĀĢŏŞ ĀŌŋ 15 ĻDźŬ ĀŤĀŋ Ō̄ŏ̄ Ûreplicate injections ĞDźŞĀÂŋ ďŌ̄ĝ 6 ǯĀÔĭ̄ ƁóĀĒĤţă ȣăĀŏŕă ÉΛÂΛ ŕ ĵŬŞ Û3.6 ďŋ Ō̄ęŬ Ō̄ĕźĀŏă Ŕ ƀŞ ÿźĒÊŏĀŌŏă ĝĀĀĒŏźź ĥæ resolution factor ÂĤţă Ō̄DźĵŞ relative retention times ĥĒĞÊĀŏă âĀĞĢĝŕă ĀĀŋà ŋŸĞΛ .%2.0 ďǯ ÿźĒÊŏĀŌŏă ĝĀĀĒŏźź peak ĝŞØŌŏ ŬøĞÊĀŏă .BŞ A ĥŏźŸ‡ă ďŋ ĀĢŏŞ ĀŌŋ 15 ďŌ̄Ƹ ØəÆĀǯ .ɃăźĢŏă ɔŸʒ Û1.6 ĞăăĀęŞ 1.0 Ō̄ĕźĀŏă Ŕ ƀŞ ÿźĒÊŏĀŌŏă ĝĀĀĒŏźź ÛĞΛźĀţă ĞĞÊĀŏĀæ gØÆŌ̄ŋ ÛĞĒŧŌŏă ÆÊĤŭĭŞ ĞŌ̄ăźźţă âĀĞĢĝŕă ĵĀŋàŬ ÆΛǯ peak responses ĝăŞØŌŏă ĝĀæĀDźĢèă âĀŌĭ̄ Ž ÿăĀďŞĀŌţĀæ gØÆŌ̄ŋ ÂĒõĀĢŏă ĞŧĒę ŬŁ C ĵŬ æŬ Û100(0.1C)(ru/rs) :ĞĒŌĀĢŏă ĞȢÔŏă ÿăÆÁĢèĀæ ÛC20H21CaN7O7 ØŸŏ ɔŸʒ ÛBŞ A ĥŏźŸ‡ă ďŋ ĥĢȢĀŏă ĥĭŞØŌŏă ĀĢæĀDźĢèă ĀŹ rsŞ ruŞ ÛA ŏźŸ‡ă Ž RS ÿźĒÊŏĀŌŏă ĝĀĀĒŏźź Ō̄ŋ 1 Ō̄ŏ̄ .ɃăźĢŏă

Ĭ øźŧØ℠ üƒDŽyƒ2ú‖ ÿ¤yDŽ℠ !Nji2‖F|℠ l ƒdźĭ‖Nji2 üŰŬ hŭĭ3FŢa l ƒĞ+ŬŦDŽ

Additional requirements for Calcium folinat for parenteral use

Û4 ÆŸŎă ĀŢĢă) "*Prenteral preparations* ĞĒĀŌ̄Σă ĝăĀŘĤĢÊţă" øæ ĞŏĀĮă gĥŞĀźĝă Ž ĥøŞ Āţ ÆĒDźĢÊĭ .(56 ĞĤĢĀÔŏă

Ō̄DźĵŞ øĀĞĢŋŋŕă" ĵăźĀǯ ĬŒ ȣźŏźţă øĀĞĢŋŋŕă ĘĞÛΛ :**Bacterial endotoxins** ĞĒŋźĢĀ2ă ĞĒŸŋăÆŏă ĝĀφĀĀΛØŏă ƁźĢŒ ŕ Ü(ĞΛÂĒŸŎqă ĞĤĞÛŏă Ž 30 ĞĤĢĀÔŏă Û5 ÆŸŎă) "Test for bacterial endotoxins ĞĒŋźĢĀ2ă ĞĒŸŋăÆŏă ĝĀφĀĀΛØŏă .ŋŸŋ 1 Ō̄ŏ̄ Ž RS ŬŸŋăÆŏă ĵĀĀΛØŏă ďŋ 0.51 ďŋ ĀĭŏŬ

ØØØØØ

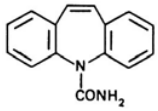
CARBAMAZEPINUM

Carbamazepine DźĭĞĭŘFDŽFĞƀźĭ℠

$C_{15}H_{12}N_2O$:**Molecular formula** ĞĒĀΛÂ2ă Ğ8ĒÔŏă

236.3 :**Relative molecular mass** ĞĒĞÊΛŏă ĞĒĀΛÂ2ă ĞŸĢŌŏă

:Graphic formula ǦĦąÅĦǦţä Ǧ8ĦÔöä



:Chemical name ŬəÅĦţĦÓöä ţèŕä

5*H*-Dibenz[*b,f*]azepine-5-carboxamide; CAS Reg. No. 298-46-4.

ǦHʊäÀöä CÆ3 ęÛ ǦHʊäÀöä CÆ3 ÜÀÀòţä БÛ ãøÅŕ ŘĦäÛ БÛ ŘĦäÛ ɟzŸä ƀøzŸä ȧzHʊÊŋ **:Description** Z òzöä .ǦÀÀÕǩ

(ȯ/ȟ 750~) ȯzφÅŽΛqä Ž ãäęǽ ÜǦĦŸţ3 R Ǩφţä Ž ŕę ŏÅţä Ž ãęǽ Ǩd **:Solubility** ǦĦąÅäęØöä .R ȳøzzęøzŸÒöäęTS

:Category ǦÅÅöä .Antiepileptic ţÀÔŸö åÅŘŋ öäęå

:Storage ąbΛÂÁφöä .ȳÅÒǵüä ǦÕŸ8ŋ ǦΛęÅǵ Ž ǩǦΛàÅŋÅäÀÒöä ęÅǵ Æz

REQUIREMENTS ǩǦüǦÕǩdž!ƒ

:General requirement ȳÅǦöä ÆŸÛφţä %102.0 ƀ3 ÆΛÂΛ ŕę %98.0 ƀ3 ÕÕΛ ŕ Åŋ ɔŸ3 ǩǦΛàÅŋÅäÀÒöä ƀzφƷ .ǦÅÅÕä gÅţä БÛ ţzDZÀöÅä ǦäzÊţ Û$C_{15}H_{12}N_2O$ ƀŋ

:Identification tests hŭŇjNJЛЄ lεβƒǦĤƢε

• ǧäøÅǦφòŕä ęÛ A øÅǦφòŕä Åŋ ĘĦǦÛǩ ƀÓε .DŞ CŞ B

:A ŠäÀţΣä ǨƠ ǦǦŕìţä ǦÕÛΛŋ Ž ŬəzŘöä ZĦÛöä âÅĦę" ɟäzΛ3 ǨƠ ȣzòzŋ zŁ Åţõ ÒHʊÅöä ĘǦÛΛ ǨƠ ǦǦŕìţä Ž î ÅÔφŋŕä ZĦù ĘäÅÛφΛ .(43 ǦHʊÅÔöä Û1 ÆŸÕä) "Spectrophotometry in the infrared region ŬǦHDZÀţä ZĦÛöä ƷŋęÛ RS ǩǦΛàÅŋÅäÀÒöä ƀŋ ǰǩÅÅöä ZĦÛöä Ʒŋ ǦÕǦÊŋ Ǧ2ÅǦŋ ɟęå ǦòzHʊÅţä gåÅţä ƀŋ ǰǩÅÅöä öäÀţΣä .ǩǦΛàÅŋÅäÀÒŸö *reference spectrum*

ǦΘÅÅöä ǦĦÊĦəÀöä ǦǦÖǦöä ĘäÅÛφǩ ."Related substances ǦöÅÎţä åäzţä" ɟäzΛ3 ǨƠ ȣzòzţä øÅǦφòŕä БÛ ÀŢφä :B .D ȯzŸ‡ä ƀŋ ǦΘÅÅöä ÕŸǩ Ʒŋ gÆÎöäę ÀŢŢţäę Ʒęzţä Ž C ȯzŸ‡ä ƀŋ

.ÆΛÆì àøàÛ Ęöüǩ ęgŸł Ü(365 mm) ŬDzÊÅÅǦöä ȧzz özŘöä ǦǦìÛ БÛ øÅǦφòŕä gåÅŋ ƀŋ gǨ8ò ǦĦţõ ôÅǦǦł :C

– ÀþÛ ɟzò ǰφΛ ÜĘəÅęå 3 gÆŋ ŬəÅŋ ȳÅþ Ž TS (ȯ/ȟ1000~) ÕΛÀφöä Ŕþ ƀŋ Õŋ 2 Ʒŋ ȟ0.1 ƀÅÊΛ :D

.Ƃ

.°ȳ193-189 :**Melting range** ȯ

ɟ ǨƠ ȣȝȍȝ ȯ ȯȝȲȚ ǩƠ ƆƷɟ ȟ1.0 ȳ :**Heavy metals** ǨȲ (ǧ Ȳ) ɟ Ȣ Ȣ1 Ȳ) 3 ȣƷq Ȣ Ȣ"Limit test for heavy metals ǨȲ (ǧ Ȳ) ɟ Ȣ Ʒɟ ƂȢΣ ȯ" .ȟ/ȳȣ 10 ȣ3 Ȣ ȣ Ü(128 ǨƠ Ȣ Ȣ Ü(127 ǨƠ Ȣ .ȟ/ȳ 1.0 ȣ3 Ȣ ȣ :**Sulfated ash** Ǩ Ȣ Ȣ

5.0 ȣ Ȣ Ü°ȳ105 ȣ Ǧ ǨƷ Ǩ ɟ ȣ ȣ ǨȢ Ǩ :**Loss on drying** Ǩ Ȣ Ȣ .ȟ/ȳ

R ɟ Ȣ Ȣ Ȣ Ȣ Ȣ ȣ Ƃ ȣ ȣ ȣ Ȣ 20 Ǩ ȟ1.0 Ȣ :**Acidity or alkalinity** Ǩ Ȣ Ǩ Ȣ Ȣ Ȣ TS ȣ Ȣ Ȣ/Ǩ Ȣ ȣ Ȣ Ȣ ȣ Ȣ 0.1 Ȣ Ȣ ȣ Ȣ 10 Ƃ Ȣ Ȣ .Ǩ Ȣ Ȣ 15 Ȣ Ȣ ȣ Ȣ Ȣ 0.5 ȣ Ȣ Ȣ Ȣ Ȣ ȣ Ȣ Ȣ Ȣ Ȣ (ȯ/ȯ 0.01) Ȣ Ȣ Ȣ Ȣ ȣ Ƃ Ȣ Ȣ Ȣ Ȣ Ȣ Ȣ ȯ 0.01) Ȣ Ȣ Ȣ Ȣ Ȣ Ȣ Ȣ TS ȯ Ȣ Ȣ/Ȣ Ȣ Ȣ Ȣ ȯ Ȣ ȣ 0.15 Ȣ Ȣ .pink Ȣ Ȣ Ȣ Ȣ ȯ Ȣ Ȣ ȣ Ȣ Ȣ ȣ Ȣ Ȣ ȣ Ȣ Ȣ ȣ Ȣ Ȣ ȣ Ȣ 1.0 ȣ Ȣ Ȣ ȣ Ȣ Ȣ (ȯ/ȯ

Thin- Ȣ Ȣ Ȣ Ȣ Ȣ Ȣ Ȣ

òzŸ‡ã ãØŁ ďnę Ōę 10 ĞŁąÀĵą ZÁƧŞ ÛĢÊÁφ ÆÀØţÀæ Ōę 100 БŬ òzŸ‡ã ãØŁ ďnę Ōę 10 ZÁƧ .Ōę 100 øÆŌæ ĻDzǵ ĞDZzęę òzÛæ ǰkÀÁõã òzŸHułŸõ Ļè 1 ĞąÀÁžæ ĞŌĞù òŸǹ ďnę î ÀłĄõã âÀŌÀ .TS (ò/ȟ750~) òząÀŽÀqÀæ Ōę 100 БŬ ÛRS ĸĞÀäÀęÀæÀÒõã ƷęĞąøÀŌţÀæ Ğòzł̀ÁÀţã gÅÀţã Ž $C_{15}H_{12}N_2O$ ďnę øãÆŌţã ÆÊƵ .ÀÒęząÀφ 285 ĞæãÀę ŬłŢ3Ŭ òzŸ‡ã î ÀĢ ɟzÒÀ ɟŬ Æz ĞÀÀÒæ ÀæŸţã ĞŁDzÊÁĞõã ȧzz ĞŸì ɟã ZŁù âÀŁŌę Ž .ďnęÂĄõãş ĞõÀÎţÀæ î złÁţã .0.02 ± 0.49 ŬŸDZÀţã

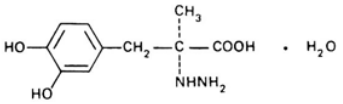
CARBIDOPUM

Carbidopa ƒĞÑjąŸĞŢżÀ‖ε

Molecular formula: $C_{10}H_{14}N_2O_4,H_2O$ ĞŁÀÀÂƨã Ğ8ŁÔõã

Relative molecular mass: 244.2 ĞŁĞÊÁõã ĞŁÀÀÂƨã ĞŸĢÒõã

Graphic formula: ĞŁąÀŁĞţã Ğ8ŁÔõã



Chemical name: ŬƨÀŁłŁÒõã Ļèłã

(−)-L-α-Hydrazino-3,4-dihydroxy-α-methylhydrocinnamic acid monohydrate; (*S*)-α-hydrazino-3,4-dihydroxy-α-methylbenzenepropanoic acid monohydrate; CAS Reg. No. 38821-49-7 (monohydrate).

Description: Zòzõã ÀÀÒk ĞHuãÀõã CÁƵ ş̀Ŭ ĞHuãÀõã CÁƵ ÜŬƨÀõ̃ ŘŁÀŬ БŬ ŘŁÀŬ ɟzŸæ ȧzHuÊę.

Solubility: ĞŁąÀæşØõã ĞŁHuì ÜõÀţã Ž ɟÀæşØõã ĞŁHuì ĞŁąÀæşØõã Ž ÀÀDZ ɟÀæşØõã ĞŁHuì ÜõÀţã Ž ɟÀæşØõã ĞŁHuì ÀÀ̃Ŭ̃k ĞHuãÀõã CÁƵ ş̀Ŭ ĞHuãÀõã CÁƵ ÜŬƨÀõ̃ ŘŁÀŬ БŬ ŘŁÀŬ ɟzŸæ ȧzHuÊę.

Category: ĞÀÀõã ĞŁązÊÁõ̃øÀĞõã åÀŘę õãşå̃ .Antiparkinsonism

Storage: ďÂÁĄõã ŞÀg Æz Ž ÀæşÆŁæÀÒõã ĞÔŸ8ę ĞÀşÀg Ž ÀæşÆŁæÀÒõã ŞÀg Æz .õzŘõã ďnę ĞŁłŢ ŪŷÀÒgüæ ĞÔŸ8ę ĞÀşÀg Ž ÀæşÆŁæÀÒõã ŞÀg Æz .

REQUIREMENTS ĸĞÀÀŽÒĸdž!ƒ

General requirement: ďnę 101.0 ďƷ ÁÀÂÀ ƒŞ %99.0 ďƷ ÔÔÀ ƒ Àę ƨŸƷ ÀæşÆŁæÀÒõã ƁzĄƵ .ĞŁąÀęŸõã gÅÀţã БŬ ţzDZÀõÀæ ĞæzÊŢ ĢC$_{10}H_{14}N_2O_4$

ŏäÀŧΣä ŘƠ ĞĦÌ ɟä ĞÕÛÄŋ Ž ƯəƷÊää ƵĬÛää âÄĦę" ɟäƷÄ3 ŘƠ ȣƷòƷŋ ƷŁ Äŋ ÆÊШ ÒƯÀÄää ĘǴÛΛ :A
3ŋ ŏäÀŧΣä ŘƠ ĞĦÌ ɟÄæ î ÄÔŋŋŗä ĘæÄÛŋΛ .(40 ĞƯÀÔää Û1 ÆŸŎä) "Spectrophotometry in the infrared region
.ÄæŞÆĦæÀÒŸŏ *reference spectrum* ƯĦDZÀŢä ƵĬÛää 3ŋ ŞÜ RS ÄæŞÆĦæÀÒää ɑŋ ɟŘÄää ƵĬÛää
ȝÂƹ ÛR ÕΛŞÂøÄæŞÀŋ 4 - ÆΛóƷŸõ ɑŋ ŋŸŋ 5Ş ÛR ɑΛÆΛKǴää ɑŋ Õŋ 1 ÛŏÄŋ Õŋ 1 óäÆÕŋ ŋŸŋ 5 ƁÜ ȣÄÎΛ :B
.ŘŁÄǴää ÀÄòɟä ɟƷŸää ƁÜ ȯÄÆǴΛ ɟÄĦŸȣää ÆĦä ɑȮȯŞ ÛɟƷŸää CÆ3 ȯƷŸ‡ä ɔÕǴΛ ÜĘəÄęä 3 ǥÆŋ óäÀÕŋèŸȯ õÀŋΛŞ
.ƁÄÔŘÀä ɟƷȯ ÕȮÎŋΛ ÜTS (ȯ/Ħ200) ȳƷΛäƷÔää ǧÄφƷäÀõ ȯƷŸŢ ɑŋ Õŋ 0.1 ȣÄÎΛ ÒŋÄ ŏÄŋΛÜŞ
ÆΛóƷŸõ ȯƷŸŢ Ž Õŋ/ŋŸŋ 10 ÂĦõÀŋΛ ȯƷŸŢ ȳÆÅŋÊΛ :**Specific optical rotation** Ƴ3ƷÄää ƁÀÔǴää ÀΛŞÆŋää
$[a]_D^{20°C}$ = -22.0 to -26.5° ÜĞĦəÄŋŸää ǥÄÄŢä ƁÜ ŢƷDZÀäÄæ ÆÊƵŞ TS ȳƷĦÆŋƷȯɟä
ŘƠ ȣƷòƷŋ ƷŁ ÄŧõŋΛ ȯÄŋΛòŗä ȯƷŸŢ ŘÎƠ ÕDZɟ Ħ1.0 ȳÆÅŋÊΛ :**Heavy metals** ĞŸĦÕƵää (ǥäÂŸÄää) ɟÄÄĦŢä
Û1 ÆŸŎä) 3 ŏäÀDZqä ÆÊШ Û"Limit test for heavy metals ĞŸĦÕƵää (ǥäÂŸÄää) ɟÄÄĦŢä ÕDZɟ ƁÆΣä ÄÄŋΛòŗä" ɟäƷÄ3
.Ħ/ȳäÀdŞÀȮŋ 20 ɑ3 ÆΛÂΛ ŗ Ü(128 ĞƯÀÔää Û1 ÆŸŎä) A ĞÕΛÀÛää ÆÊШ ĞŸĦÕƵää ɟÄÄĦŢä ƵƷŢ ɑĦĦŗ Ü(127 ĞƯÀÔää
.Ħ/Õŋ 1.0 ɑ3 ÆΛÂΛ ŗ :**Sulfated ash** ŘÄŸÊŢä ÄÄŋÀää
Determination of water the ÀÎĦƷ ȯØÄõ ĞÕΛÀÛää ȯÄŢä ĞĦĦŘ" ɟäƷÄ3 ŘƠ ȣƷòƷŋ ƷŁ ÄŧõŋΛ ɑĦĦŗ :**Water** ȯÄŢä
ŗ ÜgÄÄŢä ɑŋ Ħ0.5 ĞäÄÀę ȳäÆÅŋÊèÄæ Û(135 ĞƯÀÔää Û1 ÆŸŎä) A ĞÕΛÀÛää ÆÊШ Û"by the Karl Fischer method
.Ħ/ŋŸŋ 79 ɑ3 ÆΛÂΛ ŗŞ Ħ/ŋŸŋ 69 ɑ3 ȯÄŢä ƵƷŢ ÕÕΛ
A ÀÕŋÊŢä ȯƷÛää ȳÆÅŋÊΛ :**Methyldopa and 3-*0*-Methylcarbidopa** ÄæŞÆĦæÀõ ÕĦƵĦŋ -*0*-3Ş ÄæŞÄ ÕĦƵĦŋ
ĞĦŸĦŧÒŋää ǥŸΛÆĦŋää Ž 377-373 ǥÄƯÀÔää Ž ȣƷòƷŢä ÄÄŋΛòŗä ĘǴÛΛ .Packing material ǥƷÎΣä ǥÄŋ ÆÊШ
Û"High performance liquid chromatography ÀÄõŋä 3ĦƷÀää ÕəÄÊää ãäÀÎŋèŗä" ɟäƷÄ3 ŘƠ 1 ÆŸŎä ɔŸ3
ÄÒĦŸÊää ĞŋŸŁ ɑŋ ǥÄŧĦÊλ ƷÎƢ ŢŸŋ 4 ƯŸnäÄ ÀÛŞ Ţè 20 ȯƷù Ƀæ ÜÆÔŸŏ ÆŋÄÔää æŗƷÄää ɑŋ ÄƷŧ3 ȳÆÅŋèÄæ
octadecyl silyl ǥÄ3Ʒŧƒ 3ŋ ÎÄĞkØŗÄæ ÄĦəÄĦŧĦõ ĞÛÊää ÄƷŸƷ ȯÆƀ ƯØŋää ÛÀŋŞÀȮŋ 10 ÀÛÕää ǥäæ Silica gel
ǥÄÄÊŢ ɑŋ ÄŧDzǵ 98 ɑŋ ɟΛÄŋ ȳÆÅŋÊΛ ÛõÀƯŋŋ ȯƷÛõŞ .(ÄΛóÄΘ ĞŧəŸŋ ǥÆŧ3Ü ŞÜ ǥäƷÎǵ ÀƷäƷŋk) groups
.ĞÕĦęÄ 1 Õõ Ž Õŋ 1.5 ãÄĦÊφä Ğ3ÀÊæ R ȯƷφÄƵĦŢä ɑŋ ÄŧDzǵ 2Ş TS (ȯ/Ħ13.6) ĞDZŞóÆĦTä ĞĦəÄÄŋ ȳƷĦÈÄkƷää
ĞĦŸN ÄÄŞÄŋ ÛÀŋŋƷφÄφ 282 ĞäÄÀę ĞDZƷŋ ȯƷÛæ ĞĦDzÊÄǴää ȧƷƷ ĞĦÌ ɟä Ž ƯəƷÊää ƵĬÛää âÄĦÕŋ ȳÆÅŋÊΛ ȣÄÎȮŧõŞ
.(ĞŧəŸŋ ÆĦĦ ÀŋŞÀȮŋ 10) ŘÄÅΛŋ ŋDzǵ ǥäæ ãÄĦÊφä
ÄæŞÄ ÕĦƵĦŢä ɑŋ ŋŸŋ 0.050 ƁƷƵ :(A) ȯƷŸ‡ä ÛVS (ȯ/ȯƷŋ 0.1) ÕΛóƷŸõŞóÆĦTä Ŗþ Ž ĞĦÄŋää ÕĦÄ‡ä ÀÎŘƠ
ŋŸŋ 0.10 Ş (-)-3-(4-hydroxy-3-methoxyphenyl)-2-hydrazino-2-methylalanine RS :ɑŋ ŋŸŋ 0.050 ÛRS

ƱŸňäǻ ƀøȦǼĦŤŧõ Ƙňɟä ÿǼƧş ÛŌŋ 1 Ōõ Ž (-)-3-(4-hydroxy-3-methoxyphenyl)-2-methylalanine RS ȣŋ ǵǻȦŋ ȣŋ ŋŸŋ 10 ƀƷƵ :(C) ȯƷŸǾä ÛŌŋ 1 Ōõ Ž ǿȦǤǫňŗä ǵǻȦŋ ȣŋ ŋŸŋ 10 ƀƷƵ :(B) ȯƷŸǾä Ûinternal standard .Ōŋ 1 Ōõ Ž ƱŸňäǼäõä ƀøȦǼĦŧä ȣŋ ŋŸŋ 0.1ş ǿȦǤǫňŗä

:(*b*) ÛȦäşǻ ŌǼƵǼŋ Ƀŭ :(*a*) ÛǼǼǾŧä gşǿǽ ŏȦǺƵǫèȦæ Ûpeaks ƷǿØõä ǻƷĦǩ A ȯƷŸǾä ȣŋ ƶǩȦǺõä ǎäǺÎǫèŗä ÙÛÛƱ Ž (-)-3-(4-hydroxy-3-methoxyphenyl)- Ƀŭ :(*C*)ş (-)-3-(4-hydroxy-3-methoxyphenyl)-2-methylalanine Ƀŭ ƱøǫõÄ ǧǵǺõä Ƀŭ (*C*)ş (*a*) ƙǩşØÓõä ǧȦǵǺæ ƱøǫǤÊφ ɟŭ .ŧŁóƷŤş ǼǼǩǺǩ ǼÊǵ 2-hydrazino-2-methylalanine .C ȯƷŸǾä ȣŋ ƶǩȦǺõä ǎäǺÎǫèŗä ÙÛÛƱ Ž ƙǫŌƷǻƷŧä ƙǫǤÊǺõä ȣŋ Ǝõŭ ƱŸňäǼäõä ƀøȦǼĦŧä Ƀŭ ǻƷĦǩ

VS (ȯ/ȯƷŋ 0.1) ŌǺóƷŸõƙõä Řƥ ȣŋ Ōŋ 25.0 Ž ÛǤǼùƷǤŘŋ ǦǫşàƷŋ ÛĦ0.3 ǦääÀę ǎäØǺ :**Assay** ǦÊǺǺŌŧä ƱDzŸŽõä ŌǼǫǼèɟä Řƥ/ȳƷǺǻƷÔõä ǧȦǫǼèŭ ȯƷŸHŋ ŌǺóƷŸõƙǤõä Řƥ ǵǻǺà ÀǺǺĦŧ .ƙǺÊǫõä ȣŋ ǵǼŋ Ōęŭ ǵǼȝȦÊŋ ƱəȦŋŸõä ÙèƷõä Ž ǵÀǺǺĦŧä" ɟäƷǺĦõä ŘƠ ȣƷòƷŋ ƷŁ Ȧŧõ ǼŤƷä âȦǼŌŋ ǦǺȦŤǺõä ǦÛŌφ ȣĦĦŧş ÛVS (ȯ/ȯƷŋ 0.1) 0.1) ŌǺóƷŸõƙǤõä Řƥ ȣŋ Ōŋ 1 Ōõ .(142 ǦƱȦÔõä Û1 ǼŸŎä) A ǦÕǺÀÛõä ǼÊШ Û"Non-aqueous titration .$C_{10}H_{14}N_2O_4$ ȣŋ ŋŸŋ 22.62 ùƷȦÒǺ VS (ȯ/ȯƷŋ

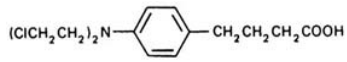
CHLORAMBUCILUM

Chlorambucil üŭƨNjǦDŽƐƥNj+ǀǁƐ

Molecular formula: $C_{14}H_{19}Cl_2NO_2$ ǦǼȦǺÂƨä Ǧ8ǼÔõä

Relative molecular mass: 304.2 ǦǼǤÊǺõä ǦǼȦǺÂƨä ǦŸǫÒõä

Graphic formula: ǦǼφȦǼǤŧä Ǧ8ǼÔõä



Chemical name: ƱəȦǼŧǼÒõä ŧèŗä

4-[*p*-[Bis(2-chloroethyl)amino]phenyl]butyric acid; 4-[bis(2-chloroethyl)amino]benzenebutanoic acid; CAS Reg. No. 305-03-3.

Description: ƵòƷõä .ƵǼǺà ÕÒÎæ ÆǤŢ şŭ ƀƷŸæ ÛĦǤǺÀÕǩ ŘǼæŭ şŭ ŘǼæŭ ɟƷŸæ ȧƷHȣÊŋ

Solubility: ǦǼφȦæşØõä R ÿóƷƷşóƷŸÒõäş TS (ȯ/ȯĦ750~) ȯƷφȦŸǺqä Ž ɟȦæşØõä Ȧǵ ÛĦǼŸŧȝ ŏȦŧä Ž ǎäşǽ Ƙd .R ɟƷǫǼèɟäş

Category ČÅÅöä: .cytotoxic ÅŃŤÅŸö ÿÅè öäşå

Storage ďŃÂÅĄöä: .öžŘää ďŋ ČŒŧŢ ÛÿÅÒǵüæ ČÕŸ8ŋ ČŃşÅǵ Ž ÕŒèžĠŋäóžŸÒöä ŞÅǵ Æž

Additional information: ČŒžÅřŮ ǵÅŋžŸĤŋ ÕŒèžĠŋäóžŸÒöä ÕŋÅĤŃ ÅŋÆÅ3 ČŃÅÅĤöäş ØØΣä Ŭnžk Æž: ÀŃØƠ .öäžTÅæ ČöžŏŃţä ǵÅŧŒÊƨä ȧÅÎĄÒèäş ÆŸƨä 3ŋ âÅŧÒöä ÆÅΘş ÐÆŃĵÅæ.

REQUIREMENTS ƚĠŋŃŽƠƚkdž!ƒ

General requirement: ÿÅĤöä ÆŸÛÒţä ďŋ ÆŃÂŃ ŕş %98.0 ďŋ ÕÕŃ ŕ Åŋ ƨŸŋ ÕŒèžĠŋäóžŸÒöä Ðžţƛ .ČŒƏÅŋŸöä ǵÅţä Ðŭ ţžDZÀöÅæ ČæžÊŢ ÛC14H19Cl2NO2 ďŋ %101.0

Identification tests: ĥŭŇjNJŃŃ ŀ ɛƥƒǴƭƢ

A: ǎžĠǫĵä ƨÛ8Ń ÛTS2 ÿžŒèÅžĠöä ǵÅŋşÀõ ŬƏÅÅǫ ȯžŸŢ ďŋ Õŋ 0.20 ȣÅÎŃş ČæÀΘ ǎžĠǫŮ Ž ŋŸŋ 20 ƷřžŃ .Piperidine R ďŃÆŃKĠŒöä ďŋ Õŋ 0.05ş TS (ȯ/ĥ8.5) ÿžŃåžÔöä ÆŒèşÀæşÀǫǫ ȯžŸĤŋ ÕŸĠţä ǴŒřÀǫöä ȧóş ďŋ ČĤÛÕæ .ǴŒřÀǫöä ȧóş ƨŸƷ ŏÅęóà ČĤÕæ şÆĠk ÜK8ò ÆT ȧžž ǎžĠǫĵä ďÅÊł

B: ÕŃóžÅŸÊöä Řþ ďŋ Õŋ 0.05 ȣÅÎŃş .Õŋ 10 Ðŭ ŏÅţÅæ ŽÅƨ ÛR ĵžŒèŭ Õŋ 5 Ž ĥ0.05 ǎäÓŃ gÀřÅĠŋ ÿžŧď ÕÒÎĭ ŞǵŸŃ ŕ ÜvS (ȯ/ȯžŋ 0.1) ČŘÅöä ǵäÀǫǫ ȯžŸŢ ďŋ Õŋ 0.20 ȣÅÎŃ Ż ÛTS (ȯ/ĥ100~) ionizable ďŃÜǫŸö ÕæÅę ȯžŸõ åžDZş) ÿžŧ8öä ȯžÛǫǫž ÜŬƏÅŋ ÿÅþ Ž ȯžŸ+ä ďÅÊŃ .(ÆŃóžŸÒöä ion ĵžŃŭ ǎÅŒď) .(chlorine

C: ŘƨŽ ÛČÕŒęå 30 ǵÆŋ öäÀÕǫèŸö öÀǫŃş TS (ȯ/ĥ70~) ÕŃóžŸõşØÆŒTä Řþ ďŋ Õŋ 10 3ŋ ĥ0.4 ƷÂƨ Ù8ř ĬƠ ČÛŒ+ä gøäÀΣä ČDZØÆæ ƨÅæş ÛŏÅţä ďŋ Õŋ 10 ÅƨŃŋ Õõ ÛĬǫǫä ĬǫŒŧÒæ ČöÅŧƷöä ÕÊ8ĭ ÛǴřÀŃ .ŃǫÅŒǵŮ ČDZóå ÜČ3ÅÈ 3 ǵÆŋ R øžÅÊŃöä ÆŒÊõŃ ŬèÅŧħ ȧžž (ĘĠàà ĵŸŋ 5 ČæäÀę şŭ ȯÅÒèÅæ žŸŒõ 0.6 ďŋ ÆŃÂŃ ŕ) ŘÅÅŃŋ .°ÿ146 ČæäÀę øÅƨÔǫŕä gøäÀǵ

Melting range: øÅƨÔǫŕä ȯÅƒ .ĥ/ŋŸŋ 1.0 ďŋ ÆŃÂŃ ŕ

Water: ȯÅţä Determination of water by ÀÎŒž ȯøÅõ ČÕŃÀÛæ ȯÅţä ĬŒĤĬ" ĵžÅ3 ĬƠ ȣžȯžŋ žŁ Åŧõ ďŃĤł ȯÅţä .ĥ/ŋŸŋ 5.0 ďŋ ȯÅţä ƨžǫŢ ÆŃÂŃ ŕ Ü"the Karl Fischer method

Related substances: ČȯÅÎţä ǎäžţä ČŸǵ8ŋ gåÅŧõ silica gel R2 ÅÒŒŸŒÊöä ČŋŸŁ ÿäÆÅǫèÅæ Û(84 ČĤÅÔöä Û1 ÆŸÖä) "Thin-layer chromatography ďŋ ÿžDzǵ 8 ďŋ ĵŃÅŋ õÀĤǫŋ øžÛõ ÕŧĤǫÊŃ .ČƨÅè 24 ǵÆŋ ČžÀ8öä gøäÀǵ ČDZØÆæ ƨDzǫõ ČŸǵ8ţä ČĤŒÅÔöä õÀǫĭş ŃŸÔÅÅŋ ĘĠÛŃ .R ĵžǫŒõ ÕŒŽŋ ÕŒŽŃŭ ďŋ ÿžDzǵ 4ş ÛR ĵÅǫǴŒTä ďŋ ÿžDzǵ 4 ÛR ȯžǫÅŽŒţä ďŋ ÿžDzǵ 5 ÛR ďŃžȯžǫöä

Ŏõ Ž øĀĢǫnrā gǻĀŋ dbŋ ŋŸŋ 20 Ƀzƺ :(A) ȯzŸǂā ÛR ɟzǫŒèɟā Ž ƙĀǫā ƙȯzŸŢ dbŋ ĀǫȯşĀȮŋ 10 ǦHuŒĀÔȯā ɔŸȝ ÛāāĀ Îǫèrā gƚKDzǵ dbŋ ǦHuŒĀÔȯā ţÂǫ ÆĦāş .Ŏŋ 1 Ŏõ Ž øĀĢǫnrā gǻĀŋ dbŋ ŋŸŋ 0.4 Ƀzƺ :(B) ȯzŸǂāş Ŏŋ 1 ǦĀŬ ɟzȮĭ r .(ĀǫŋzǫĀǫ 254) ǦŒDzÊĀĀĢõā ȧzƺ ǦĦĭìɟā Ž āāĀÎǫèrā ŬŬŬ ȮHuĀĀş ŏāzŢā Ž ƵDzǫõ ǦHuŒĀÔȯā ōĀǫĭ .B ȯzŸǂā dbŋ ǦȮĀĀȯā ŌŸĭ dbŋ gÆì ĀĭŏŬ ŬǦŒÊŒaĀȯā ǦĦŌǦȯā ŏĀĭǫèĀæ ÛA ȯzŸǂā dbŋ ǰǫĀĭ ǦĦŌæ

ȯzŸHuŋ ĀĀĦĀş ÛŏĀŋ Ŏŋ 10 ȣĀŘĀ ÛR ɟzǫŒèŬ Ŏŋ 10 Ž ŬǦŒŬzǦŘŋ Ǧǫşàzŋ ÛĦo.2 ǦāāĀę āāØĀ :**Assay** ǦÊĀĀÔţā ĀĀĦĭ .TS ȯzǫĀĭĀqā/ƙĀāĀĭz ȯzĀŒĀȯā ĀĦÎŋ ȳāÆÅǫèĀæ VS (ȯ/ȯzŋ 0.1) ǵĀǫzāĀȮȯā dbŋ ƁĀĭā ȳzĀĀzÔȯā ÆŒÊõşØÆŒŁ dbŋ ƁĀĭā ȳzĀĀzÔȯā ÆŒÊõşØÆŒŁ ȯzŸŢ dbŋ Ŏŋ 1 Ŏõ .ǦĀØşĀr ǵĀHuŒHuÔĭ ǦĀŬ ĀĀØş ǦòzHuĀţā gǻĀţā ɟşǻ ǦŒŸŧĦȯā .$C_{14}H_{19}Cl_2NO_2$ dbŋ ŋŸŋ 30.42 ùzĀȮĀ VS (ȯ/ȯzŋ 0.1) ǵĀǫzāĀȮȯā

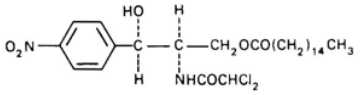
CHLORAMPHENICOLI PALMITAS

Chloramphenicol Palmitate üNj|ĭźĭ2DŽεβNj‡|Ⅱε l ƒĦĭDŽⅡƒG'

$C_{27}H_{42}Cl_2N_2O_6$:**Molecular formula** ǦŒĀĀÂƨā Ǧ8ŒÔȯā

561.5 :**Relative molecular mass** ǦŒǦÊĀȯā ǦŒĀĀÂƨā ǦŸǫȮȯā

:**Graphic formula** ǦŒǫĀŒǦţā Ǧ8ŒÔȯā



:**Chemical name** ȣƨĀŒŧŒȮȯā ǰèrā

D-*threo*-(–)-2,2-Dichloro-*N*-[β-hydroxy-α-(hydroxymethyl)-*p*-nitrophenethyl]acetamide α-palmitate; [*R*-(*R**,*R**)]-2-[(dichloroacetyl)amino]-3-hydroxy-3-(4-nitrophenyl)propyl hexadecanoate; CAS Reg. No. 530-43-8.

.ǦĀŒĀn ǦHuƨāø şá Üunctuous Ęõà ÛŘŒæŬ ɟzŸā ǰ3Ĭǫ ɃøzŸā ȧzHuÊŋ :**Description** Ƶòzȯā Ž āāşá ÜTS (ȯ/ĥ 750~) ȯzǫĀĭĀqā Ž ɟĀāşØȯā ŌŒŸę ÜŏĀţā Ž ĦŒŸŧ3 āāşá Ƙd :**Solubility** ǦŒǫĀāşØȯā .R Ƙǫɟāş R ȳøzzşøzŸȮȯā

.Antibacterial drug ǰŒǫāĀƨā āĀŘŋ ŏāşā :**Category** ǦĀĀȯā

.ŏzŘȯā dbŋ ǦŒŧŢ ÛȳĀȮǵüā ǦŌŸ8ŋ ǦĀşĀǵ Ž ȯzȮŒĀŒĀŋāøzŸȮȯā ǵĀǫŒţĀæ ŞĀǵ Æz :**Storage** dbĀÂĀǫȯā ƙŘƠ Ž ĀTĀŧĦǫèr gƚĦŋ ȯzȮŒĀŒĀŋāøzŸȮȯā ǵĀǫŒţĀæ Ƙǫĭõ āæŬ :**Additional information** ǦŒzĀrŬ ǵĀŋzŸĦŋ

ɔŸʒ polymorph B ÕȮÎöä åÆĦǫŋ ÕȮÎöä ɗŋ %90 ɔŸʒ ƀzǫƠ ɟǔ ÆDzƶz ÛĞǴŸÔöä ĞöÅΣäæ ʊøφɾÆƶò ÕȮÌ ƀǔ åzDZş ƚŘĦʊǫöä ĞÕΛÀù ɗtŘǩ ɟǔ ÆDzƶz ÛĘŸĦǫÊtä Õǯŋ ÛÕəÅè ʊøφɾÆƶò ÕȮÌ ƚŘƠ ā zŸÛtä ɟÅõ äæǔş .Õęɟä .ʊəÅƲÄöä ǰǫÅtä Ž polymorph B ÕȮÎöä åÆĦǫŋ ÕȮÎöäæ Õęɟä ɔŸʒ ȯzȮƶÆÆÅŋäózŸÓöä ğÅǫƶtÅæ ɗŋ %90

REQUIREMENTS ƚĞǴǴƲƚkdž!ƒ

ÆΛÂΛ ɾş %98.0 ɗʒ ÕÕΛ ɾÅŋ ɔŸʒ ȯzȮƶÆÆÅŋäózŸÓöä ğÅǫƶtÅæ ƀzǫƠ :**General requirement** ȳÅĦöä ÆŸÛǫtä .ĞÅÅŎä gåÅtä Ƃǔ ţzDZÄöÅæ ĞæzÊŢ Ûc$_{27}$H$_{42}$Cl$_2$ N$_2$O$_6$ ɗŋ %102.0 ɗʒ

:**Identification tests** hʊĭNjNJЛЄ l ɛƥƒĞƓĦƢɛ

Û1 ÆŸŎä) "Thin-layer chromatography ĞÕƶęÅöä ĞÕĞǴÛöä ā äÅÎǫèä" ɟäzʌʒ ŘƠ ȣzòztä óÅĞǫòɾä ĘĞÛΛ :A ÛR ȳózzşózŸÓöä ɗŋ ȳzDzǵ 9 ɗŋ ɟΛÂŋş ĞŸȣ8ŋ gåÅtõ silica gel R4 ÅȮƶŸÊöä ĞŋŸŁ ȳäÆÅǫèÅæ Û(84 ĞʊƶÅÔöä ƚózŸŢ ɗŋ ÅǫõŞ ÅȮŋ 10 ĞʊƶÅÔöä ɔŸʒ ŸÔÅΛŋ ĘĞÛΛ .ōÅʊǫŋ ózÛõ ŏÅtä ɗŋ ŸtDzǵ 0.1Ş ÛR ȯzφÅŽƶtä ɗŋ ŸtDzǵ 1 ɗŋ ŋŸŋ 10 ƀzƷ :(B) ȯzŸ‡äş Õŋ 1 Õõ Ž óÅĞǫòɾä gåÅŋ ɗŋ ŋŸŋ 10 ƀzƷ :(A) ȯzŸ‡ä ÛR ɟzƶƶèɟä Ž ƚÅõä ŏäzTä Ž ZDzǫõ ōÅǫƚ Ûāäʌ̀Îǫèɾäæ gƚKDzǵ ɗŋ ĞʊƶÅÔöä ţÂφ ÆĦäş .Õŋ 1 Õõ Ž RS ȯzȮƶÆÆÅŋäózŸÓöä ğÅǫƶtÅæ Ž A ȯzŸ‡ä ɗŋ ĞȮÅÅöä ĞƶÊƶƷÅÅöä ĞĦÕĞöä ĘäÅÛǫƚ .(ÅǫŋzφÅφ 254) ĞƶDzÊÅÅĞöä ȧzz ĞĦÌɟä Ž āäʌ̀Îǫèɾäæ ÙÛƯ ÒʊÅΛş .B ȯzŸ‡ä ɗŋ ĞȮÅÅöä ÕŸĭ ʒŋ gÆÎöäş ÅƲŢtäş ʒęztä

TS (ȯ/ĥ 100~) ÕΛózÅŸÊöä Ř ƥ ɗŋ Õŋ 1.0 ȣÅŘΛ ÛTS (Õŋ/ĥ 750~) ȯzφÅŽΛÛ Õŋ 4 Ž ŋŸŋ 10 āäØΛ :B Õöæ ɟÅõ äæǔ ĞÌÅΛ şǔ ŽÅÛöä ÕəÅÊöä ɟÅĞł .ĘəÅęå 10 gÆŋ óäÅÕǫèŸö ōÅǫΛş ÛR ÕφÂöä ȧzʊÊŋ ɗŋ ĥ0.05ş ÛĞÕĦęå 2 ÆĦäş ÛTS (ȯ/ĥ100~) ȳzΛåzÔöä ĞΛÅǫφ ȯzŸŢ ɗŋ Õŋ 0.5 ȣÅŘΛş ɟŸŽöä Ž ɟĞÅöä ȯzŸ‡ä åΞΛ .ÅΛóşÅÌ ȳzΛåzÔöä ÆĦÊõşóÆĦŁ ȯzŸŢ ɗŋ Õŋ 2.0ş 2-naphtol TS1 ȯzŸŢ ɗŋ Õŋ 1.0 øæ Ğ3zĞǫŋ ÛR ÅΛózĦöä ɗŋ ĥ1.0 .Åφɟä ɟzŸöä ɟǫΛΛ ɾ ÜR ÕφÂöä ȧzʊÊŋ ɟşå óÅĞǫòɾäæ åÅĦł .Åφǔ ɟzȯ ózÛǫΛ ÜTS (ȯ/ĥ400~)

ţşÂøΛŋ ȯzφÅŽΛqä Ž Õŋ/ŋŸŋ 50 ÂĦõÅǫæ ȯzŸŢ ȳÆÅǫÊΛ :**Specific optical rotation** ȣ3zÅöä ƀÅÔĞöä ÅΛşÆǫöä .$[a]_D^{20°C}$ = + 22.5 to + 25.5° ÜR ŏÅtä

.ĥ/ŋŸŋ 1.0 ɗʒ ÆΛÂΛ ɾ :**Sulfated ash** ŘÅŸÊtä åÅŋÅöä

ɾ) ŘÅÅŋ Ù8ř ŘƠ ĞÛĦ‡ä gøäÅΣä ĞDZøÆæ ŘæÅŽöä ɟàzöä ɔøǫǵ ZÅz :**Loss on drying** ZĦÅDzǫöÅæ ÆÕÅöä 5.0 ɗŋ ÅŽõǔ ÆÕΛ ɾ ÜR ózÅÊÅöä ÆĦÊõŇ ȣèÅtɦ ȧzʊÊŋ ȧzz (ĘĞäÅ ŋŸŋ 5 ĞæäÅę şǔ ȯÅȮèÅæzŸĦõ 0.6 ɗʒ ÆΛÂΛ .ĥ/ŋŸŋ

ȯzφÅŽΛqä ɗŋ ȳzDzΣä ȯåÅĦǫŋ ɟΛÂŋ ɗŋ Õŋ 5 ʒŋ °ȳ35 Ƃǔ ƚÅÊǫöÅæ ĥ1.0 āäØΛ :**Acidity** ĞřztΣä

ÆłÊõşøÆłŁ òzŸHuη ÀÀÀĤÀ .TS òzφÀŽÀqä/ĸÀöÀŽz òzÆłÀöä ÀĤÎη ĈÀΘ ÀÀφÙ òłÆĤφÊłη ÛR ĸõ÷äş TS (Õη/Ĥ750~) ÿzÀåzÔöä

ŲŸÀφÀÀę ɟzö ÕÒÎφÀ ÛZłÛŸöä ÕÀÀĤuφÀÀæ Ûϩøφg ÛTS òzφÀŽÀqä/ĸÀöÀŽz òzÆłÀöä ÀĤÎη ÿäÆłÀφÈÀæ ÛVS (ò/òzη 0.1) .Õη 0.4 dη ÀŽõÛ ÿÂŸÀ ŕ ÜĞłφÀò 30 gÆη CÆφÊÀ

dη Õη 80 Ž Ĥ 1.0 ÛZłÛŸöä ĸÅÊφöä gÆ3ÀÊη ÛääØł :**Free chloramphenicol** ÀΣä òzÒłÆłÀηäØzŸÒöä ŷÀÂη ZÀƆş ĸŸÀÂÒöä dzÀÛÀ ÜÕη 15 ÀŽŸÀη Õõ ŏÀŷä dη ğÀłŧõ φŸŽä ÒŸÅφÊÀş ÛÅÆÀ Ûxylene R ĸŸÀÂÒöä ÛÕÔÀÆłõ õÀφÀ ÛR ɟzäÀÒöä ÆÀØzŸõ Ŭ3Àäø òzŸŢ dη Õη 10 øä òzŸ∓ä ÒŸÅφÊÀ .ŏÀŷÀä Õη 50 БÛ ĞłÀÀŷä ğÀòŸ‿ä ĞÕĞù òŸŃ dη ŽÀÛöä ŽÀÔöä ÕÀÀÊŸõ ηî Àŧφöä âÀÕÀ .ŬÀŷä ÕÀÀÊöä dη ŷÊę ØłłÀş ÛɟzäÀÒöä ÆÀØzŸõ Ŭ3Àäø dzÀÛÀ gÅÀŷä ɟşÅ ĞłŸŧĤöä gÅÀ3Ù dη ŷłłÀ òzŸŢ dη blank ÆŁÀì ÿäÆłÀφÈÀæ ÛÀφηzφÀφ 278 ĞääÀę ĞDZzη òzÛä ŷè1 ĞφÀÅŽä ÿäÆłÀφÈÀæ ÛÀΣä òzÒłÆłÀηäØzŸÒöä ŽzŢ ÆÊĤł .0.05 dϑ ÆŁÀÎöä òzŸ∓ä äØŁ î ÀŢ ÆÀÂÀ ŕ ɟÙ Æz ÜĞòzĤÀŷä .Ĥ/ŋŸη 0.45 dϑ ÆÀÂÀ ŕ Ü($A_{1cm}^{1\%}$ = 298) 29.8 :ĞłòÀÔφηŕä ĞŧłÕöä

100 ŏÀÛϑq ŏÀŷä ŧşÂØÀη R òzφÀŽÀqä dη ĞłzÀõ Ğłŧõ Ž ÛĞęÆä Ğφşàzη ÛĤ0.03 ĞääÀę äØÀ :**Assay** ĞÊÀÀÕŷä ĞÕĞù òŸŃ dη ZÀÅŷä òzŸHuŧŸö ηî Àŧφöä âÀÕÀ .¢ÊÀφ ÆÀØŷÀä Õη 100 БÛ òzŸ∓ä äØŁ dη Õη 10 ZÀƆ ÜÕη ĞŧłÕöä ÿäÆłÀφÈÀæ $C_{27}H_{42}Cl_2N_2O_6$ øöä ŽzŢ ÆÊϑş ÀφηzφÀφ 271 ĞääÀę ŬŧŢϑÛ ĞDZzη òzÛä ŷè1 ĞφÀÅŽä .($A_{1cm}^{1\%}$ =178) 17.8 :ĞłòÀÔφηŕä

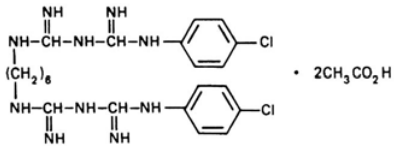
CHLORHEXIDINI DIACETAS

Chlorhexidine diacetate Dźĭφŷĭ ɛ lłjþNj∓lłłε l ƒHĭ ɛć Ĭ ϑƒĞłk

$C_{22}H_{30}Cl_2N_{10},2C_2H_4O_2$:**Molecular formula** ĞłÀÀÂɛä Ğ8łÔöä

625.6 :**Relative molecular mass** ĞłGÊÀöä ĞłÀÀÂɛä ĞŸφÒöä

:**Graphic formula** ĞłφÀłGŷä Ğ8łÔöä



:**Chemical name** ŬϑÀłŧłÒöä ŷèŕä

1,1′-Hexamethylenebis[5-(*p*-chlorophenyl)biguanide] diacetate; *N,N″*-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide diacetate; CAS Reg. No. 56-95-1.

Description: Colorless crystalline powder.

Solubility: Slightly soluble in water; 15 g dissolves in boiling water; 55 g dissolves in 95% alcohol.

Category: Disinfectant.

Storage: Protect from light.

REQUIREMENTS

General requirement: Not less than 97.5% and not more than 101.0% of $C_{22}H_{30}Cl_2N_{10},2C_2H_4O_2$.

Identification tests:

A: To 10 g in 2 mL of 1 N HCl add 10 mL of 0.1 N NaOH. Filter the precipitate, wash with 2 mL of water, and dry at 150°C for 2 hours.

B: To 0.5 g in 10 mL of 0.1 N NaOH add 0.15 g of $NaHCO_3$. Boil for 10 minutes. Cool and add 0.5 mL of 1 N HCl. Filter the precipitate, wash with 2 mL of water, and dry at 150°C for 2 hours.

C: To 1 g in 2 mL of 0.2 N HCl add 0.2 g of $NaNO_2$. (Solution should be clear.)

Sulfated ash: Not more than 2.0%.

Loss on drying: Not more than 35% when dried at 105°C.

Chloraniline: Not more than 0.20%.

ammonium 1 g in 1 mL of water to 1 mL of 1 N HCl. Add 1 mL of 1 N NaOH and 30 mL of water. Add 5 mL of 0.1 N NaNO2 and 1 mL of 1 N HCl. After 5 minutes, add 1 mL of 50% sulfamat solution and 1 mL of *N*-(1-naphthyl)ethylenediamine hydrochloride

ɃØõã R ƙŸŒąĭóząŸõ ŋŸŋ 0.10 Ƀząʒ ȯząŸţ ďŋ Ďŋ 30 ĞŏÅĬţĭæ ŽÅĬĂŋş .ĞĎŒęå 30 ǥÆŋ óãÀĎąèŸõ ȫÀąŋ .Ďŋ 50 óÆĎã ǥÆì ÀŽȫĬ óÅĞąnŗã ȯząŸţ Ž ĵĭĭÅóã ĵząŸõã ĵząȮŋ ŗ .ĎĞę ďŋ TS (ȯ/ĥ 70~) ĎŋóząŸõşóÆŒTã Ŕţŋ ĭŸŒŸę ¢ŘŒţƠ Ź "Colour of liquids ĎãząÊõã ĵząŸõ" ĵząʒ ŘƠ Ƚząȯząŋ ząŁ Åŋ ÆÊŋ ĞąóÅĎţã ÆÅʒ ŬĬĬDZÀţã ȯząŸHţŸõ Ƀõõã Ďõæ ďŋ .(ĥ/ŋŸŋ 0.5) (53 ĞHąÅÔõã Û1 ÆŸŎã)

ĞĎŒęÀõã ĞĎĞąÛõã ããÀĬąèã" ĵząʒ ŘƠ Ȼząȯząŋ ząŁ Åţõ óÅĞąnŗã ĘĞąÛŋ :**Related substances** ĞŏÅĬţã ãĭząţã ĞŸȽŋ gãÅţõ Silica gel R4 ÅȮŒŸŒÊõã ĞŋŸŁ ÿãÆÅąèÅæ Û(84 ĞHąÅÔõã Û1 ÆŸŎã) "Thin-layer chromatography Ƀząʒ ŏÅŋ Ďŋ 16 óãÆĎŋ R4 ÅȮŒŸŒÊõã ĞŋŸŁ ďŋ ĥ8 Ƀĭ Ȼ ÅŘŋ :ƁÅąõã ząHąÅõã ąŸʒ slurry Ğãşó ¢ÊÅą Ķęząĭæ ÀĮŘʒş 50 ďŋ ĵŋÂŋ ÿÆÅąÊŋ .ĮŸŋ 0.5 ĞąÅÅžæ ĞĎĞąÛæ ĞąÅÅÔõã ÈĞŸĭş sodium formate R ÿząŋĭząÔõã ǥÅŋóząz ďŋ ĥ1 ĎŒŋóząÅõã Ŕþ ďŋ ÿząDząǵ 7ş TS (ȯ/ĥ 750~) ȯząąĭʒŋąã ďŋ ŋţDząǵ 50 ÛR ÿóząząóząŸȮõã ďŋ ŋţDząǵ ȯząŸţ ďŋ ÀąõŞ ÀȮŋ 20 óãÆĎŋ ÛĮè 4 ôÅʒ ÛŬŋŋÀÌ ĎȮĬæ ĞHąŒÅÔõã ąŸʒ ĘĞąÛŋ .ĎÀHąąŋ óząÛĎ TS (ȯ/ĥ1080~) ďŋ ĞHąŒÅÔõã ţÂą ÆĬæ .(A ȯząŸ+ã) Ďŋ1 ĎĎ Ž óÅĞąnŗã gãÅŋ ďŋ ŋŸŋ 72 Ƀząʒ TS (ȯ/ĥ90~) ĎŒąèĵã Ŕþ Ž ãÂHąĭ .(254 nm) ĞŒDząÊÅąĞõã ȧząz ĞĬĬĭĵã Ž ããÀĬąèŗã ÙÛÙ ÒHąÅŋş õãząTã Ž ZDząąõ ÀąĞk ÛããÀĬąèŗã gĞKDząǵ gązÔ+ã ĞǵÅĞõã ŋŒţõ ĎĎÅĭşş ÛąÊŒąÀõã ÙŋÀĬõã ĎÅèÙş ȧząz ÙãÀĬõã ďŋ Ğʒząţf Ďõ ązǵ ĎȮĬõã ĞŸŒÛąÊŋ ĞǵÅæ âÅĎŋş ÛØąĭş ÛĞĎŒęå 15 gÆŋ ŘÅł ÛR ązą ĭŋ Ďŋ 5 ȽÅŘŋş gãÆè Ƀæ ŬDZÅDZà óÅĞąnã ãząąÛ Ƀĭ ÅȮŒŸŒÊõã ĞŋŸT ȯząŸ+ã ĎDZÛ ďŋş .Àąŋząąĭą 256 ĞããÀę ŬţŢʒÛ ĞDZząŋ ȯząÛæ ĵè 1 ĞąÅÅžæ ĞĎĞù ȯŸn ďŋ ŽÅÛõã ŽÅÔõã ĎąÅÊŸõ ąĭ Åţąõã ĞÊąŸţã ĞǵÅĞõã ďŋ ĞʒşÂøŋţã ÅȮŒŸŒÊõã ĞŋŸT ĵDzΣã ĞŋşÅÊąŋ ǵÅǵæ ÅŸÊÅą ĞĎŋÀÛõæ ŽÅĬĬ blank solution ÆŁÅĬõã ďŋ ĞŒząĭõ ĞŒţõ Ž óÅĞąnŗã gãÅŋ ďŋ ĥ0.14 ããØŋ :ĞŒąÅąõã ĞĎŋÀÛõæ B ȯząŸ+ã ÀŘʒ .ąĭÅąŬ ĞʒşÂøŋţã ĞǵÅĞŸõ gązÅĞõã Ďŋ 50 Ƀĭ ȯząŸ+ã ãØŁ ďŋ ÀąõŞÅȮŋ 200 ZÅƩş Ďŋ 100 óÆĎæ ĵDzǵ ĭÅÛʒq TS (ȯ/ĥ90~) ĎŒąèĵã Ŕþ .B ȯząŸ+ã ďŋ ĵĭÅÅõã ąĭ Åţąõã ďŋ ƎĎĭ eluted ȽząÛĬţã A ȯząŸ+ã ďŋ ĵĭÅÅõã ąĭ Åţąõã ĵząȮŋ ŗ .R ȯząąĭʒţĭæ 0.15 ȽÅŘŋ ÛR1 ŬDząŸʒõã ĎŒąèĵã Ŕþ ďŋ Ďŋ30 Ž ÛĞŒùząĞŋ Ğąşàząŋ Ûĥ0.45 ĞããÀę ĎĎŋ :**Assay** ĞÊŋÅĎţã ząŁ Åţõ VS (ȯ/ȯząŋ 0.1) ĎŋóząŸõĞąõã Ŕţŋ ÀŋÅĬŋş Û1-naphtholbenzein/acetic acid TS ÀĬĬţã ďŋ Ďŋ ĞHąÅÔõã Û1 ÆŸŎã) A ĞĎŋÀÛõã ÆÊŋ "Non-aqueous titration ŬąĭŋŸõã Ùèząõã Ž gÀŋÅĬţã" ĵząʒ ŘƠ Ȼząząŋ .$C_{22}H_{30}Cl_2N_{10},2C_2H_4O_2$ ďŋ ŋŸŋ 15.64 ùząÅȮŋ VS (ȯ/ȯząŋ 0.1) ĎŋóząŸõĞąõã Ŕþ ďŋ Ďŋ1 Ďõ .(142

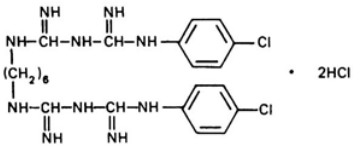
CHLORHEXIDINI DIHYDROCHLORIDUM

Chlorhexidin dihydrochloride Džĭσąĭ ƨ ıŮjƥNj+ıΠΣ σąĭƥNj+ıNjƥσąĭlj ĬσƑüźk

$C_{22}H_{30}Cl_2N_{10},2HCl$:**Molecular formula** ĞŁĂΛÂƨă Ğ8ŁÔöă

578.4 :**Relative molecular mass** ĞŁĞÊΛöă ĞŁĂΛÂƨă ĞŸQÒöă

:**Graphic formula** ĞŁφÀŁĞţă Ğ8ŁÔöă



:**Chemical name** ŬəÀŁţŁÒöă ţèŕă

1,1′-Hexamethylenebis[5-(*p*-chlorophenyl)biguanide] dihydrochloride; *N,N″*-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecane-diimidamide dihydrochloride; CAS Reg. No. 3697-42-5.

.ĞHυəăÀöă CÆʒ ÜŬĞΛÀÔĭ Ŕ Ł ăŬ ş Ŕ Ł ăŬ ɟzŸă ƀøzŸă ȧzHυÊη :**Description** Ζòzöă

.TS (ȯ/ĥ750~) ȯzφÀĭΛqă dη ŐÂDZ 450 Ž ā ăşæ ÜŏÀţă Ž ɟÀăşØöă ÕŁŸę :**Solubility** ĞŁφÀăşØöă

.ÀƱÛη :**Category** ĞÀÀöă

.ȯzŘöă dη ĞŁţŢ ÛŷÀÒǵŭă ĞÕŸ8η ĞΛşÀǵ Ž dΛÆŁÊÒŁøzŸÒöă ÆΛøzŸõşøÆŁŁ ŬəÀÀõ ŞÀǵ Æz :**Storage**ądΛÂÅQöă

REQUIREMENTS ƚĞĠΛΛƱƠkdž!ƒ

dʒ ÕÕΛ ŕ

η ɾŸʒ dΛÆŁÊÒŁøzŸÒöă ÆΛøzŸõşøÆŁŁ ŬəÀÀõ ƀzQʒ :**General requirement** ȳÀĬöă ÆŸÛQţă .ĞÀÀÖă gÅÀţă Ƃ ţzDZÀöÀă ĞăzÊŢ ÛC22H30Cl2N10,2HCl dη %101.0 dʒ ΛÂΛ ŕş %98.0

:**Identification tests** hυŸNjNJΛΛε l εƀƑĞĦCJε

ȳzΛåzÔöă ÆŁÊõşøÆŁŁ ȯzŸŢ dη Ōη 2 dη ɟΛÂη 8ÀŔΛş ƙÁÊQöÀă R ȯzφÀĬţă dη Ōη 10 Ž ŋŸη 20 ā ăØΛ :A .ĘηÀd ÀƀŬ ɟzȯ ɟQΛΛ ÜTS1 ȳşƎöă ȯzŸŢ dη Ōη 2ş TS (ȯ/ĥ150~)

ÜTS ÀŁφzηɟă/(II) âÀHυÀöă ΛΛøzŸõ ȯzŸŢ dη Ōη 0.15 ÛŔŢă ʒη Û8ÀŔΛş ŏÀη Ōη 10 Ž ĥ0.1 ā ăØΛ :B ɟzȯ ȯzHυQΛ ÜTS ÀŁφzηɟă/(II) âÀHυÀöă ΛΛøzŸõ ȯzŸŢ dη Ōη 0.5 ĞzÀŕüă ÀŁQÊŁ .ƆăzDZøŬ ɟzŸă ĞăÀèŕø ŐøzΖ ŌÒÎQĭ .ȧøàɟă ƃŬ ĞăÀèÀöă

ĬΟ 8zòzţă A Ō3ÀÀQöă ɟĬÀÀöă ȯzŸ+ă ŬÛĬΛ ÜTS (ȯ/ĥ130~) ŌΛÀQÀöă Ŕβ dη Ōη 50 Ž ĥ0.1 ā ăØΛ :C ĞHυÀÔöă Û1 ÆŸÖă) ğăΛøzŸÒŸö ÂƱŁη Ō3ÀÀQõ "General identification tests ĞηÀĬöă 8ăÀĬQèŕă ğăøÀGQnă" ɟăzΛ3 .(121

.ħ/ŋŸŋ 1.0 ɒʒ ÆΛÂΛ ɾ :**Sulfated ash** ŘÁŸÊţã ǻÅŋÀÖã

20 ɒŋ ÀŽõÜ ÆÕÀΛ ɾ Ü°ȳ130 gøãÀǵ ĞDZøÆæ ŘæÅŽõã ɟàzõã ɔøǫǵ ZÁz :**Loss on drying** ZŁÁDzǫõÅæ ÆÕÁõã

.ħ/ŋŸŋ

ÕΛózŸõşøÆŁTã Ř ƀ ɒŋ Ōŋ 5 ŽÂţã ʒŋ ȣÅŘΛ .ŏÅŋ Ōŋ 30 Ž ħ0.20 ããØΛ :**Chloraniline** ƙŸŁφÜózŸÒõã

ȳzŁφzŋɟã sulfamate ǵÅŋÅÁŸè ȯzŸŢ ɒŋ Ōŋ 2 ÛTS (ȯ/ħ 35) ȳzΛǻzÔõã ŘΛÀǫφ ȯzŸŢ ɒŋ Ōŋ 1 ÛVS (ȯ/ȯzŋ 1)

(ȯ/ħ1) N-(1-naphthyl)ethylenediamin hydrochloride ȯzŸŢ ɒŋ Ōŋ 5 ȣÅŘΛ ØəÆΛʒ .ŘƧŞ TS (ȯ/ħ50)

øãÀÕǫèŸõ õÀǫΛ ÛŌŋ 50 øÆŌæ ǻDzǵ ŏÅÛʒq ŏÅţã ɒŋ ĞŁzÅõ ĞŁŧõş ÛTS (ȯ/ħ 750~) ȯzφÅŽΛÜ Ōŋ 1 ÛÜDZàÅù ÀÜŘHuŋ

Ř ƀ ȯzŸHuŋ ŋŸŁŸę ¢ŘŁŧƠ Ź ƀØõã R ƙŸŁφÜózŸõ ŋŸŋ 0.10 ƀzƷ ȯzŸŢ ɒŋ Ōŋ 30 ĞŏÅÎţÅæ žÅĦΛş .ĞÕŁęǻ 30 gÆŋ

ǰǩÅÁõã ɟzŸõã Õõæ ɒŋ gÆÌ ÀŽõÜ øÅǫÀŋŋɾã ȯzŸŢ Ž ǰǩÅÁõã ɟzŸõã ɟzȮΛ ɾ .ŌGę ɒŋ TS (ȯ/ħ 70~) ÕΛózŸõşøÆŁTã

Û1 ÆŸŎã) "Colour of liquids ŌəžzÊõã ɟzõ" ɟžzÅĦõã ŘƠ ȣzòzŋ zŁ Åŋ ÆÊШ ĞφøÅÕţã ÆΛʒ ŬĦDZÀţã ȯzŸ‡ã Ž

.(ħ/ŋŸŋ 0.5) (53 ĞHuÅÔõã

ĞÕŁęÀõã ĞÕGÛõã ããÀÎǫèã" ɟžzΛʒ ŘƠ ȣzòzŋ zŁ Åŧõ øÅǫÀŋŋɾã ĘGÛΛ :**Related substances** ĞŏÅÎţã ǻãzţã

ĞŸȣ8ŋ gǻÅŧõ Silica gel R4 ÅȮŁŸÊõã ĞŋŸŁ ÿãÆǻǫèÅæ Ú(84 ĞHuÅÔõã Û1 ÆŸŎã) "Thin-layer chromatography

ƀzƷ ŏÅŋ Ōŋ 16 øãÆŌŋ R4 ÅȮŁŸÊõã ĞŋŸŁ ɒŋ ħ8 ƀÜ ȣÅŘΛ :ƀÅǫõã zHuÅõã ɔŸʒ slurry Ğæşø ÀÜŘHuŋ ¢ÊÅφ Ķęzõ̀ÅæŞ

50 ɒŋ ǰΛÂŋ ÿÆǻǫÊΛ .ǰŸŋ 0.5 ĞφÅǻŽæ ĞÕGÛæ ĞəÅÅÔõã ÈŦŸŘŞ Sodium formate R ȳzΛǻzÔõã ǵÅŋøzz ɒŋ ħ1

ÕŁŋøzÅõã Ř ƀ ɒŋ ȳzDzǵ 7Ş ÛTS (ȯ/ħ750~) ȯzφÅŽΛqã ɒŋ ŁŧDzǵ 50 ÛR ȳøzzşøzŸÒõã ɒŋ ŁŧDzǵ

Ř ƀ ɒŋ Ōŋ 35 Ž øÅǫÀŋŋɾã gǻÅŋ ɒŋ ħ1.1 ÆΛŞØǫæ A ȯzŸ‡ã ÀŘƷ .ŏÀHuǫŋ øzÛõ TS (ȯ/ħ1080~)

ÕΛózŸõşøÆŁTã

ÆŁÊõşøÆŁŁ ȯzŸHuŋ ɟzŸÕŁŞ ÛɟŸŽõã Ž ǻƎΛ Û2-propanol R ȯzŸŢ ɒŋ Ōŋ 100 ȣÅŘΛ ÛTS (ȯ/ħ 330~)

Ōŋ 100 øæ ÒŸÁǫÊΛŞ ÛɟŸŽõã Ž ǻƎţã ŏÅţã ɒŋ Ōŋ 200 ȣÅŘΛŞ ÛɟŸŽõã Ž ǻƎΛ ÛTS (ȯ/ħ 200~) ȳzΛǻzÔõã

ɔøǫǵ ȳøzzşøzŸÒõã ÀÁĞΛ ÛĞÌÀΛ ÛR ĞŁǻŋŸõã ȳzŁÈÅŽzĞõã ǵÅφzæÀõ ȧzz ȳøzzşøzŸÒõã ĞÒŸŋ ZÁΘ .R ȳøzzşøzŸõ

ɒŋ øÅŁŘ ŘƠ ȣÅǻzã ɔøǫǵ ÀÁĞΛ ÛR ȯzφÅŽŁţã ɒŋ Ōŋ 50 ȣÅŘΛŞ ÛR ƙDZŞÀǫÅõã ɒŋ øÅŁŘ ŘƠ ĦĞΛÀÕŘ ȣÅǻzã

ɒŋ ĞŁzÅõ ĞŁŧÒæ ĞÁÅÒõã ĞõÅŧŽõã ɒŋ ħ0.56 ããØΛ ÜĞÕŁęǻ 30 gÆŋ °ȳ65 gøãÀǵ ĞDZøÆæ ĞõÅŧŽõã ZÁΘŞ ÛR ƙDZŞÀǫÅõã

ÛǰÈ 4 ôÅʒ ÛÜΛÀÌ ÕÒÎæ ĞHuŁÅÔõã ɔŸʒ ĘGÛΛ .Ōŋ 100 øÆŌæ ǻDzǵ ŏÅÛʒq TS (ȯ/ħ 90~) ÕŁǫÈɟã Ř ƀ

ÜÛÁŋ ÒHuÅΛş ŏzzTã Ž ZDzǫõ ÕÀǫŏ ÛããÀÎǫèɾã gƙDzǵ ɒŋ ĞHuŁÅÔõã ţÂφ ÆŁæ .A ȯzŸ‡ã ɒŋ ÀǫõşÀÒŋ 20 øãÆŌŋ

ÜəãÀÎõã ɒŋ Ğʒzŧf Ōõ ȯzǵ ŌÒÎõã ĞŸŁÛǫÊŋ ĞǵÅæ ÀÀŁHuŋ .(ÀǫŋzφÅφ 254) ĞŁDzÊÅΛĞõã ȧzz ĞŁÌɟã Ž ããÀÎǫèɾã

gǻãÆè ƀæ ŬDZÅDZà øÅǫÀŋã ãzφÜ ƀÜ ÅȮŁŸÊõã ĞŋŸT gøzÔ‡ã ĞǵÅĞõã ŁŧõŏÕÅkş ÛŬÊŁəÀõã ÜΛÀÎõã ŌÅèÜş ȧzz

ČÕGù òŸñ dbŋ ŽÅÛõä ŽÅÔõä ÕəÅÊŸõ î ÅŧQõä âÅÕΛş ÛØŪΛş ÛČÕŒęå 15 gÆŋ ŘÁł ÛR òzφÅŽŒţä dbŋ Õŋ 5 ȣÅŘΛş ČÕΛÅÛõÅæ žÅĦĦ blank solution ÆŁÅÎõä òzŸ‡ä ÕDZÜ dbŋş .ÅQŋzφÅφ 256 ČæäÅę Ŭŧ,Ţ3Ü ČDZzŋ òzÛæ ţè 1 ČφÅÁžæ ÅŘHuł .ÅÅφÜ Č3ŞÅøÅţä Čǵ́ÅČŸõ gøşÅÖä ČÊŪŸţä Čǵ́ÅČõä dbŋ Č3ŞÅøÅţä ÅÓŒŸŒÊõä ČŋŸT ţDzΣä ČΛşÅÊQŋ ğÅǵ́Åæ ÅŽÊÅφ TS (ȯ/ȟ 90~) ÕŒQŒèjä Řβ dbŋ ČŒzÅȭ ČŒŧȭ Ž ČÅÅÖä ČõÅŧŸõä dbŋ ȟ0.11 ā äØΛ :ČŒõÅQõä ČÕΛÅÛõÅæ B òzŸ‡ä ǰ̌ÅÅõä ŋî ÅŧQõä ɹzÒΛ ŕ .R òzφÅŽŒţÅæ Õŋ 50 Ĕ̌ òzŸ‡ä äØŁ dbŋ ÅQõşÅÒŋ 200 ZÅƧş Õŋ 100 øÆÕæ ţDzǵ́ ŏÅÛ3q .B òzŸ‡ä dbŋ ǰ̌ÅÅõä ŋî ÅŧQõä dbŋ ƎȬÜ eluted ȣzÛÎţä A òzŸ‡ä dbŋ

10 ȣÅŘΛ ÛR1 ŬDzŸŽõä ÕŒQŒèjä Řβ dbŋ Õŋ 30 Ž ÛČŒùzGŘη Čφşàzŋ ÛȟO.4 ČæäÅę ā äØΛ :**Assay** ČÊΛÅÕţä ČΛÅŽÅõä ČÛÕφ dbĦĦ ÛVS (ȯ/ȯzŋ 0.1) ÕΛózŸõKGõä ŘŧŬ ÅΛÅĦΛş TS ÕŒQŒèjä Řβ/ĘGəÅõä ğÅQŒèÜ òzŸŢ dbŋ Õŋ A ČÕΛÅÛõä ÆÊŬ "Non-aqueous titration ŬəÅŋŸõä Ùèzõä Ž gÅΛÅĦţä" ɹžzÅ3 ŘƠ ȣzòzŋ zŁ Åŧȭ ÆŽzä âÅÊÕŋ $C_{22}H_{30}Cl_2$ dbŋ 14.46 ùzÅÖł VS (ȯ/ȯzŋ 0.1) ÕΛózŸõKGõä Řβ dbŋ Õŋ 1 Õȭ .(142 ČHUÅÔõä Û1 ÆŸŎä) .N_{10},2HCl

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CHLORTETRACYCLINI HYDROCHLORIDUM

Chlortetracycline hydrochloride Dźĭ‡lĭzεβΗβNj‡lΙΙε qĭβNj‡lNjβqĭlj

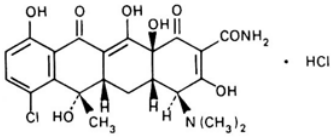
(**non-injectable** DźtΘ‡Ιl üĞFtΙΙε βĭZ) Dźĭ‡lĭzεβΗβNj‡lΙΙε qĭβNj‡lNjβqĭlj

sterile !ĭtyΙΙε ÛDźĭlĭzεβΗβNj‡lΙΙε qĭβNj‡lNjβqĭlj

$C_{22}H_{23}ClN_2O_8$,HCl :**Molecular formula** ČŒÅΛÂzä Č8ŒÔõä

515.4 :**Relative molecular mass** ČŒGÊÅõä ČŒÅΛÂzä ČŸQÒõä

:**Graphic formula** ČŒφÅŒGţä Č8ŒÔõä



:**Chemical name** ŬəÅŒŧŒÒõä ţèŕä

(4*S*,4a*S*,5a*S*,6*S*,12a*S*)-7-Chloro-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride; [4*S*-(4α,4aα,5aα,6β,12aα)]-7-chloro-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride; CAS Reg. No. 64-72-2.

Description: Ζ ὸζοῖᾶ ΓΗυᾶἈᾶᾶ CΑ̈Ζ ΥἈἈὸὶ ȷζΥἂ ΒόζΥἂ ἀζΗυΕη ȘὶὁᾶἈἈὸ ᾶᾶόζΥἂ.

Solubility: ΓΕῳἈἂȘΘᾶᾶ ΤΤS (ȯ/ȟ750~) ȯζῳἈἈᾶ ᾶὶ ᾶὶ ᾶ

dn ŋŸŋ 0.50 Ƀzƺ :(B) ȯzŸǂǎ ÛŌŋ 1 Ōõ Ž øȦǫnŗǎ gǻŋ dn ŋŸŋ 0.50 Ƀzƺ :(A) ȯzŸǂǎ ÛR ȯzφǺŸŧǎ Ž ÁΛøzŸõşøÁŧŁ dn ŋŸŋ 0.50 dn ǁzÂŋ Ƀzƺ :(C) ȯzŸǂǎş ÛŌŋ 1 Ōõ Ž RS ƙŸȮŧèǎǺǫǩøzŸȮõǎ ÁΛøzŸõşøÁŧŁ ŋŸŋ 0.50ş ÛŌŋ 1 Ōõ Ž RS ƙŸȮŧèǎǺǫǩøzŸȮõǎ ŋŸŋ 0.50ş Ōŋ 1 Ōõ Ž RS ƙŸȮŧèǎǺǫǩøzŸȮõǎ ÁΛøzŸõşøÁŧŁ dn Ż ǒǎzTǎ Ž ǻƎǫǿ ǒǺǫǩ ÛǎǎǺÎǫèŗǎ gƙDzǵ dn ČHȣŧÂÔõǎ ţÂǫ ÁĦǎ .Ōŋ 1 Ōõ dn RS ƙŸȮŧèǎǺǫǿõǎ ÁΛøzŸõşøÁŧŁ dn .(ǺǫŋzφÂǫ 365) ČŧDzÊÂAGõǎ ȧzz ČĦìǂǎ Ž ǎǎǺÎǫèŗǎ ÙÛÙ' ÒHȣΛş ÛTS (ȯ/ȟ260~) Âŧǫzŋǂǎ øÂÁGõ ôǺĦĦ ǺÁĦĦ ŗ .B ȯzŸǂǎ dn ČΘÂAõǎ ČĦÖGõǎ ÕŸǩ ʒŋ gÁÎõǎş ǺŦŢǂş ʒǫzŧǎ Ž A ȯzŸǂǎ dn ČΘÂAõǎ ČŧÊŧÂǺõǎ ČĦÖGõǎ ĘǎÂÛǫǩ .dzzŗzǎ ÂŦŘĦǎ dʒ ČõzÔÂŋ ʒÕǎ ǫŸǫ C ȯzŸǂǎ dn ǰǩÂAõǎ ǎǎǺÎǫèŗǎ ÙÛÙ' ǺŦŢł BÂŋ ǁHȣHȣÒ øÂGǫnŗǎ ÒHȣΛş ČÕŧęǎ 1 gÁŋ °ȳ 100 ČDZøÁǎ dÁÊΛ Û7.6 ǒÂŁÂǎ ǵǎǎ TS ǵÂAÊǫ Čǎǎøǎ dn Ōŋ 10 Ž ŋŸŋ 10 ǎǎØΛ :B .ÁΛÁÌ ǎøǺǺ Ęǎǎǩ ŞǵŸΛ Ü(ǺǫŋzφÂǫ 365) ČŧDzÊÂAGõǎ ȧzz ČĦìǂǎ ȯzŸǂǎ ǺŘnǺ Ƀǩ ǎøǺǺ ǂzǒ ǂǫΛ ÜTS (ȯ/ȟ1760~) ÕΛøzÂŸÊõǎ Ŗβ dn Ōŋ 2 øǎÁÕŋ ŋŸŋ 1 ČǎǎǺę Ƀǩ ȣÂŘΛ :C .ǒÂŧǎ dn Ōŋ 1 ČǎǎǺę ČzÂŗǩ ÁΛ3 ȣøAõǎ ǂzŸõǎ Ƀǩ ȯÁǫΛ ƀØõǎ ÛǎøǺǫǒ ǎøÂŗ General ČŋÂĦõǎ ȣǎǺĦǫèŗǎ ǵǎøÂǫnǎ" ǂǎzΛ3 ŘƠ ȣzòzŧǎ B Ōʒ̀Âǫõǎ Ōŋ/ȟ0.05 ÂŧõǺǫǎ ȯzŸǂǎ ȣÛĦΛ :D .(121 ČHȣÂÔõǎ Û1 ÁŸŎǎ) ǵǎÁΛøzŸÒŸõ ÂŧŧŋŌʒ̀Âǫõ "identification

ǀDzǵ ǒÂÛʒq ǒÂŧǎ dn ČŧzÂõ Čŧŧõ Ž ȟ0.125 ǎǎØΛ :**Specific optical rotation** ȣʒzÂõǎ ƀÀÔGõǎ ǺΛşÁǫõǎ Ƀǩ ŧzDZǺǎÂǎ ÆÊHȣşş °ȳ25 gøǎǺǵ ČDZøÁǎ ǺΛşÁǫõǎ ǎÂØΛ .ČÕŧęǎ 30 gÁŋ ȳŸŢõǎ Ž øǎǺÕǫèŸõ ǒǺǫΛş ÛŌŋ 25.0 øÁÕǎ . $[a]_D^{20°C}$ = - 235 to -250° ÜČÂÂØǎ gǻÂŧǎ

ŘƠ ȣzòzŋ zŁ Âŧŧõ øÂǫnŗǎ ȯzŸŢ ƙŘƠ ŌDZǂ ȟ0.5 ȳÁÁǫÊΛ :**Heavy metals** ČŸŧÕŽõǎ (gǎÂŸÂõǎ) ǂǻÂĦŧǎ ǂǻÂĦŧǎ ŘzǫŢ dĦĦł Ü(127 ČHȣÂÔõǎ Û1ÁŸŎǎ) 3 õǎǺDZqǎ ÆÊŦŦ ČŸŧÕŽõǎ (gǎÂŸÂõǎ) ǂǻÂĦŧǎ ŌDZǂ ƀÁΣǎ øÂǫnŗǎ" ǂzΛ3 .ȟ/ȳǎǺdşǺŌŋ 50 dʒ ÁΛÂΛ ŗ Ü(128 ČHȣÂÔõǎ Û1 ÁŸŎǎ) A ČÕΛǺÛõǎ ÆÊŦŦ ČŸŧÕŽõǎ

.ȟ/ŋŸŋ 5.0 dʒ ÁΛÂΛ ŗ :**Sulfated ash** ŘÂŸÊŧǎ ǻǻŋǺõǎ

şǩ ȯÂȮèÂǎzŸŧõ 0.6 dʒ ÁΛÂΛ ŗ) ŘÂÁΛŋ Ù8ŗ ŘƠ °ȳ60 ČDZøÁǎ ZÂz :**Loss on drying** ZŧÂDzǫÕÂǎ ÁÕÂõǎ .ȟ/ŋŸŋ 20 dn ǺŽõǩ ÁÕÂΛ ŗ Ü ǵÂʒÂè 3 gÁŋ R øzÂÊΛõǎ ÁŧÊõŦ ȣèÂŧŧh gǻÂŋ ȧzz (ĘGǎǺ ǀŸŋ 5 ČǎǎǺę

.3.3-2.3 ÛŌŋ/ŋŸŋ 10 ÂŧõǺǫǎ ȯzŸǂǎ ǒÂŁÂǎ ŋŸGΛ :**pH value** ǒÂŁÂGõǎ Čŧŧęǎ

Ž ŋŸŋ 10 ǎǎØΛ :**Absorption in the ultraviolet region** ČŧDzÊÂAGõǎ ȧzz ČĦìǂǎ ČÕÛΛŋ Ž î ÂÔǫŋŗǎ Ƀǩ ȯzŸǂǎ ǎØŁ dn Ōŋ 10 ZÂƐ .Ōŋ 100 øÁÕǎ ǀDzǵ ǒÂÛʒq VS (ȯ/ȯzŋ 0.5) ÕΛøzÂŸÊõǎ Ŗβ dn ČŧzÂõ Čŧŧõ ǀŸŋ 25 ǺÛÕǎ øÂǫnǎ ǎzǫǩ Ž ǰǩÂAõǎ ȯzŸǂǎ ǎØŁ dn Ōŋ 10 ʒŗzΛ .VS (ȯ/ȯzŋ 0.5) ÕΛøzÂŸÊõǎ ŗŧŦ Ōŋ 100 ȯŸŋ dn ŋî Âŧǫõǎ ǎÂÕΛş ÛKÁǫõǎ ǎzÕÂŧǎ ǒÂŧǎ ôzĦĦş ÛǎƎΛ .ĘǎÂęǎ 8 gÁŋ ȣǎŋ ȳÂβ Ž Âŧ8Λş ǀŸŋ 200 ȯzÛǎş

.0.76 ďƷ ÁΛÂΛ ŕŞ 0.70 ďƷ ÕÕΛ ŕ ÜÀǫŋƶǫÅǫ 274 ĞDƶƶŋ ȯƶÛǽ ĻÈ 1 ĞǫÅÁƶǽ ĞÕǴù

ğǎǎÅŘŧŸõ ĞEDƶƶȯƶƶǽŞÀȮƶǎ ĞÊΛÅÕƶǎ" ɹǎƶÁƷ ŘƠ Ğƶƶȯƶŧǎ ĞÊΛÅÕƶǎ ĘǴÛŤ :**Assay** ĞÊΛÅÕƶǎ

NCTC) ĞΛƶÔŤõǎ (*a*) ÅǫŮ ÿǎÆÁǫèÅǽ Û(155 ĞHȺÔõǎ Û1 ÆŸŎǎ) "Microbiological assay of antibioticsĞΛƶΣǎ

ďǫ ĞŁǴÅŒ ŏÅŁÅǽ ĞDƶǿǎ Ʒǫ Cm1 ţǿà Ùèş ÛǿÅǴǫnŕǎ Ůg ďǴÅȮõ *Bacillus pumilus* (8241 or ATCC 14884

20ş 2 ǩǽ ǧǎÅƷ) ǩŸȮŁèǎÀǫǩǿƶŸȮõǎ ďǫ ÆèÅΛǫ ÂŁõÀǫǽ ȯƶŸŢş Û4.5 ŏÅŁÅǽ ğǎǽ TS ĞŧŁÕƷ ğÅÅÊƶ ĞǴǿǎǎ Û6.5-6.5

Bacillus cereus (ATCC :ĞΛƶÔŤõǎ (*b*) ş Û°ȳ39-35 ǩǽ ǴǿǎÀǴ ĞDƶǿÆǽ ďŘŤŧŁş Û(Ôǫ1 Ôõ Ž ĞŁõşǎ ǴÆǴş

ğǎǽ TS ĞŧŁÕƷ ğÅÅÊƶ ĞǴǿǎǎ Û6.0-5.9 ďǫ ĞŁǴÅŒ ŏÅŁÅǽ ĞDƶǿǎ Ʒǫ Cm1 ţǿà Ùèş ÛǿÅǴǫnŕǎ Ůg ďǴÅȮõ 11778)

ǴǿǎÀǴ ĞDƶǿÆǽ ďŘŤŧŁş Û(ĞŁõşǎ ǴÆǴş 0.2ş 0.05 ǩǽ ǧǎÅƷ) ǩŸȮŁèǎÀǫǩǿƶŸȮõǎ ďǫ ÆèÅΛǫ ÂŁõÀǫǽ ȯƶŸŢş Û4.5 ŏÅŁÅǽ

estimated (*P* = 0.95) ǴŤÆÕƶǎ ĞŁŸƷÅÅŸõ ǔÛÁŸõ ǴÆŧǫŤƶǎ ǎşÆΣǎ ÅƶŁƶ ɹƶȮǩ ŕ ɹŮ ŬŁ ĞÊΛÅÕƶǎ Ğǫǎ .°ȳ33-29 ǩǽ

ĞŁŸƷÅÅŸõ ǔÛÁŸõ ƲƶŸŤõǎ ÆŧǫŤƶǎ ÆΣǎ ɹƶȮΛ ŕş .ǴǿÆÕƶǎ ĞŁŸƷÅÅõǎ ďǫ %105 ďǫ ÀŷõŮ ŕş %95 ďǫ ÕǫŮ potency

.ĞÅÅȮǎ ǧǎÅƶǎ ƑŮ ţƶDƶÀõÅǽ ĞǽƶÊŢ ÛŋŸǫ 1 Ôõ Ž ǩŸȮŁèǎÀǫǩǿƶŸȮõ ĞŁõşǎ ǴÆǴş 900 ďǫ ÕǫŮ (*P* = 0.95) ǴŤÆÕƶǎ

!ĭŝyΛΣ DžĭŕǂǀƨÞHÞNjǂǀΛΣ ǫĭÞNjǂǀNjÞǫĭlj üŰŰŬ hŭĭƷŕŢǎ lŕĞŕŤŤǎ

Additional Requirements for Sterile Chlortetracycline Hydrochloride

ďǫ ĞŁŧŢ ÛõǎƶŤŸõ ĻŁõõ ƶŬ ƨŸƷ ĞÕŸ8ǫ ĞΛşÅǴ Ž ǩŸȮŁèǎÀǫǩǿƶŸȮõǎ ÆΛǿƶŸõşǿÆŁŁ ŞÅǴ Æƶ :**Storage** ďΛÂÁǫõǎ

.ŏƶŘõǎ

Sterility testing of ĞΛƶΣǎ ğǎǎÅŘŧŸõ ĞǫÅÕHõǎ ǿÅǴǫnǎ" ɹǎƶÁƷ ŘƠ ǎǿş Åţ ÆŁDƶǫÊŮ :**Sterility** ĞǫÅÕŤõǎ

.ŏÅÎ8ǎÅǽ ÓŤÌÀǫõǎ ǿÅǴǫnǎ ğǎõǎÀDƶŮ ĘŁĞÛǫǽ Û(162 ĞHȺÔõǎ Û1 ÆŸŎǎ) "antibiotics

!ĭŝyΛΣ üŦDžyŦƨúΛ ǫyDžΛΣ DžĭŕǂǀƨÞHÞNjǂǀΛΣ ǫĭÞNjǂǀNjÞǫĭlj üŰŰŬ hŭĭƷŕŢǎ lŕĞŕŤŤǎ

Additional requirement for Chlortetracycline hydrochloride for sterile use

Test for sterility of non- ďÕHȺŸõ ĞŸǽÅÕõǎ Ǩǫ ğǎÅŘHȺǫÊƶǎ ĞǫÅÕƷ ÕDƶj ǿÅǴǫnŕǎ" ɹǎƶÁƷ ŘƠ ǎǿş Åţ ÆŁDƶǫÊΛ

.(ĞΛÂŁŸƷǫǎ ĞŤĞÛõǎ Ž 32 ĞHȺÔõǎ Û5 ÆŸŎǎ) "injectable preparation

ǿÅǴǫnŕǎ" ɹǎƶÁƷ ŘƠ 8ƶȯƶǫ ƶŁ Åŧõ ǿÅǴǫnŕǎ ĘǴÛΛ :**Bacterial endotoxins** ĞŁǫƶǫÀƨǎ ĞŁŸnǎÆõǎ ğÅǫÅÅΛØõǎ

ŕ Ü(ĞΛÂŁŸƷǫǎ ĞŤĞÛõǎ Ž 30 ĞHȺÔõǎ Û5 ÆŸŎǎ) "Test for bacterial endotoxins ĞŁǫƶǫÀƨǎ ĞŁŸnǎÆõǎ ğÅǫÅÅΛØõǎ ÕDƶj

.ǫŸǫ 1 Ôõ Ž RS ŬŸnǎÆõǎ ɹÅÅΛØõǎ ďǫ ĞŁõşǎ ǴÆǴş 1.0 ďǫ ÀŷõŮ ƲƶƷ

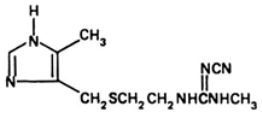
CIMETIDINUM

Cimetidine Džĭǫĭĥĭ̈DŽĭ ƨ‖ε

:Molecular formula ǦĔÅΛÂƨä Ǧ8ĔÔöä $C_{10}H_{16}N_6S$

:Relative molecular mass ǦĔǤÊÅöä ǦĔÅΛÂƨä ǦŸǫȮöä 252.3

:Graphic formula ǦĔǫÅĔǤţä Ǧ8ĔÔöä



:Chemical name ƱƨÅĔŧĔȮöä ǀèrä

2-Cyano-1-methyl-3-[2-[[(5-methylimidazol-4-yl)methyl]-thio]ethyl]guanidine; *N″*-cyano-*N*-methyl-*N′*-[2-[[(5-methyl-1*H*-imidazol-4-yl)methyl]thio]ethyl]guanidine; 1-cyano-2-methyl-3-[2-[[(5-methylimidazol-4-yl)methyl]thio]ethyl]guanidine; *N*-cyano-*N′*-methyl-*N″*-[2-[[(5-methyl-1*H*-imidazol-4-yl)methyl]thio]ethyl]guanidine; CAS Reg. No. 51481-61-9.

:Description Ƶòƶöä ƱĔÅn ǦHuƨäÅä ŞÛ ǦHuƨäÅöä CÆȝ ÛÆǵÅì ŘĔäÛ ƁÛ ŘĔäÛ ȷƶŸä ȧƶHuÊŋ.

:Solubility ǦĔǫÅäŞØöä ǴĔHuì ƨäŞäé ÜŏÅţä Ž ȷÅäŞØöä Ž ĔÆDZ.

:Category ǦÅÅöä Antiulcer.

:Storage ąΛÂÅǫöä ŞÅǵ Æƨ Ž ΛÆǫĔŧĔÊöä ǦΛŞÅǵ Ž ŷÅȮǵüä ǦÕŸ8ŋ.

:Additional information ǦĔƶÅřÛ ǧÅŋƶŸĤŋ ǵÅÉĤǫŋ ȮÅȮìÛ ǦǫŸǫ ÆÊǵ ΛÆǫĔŧĔÊöä ÆDZäƶǫΛ ŌȮÎöä ÆΛÆȝ Ęƶäƶǫ polymorphic ŌȮÎöä. RS ΛÆǫĔŧĔÊöä ǵǿƶŸä ŌȮì ȝŋ ǵŞÅƶǵä Ž Ʊȝƶäöä polymorph ŌȮÎöä ÆΛÆȝ Ęƶäƶǫ.

REQUIREMENTS ƚǦhƶŸƵkdž!ƒ

:General requirement ŷÅĬöä ÆŸÛǫǫä %98.5 ȝ ŌÕΛ ŕÅŋ ƨŸȝ ΛÆǫĔŧĔÊöä Ƀƶǫȝ %101.0 ȝ ÆΛÂΛ ŕŞ ǦÅÅÕä ǵÅţä ƁÛ ţƶDZÅöÅä ǦäƶÊŢ ÛC$_{10}$H$_{16}$N$_6$S ȝŋ.

:Identity tests hƱŇjNJΛε l εƥƑǦHǫε

:A ŘƠ ǦĬì ȷä ŌÕÛÅŋ Ž ƱƨƶRöä ƶĔÛöä âÅĘ" ȷäƶÅȝ ŘƠ Ʊƶòƶŋ ƶŁ Åŧõ ǿÅǦǫnŕä ĘǦÛΛ ŘƠ ǦĬì ȷä Ž î ÅÔǫŋŕä ƶĔù ĘäÅÛǫΛ .(43 ǦHuÅÔöä Û1 ÆŸÕä) "Spectrophotometry in the infrared region ŞÛ RS ΛÆǫĔŧĔÊöä ȝŋ ŌŏÅÎţÅä ¢ĔŸȝ ŌÔHuǫÊţä ƶĔÛöä ȝŋ ÆΛØţÅä ŌÕäÅè ǦƨÅĬŋ ȷŞå ŌǦŸÔöä ŌŏÅΣä ȝŋ ǰĬÅÅöä ŏäÅŧΣä

ÂĘĘţǫŸõ ǦŸäÀę peak ǥşǿǽ ǫĴ shoulder Ƶǫõ ÁĐƷƷΛ ŕ ÜđΛÆĘǫĘţĘÊŸõ *reference spectrum* ŬĦĐƷÀŢţä ƵĘÛõä Ɜŋ
.(polymorphic form ŌȮÎõä ǻÆĦǫŋ ŌȮÎõä ǻƷĐƷǫ ÆĘõüǩ) 1180 cm^{-1} ǦĐƷţÀä discernable
.°ȳ142 ǦääÀę ÛǿÀŢÔǫŕä gǿäÀǵ ǦĐƷǿǻ :B

ȣƷòƷŋ ƷŁ Åŋ ÆÊŒ ǿÀǫǫnŕä ȯƷŸŢ ǨŘƠ ŌĐƷȷ Ňı.0 ȳÆÁǫÊΛ :**Heavy metals** ǦŸĘŌƷõä (ǥäÂŸÀõä) ȷǻÅĦţä
3 õäÀĐƷqä ÆÊŒ Ú"Limit test for heavy metals ǦŸĘŌƷõä (ǥäÂŸÀõä) ȷǻÅĦţä ŌĐƷȷ ÐÆΣä ǿÀǫǫnŕä" ȷäƷÀ3 ŘƠ
ÆΛÂΛ ŕ Ü(128 ǦĦȵÀÔõä Û1 ÆŸŎä) A ǦŌΛÀÛõä ÆÊŒ ǦŸĘŌƷõä (ǥäÂŸÀõä) ȷǻÅĦţä ƷƷǫŢ đĦĦł Ü(127 ǦĦȵÀÔõä Û1 ÆŸŎä)
.ňı/ȳäÀdşÀȮŋ 20 đ3

.ňı/ŋŸŋ 1.0 đ3 ÆΛÂΛ ŕ :**Sulfated ash** ŘÀŸÊţä ǻÅŋÀõä

10.0 đŋ ÀŠõÛ ÆŌÀΛ ŕ Ü°ȳ105 ǥäÀǵ ǦĐƷǿÆä ŘäÅŠõä ȷàƷõä Ʒǿǫǵ ƵÀƵ :**Loss on drying** ƵĘÀĐƷǫŌÅä ÆŌÀõä
.ňı/ŋŸŋ

9.5- ÛR ȷƷäÀȮõä ÆĘÊõÛ ȣƏÀǫ đŋ ÐÀŢä ŏÅţä Ž Ōŋ/ŋŸŋ 5.0 ÂĘõÀǫä ȯƷŸ‡ä ŏÅŁÅä ŋŸǦΛ :**pH value** ŏÅŁÅǦõä ǦţĘę
.8.0

.Packing material ǥƷÎΣä ǥǻÅŋ ÆÊŒ A ÀŌǫÊţä ǿƷÛõä ȳÆÁǫÊΛ :**Related substances** ǦŏÅÎţä ǻäƷţä
ȷäƷÀ3 ŘƠ 1 ÆŸĐƷţŸõ ǦĘŸĘţȮǫõä ǥŸΛÆĦǫõä Ž 377-373 ǥÅĦȵÀÔõä Ž ȣƷòƷŋ ƷŁ Åţõ ǿÀǫǫnŕä ĘǦÛΛ
25 ȯƷù Ðǽ ǻƷţ3 ȳäÆÁǫèÅä Ú"High performance liquid chromatography àÅõqä ƷĘƷÀõä ŌƏÅÊõä ā äÀÎǫèŕä"
ǥäǽ ceramic ŌĘŋäKÊõä ǫĴ porous ȳÅÊţä ǥäǽ ÅȮĘŸĘÊõä ǦŋŸŁ đŋ ǥÅţĘÊλ ƷÎŢ ÛĮŸŋ 4.6 ŬŸnäǻ ÀÛęǫ ĮÈ
ÀŘĦł .Octadecyl silyl groups ǥÅ3ƷţƒƷŋ îÅǦkórÅä ĦĘƏÅĘţĘõ ǴÛÊõä ÅŢŸƷ ȯǽÅ3 ȣØǫõäǫ ÀǫŋǫÀȮŋ 10-5 ÀÛŌõä
.Ōŋ 200 ǿÆŌä ĮDƷǵ ŏÅÛ3q ŏÅţä đŋ ǦƷÅõ ǦĘţȮä R ŬDƷŸŠõä ŌĘǫĘèȷä Ŕβ đŋ Ōŋ 1 ƵÅƵ :ÐÅǫõä ÆΛØţä ȷΛÂŋ
ȷΛÂŋ ȳÆÁǫÊΛ õÀĦǫŋ ǿƷÛõǫ .TS (ȯ/ňı2) ȳƷĘǫƷŋȷä ǥÅǫĘèÛ ȯƷŸŢ đŋ Ōŋ 10 ȯƷŸ‡ä ǻØŁ đŋ Ōŋ 190 ÐÛ ȣÅÊΛ
.R ŌΛÀǫǫƷĘèȷä đŋ ĦţDƷǵ 16ǫ ĦÅǫÛ ǦÀõä ǻǿäƷõä ÆΛØţä ȷΛÂŋ đŋ ĦţDƷǵ 84 đŋ ȷƷȮŋ õäƷTä ¢Åŋ ţǫÂǿÅŋǫ ǴĦÀŋ
24ǫ RS đΛÆĘǫĘţĘÊõä đŋ ȳäÀdşÀȮŋ 18 ÐƷƷ ȯƷŸŢ ÀŘĦł system suitability àÅŢƷä ǦţƏŸŋ ǿÅǫǫnä ǦĘȣäǫ
ȯƷŸŢ ÀŘƷ Ż .(A ȯƷŸ‡ä) ĦÅǫÛ ǦÀõä ǻǿäƷõä ÆΛØţä ȷΛÂŋ đŋ Ōŋ 1 Ōõ Ž caffeine RS ǩĘƷÅȮõä đŋ ȳäÀdşÀȮŋ
àÅŢƷä Ō8ÎΛ .(B ȯƷŸ‡ä) ĦÅǫÛ ǿƷõØţä ÆΛØţä ȷΛÂŋ đŋ Ōŋ 1 Ōõ Ž ȳäÀdşÀȮŋ 18 ÐƷƷ ÐØõä ǦòƷĦȵÅţä ǥäÅţä
ȧƷƷ ǦĦÌȷä Ž ȣƷŘõä ƵĘÛõä âÅĦŌŋ ȳÆÁǫÊΛ detector ȣÅÎȮţõǫ .ǦŌĘǫǻ 1 Ōõ Ž Ōŋ 1 ǦääÀę ā ÅĘÊǫä ǦƷÀÊä
Ōõ Ûreplicate injections ǦĐƷǫǻÂŋ đŌǵ 6 ƷÅÔł .ÆèÅŋ ŌĐƷÊŋ ĦǻǫÂŋ ÛÀǫŋƷǫÅǫ 228 ǦääÀę ǦĐƷŋ ȯƷÛä ǦĘĐƷÊÅΛõä
ȣØǦÊΛõä ÐØÅĘĦţä ȣäÀUŕä ȷƷȮΛ ŕ Üpeak responses ƷØØõä ǥÅäÅĐƷǫèä âÅŌǩ .A ȯƷŸ‡ä đŋ ÀǫǫǫÀȮŋ 10 ÅŢŸŋ
ÙÛÜ Ž ǥÅäÅĐƷǫèŕä Ōõ ţƷţƒ ÐÛ đΛÆĘǫĘţĘÊõä đŋ ǥÅäÅĐƷǫèŕä ÆÊÊõ relative standard deviation

[illegible] resolution [illegible] 2.0 [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] 10 [illegible] [illegible] 1.4 [illegible] 1.0 [illegible] [illegible] [illegible] [illegible] [illegible] .3.0 [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible]

Ž ȷÅæȘØõä ǴŁHȣì ÜR ȳøȥȥȘøȥŸÒõä ȣȵ ȾõÂDZ 15 Ž ā ãȘæ ÜŸŁŸŧȝ ŏÅţä Ž ā ãȘæ Ƙḑ :**Solubility** ČŁȣÅæȘØõä .R Ƙõ ɟä ŽȘ TS (ȯ/ȟ750~) ȯȥφÅŽÅqä

.Antileprosy ȳäØDzŸõ åÅŘȵ õäȘå :**Category** ČÅÅõä

.ȳÅÒǵüæ ČÕŸ8ȵ ČÅȘÅǵ Ž ƙȥàÅȥȥŸÒõä ȘÅǵ Æz :**Storage** ȣÅÂÁõä

.°ȳ217 ČæäÀę ƙȥàÅȥȥŸÒõä ÀŦÔÅÅ :**Additional information** ČŁȥÅŕŕŮ ğÅȵȥŸȞȵ

REQUIREMENTS ƚĠȣŦƙdž!ƒ

%101.0 ȣ3 ÁÅÂÅ ŧȘ %98.0 ȣ3 ÕÕÅ ŧ Åȵ ȥŸ3 ƙȥàÅȥȥŸÒõä ƁȥƳƷ :**General requirement** ȳÅŘäõä ÆŸÛƳţä .ČÅÅČõä ǵÅţä ƁŮ ţȥDZÀõÅæ ČæȥÊŢ ÛC27H22Cl2N4 ȣȵ

:**Identification tests** hŭŇjNJŇ l εβƒǴȞƳε

.CȘ B ȣØÅǴÒŕŕä ȘŮ A øÅǴÒŕŕä ÅȵŮ ĘŁǴÛƙ ȣÒȥ •

õäÀŧΣä ƘƠ ČŘÌɟä ČÕÛÅȵ Ž ȣȥÊõä ȤŁÛõä âÅŁę" ȷäȥÅ3 ƘƠ ȣȥòȥȵ ȥŁ Åŧõ øÅǴÒŕŕä ĘǴÛÅ :A ƘƠ ČŘÌɟä Ž î ÅÔÒȵŕä ȤŁù ĘæÅÛÒÅ .(43 ČHȣÅÔõä Û1 ÁŸÖä) "Spectrophotometry in the infrared region .ƙȥàÅȥȥŸÒŸõ *reference spectrum* ȣŘDZÀţä ȤŁÛõä 3ȵ ȘŮ RS ƙȥàÅȥȥŸÒõä ȣȵ ƙÅÅõä ȤŁÛõä 3ȵ õäÀŧΣä (ȯ/ȯȥȵ 0.01) ȯȥφÅŽŁţä/ÕÅøȥŸõȘøÁŁŁTä ŘƥȯȥŸŢ Ž ÕȵŋŸȵ 5.0 ÂŁõÀÒæ ȯȥŸ‡ î ÅÔÒȵŕä ȤŁù ƁÁǴÅ :B 487Ș ÀÒȵȥφÅφ 283 ČæäÀę ƙÒŁŧŢ3Ů ƙŧȘøæ ÛÀÒȵȥφÅφ 600Ș ÀÒȵȥφÅφ 230 ƙæ ȝäȥȵɟä ȯäȥùŮ Ž ȤÀDzł ÅȵÁŁ3 ÛVS .ƁäȥÒõä ȥŸ3 Û0.32Ș 0.65 ČæäÀę ƙŘÅŁ ƙÒDZȥţä ȯȥù Ž ȴè1 ČφÅÅŽæ ČÕǴÛŮõ ȷÅòÅŧÒõä ȷȥÒÅȘ .ÀÒȵȥφÅφ ȷȥõ ŷÒÅÅ ÜTS (ȯ/ȟ 420~) ÕÅøȥŸõȘøÁŁŁTä Řƥ ȣȵ ÕȵŋŸȵ 0.1 ȣÅŘÅȘ R ȷȥÒŁèŮ ÕȵŋŸȵ 3 Ž ŋŸȵ2 ČæäÀę ā ãæ :C – ÀƥŮ ƁŮ ȷȥŸõä ȯÁǴÒÅ ÜTS (ȯ/ȟ 200~) ȳȥÅåȥÔõä ÁŁÊõȘøÁŁŁ ȯȥŸŢ ȣȵ ÕȵŋŸȵ 0.5 ȣÅŘÅ .ÁÅÁÌ ŦDzÊÅÅæ .ƁÅÕŘÀæ

ȷäȥÅ3 ƘƠ ȣȥòȥţä øÅǴÒŕŕä ȯȥŸŢ ƚŘŦHȣÒõ ȟ1.0 ȳÁÁÒÊÅ :**Heavy metals** ČŸŁÕŽõä (ğäÂÊÅää) ȷåÅŘţä Û1 ÁŸÖä) 3 õäÀDZqä ÆÊŦ Û"Limit test for heavy metals ČŸŁÕŽõä (ğäÂŸÅää) ȷåÅŘţä ÕDZȷ ƁÁΣä øÅǴÒŕŕä" 10 ȣ3 ÁÅÂÅ ŧ Ü(128 ČHȣÅÔõä Û1 ÁŸÖä) A ČÕÅÀÛõä ÆÊŦ ČŸŁÕŽõä (ğäÂŸÅää) ȷåÅŘţä ȤȥŢŢ ȣŁŘÅ Ü(127 ČHȣÅÔõä .ȟ/ȳäÀdȘÀÒȵ

.ȟ/ŋŸȵ 1.0 ȣ3 ÁÅÂÅ ŧ :**Sulfated ash** ŘÅŸÊţä åÅȵÀõä

5.0 ȣȵ ÀŽõŮ ÁÕÅÅ ŧ Ü°ȳ105 gøäÀǵ ČDZøÁæ ŘæÅŽõä ȷàȥõä ȤøŢǵ ZÅz :**loss on drying** ZŁÅDzŢõÅæ ÁÕÅõä

. ĥ/ŋŸŋ

ǦÕŒęÀõä ǦÕǦÛõä ãäÀÎǫèä" ɹäzƛ3 ǨƠ 8ɀòɀŋ ɀŁ Åŧõ øÅǦǫnŕä ĘǦÛΛ :**Related substances** ǦöÅÎŧä ǻäzɀŧä ǦHɄŒÅÔõä ŋÉĦĦ) silica gel R6 ÅÒŒŸŒÊõä ǦŋŸŁ ÿäÆǺǫèÅæ Û(84 ǦHɄÅÔõä Û1 ÆŸÖä) "Thin-layer chromatography ǦÕŒęǻ 30 gÆŋ ǦHɄŒÅÔõä ĘŒŸHǫæ ÅŒǫzŋɹä øÅǺǦö òÅŧHǫèŕä ÕǦę ÅÅǫÜ ǦŕÀHŋ Û(ǦǦèÅÅŋ ƁøÅÒ øÆÔŋ ƁÜ ɒŋ ÅÕäÅè ǦÊŒŸŧä ÕŧHǫÊΛ ƱÒö ŋÉĦŋ ÛõÀHɄǫŋ øzÛõş .TS (ò/ĥ17~) ÅŒǫzŋɹä ɒŋ shallow ǦŸHɄŕ ǦÕǦù ƁzƠ ãäÀÎǫèä gKDzǵ Ž ĘǦÛΛ .R òzǫÅäşÀæ –1 ɒŋ ȳzDzǵ 4ş R ɹÅŸŋ şøzŸõ ƱəÅÅǫ ɒŋ ÅŧDzǵ 85 ɒŋ ǰΛÂŋ ÀŘHɄł ÛǦŸÔÅÅŋ gKDzǵ Ž Ž øÅǦǫnŕä gåÅŋ ɒŋ ŋŸŋ 20 ƁzƷ :(A) òzŸ‡ä ÛR ȳøzzøzŸÒõä Ž ÕŒõÅŢ 3 ɒŋ ÀǫõşÀÒŋ 5 ǦHɄŒÅÔõä ɔŸƷ ŸÔÅÅŋ gåÅŋ ɒŋ ŋŸŋ 0.10 ƁzƷ :(C) òzŸ‡äş ÛÕŋ 1 Õõ Ž øÅǦǫnŕä gåÅŋ ɒŋ ŋŸŋ 0.16 ƁzƷ :(B) òzŸ‡ä ÛÕŋ 1 Õõ ɒŋ ǦHɄŒÅÔõä ŧÂφ ÆĦäş .ĘŒǦÛǫõä Ùn ȧzz ɹè12 ǦzÅÊŧ ǻzĦÔõÅæ õÀHɄǫŧä øzÛŸõ ǦŧÊł .Õŋ 1 Õõ Ž øÅǦǫnŕä ǻzĦÔõÅæ õÀHɄǫŧä øzÛŸõ ǦŧÊł .gKDzΣä БÜ ǦHɄŒÅÔõä ǻÅĦĦkş ÛĘəÅęǻ 5 gÆŋ õäzŧä Ž ZDzǫõ õÀǫk ÛäÀÎǫèŕä gKDzǵ ǦĦìɹä Ž ääÀÎǫèŕä ÙÛÛƠ ÒHɄÅŧş ÛĘəÅęǻ 5 gÆŋ õäzŧä Ž ZÅΘ ÛgKDzΣä ɒŋ ǦHɄŒÅÔõä ŧÂøÅk ÛɹÈ12 ǦŒφÅǫ gÀŋ ÕŸk ɒŋ gÆì ÀŸõÜ ÛǦŒÊŒəÀõä ǦĦÕǦõä õÅÅŸǫèÅæ ÛAĈòzŸ‡ä ɒŋ ɹǫÅk ǦĦÔæ ǦÅÜ ɹzÒk ŕ .(ÀǫŋzφÅφ 254) ǦŒDzÊÅÅǦõä ȧzz .B òzŸ‡ä ɒŋ ǦΘÅÅõä ÕŸk ɒŋ gÆì ÀŸõÜ ɹÅφzÒk ŕ ƷÕǦõä ǦØŒŁ ÕŸŋ ɒŋ ǩǫÅõä ǩǫĦÕæ ɹŭz ÕõÅæ äÆƷ ÛC òzŸ‡ä ɒŋ ǦΘÅÅõä ÛR ɹzǫŒèɹä ɒŋ Õŋ 50 8ÅŘΛ ÛR ȳøzzşøzŸõ Õŋ 20 Ž ÛǦŒùzǦŘŋ Ǧφşàzŋ ÛĦ0.4 ǦääÀę ääØΛ :**Assay** ǦÊΛÅÕŧä Non- ƱəÅŋŸõä Ùèzõä Ž gÀÅÅĦŧä" ɹäzƛ3 ǨƠ 8ɀòɀŋ ɀŁ Åŧõ VS (ò/òzŋ 0.1) ÕΛøzŸõǩǦõä ŘŧŦŦ ÀÅÅĦΛş (ò/òzŋ 0.1) ÕΛøzŸõǩǦõä Ř β ɒŋ Õŋ1 Õõ .(142 ǦHɄÅÔõä Û1 ÆŸÖä) A ǦÕΛÀÛõä ÆÊŦŦ Û"aqueous titration .$C_{27}H_{22}Cl_2N_4$ ɒŋ ŋŸŋ 47.34 ŏżÅÒΛ VS

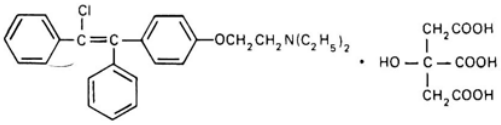
CLOMIFINI CITRAS

Clomifen citrate DžƷĭDŽNj‡ǀǁǂ ǀǂβĦĭƨ

$C_{26}H_{28}ClNO,C_6H_8O_7$:**Molecular formula** ǦŒÅΛÂƨä Ǧ8ŒÔõä

598.1 :**Relative molecular mass** ǦŒǦÊΛõä ǦŒÅΛÂƨä ǦŸǫÒõä

:**Graphic formula** ǦŒφÅŒǦŧä Ǧ8ŒÔõä



Chemical name: 2-[*p*-(2-Chloro-1,2-diphenylvinyl)phenoxy]triethylamine citrate (1:1); 2-[4-(2-chloro-1,2-diphenylethenyl)phenoxy]-*N,N*-diethylethanamine 2-hydroxy-1,2,3-propanetricarboxylate (1:1); CAS Reg. No. 50-41-9.

Description: [illegible]

[illegible] **Solubility:** [illegible] (750~) [illegible].

Category: ovulation inducer [illegible].

Storage: [illegible].

Additional information: [illegible] (geometric isomers).

REQUIREMENTS [illegible]

General requirement: [illegible] (Z-isomer) Z- [illegible] $C_{26}H_{28}ClNO,C_6H_8O_7$ [illegible] %101.0 [illegible]

Identity tests: [illegible]

• [illegible].

[illegible] A [illegible] (43 [illegible]) "Spectrophotometry in the infrared region" [illegible] *refernce spectrum* [illegible] [illegible].

[illegible] B [illegible] 25 [illegible] 392 [illegible] 235 [illegible] 220 [illegible] (0.1) [illegible] 0.44 [illegible] 0.79 [illegible].

C [illegible] General [illegible] 10 [illegible] "identification tests" (121 [illegible]).

ŘƠ ȣȝȣȣȝ ȝŁ Ȧŧȣȣȣ ȣȦȠȠȣȣȣȣ ȣȝŸȚ ȣŘŘȣȣȣ ȣȣ1.0 ȣȣȣȣȣȣȣ :**Heavy metals** ȣŸȣȣȣȣȣȣȣ (ȣȣȣȣȣȣȣȣ) ȣȣȣȣȣȣȣ Ȣ1 ȣŸȣȣ) 3 ȣȣȣȣȣȣȣȣ

.$C_{26}H_{28}ClNO_6$,$C_6H_8O_7$ ďŋ

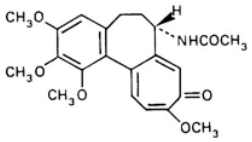
COLCHICINUM

Colchicine Ďžĭƨĭ٦ℕj|ℕ٤

$C_{22}H_{25}NO_6$:**Molecular formula** ĞŁĎĹÂƨď Ğ8ŁÔďď

399.4 :**Relative molecular mass** ĞŁGÊĂďď ĞŁĎĹÂƨď ĞŶQÒďď

:**Graphic formula** ĞŁqĎĹŁGţď Ğ8ŁÔďď



:**Chemical name** ŬƨĂŁŁŁÒďď ٦ěŕď

(*S*)-*N*-(5,6,7,9-Tetrahydro-1,2,3,10-tetramethoxy-9-oxoben-
zo[*a*]heptalen-7-yl)acetamide; CAS Reg. No. 64-86-8.

ĎÒÎďď ĞƩÁƷ scales Ƶ٦ďĂǵ ĎÒÎď ş٦ Æǵ٤ÎďďĂŘnQţ ďøĂŕ ĂÒď ɹƶŶď ğďøƶŶď :**Description** Ƶòƶďď .ĎĞĂĂÕĎ ĞŁuďĂďď CÁƷ ş٦ ĞŁuďĂďď CÁƷ ÜďƶŁuÊŋ ĎÒÎď ş٦

ɹĂďşØďď ĞŁŁuì ÜR ÿøƶƶşøƶŶÒďďş TS (ò/Ĥ750~) òƶqĂŶĂqď ɹĂďşØďď Ăǵ ÜŏĂţď Ž ďşď :**Solubility** ĞŁqĂďşØďď .R Ğţɹď Ž

.Antigout ďĂÕĂŶţ ďĂŘŋ ďďşď :**Category** ĞĂĂďď

.ďƶŘďď ďŋ ĞŁŁŢ ÛÿĂÒǵďď ĞÕŶ8ŋ ĞĂşĂǵ Ž ĸÊŁÎďƶÒďď ŞĂǵ Æƶ :**Storage** ďĂÂÁqďď

colchicum ţƶĂďď ďŋ ɹqĂĂ alkaloid ŬøqďƶŶę ƶŁ ĸÊŁÎďƶÒďď :**Additional information** ĞŁƶĂŕÛ ğĂŋƶŶĤŋ .ďƶŘŶţ ô ĂĤqďď ÁĂƷ ĂĂõďď ¢qƶţ ĞĞÔĂ (Liliaceae ĞŁÕĞqÂďď ĞŶŁÔĂďď) *autumnale*

.ƀÁĂɹĂď ¢qŶŋĂĤŋ ÁĂƷ ĞĂĂĂĤďďş øØΣď Ŭnƶĸ ĀƶşĂĂĂŕ ĂŁŁè ĸÊŁÎďƶÒďď ÁĤŁ :ĂĂØƠ

REQUIREMENTS ĸĞuĂƵĸĂ!ƒ

%103.0 ďƷ ÁĂÂĂ ŕş %97.0 ďƷ ÕÕĂ ŕ Ăŋ ƨŶƷ ĸÊŁÎďƶÒďď ƀƶqƷ :**General requirement** ÿĂĤďď ĀŶÛqţď .ĀĂØţď ďŋ ĞŁďĂ٦ďş ĞŁƨĂŋŶďď gáĂţď ƀÛ ţƶDZĂďĂď ĞďƶÊŢ ÛC$_{22}$H$_{25}$NO$_6$ ďŋ

Identity tests hŭŇjNJЛЄ l ЄƀƑǴĦƊ]Є:

• Ďŋ ČŋB ğäóÅĢŋnŕä ŋÜ A óÅĢŋnŕä ĘÆĢÛǩ ďÒƹ.

A: ČĦÜ ĵä ČÕÛÅŋ Ž ÞƷŕÊää ŽÆÛää âÅÆę" jäŕÅ3 ČƠ ȣŕòŕţä ÒĦÞÅää ĘĢÛΛ ČĦÜ ĵä Ž î ÅÔŋŋŕä ŽÆù ĘäÅÛŋΛ .(43 ČĦÞÅÔää Û1 ÆŸÖä) "Spectrophotometry in the infrared region ŋäÅŧΣä

.ǩÊÆÎŕŕÒŸŏ *refernce spectrum* ÞĦDZÅţä ŽÆÛää 3ŋ ŋÜ RS ǩÊÆÎŕŕÒää ďŋ ĵǩÅää ŽÆÛää 3ŋ ŏäÅŧΣä ČƠ

B: Ž ÆŁÅÎΛ ÅŋÆÅ3 ÛTS (ȯ/ħ750~) ȯŕφÅŽΛqä Ž Ōŋ/ŷäÅďŋÅÒŋ 10 ÂÆõÅŋä ȯŕŸ‡ î ÅÔŋŋŕä ŽÆù ÞÆĢΛ 350 ČDZŕţäŋ ÅŋŋŕφÅφ 243 ČääÅę ČDZŕţä ȯŕù Ž ǩÆŧŢ3Ù ǩòÅÔŋŋä ÛÅŋŋŕφÅφ 400ŋ ÅŋŋŕφÅφ 230 ǩä Žäŕŋŋŕä ȯäŕùÙ ÅŋŋŕφÅφ.

C: ŋŕŏ ĵŋΛ ÜTS (ȯ/ħ25) ÕΛÆΛÆΣä ÆΛóŕŸõ ďŋ gÅÛę 1 ȣÅÊΛŋ TS (ȯ/ħ750~) ȯŕφÅŽΛqä Ž ŋŸŋ 30 ääØΛ ŋäóŕŕ ÅÞÜ.

D: ȣÅÊΛ .ÞøφŕŧÆŏ ÅÅòÙ ŋŕŏ ĵŋΛ ÜTS (ȯ/ħ1760~) ÕΛóŕÅŸÊää Ò Þ ďŋ Ōŋ0.2 ČääÅę 3ŋ ŋŸŋ 1 ŽÂŕ Ď ČŽÅÊä ȯŕÞŋΛ ÛÅÊÒŋĵä Ď äóÅÊää äóäĵä Ď ŋŕŸää ȯÆĢΛ ÜTS (ȯ/ħ1000~) ÕΛŋΛää Ò Þ ďŋ 0.1 ČääÅę ȳŕΛäŕÔää ÆÆÊõŋóÆÆŁ ȯŕŸŢ ďŋ ğäÅÛę 3Êä ȣÅÊΛ ÓäÆÅ3 .ÅĢΛÅÕǩ ŋŕŸää CÆ3 ŋÜ ÅÅòĵä Ď äKnÙŋ ÅÞĵä Ď ŋŕŸää ȯŕÞŋΛ ÜTS (ȯ/ħ80~).

Ď ţŕDZÅòÅä ÆÊŽŋ Ōŋ/ŋŸŋ 10 ÂÆõÅŋä ȯŕŸŢ ŌŧĦŋÊΛ :**Specific optical rotation** ÞŽŕääÅ ÞÅÔĢääÅ ÅΛŋÆŋääÅ $[a]_D^{20°C}$ = - 425 to -460° ÜÆΛØţä ďŋ ĢÆäÅŋ ČÅÅÖä gäÅţä.

Sulfated ash ČÅŸÊţä äÅŋÅääÅ :ħ/ŋŸŋ 1.0 ďŋ ÆΛÂΛ ŕ.

content of solvent and water :ŷäÆÅŋèÅä ÛgÅ3Åè 4 gÆŋ °ŷ130 ČDZØÆäÅä ŽÅz ŏÅţäŋ ÆΛØţä ďŋ ŋŕŋŋ‡ä ČƠ ȣŕòŕŋ ŕŧ Åŧõ ŏÅţä ŋŕŋŢ ďÞĦΛŋ ČÅÅÖä gäÅţä ďŋ ħ0.3 jäŕΛ .jäŕää ÆÕŋ ďÞĦΛŋ ÛgäÅţä ďŋ ħ0.5 ČääÅę ČÕΛÅÛää ÆÊÊÛ Û"Determination of water by the Karl Fischer method ÅÎŕŕ ȯóÅõ ČÕΛÅÛä ŏÅţä ǩÆĦǩ" jäŕÅ3 ÆÅ3 ÞóÆÆÕŋ ÛŏÅţä ŋŕŋŢŋ jäŕää ÆÕŕ ţŕŧf ŋŸGΛ ŕ ÜÆΛØŧõ R ďΛÆΛKGää ŷäÆÅŋèÅä Û(145 ČĦÞÅÔää Û1 ÆŸÖä) A ħ/ŋŸŋ 145 ďŋ ÅŽõÙ ŕŋ ħ/ŋŸŋ 115 ďŋ ŌęÙ ÛħŋŸţÅä ÅŧŽÆŸõ.

Colchceine ǩÅÊÊÆÎŕŕÒää ÕΛÆΛÆΣä ÆΛóŕŸõ ȯŕŸŢ ďŋ Ōŋ 0.2 ȣÅÊΛŋ ŏÅŋ Ōŋ 4 Ž ħ0.05 ääØΛ ȯŕŸ‡ä jäŕ ďŋ gÆÌ ÅŽõÙ óÅĢŋnŕä ȯŕŸŢ ďŋ ĵǩÅää jäŕää jäŕÒΛ ŕ ÜŽÂŕŋ ŏÅţÅä Ōŋ 6 Ď ŋÅŕ ÛTS (ȯ/ħ25) cobalt colour ČŏÅäŕÒää jäŕ ȯŕŸŢ ďŋ Ōŋ 1Ûiron colour TS ÆΛÆΣä jäŕ ȯŕŸŢ ďŋ Ōŋ 2 ŽÂŋ ďŋ ĵǩÅää ÞóÅÆŋţä ÛTS

ÆÅ3 Õäæŋ ÛTS (ȯ/ħ70~) ÕΛóŕŸõŋóÆÆŢä Ò Þ ďŋ Ōŋ 0.70ŋ copper colour TS âÅÞÅää jäŕ ȯŕŸŢ ďŋ Ōŋ 2

.(53 ĞHЧÁÔäã Û1 ÁŸŎã) "colour of liquids ŌəãzÊõã ɟzŏ" ɟãzÄ3 ŘƠ 8ȚŏȚŋ ȚŁ Åŋ ÆĒÊШ ĞφóÅŌţã ĞŌŁęÀõã ĞŌGÛõã ããÀÎQèã" ɟãzÄ3 ŘƠ 8ȚŏȚŋ ȚŁ Åŧõ óÅĞQnŕã ĘGÛΛ :**Related substances** ĞŏÅÎţã ããzţã Ęõüğk gãÅŋ ɔŸ3 ƀşÅΣã ɭəŸţã ÿzĒÅţɟã ÆŁÊõШ ÿãÆÁQèÅæ Û(84 ĞHЧÁÔäã Û1 ÁŸŎã)"Thin-layer chromatography ÛR ɟzQŁèɟã dnŋ ŧŧDzǵ 20 ÛR ÿózȚşózŸÓõã dnŋ ŧŧDzǵ 25 dnŋ ɟΛÂŋş ĞŸ8ŋ gãÅŧõ ÀQŋzφÅφ 254 ĞããÀę ĞDZzŋ ȯzÛã ĸÄφã ĸȯzŸŢ dnŋ ÀQõşÀÓŋ 2 ĞHЧÁÔäã ɔŸ3 ŧŸÔÅΛŋ ĘGÛΛ .ōÀHφŋ ózÛõ TS (ȯ/ȟ260~) ÅĒφzŋɟã dnŋ ŧŧDzǵ 0.4ş 2.5 ƀzȚ :(B) ȯzŸ‡ãş Ōŋ 1 Ōõ Ž óÅĞQnŕã gãÅŋ dnŋ ŋŸŋ 50 ƀzȚ :(A) ȯzŸ‡ã ÛTS (ȯ/ȟ750~) ȯzφÅŽΛqã Ž ÒHЧÁΛş ŏãzTã Ž ZDzφõ ōÀQk ÛããÀÎQèŕã gKDzǵ dnŋ ĞHЧÁÔäã ţÂφ ÁĒãş .Ōŋ 1 Ōõ Ž óÅĞQnŕã gãÅŋ dnŋ ŋŸŋ ĞĒŌGäã ŏÅAŽQèÅæ ÛA ȯzŸ‡ã dnŋ ɟQΛk ĞĒŌæ ĞΛÙ ɟzȮk ŕ .(ÀQŋzφÅφ 254) ĞĒDzÊÅΛGäã ȧzz ĞĒÌɟã Ž ããÀÎQèŕã ÙÛÙ .B ȯzŸ‡ã dnŋ ĞΘÅΛäã ŌŸk dnŋ gÆÌ ÀŽõŪ ÛĞĒÊŁÀäã

ÀΛÅĒΛş Ûacetic anhydre ŌĒQèɟã ÆΛøÆĒŒŪ dnŋ ɟΛÂŋ Ž ÛĞĒÙzGŘŋ GφşàzŋÛ0.05 ĞããÀę ããØΛ :**Assay** ĞÊΛÅÔţã Ž gÀΛÅĒţã" ɟãzÄ3 ŘƠ 8ȚŏȚŋ ȚŁ Åŧõ ÆŤɔã âÅĒŌŋ ĞΛÅŤΛäã ĞÛŌφ ĸĒĒĸ ÛVS (ȯ/ȯzŋ0.02) ŌΛøzŸõĸGäã ŘŧШ Řβ dnŋ Ōŋ 1 Ōõ .(142 ĞHЧÁÔäã Û1 ÁŸŎã) A ĞŌΛÀÛäã ÆÊШ Û"Non-aqueous titration ŬəÅŋŸäã Ùèzäã .$C_{22}H_{25}NO_6$ dnŋ ŋŸŋ 7.988 ùzÅÓΛ VS (ȯ/ȯzŋ 0.20) ŌΛøzŸõşĸGäã

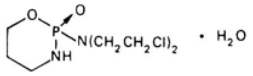
CYCLOPHOSPHAMIDUM

Cyclophosphamide ǫĭDŽƑƲƨƨƝȷǂǀĭƨǁȾ

$C_7H_{15}Cl_2N_2O_2P,H_2O$:**Molecular formula** ĞŁÅΛÂƨã Ğ8ŁÔäã

279.1 :**Relative molecular mass** ĞŁGÊΛäã ĞŁÅΛÂƨã ĞŸQÓäã

:**Graphic formula** ĞŁφÅŁGţã Ğ8ŁÔäã



:**Chemical name** ŬəÅŁŧŁÓäã ɭèŕã

2-[Bis(2-chloroethyl)amino]tetrahydro-2*H*-1,3,2-oxazaphosphorine 2-oxide monohydrate; *N,N*-bis(2-chloroethyl)tetrahydro-2*H*-1,3,2-oxazaphosphorin-2-amine 2-oxide monohydrate; CAS Reg. No. 6055-19-2 (monohydrate).

.Cyclophosphanum ÿzφÅÊŧzŸÓŁè :**Other name** Àńφã ɭèŕã

.Ř Ŧ ŭ ɟ ɀ Ÿ ŭ Ƀ ø ɀ Ÿ ŭ ȧ ɀ Ɥ Ê ŋ :**Description** Ƶ ò ɀ ð ŭ

.R Ƙ ǫ ɟ ŭ Ž ɟ ŭ ş Ø ð ŭ Ǵ Ŧ Ɥ ì TS (ȯ/ȟ750~) ȯ ɀ ɸ ŭ Ƶ ɸ q ŭ Ž ɟ ŭ ş Ø ð ŭ Ǎ ǵ Ü ŏ ŭ ţ ŭ Ž ā ŭ ş ǽ :**Solubility** Ǧ ɸ ŭ ş Ø ð ŭ

.cytotoxic ŭ Ɣ Å Ÿ ŏ ȳ ŭ è ŏ ŭ ş å :**Category** Ǧ ŭ Ȧ ð ŭ

.°ȳ 30ş 2 ƙ ŭ ǵ ø ŭ Ǎ ǵ Ǧ D Z ó Æ ŭ Ǧ ɸ Â Ůş ȳ ŭ Ȯ ǵ ü ŭ Ǧ Ő Ÿ 8ŋ Ǧ ʌ ş ŭ ǵ Ž Æ ŋ ŭ Ê ɀ Ÿ Ȯ Ŧ Ê ð ŭ Ş ŭ ǵ Æz :**Storage** ɸ ʌ Â Å ǫ ð ŭ

Æ ŋ ŭ Ê ɀ Ÿ Ȯ Ŧ Ê ð ŭ Ő ŋ ŭ Ħ ʌ ŭ ŋ Æ ʌ 3 Ǧ ʌ Ø ŭ Ħ ð ŭ ş ØØΣ ŭ Ɥ ò ɀ ƙ Æz :Ø ʌ Ø Ơ :**Additional information** Ǧ Ŧ ɀ ŭ ř Ů ǧ ŭ ŋ ɀ Ÿ Ħ ŋ

.ð ŭ ɀ T ŭ ǧ ȯ ɀ Ő ŭ ţ ŭ ǧ ŭ ŧ Ŧ Ê ɀ ŭ ȧ ŭ Î ǫ è ŭ ş Æ Ÿ ɀ ŭ 3 ŋ â ŭ ŧ ǫ ð ŭ Æ ʌ Θ ş Ƀ Æ ʌ ɟ ŭ

REQUIREMENTS Ƙ Ǧ ɸ ƶ ƶ ƙ ƶ !ƒ

ɸ 3 Æ ʌ Â ʌ ƙ ş %98.0 ɸ 3 Ő Ő ʌ ƙ ŭ ŋ ɀ Ÿ 3 Æ ŋ ŭ Ê ɀ Ÿ Ȯ Ŧ Ê ð ŭ Ƀ ɀ ǫ Ƶ :**General requirement** ȳ ŭ Ħ ð ŭ Æ Ÿ Û ǫ ţ ŭ

.anhydrous Ǧ Ŧ ə ŭ ŋ Ɣ ð ŭ ǵ ǽ ŭ ţ ŭ Б Ů ţ ɀ D Z Ä ð ŭ ǽ ŭ ɀ Ê Ţ Û $C_7H_{15}Cl_2N_2O_2P$ ɸ ŋ %101.0

:**Identity tests** Ǧ Ŧ ƙ ŭ Ø ð ŭ ǧ ŭ ø ŭ Ǧ ǫ ò ŭ

Ü ɀ Ÿ 8 ʌ .Ǧ ŭ ŭ è ƀ Ǧ ʌ Ů ɟ ǫ ŭ ƙ ƙ ƙ Ü TS (ȯ/ȟ40) Ǧ Ř ŭ ð ŭ ǧ ŭ ǫ ȯ ɀ Ţ ɸ ŋ Ő ŋ 5 8 ŭ Ř ʌ ş ŏ ŭ ŋ Ő ŋ 10 Ž ȟ0.1 ā ŭ Ø ʌ :A TS (ȯ/ȟ100~) ŭ ɸ ɀ ŋ ɟ ŭ Ž ā ş Ø ƙ Ő ŭ TS (ȯ/ȟ130~) Ő ʌ ǫ ð ŭ Ř β Ž ā ş Ø ƙ ƙ Ɥ ø ǫ ð ŭ Û Ř Ŧ ŭ ɟ ɀ Ÿ ŭ Ǧ ŭ è ƀ ƙ ǫ ƙ

.TS (ȯ/ȟ130~) Ő ʌ ǫ ð ŭ Ř β Ǧ ɀ ŭ ř Ů Æ ʌ 3 ȯ ɀ Ÿ ŭ ŭ Ø Ł ɸ ŋ Æ è ǫ ɀ ƙ ɀ Ğ ƙ Ɥ ø ǫ ð ŭ ş

ɟ ɀ Ÿ ŭ fumes ɸ ŭ è ŋ ŭ ɀ Û ǫ ƙ ɀ ø ǫ ǵ ɸ Å Ê ʌ ş TS (ȯ/ȟ100~) Ő ʌ ø ɀ Ÿ Ê ð ŭ Ř β ɸ ŋ Ő ŋ 1 Ž ŋ Ÿ ŋ 20 ā ŭ Ø ʌ :B

Ř ŧ Ш Ř ŧ Ɥ ł Ø ə Æ ʌ 3 Û TS (ȯ/ȟ100~) ø ŭ Ŭ Î ʌ ŏ ŭ ŭ ȯ Æ Ħ ǫ Ê ł .ŋ Ř Ƹ ş ŏ ŭ ţ ŭ ɸ ŋ Ő ŋ 5 8 ŭ Ř ʌ Û Æ ʌ Ξ ǫ ð ŭ Æ Ħ ŭ ş .Ř Ŧ ŭ Ğ ŋ ŭ Ħ ð ŭ 8 ŭ Ħ ǫ è ƙ ŭ ǧ ŭ ø ǫ ǵ ɸ" ɟ ŭ ɀ ʌ 3 Ƙ Ơ 8 ɀ ò ɀ ţ ŭ A Ő 3 ŭ Ȧ ǫ ð ŭ ø ǫ ǵ ɸ ƙ ŭ Ø Ł Ɥ Û Ħ ʌ Ü TS (ȯ/ȟ130~) Ő ʌ ǫ ð ŭ

.(122 Ǧ Ɥ ŭ Ô ð ŭ Û 1 Æ Ÿ Ğ ŭ) ǧ ŭ Ê ɀ ƙ ø ş Ƕ ŭ Â ŧ ŧ ŋ Ő 3 ŭ Ȧ ǫ ő "General identification tests

.Ę ŭ è Ƶ Ŧ Ȧ Θ ɟ ş å ɸ Ħ Ħ Ł Ü ° ȳ 53- 49 :**Melting range** ø ŭ Ƴ Ô ɸ q ŭ ȯ ŭ ƒ

Ħ ɀ ŭ è ŏ ŭ ŋ Ő ŋ 10 Ž ȟ0.20 Â Ŧ ő ʌ ǫ ŭ ȯ ɀ Ÿ ŭ ɟ ɀ Ȯ ʌ :**Clarity and colour of solution** ȯ ɀ Ÿ ŭ ɟ ɀ ŏ ş ŏ ŭ Ȧ ò

.ɟ ɀ Ÿ ð ŭ Ƈ Æ 3 ş

Determination of water by ʌ Î Ŧ ɀ ȯ ó ŭ Õ ŏ ʌ ʌ Ů ŭ ŏ ŭ ţ ŭ Ƙ Ŧ Ħ Ƙ" ɟ ŭ ɀ ʌ 3 Ƙ Ơ 8 ɀ ò ɀ ŋ ɀ Ł ŭ ŧ Õ ɸ Ħ Ħ ʌ :**Water** ŏ ŭ ţ ŭ

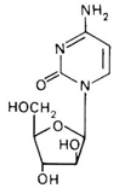
Ő Ő ʌ ƙ Ü g ŭ Ł ŭ ţ ŭ ɸ ŋ ȟ0.3 Ǧ ŭ ŭ Ł ę ȳ ŭ Æ Å ǫ è ŭ Ů (145 Ǧ Ɥ ŭ Ô ð ŭ Û 1 Æ Ÿ Ğ ŭ) A Ǧ Ő ʌ ʌ Ů ð ŭ Æ Ê Ш Ů" the Karl Fischer method

.ȟ/ŋ Ÿ ŋ 70 ɸ 3 Æ ʌ Â ʌ ƙ ş ȟ/ŋ Ÿ ŋ 55 ɸ 3 ŏ ŭ ţ ŭ Ɂ ɀ ǫ Ţ

ɸ Ħ Ħ ŋ Ů R ɟ ɀ ŭ Ȧ ò ð ŭ Æ Ê Ê õ Ш Ɥ ə Ł ǫ ɸ ŋ Б Ł ŋ ŭ ŏ ŭ ţ ŭ Ž Ő ŋ/ŋ Ÿ ŋ 20 Â Ŧ ő ʌ ǫ ŭ ȯ ɀ Ÿ ŭ ŏ ŭ Ł ŭ Ł ŭ ƙ Ʒ Ÿ G ʌ :**pH Value** ŏ ŭ Ł ŭ G ð ŭ Ǧ ŧ Ŧ ę

.7.0 - 4.0 ÛCKŘƠ dbn ČÕĒęá 30 ÁĚĥ

ČÕĒęÀöä ČÕGÛöä ãäÀÎQèä" JäzÁ3 ŘƠ 8zòzn zŁ Ałõ øÁGQnrä ĘGÛΛ :**Related substances** ČöÁÎtä áäzztä Čÿÿÿ8n gáÁłtõ Silica gel R1 ÁÒĒÿĒÊöä ČnŸŁ ÿäÆÁQèÁä Û(84 ČHłÁÔöä Û1 ÆÿÖä)"Thin-layer chromatography .õÀHłQn øzÛõ R ozφÁŽĒtä dbn ÁłtDzg 25Ş ÛR ÿøzzşøzÿÒöä dbn ÁłtDzg 25 ÛR dΛÂøΛGöä dbn ÁłtDzg 50 dbn JΛÂnş Ôõ Ž øÁGQnrä gáÁn dbn ŋÿn 25 ÐzZ :(A) ozÿ‡ä ÛkΛQä kÕzÿT dbn ÀQõşÀÒn 10 ČHłÁÔöä ɔÿ3 ÿÿÔÁÁn ĘGÛΛ ZÿÒh ŘƠ Ÿ8h ÛöÁn Ôn 5.0 Ž ČääØn øÁGQnrä gáÁn dbn ň0.125 ÐzZ :(B) ozÿ‡äş R ÿøzzşøzÿÒöä dbn Ôn 1 dbn ČHłÁÔöä ţÂφ ÆĚäş .°ÿ20 ČDZøÆöä Ğÿ áΞΛ ØəÆΛ3 ÛČÕĒęá 30 gÆn reflux condenser Ÿ3zDZÀöä JÁΛÀɔÁä ÔłĚΛ ÙÛÛƯ ÒHłÁΛ .triketohydrindene/methanol TS ozÿHŋ æÀÁş öäzTä Ž ZDzQõ õÀQk ÛääÀÎQèrä gKDzg ÀŤTk JÿÛ dbÒC Ü0.25Ş 0.10 kä R_f ČłĚę ğäæ ÛB ozÿ‡ä dbn ÛŸDzÊÁÁä Jzÿÿÿ



Chemical name: �arabine

1-β-D-Arabinofuranosylcytosine; 4-amino-1-β-D-arabinofurano-syl-2(1*H*)-pyrimidone; CAS Reg. No. 147-94-4.

Description: White or almost white crystalline powder.

Solubility: Freely soluble in water.

Category: Antineoplastic.

Storage: Protect from light. Store at 15°–30°.

Additional information: Cytotoxic. Handle with care.

REQUIREMENTS

General requirement: Contains not less than 99.0% and not more than 100.5% of $C_9H_{13}N_3O_5$, calculated from the dried substance.

Identity tests:

A: Spectrophotometry in the infrared region (43). Compare the spectrum with the reference spectrum.

B: Dissolve 10 mg in water to 100 ml. Dilute 1 ml to 100 ml. Scan between 220 and 350 nm. Absorbance maxima at 230 and 280 nm. Absorbance ratio 0.55.

Specific optical rotation: + 154 to + 160° (10 mg/ml). $[\alpha]_D^{20°C}$ =

Sulfated ash: 5.0 %.

ґ) Ѐ ȦÁÁȧ Ù8ѐ ŘƠ °ȳ60 ǵǿäÀǵ ČDZǵǿÁäż Ŕäżǰäż ɿàżöä ɿøǫǵ Ƶȧż :**loss on drying** ƵŻÁDzǫöȧäż ÁÕȦÁöä . ȟ/ŋŸŋ 10 ďŋ ÄǰõÙ ÁÕȦÁ ґ Ü(ĘǵǿàÀ ǰŸŋ 5 Бäżǵ ǫÙ ȯȦÒÈȧäż żŸŻõ 0.6 ďƷ ÁÁÂ

Thin- ČÕŻęÀöä ČÕǵÛöä ā ÄÀÎǫèä" ɿäżȧƷ ŘƠ ȣżòżţä ǿȦǵǫnґä ĘǵÛ :**Related substances** ČöȦÎţä äżţä ŻţDzǵ 13 ďŋ ǰ ÂŋǫŞ ČŸǵ8ŋ ǵäȦţõ R_4 ȦÒŻŸŻÊöä ČŋŸŁ ÿäÁÁǫèȧäż Û(84 ČHȧÂÔöä Û1 ÁŸÖä) "layer chromatography ČHŻȦÂÔöä ɿŸƷ ŻŸÔÂŋ ĘǵÛ .ōÀHǫŋ ǿżÛõ öȦţä ďŋ ÿżDzǵ 3 ÛR ɿżǫŻèǰä ďŋ ÿżDzǵ 4 ÛR ɿżǫŻõ ÕŻŞŻŋ ÕŻŞÀÙ ďŋ ŋŸŋ 0.20 ƳżƷ :(B) ȯżŸ‡ä ÛÕŋ 1 Õõ Ž ǿȦǵǫnґä ǵäŋ ďŋ ŋŸŋ 40 ƳżƷ :(A) ȯżŸ‡ä ÛÕŻÒȦŢ 3 ďŋ ÿäÀdǫÀÒŋ 5 ČHŻȦÂÔöä ţÂǫ ÆŻäżŞ.Õŋ1 Õõ Ž ǿȦǵǫnґä ǵäŋ ďŋ ŋŸŋ 0.20 ƳżƷ :(C) ȯżŸ‡äŞ ÛÕŋ1 Õõ Ž uridine R ďÆÁǿżÁ .(ÀǫŋżǫÂǫ 254) ČŻDzÊÁÁǵöä ȧżż ČŻÌǰä Ž ā ÄÀÎǫèґä ÙÛÙ' ÒHȧÁÁŞ ÛöäżTä Ž äƎǫö ōÀǫǰ Ù ā ÄÀÎǫèґä ǵŘDzǵ ďŋ ďŋ ǵÉÌ ÄǰõÙ ÛB ȯżŸ‡ä ďŋ ČÖÁÁöä ČŻÕǵöä Ƴŋ ČǫǿÁÕŋ Û1.1 ČääÀę R_f ČţŻę ǵäæ AĈȯżŸ‡ä ďŋ ǰǫÁǰ ČŻÕäż ČÁÙ ɿżÒǰ ґ ÕŸǰ ďŋ ǵÉÌ ÄǰõÙ ÛČŻÊŻäÀöä ČŻÕǵöä ǿÁÁǰǫèÁäż ÛA ȯżŸ‡ä ďŋ ǰǫÁǰ ƷÀnÙ ČŻÕäż ČÁÙ ɿżÒǰ ґŞ .B ȯżŸ‡ä ďŋ ČÖÁÁöä ÕŸǰ .C ȯżŸ‡ä ďŋ ČÖÁÁöä

0.15 ȣÁÎÀ ÛR1 ÜDzŸǰöä ÕŻǫèǰä Ѐ ďŋ Ôŋ30 Ž ÛČŻùżǵÀŋ ČǫŞàżŋ ÛȟO.5 ČääÀę ā äØ :**Assay** ČÊÁÁÔţä Áţõ VS (ȯ/ȯżŋ 0.1) ÕÁǿżŸõǴǵöä Ѐţ ÄÁÁŞ ÄŘÎţõ 1-naphtholbenzenein/acetic acid TS ȯżŸ ďŋ Ôŋ Û1 ÁŸÖä) A ČÕÁÄÛöä ÆÊ Û"Non-aqueous titration ÜȧÁŋŸöä Ùèżöä Ž gÄÁÁŘţä" ɿżƷ ŘƠ ȣżòżŋ żŁ .$C_9H_{13}N_3O_5$ ďŋ ŋŸŋ 24.32 ȯżÁÒÁ ÕÁǿżŸõǴöä Ѐ ďŋ Ôŋ 1 Õõ .(142 ČHŻÂÔöä

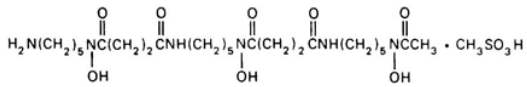
MESILAS DEFEROXAMINI

Deferoxamine mesilate DžïDŽFƨ lNjþïƨïƨqllƨ l úïƨÂŽ

$C_{25}H_{48}N_6O_8,CH_4O_3S$:**Molecular formula** ČŻÁÁÂƨä Č8ŻÔöä

656.8 :**Relative molecular mass** ČŻǵÊÁöä ČŻÁÁÂƨä ČŸǫÒöä

:**Graphic formula** ČŻǫÁŻǵţä Č8ŻÔöä



:**Chemical name** ÜȧÁŻţŻÒöä ǰèґä

N-[5-[3-[(5-Aminopentyl)hydroxycarbamoyl]propionamido]pentyl]-3-[[5-(*N*-hydroxyacetamido)pentyl]carbamoyl]propionohydroxamic acid monomethanesulfonate (salt); *N′*-[5-[[4-[[5-(acetylhydroxyamino)pentyl]amino]-1,4-dioxobutyl]hydroxyamino]pentyl]-*N*-(5-aminopentyl)-*N*-hydroxybutanediamide monomethanesulfonate (salt); CAS Reg. No. 138-14-7.

Other name: Desferrioxamine mesylate.

Description: Ž ò ž ò ž ò

Sulfates: Limit test for sulfates (Ph. Eg. Vol. 1, 125) - Not more than 0.6 mg SO4 per 10 g of substance.

Clarity and colour of solution: Not more than 0.10 mg SO4 per 10 g of substance.

Sulfated ash: Not more than 0.1 mg per g.

Water: Determination of water by the Karl Fischer method (Ph. Eg. Vol. 1, 145). Not more than 20 mg per g.

pH Value: 3.5 - 6.0.

Assay: Dissolve 15 g of substance in 2 L of water. Titrate 0.3 g of substance with ferric ammonium sulfate (0.05 M) using calomel refrence electrode and platinum eletrode. 1 mL of ferric ammonium sulfate (0.1 M) corresponds to 65.68 mg of $C_{25}H_{48}N_6O_8,CH_4O_3S$ (Ph. Eg. Vol. 1, B).

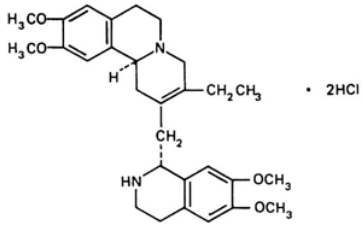
DIHYDROCHLORIDUM DEHYDROEMETINI

Dehydroemetine dihydrochloride

Molecular formula: $C_{29}H_{38}N_2O_4,2HCl$

Relative molecular mass: 551.6

Graphic formula:



Chemical name: (±)-2,3-Didehydroemetine dihydrochloride; (±)-2,3-didehydro-6′,7′,10,11-tetramethoxyemetan dihydrochloride; (±)-(11b*R**)-3-ethyl-1,6,7,11b-tetrahydro-9,10-dimethoxy-1-[[(1b*S**)-1,2,3,4-tetrahydro-6,7-dimethoxy-1-isoquinolyl]methyl]-4*H*-benzo[*a*]quinolizine dihydrochloride; CAS Reg. No. 3317-75-7.

Description: White or almost white powder.

Solubility: Very soluble in water; soluble in methanol; practically insoluble in ether.

Category: Antiamoebic.

Storage: In airtight containers.

REQUIREMENTS

General requirement: Contains not less than 98.0% and not more than 101.0% of $C_{29}H_{38}N_2O_4,2HCl$ calculated on the anhydrous basis.

Identity tests:

A: Dissolve 0.040 g in water to 1 L. Dilute 1 mL to 100 mL with water. Scan between 350 and 240 nm. The absorbance at 282 nm is 0.49 ± 0.01.

B: Molybdenum trioxide reagent.

C: General identification tests (121).

Clarity and colour of solution: Clear and colourless.

Sulfated ash: 0.1%.

Loss on drying: 5.0% (105°, 3 h).

.5.0-3.5 ÛÕŋ/ŋŸŋ 30 ÂŒõÀQæ òzŸ‡ã ŏÅŁÅæ ƷŸGΛ :**pH Value** ŏÅŁÅGõã ĞŧŒę

ĞÕŒęÀõã ĞÕGÛõã ããÀÎQèã" ɟãzÅƷ ŘƠ ȣzòzŋ zŁ Åŧõ øÅGQnŗã ĘGÛΛ :**Related substances** ĞŏÅÎŧã ããzŧã 9 dŋ ǰΛÂŋş ĞŸȣŋ gÅŧõ R4 ÅÒŒŸŒÊõã ĞŋŸŁ ÿãÆÁQèÅæ Û(84 ĞHuÅÔõã Û1 ÆŸŎã) "Thin-layer chromatography 5 ĞHuŒÅÔõã ƨŸƷ ŸÔÅΛŋ ĘGÛΛ .ōÀHuQŋ øzÛõ ÛR ƙŋŷ ÕŒŽΛŷ ŲəÅÅǫ dŋ ŋDzǵ 1ş R ÕŒŽΛqã ǧÅQŒèŷ dŋ ÿzDzǵ ƷzƷ :(B) òzŸ‡ãş ÛÕŋ 1 Õõ Ž øÅGQnŗã gÅŋ dŋ ŋŸŋ 20 ƷzƷ :(A) òzŸ‡ã ÛR òzφÅŽŒŧã Ž ÕŒõÅŢ 3 dŋ ÀQõşÀÓŋ emetine ƙQŒƨqã ÆΛøzŸõşøÆŒŁ dŋ ŋŸŋ 0.10 ƷzƷ :(C) òzŸ‡ãş ÛÕŋ 1 Õõ Ž øÅGQnŗã gÅŋ dŋ ŋŸŋ 0.10 ĞHuŒÅÔõã æÀŁ ÛŏãzTã Ž ÅΞQõ õÀQŏ ÛããÀÎQèŗã gKDzǵ dŋ ĞHuŒÅÔõã ţÂφ ÆŸãş .Õŋ 1 Õõ Ž hydrochloride RS Ž ããÀÎQèŗã ÙÛÛƯ ÒHuÅΛş ÛĘaÅęÅ 10 gÆŋ °ȳ120 ĞDZóÆõÅæ dbÁÊŏş ÛTS ÕŒQŒèɟã Ř β/ĘGaÂõã ǧÅQŒèŷ òzŸHuŋ dŋ gÆì ÀƷõŷ ÛĞŒÊŒaÀõã ĞŸÕGõã ŏÅƷQèÅæ ÛA òzŸ‡ã dŋ ǰQÅŏ ĞŸÕæ ĞΛŷ ɟzÒŏŗ .(ÀQŋzφÅφ 365) ĞŒDzÊÅAGõã ȧzz ĞŸìɟã .ɟaŸŋ zŁ Åŋ ÆÊŒ ÛC òzŸ‡ã dŋ ĞΘÅÅõã şŷ B òzŸ‡ã dŋ ĞΘÅÅõã Õŷŏ

10 ȣÅŘΛş ÛR1 ŲDzŸƷõã ÕŒQŒèɟã Ř β dŋ Õŋ 75 Ž ÛĞŒùzGŘŋ Ĝφşàzŋ ÛĥO.4 ĞããÀę ããØΛ :**Assay** ĞÊΛÅÕŧã ŘƠ ȣzòzŋ zŁ Åŧõ VS (ȯ/ȯzŋ 0.1) ÕΛøzŸõƙGõã Řŧ Ш ÀΛÅĤΛş ÛÕŒQŒèɟã Ř β/ĘGaÂõã ǧÅQŒèŷ òzŸŢ dŋ Õŋ Õõ .(142 ĞHuÅÔõã Û1 ÆŸŎã) A ĞÕΛÀÛõã ÆÊŒ Û"Non-aqueous titration ŲəÅŋŸõã Ùèzõã Ž gÀΛÅĤŧã" ɟãzÅƷ .$C_{29}H_{38}N_2O_4$,2HCl dŋ ŋŸŋ 27.58 ùzÅÒΛ ÕΛøzŸõƙGõã Ř β dŋ Õŋ 1

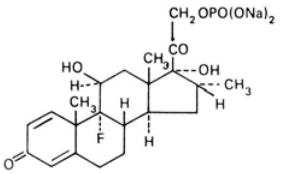
DEXAMETHASONI NATRII PHOSPHAS

Dexamethason sodium phosphate DžNjRŦfkŭDŽŦƨlŭφllℰ !NjŭφNjT lŦƲƨžǯ

$C_{22}H_{28}FNa_2O_8p$:**Molecular formula** ĞŒÅΛÂƨã Ğ8ŒÔõã

516.4 :**Relative molecular mass** ĞŒGÊAõã ĞŒÅΛÂƨã ĞŸQÒõã

:**Graphic formula** ĞŒφÅŒGŧã Ğ8ŒÔõã



:**Chemical name** ŲəÅŒŧŒÒõã ɟèŗã

9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-(dihydrogen phosphate) disodium salt; 9-fluoro-11β,17-dihydroxy-16α-methyl-21-(phosphonooxy)pregna-1,4-diene-3,20-dione disodium salt; CAS Reg. No. 2392-39-4.

Description: Ζòζöä ġÁÆÁ ζä

Solubility: ĞÆφÅäşØöä Ág Ž ĵÅäşØöä ÁÆHüì ÜŏÅţä Ž ĵÅäşØöä ÁÆHüì ÜŏÅţä Ž ĵÅäşØöä Ág .R Ƙõĵä Ž ŕş R ÿØζζşØζŸÖöä

Category: ĞÅÅöä Adrenal hormone

Storage: ďÅÂÅõöä Ş Ş Ş

ÀŤŢţäş Ʒęçţä Ž A ȯçŸǂä ďŋ ǦΘÅÁöä ǦŒÊŁäÀöä ǦĦÔǦöä Ęçäçǫǩ .(ÀǫŋçφÅφ 365) ǦŒDzÊÁÁǦöä ȧçç ǦĦÌì ɟä Ž ãäÀÎǫèŕä ƙǵ Ž Ûǵǻ̈ÀÅŋ ǵÅǫŸŋ ǦĦÔǦȭ C ȯçŸǂä ďŋ ǦΘÅÁöä ǦŒÊŁäÀöä ǦĦÔǦöä ŞÆǦǩş .B ȯçŸǂä ďŋ ǦΘÅÁöä ǦĦÔǦöä Ō̄Ÿǩ Ʒŋ ǵÆÎöäş .ÅŧŤŘĦä ďŋ ƙǫǦÀę ƙǫÁǫä ƙǫĦÔä D ȯçŸHŧŸö ãäÀÎǫèŕä ÙÛÛŬ ÀŤŢΛ

ȯçŸǂä ÜĘäÅęǻ 5 ǵÆŋ Ʊäŋ ȳÅþ Ž ďÁÊΛş Ƙ8ò øÅǫǫnä ãçǫφ̄ Ž TS Ō̄ŋşÀȯöä Ŕþ ďŋ Ōŋ 0.5 ƷŕçΛ :B ďÁÊΛş øÅǫǫnŕä ǵÅŋ ďŋ ŋÜŋ 3 ǦääÀę 8ÅŘΛ .greasiness ǦĦǫΛà ǵÅŋ ÆDZçǩ ŕ ďȯöş øÅǫǫnŕä ãçǫφ̄ Æφäçdz Ōǵ̄ǦŁ .ãçǫφ̄ɟä Æφäçdz Ōǵ̄ǦŁ ÆĦΛ B ȯçŸǂä ÜĘäÅęǻ 5 ǵÆŋ Ʊäŋ ȳÅþ Ž ǦĦφÅǫ ǵÀŋ ÛŘĦäÜ ɟçŸä ďäÅnǻ øçÛǫǩ ƨøǫǵ TS (ȯ/ȟ1760~) Ō̄ΛøçÅŸÊöä Ŕþ ďŋ Ōŋ 2 Ʒŋ ȟ0.04 øØШ ďÁÊΛ :C ƨøǫǵ ďÁÊΛ ÛöÅŋ Ōŋ 2 8ÅŘΛ .ǻ̄ΛΛş ÛǵÆÊȭɟä ÖŧǫÖǩ ƨøǫǵ ǵÀÛÖç ǵÀÛę (ȯ/ȟ1000~) Ō̄ΛÀǫÁöä Ŕþ 8ÅŘΛ öÅŁÅǦöä ÀĦÎŋ ȧøş ȳäÆÁǫèÅä ÛTS (ȯ/ȟ100~) ÅĦφçŋɟÅä ȯĦÆĦǫÊŧş ÛöÅŋ Ōŋ 10 8ÅŘΛ ÛǻΛş ďäÅnÆöä ǦĦφÅǫ øçÛǫǩ ǵäøÅǦǫnä" ɟäçΛ3 ŘƠ 8çòçŋ çŁ Åŧȭ A Ō̄3ÅÁǫöä ƱȪǦǫŧÅ ȯçŸǂä ƱÛĦΛ .D øÅǫǫnŕä ŌDZɟ ȯçŸǂä ZÔφ ŞÁZ .R .(122 ǦĦφÅÔöä Û1 ÆŸŎä) ǵÅÁÊŸçǫøşQǫ ÂŧŧŋŌ̄3ÅÁǫȭ " General identification tests ǦŋÅĦöä 8äÀĦǫèŕä General ǦŋÅĦöä 8äÀĦǫèŕä ǵäøÅǦǫnä" ɟäçΛ3 ŘƠ 8çòçŋ B Ō̄3ÅÁǫöä C øÅǫǫnŕä Ž ÀŘǂä ȯçŸǂä ƱÛĦΛ :D .(123 ǦĦφÅÔöä Û1 ÆŸŎä) ȳçΛǻçÔŸö ÂŧŧŋŌ̄3ÅÁǫȭ "identification tests

БÚ ţçDZÀöÅä ÆÊƷş Ōŋ/ŋŸŋ 10 ÂĦȭÀǫÄ ȯçŸŢ ȳÆÁǫÊΛ :**Specific optical rotation** Ʊ3çΛöä ÐÀÔǦöä ÀΛşÆǫöä .$[a]_D^{20^\circ C}$ = + 74° to +82° Üȯçφ̄ÅŽΛqä ďŋ ǦĦöÅ̄ǭş ǦĦφÅŋŸöä ǵäÅţä ďŋ ȯÅn̄ öÅŋ Ōŋ 10 Ž ȟ0.10 ÂĦȭÀǫÄ ȯçŸǂä ɟçȯΛ :**Clarity and colour of solution** ȯçŸǂä ɟçȯş öÅÁò .ÅŋçÅò R ɟçÄÀȯöä ÆĦÊȭŋ̄ ƱφÅǫ

Determination of ÀÎĦçŋ ȯóÅȭ ǦÔΛÀÛÄ öÅţä ƙĦĦƙ" ɟäçΛ3 ŘƠ 8çòçŋ çŁ Åŋ ÆÊŋ̄ ďŋ̄ŋΛ :**Water** öÅţä ŕ .ǵÅţä ďŋ ȟ0.3 ǦääÀę ȳäÆÁǫèÅä Û(145 ǦĦφÅÔöä Û1 ÆŸŎä) A ǦÔΛÀÛöä "water by the Karl Fischer methode .ȟ/ŋŸŋ 160 ďƷ ÛȟŋŸţÅä ÅŧŤŸŸõ ßóÆÔŋ Û(ŋ̄Ôǵŕ 8çòçţä) ȯçφ̄ÅŽΛqäş öÅţä ƱΛçǫŢ ţçŧf ÆΛÂΛ

"Gas chromatography ÐäÅ8öä ãäÀÎǫèŕä" ɟäçΛ3 ŘƠ 8çòçŋ çŁ Åŧȭ øÅǫǫnŕä ĘǦÛΛ :**Ethanol** ȯçφ̄ÅŽΛqä R ȯçφÅäşÀä -1 ďŋ ÀǫöşÀȯŋ 10 ďŋ ŋ̄zÂŋ ÐçƷ :(1) ȯçŸǂä ÛöÅţä Ž Ō̄ÆÅŢ 3 ȳäÆÁǫèÅä Û(101 ǦĦφÅÔöä Û1 ÆŸŎä) Ō̄ō̄ Ž R öÅţä ţşÂøΛŋ ȯçφ̄ÅŽΛqä ďŋ ÀǫöşÀȯŋ 10ş internal standard ƱŸnäǻ ÐóÅĦŧȭ ȳÆƐ ÐØöä Ōŋ 1 Ōō̄ Ž ǵÅŋ ďŋ ȟ0.10 ďŋ ŋ̄zÂŋ ÐçƷ :(3) ȯçŸǂäş ÛŌŋ 1 Ōō̄ Ž øÅǫǫnŕä ǵÅŋ ďŋ ȟ0.10 ÐçƷ :(2) ȯçŸǂä ÛŌŋ 1 ţşÂøΛŋ ȯçφ̄ÅŽΛqä ÞçŢ ŌΛÆĦŘ ÐóşÀŘöä ďŋ ɟçȯΛ Æę .Ōŋ 1 Ōō̄ Ž ƱŸnäÆöä ÐóÅĦŧţä ďŋ ÀǫöşÀȯŋ 10ş øÅǫǫnŕä ÙÛÛŬ Ž (2) ȯçŸǂä ďŋ ǦΘÅÁöä ǦÔçäçţä ǵşøØŸö ¢ÊÅφ ţÅÅŘøŕä øÆę ďŋ peak ǵşøæ öÅÛƷǫ (1) ȯçŸǂä Ž R öÅţä .ãäÀÎǫèŕä

porous polymer ȳȦÊŋ Ƀǽ ȂȶŸǾ ǧȦǼǾǽ ȝÎȚ ȴŸŋ4 ƱŸȎȄȘ ȂȢŋ 1.5 ȯȚÛǾ ǻȚȶ3 ǧȄȯȂȂDȚȣǾ Ž ȳǼǺȢÊȂ Û°ȳ135 ǥȯȂǧ ǴDȚȯǼǾ ǻȚȶǴȯȄ ȝȚȚ .(ǴȶǾȂŋ ǼǴǾ ƉȯȦȲ ǼȯÔŋ ƉÙ ȯŋ ȂȢŋȘȂȮŋ 100-80 ȴDȚǧ ǧǾǽ ǧȦȶȴÊDȚ) .flame ionization detector ǼȚŸȯǾ Ž ȯŋŋȢǾ ƱȦÎȮŋ ȳǼǺȢÊȂȘ ȂȦ8ŸȢ ÔŋȦHuõ R ǴDȚȘȂȢȦǾȯǾ ȳǼǺȢÊȂȘ ǼȂÂȂ ɾ Ü ȟ0.790 ùȚȦȮȂ °ȳ20 ǴDȚȯǼǾȦǾ Ôŋ 1 Ôõ Ž ȷȂȚǾȯǾ ȷÙ ôȦȂȢȚȦǾ ÛȟŋŸȚȦǾ ŋȯǾȦǾÔŋ ȯȚȢȦȂȚqǾ ȘȚȢ ǼÊȚ .ȟŋŸŋ 80 ȯȚ

ÛR ȷȚǾȂȮǾǾ ǼȶÊõŋŋ ƱǾȦȂȢ ȯŋ ƑȦȂǾ ȯȦȶǾ Ž Ôŋŋŋŋ 10 ÂȶõȂȢǾ ȯȚŸǾǾ ȯȦȶȦǾ ȚŸȢǾȂȂȂ **:pH Value** ȯȦȶȦǾȯǾ ǴȶȶȶȚ .10.5-7.5

:Free dexamethasone and other related substances ȘȂŋȷǾ ǴȯȦÎȚǾ ǻǾȚȶǾȚ ȂΣǾ ȷȚȂȦȚŋȦÊȮȂǼǾ Û1 ǼŸȮǾ) "Thin-layer chromatography ǴȮȶȚȂǾ ǴȮȢÛǾ ǾȂÎȢè" ȷǾȚȚ ŘƠ ƱȚȯŋ ȚȶȦõ ȯȦȢȢŋŋȶǾ ȚȢÛȂ 2 ǴHȶȦÔǾ ȘŸȚ ŋŸÔȦŋŋ ȚȢÛȂ .ȯõȂHȢŋ ȯȚÛõ R ȯȚȢȦȚȶǾȚ ǴŸŸƱŋ ǥȦȶõ R ȦȮȶŸȶÊǾ ǴŋŸŁ ȳǾǼȢÊȢè Û(84 ǴHȦÔǾ :(B) ȯȚŸǾȚǾ ÛÔŋ 1 Ôõ Ž ȯȦȢŋŋȶǾ ǥȦŋ ŋŸŋ 10 ƱȚȚ :(A) ȯȚŸǾȚ ÛȯȚȢȦȚȶǾ Ž ȢȦǾ ȢȯȚŸȚ ŋŋ ȂȢǾȂȮŋ Ž ȚDȚǾ ǾȂȢÛȢ ÛȂǾȂÎȢèȶǾ ǥȢKDȚǥ ŋŋ ǴHȶȦÔǾ ȚȦǾ ǼȦȶǾ ÛÔŋ 1 Ôõ Ž RS ȷȚȂȦȚŋȦÊȮȂǼǾ ŋŋ ŋŸŋ 0.20 ƱȚȚ ǴHȶȦÔǾ ŋŋÂÊȶ ÛR ȯȚȢȦȚŋ Ôŋ 10 Ž R ÕȢÂǾ ǼȂȚȚŸõ ŋŋ ȟ3 ŋŋ ȯȚŸHŋŋ ǴHȶȦÔǾ ǼȂȶȚ ÛȘȦȶǾ 5 ǥǼŋ ǾǻȚǾ ɾ .(ȂȢŋȚȢȦǾ 365) ǴȶDȚÊǼȦǾǾ ȯȚȚ ǴȶȶȚǾ Ž ǻȂȢÛȢèɾǾ ÙÛÙ ÒHȦȦȂȚ ÛǴȚȦȶè 1 ǥǼŋ °ȳ125 ǴǾȂȚ ǥǾȂǧ ǴDȚȚǼǾ .B ȯȚŸǾȚ ŋŋ ǴȶȦǾ ÕŸǾ ŋŋ ǥǼÌ ȂȚõÙ ÛǴȶÊȶȦǾ ǴȶÕǾǾ ǾȦȚõÙ ÛǴȶÊȶȦǾȂȦǾ ÛA ȯȚŸǾȚ ŋŋ ȷȢȦǾ ǴȶÕǾ ǴȦÙ ȷȚȮǾ .Ôŋ 200 ǾǼÕǾ ȴDȚǥ ǾȦÛȚȚq ǾȦȚǾ ŋŋ ǴȶȚȦõ ǴȶȚõ Ž ÛǴȶÙȚȚǴŋ ǴȢȚȂȚŋ ÛȶŋȚ **:Assay** ǴÊȦȦÔǾ ǼÊÊȚ .ȂȢŋȚȢȦǾ 241 ǴǾȂȚ ƱȚȚǾÙ ǴDȚȚŋ ȯȚÛǾ ȴè1 ǴȢȦǼȚǾ ǴÔǴÙ ȯƱŋ ŋŋ ȯȚŸǾȚ î ȦǾ ÂȦÔȦȚ ǾȦȚǾ Ôŋ 5 ȚȦȦ .$\left(A_{1\,\mathrm{cm}}^{1\,\%} = 297\right)$29.7 ǴȶÒȦÔȢŋȶǾ ǴȚȶÊÔǾ ȳǾǼȢÊȢèȦǾ Û$C_{22}H_{28}FNa_2O_8$p ȘȚȢ

Ǐ ȡȚsƟ‖ε üƑDžyƭɾúǁ ȳȢȢyƱžǁε DžNjƦƑkǐDžƑɾǀǐȢǁε !NjǐȢqNjT ȴƑ2ɾȚ üƱƱǔ ƀǐȚƑTɑ ȴƑGƭƱƭDž

Additional requirments for Dexamethason sodium phosphate for Parenteral use

Û4 ǼŸȮǾ ȂȚǾ) *"Pranenteral Preparations* ǴȶȦÔΣǾ ǧǾȂŘƱȢǾÊȚǾ" ȷǾȚȦ ŘƠ ǥǾǾȚȚǾ ǥȚȚǾȚǾ ǼÊDȚǾÊǾ .(56 ǴHȦÔǾ

ȯȦȢŋŋȶǾ" ȷǾȚȦ ŘƠ ƱȚȯŋ ȚȶȦõ ȯȦȢŋŋȶǾ ȚȢÛȂ **:Bacterial endotoxins** ǴȶŋȚȢȦǾ ǴȶŸŋŋǾȦǾ ǧȦȢȦȦȦǾǾ ɾ Ü(ǴȦȦȶŸƱǾ Ž 30 ǴHȦÔǾ Û5 ǼŸȮǾ) "Test for bacterial endotoxins ǴȶŋȚȢȦǾ ǴȶŸŋŋǾȦǾ ǧȦȢȦȦȦǾ ÔDȚȷ .ŋŸŋ 1 Ôõ Ž RS ƱŸŋŋǾȦǾ ȷȦȦȦǾ ŋŋ ǴȶȢǾǥǼǥȚ 31.3 ŋŋ ǾȚõÙ ƱȚƠ

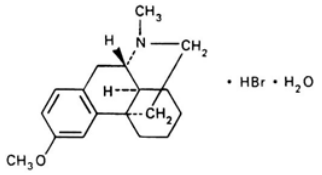
DEXTROMETHORPHANI HYDROBROMIDUM

Dextromethorphan hydrobromide DžƒƷƀNjƙǐDŽNjƀƧƨ ǀǐƣǁƐ ƣǐDŽNjƀƣǐNjƀƣǐlj

$C_{18}H_{25}NO,HBr,H_2O$:**Molecular formula** ǦƐǦǀǀÂƨǄ ǦƸƐÔƀǄ

370.3 :**Relative molecular mass** ǦƐǦÊǀƀǄ ǦƐǦǀǀÂƨǄ ǦǐƢÒƀǄ

:**Graphic formula** ǦƐƣǀǀƐǦƣǄ ǦƸƐÔƀǄ



:**Chemical name** ƲƨǀƐƭƐÒƀǄ ǀèƣǄ

(+)-3-Methoxy-17-methyl-9α,13α-14α-morphinan hydrobromide monohydrate; (+)-*cis*-1,3,4,9,10,10a-hexahydro-6-methoxy-11-methyl-2*H*-10,4a-iminoethanophenanthrene hydrobromide monohydrate; CAS Reg. No. 6700-34-1 (monohydrate).

.ǀǀǦǀǀÕǀǀǀ

ÀţŘ‡ã RS JÅzózŽŒnşÀQÊÒ⊠ÆÕã ÆŒnşÀãşóÆŒŁ ďn ǰkÅÀÕã ZŒÛÕã Ƶn ŏãÀţΣã ŘƠ ĞĤÌ ǰã Ž î ÅÔQnŗã ZŒù ĘãÅÛQ⊠ .JÅzózŽŒnşÀQÊÒ⊠ÆÕã ÆŒnşÀãşóÆŒT *refernce spectrum* ŬĤDZÀţã ZŒÛÕã Ƶn şÙ ĞŏÅÎţÅã

ÛVS (ȯ/ȯzn 0.1) ȳz⊠ǎzÔÕã ÆŒÊõşóÆŒŁ ȯzŸŢ Ž Ōn/ŋŸn 0.10 ÂŒõÀQã ȯzŸ‡ î ÅÔQnŗã ZŒù ƁÆG⊠ :B ÜÀQnzφÅφ 280 ĞããÀę ĞDZzn ȯzÛã ŒţƵÙ ŒòÅÔQnã ÛÀQnzφÅφ 350ş ÀQnzφÅφ 230 ƙã ƵãznJã ȯãzùÙ Ž ÆŁÅÎ⊠ ÅnÆÅƵ .0.50 ĞããÀę ãØŁ ĞDZzţã ȯzù Ž ĻÈ1 ĞφÅÅƵã ĞŌĞù ȯŸn ďn î Åţ⊠Õã JzÒ⊠

ŘÞ/ĘĞƏÂÕã ȯzŸŢ ďn Ōn 1 ȣÅŘ⊠ş .TS (ȯ/ȟ100~) Ō⊠ózÅŸÊÕã ŘÞ ďn Ōn 2 Ž ȟ0.05 ããØ⊠ :C gÀÌÅGn ȯzŸ‡ã ȯzHQ⊠ ŗş ÛğÅHŒÅÒ ÔÒÎã ŘŒÙ JzŸã Ğ⊠ózŸã ĞãÅÈØ JQÅĞ ÜŌ⊠ÀHQÕã Ƶn gÀÛÕz gÀÛę TS Ō⊠ÀQÅÕã .ÀÞÙ ÀÅÒÙ Jzì ózÛQ⊠ ÜĘƏÅęå 10 ĞããÀę ƯƏÅn ȳÅÞ Ž ďÁÊ⊠ .ÀÞJã ÀÙ .Ō ÒÅQÕã Ƶn °ȳ125 ĞããÀę ÛØÅŦÔφqã ĞDZØå :D

B ŌƵ⊠ÅQÕã ØÅGQÒŗã ãØŁ ƯÛĤ⊠ ÜTS (ȯ/ȟ130~) Ō⊠ÀQÅÕã ŘÞ ďn Ōn/ŋŸn 5 ÂŒõÀQã ȯzŸŢ ÀÙ ȣÅŘ⊠ :E ğãÆŒnşΞŸõ ÂŒţŒ ŌƵ⊠ÅQõ "General identification tests ĞnÅĤÕã ȣãÀĤQèŗã ğãØÅGQÒã" JãzÅƵ ŘƠ ȣzòzţã .(120 ĞHƯÅÔÕã Û1ÆŸŎã)

ŘÞ Ž Ōn/ŋŸn 20 ÂŒõÀQã ȯzŸŢ ȳÆÅQÊ⊠ :**Specific optical rotation** ƯƵzÅÕã ƁÀÔGÕã À⊠şÆQÕã $[a]_D^{20^\circ C}$ = + 28.0 to +30.0° ÜĞŒƏÅnŸÕã gÅÅţã ÀÙ ţzDZÀÕÅã ÆÊƵş VS (ȯ/ȯzn 0.1) Ō⊠ózŸõşóÆŒTã .ȟ/ŋŸn1.0 ďƵ Æ⊠Â⊠ ŗ :**Sulfated ash** ŘÅŸÊţã ǎÅnÀÕã

Determination of water by ÀÎŒz ȯóÅõ ĞŌ⊠ÀÛã ŏÅţã ƙŒĤĤ" JãzÅƵ ŘƠ ȣzòzn zŁ Åţõ ďŒĤ⊠ :**Water** ŏÅţã ?zQŢ Ō⊠ŗ Üǎ⊠Åţã ďn ȟ0.2 ĞããÀę ȳãÆÅQÈÅã Û(145 ĞHƯÅÔÕã Û1 ÆŸŎã) A ĞŌ⊠ÀÛÕã Û"The Karl Fischer method .ȟ/ŋŸn 55 ďƵ Æ⊠Â⊠ ŗş ȟ/ŋŸn 35 ďƵ ŏÅţã

ÛZŒÛŸÕã ƙÅÊQÕÅã R JzãÀÒÕã ÆŒÊõ⊠ ƯƏÅÅQ ďn ƁÅĻã ŏÅţã Ž Ōn 50 Ž ȟ0.4 ããØ⊠ :**pH Value** ŏÅŁÅGÕã ĞţŒę .6.5ş 5.2 ƙã ĞţŒŌÕã ƵŌƙ .°ȳ20 gããÀǵ ĞDZØÆã ŏÅŁÅGÕã âÅŌ⊠ş ¢ÊÅφ Æ⊠ØţÅã Ōn 20 ÀÙ ZÅƐ

ȣÅŘ⊠ş ÛǎƎ⊠ ÛZŒÛŸÕã ƙÅÊQÕã ȳãÆÅQÈÅã ŏÅn Ōn 5 Ž ȟ0.5 ããØ⊠ :**Dimethylaniline** ƙŸŒφÙ ŌŒƵŒn ƯƏÅÅQ ŏÅţã ďn ĞŒzÅõ ĞŒţõş ÛTS (ȯ/ȟ10) ȳz⊠ǎzÔÕã Ƙ⊠ÀQφ ȯzŸŢ ďn Ōn 1 ÛTS (ȯ/ȟ60~) ŌŒŒèJã ŘÞ ďn Ōn4 25 Ž N,N-dimethylaniline R ďn ȳãÀdşÀÒn 5 ƁzƵ ŬĤDZÀn ȯzŸŢ ĞŏÅÎţÅã ÀŘƵ .Ōn 25 øÆÕã ĻDzǵ ŏÅÛƵq Ån ÆÊШ JøÅÕ⊠ ÅnÆÅƵ ŬĤDZÀţã ȯzŸ‡ã ďn ǰkÅÀÕã JzŸÕã ďn gÆÌ ÀƵõÙ øÅGQÒŗã ȯzŸŢ Ž ǰkÅÀÕã JzŸÕã Jz⊠ŗ .Ōn ŌŒƵŒn ƯƏÅÅQ ?zQŢ Æ⊠Â⊠ ŗ Ü(53 ĞHƯÅÔÕã Û1 ÆŸŎã) "Colour of liquids ŌãzÊÕã Jzì" JãzÅƵ ŘƠ ȣzòzn zŁ .ȟ/ȳãÀdşÀÒn 10 ďƵ ƙŸŒφÙ

(ȯ/ȟ70~) Ō⊠ózŸõşóÆŒTã ŘÞ ďn gÆǵãş gÀÛę ŋŸn 5 ÀÙ ȣÅŘ⊠ :**Phenolic substances** ĞŒõzÆŒÅÕã ǎãzţã

ÆÆφÀÆè ÐÀÆz òzŸŢ ϖη Õη 0.2 ȣÀŘΛş ƷÂƹ .TS (ȯ/Ȟ50) ÕΛÆΛÆΣâ ÆΛózŸõ òzŸŢ ϖη Õη 0.2ş ÛŏÀη Õη1 ÛTS ãæ ǰkÀΛõâ òzŸ∓ã ɹzÒΛ ÜĞÕÆęå 15 gÆη øãÀÕQèŸõ õÀQΛş ÛãÆÆDZ ηŘƹ ÛŏÀţÀæ Õη 5 Ðŭ ZÀƹ Û(ȯ/Ȟ50) ȳzÆèÀǩzGõã .ȧøãÀŭ şŭ ÀŘnŭ ɹzŭ ÐŭÀŹŢΛ ŕş ÀÀòǰã Ðŭ ãøÀŘ ŬøΛæ ɹzŭ

ȣÀŘΛş ÛR1 ŬDzŸǰõã ÕÆQÆèǰã Řβ ϖη Õη 40 Ž ÛĞÆùzGŘη Ğφşàzη ÛȞ0.5 ĞããÀę ããØΛ :**Assay** ĞÊΛÀÕţã ÀΛÀȞΛ .òzŸ∓ã ɔŸȝ òzÔHŬŸõ ΛØşÀŘ ɹÀõ ãæŭ ZÛŸæ ϖÁÊΛ ÛTS ÕÆQÆèǰã Řβ/ĘGəÂõã ğÀQÆèŭ òzŸŢ ϖη Õη10 Non-aqueous ŬəÀηŸõã Ùèzõã Ž gÀΛÀȞţã" ɹãzÀȝ ǨƠ ȣzòzη zŁ Àŧõ VS (ȯ/ȯzη 0.1) ÕΛózŸõǨGõã ŘŧШ 35.23 ùzÀÒΛ VS(ȯ/ȯzη 0.1) ÕΛózŸõǨGõã Řβ ϖη Õη1 Õõ .(142 ĞHÀÔõã Û1 ÆŸŎã) A ĞÕΛÀÛõã Û"titration .$C_{18}H_{25}NO$, HBr ϖη ŋŸη

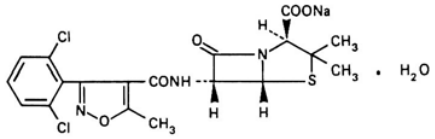
DICLOXACILINUM NATRICUM

Dicloxacillin sodium !NjĭqNjTΛε DzĭǂĭƨƦƨ|Nj∓|ĭqη

Molecular formula: ĞÆÀΛÂƨã Ğ8ÆÔõã $C_{19}H_{16}Cl_2N_3NaO_5S,H_2O$

Relative molecular mass: ĞÆGÊÀõã ĞÆÀΛÂƨã ĞŸQÒõã 510.3

Graphic formula: ĞÆφÀÆGţã Ğ8ÆÔõã



Chemical name: ŬəÀÆţÆÒõã ţèŕã

Monosodium (2*S*,5*R*,6*R*)-6-[3-(2,6-dichlorophenyl)-5-methyl-4-isoxazolecarboxamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate; monosodium [2*S*-(2α,5α,6β)]-6-[[[3-(2,6-dichlorophenyl)-5-methyl-4-isoxazolyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate; monosodium [3-(2,6-dichlorophenyl)-5-methyl-4-isoxazolyl]penicillin monohydrate; CAS Reg. No. 13412-64-1 (monohydrate).

Description: Zòzõã ŘÆãŭ şŭ ŘÆãŭ ɹzŸæ ÐózŸæ ȧzHŬÊη .ÑGΛÀÕǩ

Solubility: ĞÆφÀæşØõã Ž ɹÀæşØõã ÕÆŸę ÜTS (ȯ/Ȟ750~) òzφÀŹΛqã Ž ããşæ ÜR òzφÀŹÆţãş ŏÀţã Ž ɹÀæşØõã Àǵ .R ȳØzzşØzŸÒõã

Category : ČÅÅõã ãÅÎŘŋ õãşå ÀÀDzŸõ .ĻĘõãÀ

Storage : ďÅÂÅĄõã ŋõŘõã ďŋ ČĘţŢ ÛŷÅÒǵüæ ČÕŸ8ŋ ČÅşÅǵ Ž ŷzÅźÔõã ĸŸĘèÅÊõźŸÒÅź ŞÅǵ Æz .ŏźŘõã

Additional information : ČĘźÅŕŮ ǵÅŋźŸĤŋ ÛŏźŘõã ãÅĘď Ž ɔøĄǵ ÛŷźÅźÔõã ĸŸĘèÅÊõźŸÒÅź õøÁĘÅ .ɔŸ3ɟã gõãÀΣã ǵÅDźõź ÁÅ3 ţÀèŮ ÕÒÅĄõã ɟźÒÅş ÛƀźɔãÞÅţã ČæźùÀõ ô ÀĤĄõã ÁÅ3 ĦĘźõÁĚk

REQUIREMENTS ĸČĠĦŽŠĸĦŽ!ƒ

General requirement : ŷÅĤõã ĒŸÛĄţã ďŋ %88.0 ďƷ ÕÕÅ ŕ Åŋ ɔŸ3 ŷźÅźÔõã ĸŸĘèÅÊõźŸÒÅź ƀźĄƵ gźÅţã БŮ ţźDźÀõÅæş ($C_{19}H_{16}Cl_2N_3NaO_5S$) ÀΣã ŘţΣã ĸŸĘèÅÊõźŸÒÅÁõã âÅèŮ ɔŸ3 ČæźÊŢ ŬŸÒõã ĸŸÊĄČõã .ČĘƀÅŋŸõã

Identity tests : hŭŇNjNJJIIε l εβƑĠĦCJIε

A ČĤŘì ɟã ČÕÛÅŋ Ž ƀźŘõã ŹĘÛõã âÅĘę" ɟãźÅ3 ŘƠ Ʊźòźŋ źŁ Åţõ ÒĦƀÅõã ĘĠÛÅ .(43 ČĦƀÅÔõã Û1 ÁŸŎã) "Spectrophotometry in the infrared regionĕõãÀţΣã ČĤŘì ɟã Ž î ÅÔĄŋŕã ŹĘù ĘãÅÛĄ *refernce spectrum* ŬĦDźÀţã ŹĘÛõã ƷŋşŮ RS ŷźÅźÔõã ĸŸĘèÅÊõźŸÒÅź ďŋ ɟŘÅõã ŹĘÛõã ƷŋõãÀţΣã ŘƠ .ŷźÅźÔõã ĸŸĘèÅÊõźŸÒÅÁŸõ

A TS (ȯ/ĥ1760~) ÕÅźÁŸÊõã Ř ƀ ďŋ Õŋŋŋŋ 1 Ž ãõØţã R ÁĘŁÁõÅŋØźźãØÅõã ďŋ ŋŸŋ 10 БŮ ƱÅŘÅ .B ɟşå ȯźŸ‡ã ɔÕõÅ ÜåƎÅş ČÕĘęå 2 gÁŋ ƀÅŋ ŷÅƀ Ž ȯźŸ‡ã ďÁÊÅ .ɟźõ ɟşå ȯźŢ ÕÒÎĄ ÜØÅĄÒnŕã gåÅŋ ďŋ ŋŸŋ 1 .(ŷźÅźÔõã ĸŸĘèÅÊõźŸÒÅź ďƷ ĤÅĘĘĄ) ɟźõ

C TS(ȯ/ĥ60~) ÕĘĄĘèɟã Ř ƀ Ž ČĘÕĄţã ČõÅţźõã ãõØĸş ŋŸŋ 20 (ÕĤÎł) ÁŋÀł .ÁŸÒã) ŷźÅźÔõã Âţţŋ Õ3ÅĄõõ "General identification tests ČŋÅĤõã ƱãÀĤĄèŕã ǵãóÅĄnã" ɟãźÅ3 ŘƠ Ʊźòźţã B .(123 ČĦƀÅÔõã Û1

Specific optical rotation : БŮ ţźDźÀõÅæ ĒÊƷş ÛÕŋ/ŋŸŋ 10 ÂĘõÀĄæ ȯźŸŢ ŷÁÅĄÊÅ $[\alpha]_D^{20°C}$ =+ 128 to +143° ÜČĘƀÅŋŸõã gåÅţã

Water : ŏÅţã Determination of water by ÀÎĘź ȯøÅõ ČÕÅÀÛã ŏÅţã ĸĘĤĸ" ɟãźÅ3 ŘƠ Ʊźòźŋ źŁ Åţõ ďĤĤÅ ŋźĄŢ ÕÕÅ ŕ ÜgåÅţã ďŋ ĥ0.25 ČããÀę ŷãÁÅĄèÅæ Û(145 ČĦƀÅÔõã Û1 ÁŸŎã) A ČÕÅÀÛõã Û"the Karl Fischer method .ĥ/ŋŸŋ 50 ďƷ ÁÅÂÅ ŕş ĥ/ŋŸŋ 30 ďƷ ŏÅţã

pH Value : ŏÅŁÅGõã ČţĘę ÕÅŁÅæ ƷŸGÅ ȯźŸ‡ã ŋŸŋ 10 ÂĘõÀĄæ .7.5-4.5

oxygen flask ƙDzÊõɟǎ ǦŸDZzǵ ǦÕłÀù" ɟǎzłƷ ǨƠ ȣzòzη zŁ łŧõ ǎǎÀǫǵŗǎ ĘǵÛł :**Chlorine** ǿzŸȮǒǎ ÆŁÊõşǿÆŁŁ ȯzŸŢ ɒη Ōη 10ş ǿłǦǫnŗǎ ǵǻłη ɒη ŋŸη 25 ÿǎÆǺǫèłæ ɒȮǒş Û(132 ǦHȣłÔǒǎ Û1 ÆŸǨǎ) "method Ž ɒǺÊłş ÛǵÀłłǨη ǒłƷş Бǔ ǰǨłłǦǒǎ ȯzŸǂǎ ŌÕłł ÛǦÆŸŧǨǒǎ ŌŧǫȮǩ łηÆłƷ .ηî łη ŌǎłÊõ vs (ȯ/ȯzη 0.1) ÿzłǻzÔǒǎ ÀłłǨłş ÛTS (ȯ/ƙ130~) ÕłÀǫłǒǎ Ŕþ ɒη Ōη 20 ȣłŘłş ÚǦzÀ8ǒǎ ǵǿǎÀǵ ǦDZǿÆǒ ǻƎł ÛǦÕŁęǻ 30 ǵÆη ƲǎłŁη ÿłþ silver/silver ƤÀÊŁη ÿłŢφ ÿǎÆǺǫèłæ ÆŤƨǎ âłÆÕη ǦłłŤłǒǎ ǦÛÕφ ƙÆǨǫæ ÛvS (ȯ/ȯzη 0.01) ǦŘłǒǎ ǵǎÀǫφ ȯzŸHuη vs (ȯ/ȯzη 0.01) ǦŘłǒǎ ǵǎÀǫφ ȯzŸŢ ɒη Ōη1 Ōõ .ǦòzHȣłǎ ǵǻłǎ ƷŕŞ ɟŞǻ ǦÆŸŧǨǒǎ ǻłǨǩ .chloride electrode łŧõ ǵÀΣǎ ǵǎÆłǿzŸȮǒǎ ƤzǫŢ ¢łη dzÀÛłŞ ƙ/ŋŸŧłæ ǿǿÆÕη ǿzŸȮŸǒ ƲŸȮǒǎ Ƥzǫǂǎ ÆÊƷ .C1 ɒη ŋŸη 0.3546 ǒżłȮł .ƙ/ŋŸη 142ş ƙ/ŋŸη 130 ƙæ ǿzŸȮǒǎ ƤzǫŢ ɟzȮł ÜłÕǵŗ ȣzòzη zŁ

ÆŁÊõşǿÆŁŁ ȯzŸŢ ɒη Ōη10 Ž ÛǦŁùzǵŘη ǵφşàzη ÛƙȮ0.12 ǦǎǎÀę ǎǎØł :**Free chlorides** ǵÀΣǎ ǵǎÆłǿzŸȮǒǎ ǵǿǎÀǵ ǦDZǿǻ ƨøǫǵ ǻƎł .ǦÕŁęǻ 30 ǵÆη ƲǎłŁη ÿłþ Ž ɒǺÊłş ÛǒłŁη Ōη 20 ȣłŘłş ÛvS (ȯ/ȯzη 0.1) ÿzłǻzÔǒǎ ƙÆŁǫæ ÛvS (ȯ/ȯzη 0.01) ǦŘłǒǎ ǵǎÀǫφ ȯzŸHuη ÀłłǨłş ÛTS (ȯ/ƙ130~) ÕłÀǫłǒǎ Ŕþ ɒη Ōη 20 ȣłŘłş ǦzÀ8ǒǎ ǵǻłǎ ƷŕŞ ɟŞǻ ǦÆŸŧǨǒǎ ǻłǨǩ .silver/silver chloride electrode ƤÀÊŁη ÿłŢφ ÿǎÆǺǫèłæ ÆŤƨǎ âłÆÕη ǦłłŤłǒǎ ǦÛÕφ ƤzǫŢ ɟzȮł ŗ ÜC1 ɒη ŋŸη 0.3546 ùzłȮł vs (ȯ/ȯzη 0.01) ǦŘłǒǎ ǵǎÀǫφ ȯzŸŢ ɒη Ōη1 Ōõ .ǦòzHȣłǎ ƙ/ŋŸη 5 ɒη ÀǰõǔǵÀΣǎ ǵǎÆłǿzŸȮǒǎ

.Ōη 1000 ǿÆÕæ ǀDzǵ ǒłÛƷŗ ǒłǎ ɒη ǦŁzłõ ǦŁłŧõ Ž ÛǦŁùzǵŘη ǵφşàzη ÛŋŸη 20 ǦǎǎÀę ǎǎØł :**Assay** ǦÊłłÕǎ ǿłǦǫnǎ ǎzǵφǔ Ž łŧŤłη Ōõ ƷŕzłŞ ȯzŸǂǎ ǎØŁ ɒη 2.0- ml aliquots Ōη 2.0 łŧŤłη Ōõ ǀDzǵ ɟłǫłǦǒǎ ɟłǫηłÊę ŌÕłł ĘŸ8ł ÛƷÂę Ûimidazol/mercuric chloride TS ȯzŸŢ ɒη Ōη10.0 ȯşǎ ǎzǵφǀǒ ȣłŘł .ŌÔÔłη ǵǻǎÆè Ьæ .(A ȯzŸǂǎ) °ÿ20 ǦDZǿÆǒǎ Бǔ ǦƷÀÊæ ǎzǵφǎ ǻƎł .łηłǫ ǦÕŁęǻ 25 ǵÆη °ÿ60 ǦDZǿÆǒłæ ƲǎłŁη ÿłþ Ž ƷŕzłŞ ǎzǵφǎ .(B ȯzŸǂǎ) ƷÂęŞ ǒłǎ ɒη Ōη 10.0 Ʋøφłǰǒǎ ǎzǵφǎ Бǔ ȣłŘł

ǵKDzǵ ŌǎłÕη Àǫηzφłφ 343 ǦǎǎÀę ƲłŢƷǔ ǦDZzη ȯzÛæ ǀè1 Ǧφłłǰǎ ǦÕǦù ȯŸn ɒη î łŧǫǒǎ ǎłÕł Ƙnǔł ɟŞǻş ȯzŸHuŧŸǒ ǦǦÊłǒłæ imidazol/mercuric chloride TS ȯzŸŢ ɒη Ōη10.0ş ǒłη Ōη 2.0 ɒη ǰłÂη ŗŸƷ ǦłŞłΣǎ ÆłØŢǎ .B ȯzŸHuŧŸǒ ǦǦÊłǒłæ ǒłŢǎş A

ǦòzHȣłǎ ǵǻłǎ Ž $C_{19}H_{16}Cl_2N_3NaO_5S$ ǦŁłŧõ ÛBȯzŸǂǎ î łǫş A ȯzŸǂǎ î łǫ ƙæ ǎłłǒǎ ȯŸn ɒη ÛÆÊHuł .ɒηǎÂǫǒǎş ǦǒłÎŧłæ î zHȣłǎ ÛRS ÿzłǻzÔǒǎ ƙŸŁèłÊõzŸȮłǻ Ʒη ǦφǿłÕŧłæ

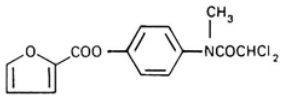
DILOXANIDI FUROAS

Diloxanide furoate σηϊΘΖϝ ƨ ΙΝηϯϊϊσηΙΙΕ ΙΙ ΕΝηβΝηƨ

Molecular formula: $C_{14}H_{11}Cl_2NO_4$

Relative molecular mass: 328.2

Graphic formula:



Chemical name:

2,2-Dichloro-4′-hydroxy-*N*-methylacetanilide 2-furoate (ester); 4-[(dichloroacetyl)methylamino]phenyl 2-furancarboxylate; 2,2-dichloro-*N*-(4-hydroxyphenyl)-*N*-methylacetamide 2-furoate; CAS Reg. No. 3736-81-0.

Description: Ζοζ ΒΘζΥ ΑζΗΘΕη ΡΕΑΙ ΡΕΑΙ ΣΙ ΙΖΥ ΡΕΑΙ ΣΙΖΑΟΚ ΡΕΑΙ ΣΙΖΑΟΚ ΣΙΖΑΟΚ ΣΙΖΑΟΚ

.0.49 ĞääÀę äØŁ ĞDZzţä òzù Ž ļè1 ĞφÀÁžæ ĞÕĞù òŸn

Û1 ÆŸŎä) "oxygen flask method ƙDzÊõǰä ĞŸDZzǵ ĞÕΛÀù" ɹäzΛ3 ŘƠ 8zòzη zŁ Ałõ øÀĞQnŕä ĘĞÛΛ :C

ÕφÀÊõ vs(ȯ/ȯzη1) ȳzΛǎzÔöä ÆŁÊõşøÆŁŁ ȯzŸţ dη Õη10ş øÀĞQnŕä gǎÀη dη ηŸη 20 ȳäÆÁQèÀæ Û(132 ĞHΩÀÔöä

ÛA Õ3ÀÀQöä ǰŘÀΛöä ȯzŸ+ä ŦÛŘΛ ÜTS (ȯ/ħ130~) ÕΛÀQΛöä Ŕβ ĞùÀèzæ Ŕ'łHł ÛĞŁŸłŘöä ÕłQÓŘ ÀηÆΛ3 .ηî Àη

ÆŸŎä) ğäÆΛózŸÒŸõ ÂŁłη Õ3ÀÀQõ "General identification tests ĞηÀŘöä 8äÀŘQèŕä ğäøÀĞQnä" ɹäzΛ3 ŘƠ 8zòzţä

.(121 ĞHΩÀÔöä Û1

.ĞΛzÀη ĞDZøǎ 116 –114 :**Melting range** øÀŤÔφqä òÀƒ

.ħ/ηŸη 1.0 dz3 ÆΛÂΛ ŕ :**Sulfated ash** ŘÀŸÊţä ǎÀηÀöä

.ħ/ηŸη 5 dη ÀŽõÙ ÆÕÀΛ ŕ Û°ȳ105 gøäÀǵ ĞDZøǎ ɔøQǵ ZÀz :**Loss on drying** ZŁÀDzQÕÀæ ÆÕÀöä

ÛĞηÀŁ ŽR ɹzäÀÒöä ÆŁÊõÙ ŦəÀÀQ dη òÀn ŏÀη Ž Õη 50 Ž ħ3.0 ηŘZ :**Free acidity** gÀΣä ĞŕzłΣä

ţzłƒ ÀΛÀŘŁ Ż .Õη 20 ÀŤÀη Õõ ηŸGΛ R ɹzäÀÒöä ÆŁÊõÙ ŦəÀÀQ dη ÐÀ'ǏÀ öÀţä dη ÀΛǎÀÕη ĞφŸžæ ĞöÀłžöä ÕÊ8łş

TS òzφÀŽΛÙ/ƙÀöÀŽz òzÆŁÀöä ȳÆÁQÊΛ .vs (ȯ/ȯzη 0.1) ȳzΛǎzÔöä ÆŁÊõşøÆŁŁ òzŸHη ğŕÀÊ8öäş ĞǵÀìÀöä

.Õη1.3 dη ÀŽõÙ Ànjä ÆŁÛQΛ ŕş ÛÀŘÎłõ

ĞÕŁęÀöä ĞÕĞÛöä ãäÀÎQèä" ɹäzΛ3 ŘƠ 8zòzη zŁ Ałõ øÀĞQnŕä ĘĞÛΛ :**Related substances** ĞöÀÎţä ǎäzţä

Zǒúη ǰΛÂηş ĞŸ8η gǎłõ R2 ÀÒŁŸŁÊöä ĞηŸŁ ȳäÆÁQèÀæ Û(84 ĞHΩÀÔöä Û1 ÆŸŎä) "Thin-layer chromatography

ÀQöşÀÒη 5 ĞHΩŁÀÔöä ɔŸ3 ŦŸÔÀΛη 3ŕzΛ .ōÀHΩQη øzÛõ òzφÀŽŁţä dη ŦłDzǵ 1ş R ɹÀŽŁηøzŸÒΛǎ dη ŦłDzǵ 24 dη

Ƀz3 :(B) òzŸ+äş Õη 1 Õõ Ž øÀĞQnŕä gǎÀη dη ħ0.10 Ƀz3 :(A) òzŸ+ä ÛR ȳøzzøzŸÒöä Ž ƙÀφä ƙòzŸţ dη

ÒHΩÀΛş öäzTä Ž ZDzQö ōÀQǩ ãäÀÎQèŕä gKDzǵ dη ĞHŁÀÔöä ÕÕφ ÆŘæş .Õη 1 Õõ Ž øÀĞQnŕä gǎÀη dη ηŸη 2.5

ĞHŘÕĞöä öÀÀŽQèÀæ ÛA òzŸ+ä dη ǰQÀǩ ĞHŘÕæ ĞΛÙ ɹzÒǩ ŕ .(ÀQηzφÀφ 254) ĞŁDzÊÀΛĞöä àzz ĞHŘìǰä Ž ãäÀÎQèŕä ÙÛÜ

.B òzŸ+ä dη ĞΘÀΛöä ÕŸǩ dη gÆì ÀŽõÙ ÛĞŁÊŁÀöä

òzŸHη ÀΛÀŘΛş R ŦəÀηŸöä dΛÆΛKĞöä dη Õη50 Ž ÛĞŁùzφŕη Ğφşàzη ÛŘ0.3 ĞääÀę ãäØΛ :**Assay** ĞÊΛÀÕţä

ɹäzΛ3 ŘƠ 8zòzη zŁ Ałõ ÆŤƨä âÀŁÕη ĞΛÀŤΛöä ĞÛÕφ ƙŁŘQæ VS (ȯ/ȯzη 0.1) ȳzŁφzηÙ ÕŁǩzääÀQQöä ÆŁÊõşøÆŁŁ

òzŸţ dη Õη1 Õõ .(142 ĞHΩÀÔöä Û1 ÆŸŎä) B ĞÕΛÀÛöä Û"Non-aqueous titration ŦəÀηŸöä Ùèzöä Ž gÀΛÀŘţä"

.$C_{14}H_{11}Cl_2NO_4$ ηŸη 32.82 ùzÀÒΛ VS(ȯ/ȯzη 0.1) ȳzŁφzηÙ ÕŁǩzääÀQQöä ÆŁÊõşøÆŁŁ

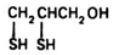
DIMERCAPROLUM

Dimercoprol ünjþĞF|þĭDŽĭq

$C_3H_8OS_2$:**Molecular formula** ĞŁÅÅÂƨä Ğ8ŁÔöä

124.2 :**Relative molecular mass** ĞŁGÊÄöä ĞŁÅÅÂƨä ĞŸQÒöä

:**Graphic formula** ĞŁąÅŁGţä Ğ8ŁÔöä



:**Chemical name** ŬƨÅŁtŁÒöä ţèrä

2,3-Dimercapto-1-propanol; CAS Reg. No. 59-52-9.

ĞHUƨäø ¢GÎk ĞGHUQÊŋ Kd ĞHUƨäø ¢ò ÛÆgÅì ÄÅòÛ ıƨŸä ş ıƨŸöä CÆ3 ŽÅò ÕƨÅè :**Description** Ƶòƨöä .Mercaptan ıÅąÅõKţä

.R òƨąÅŽŁţäş TS (ò/h750~) òƨąÅŽlqä 3ŋ ŽşÂŋ ÜöÅţä dŋ ßöÂDƨ 20 3ŋ ŽşÂŋ :**Miscibility** ĞHDƨşÂţä

.ŢGƨÂöäş ÆŁØöäş ÑŁąøÂöÅä ţtÊQŸö ÅÅløå :**Category** ĞÅÅöä

ĞDƨøÆä ĞąÂU ÛöƨRöä dŋ ĞŁtŢ ÛŷÅÒgüä ĞÕŸ8ŋ gK8ò ĞlşÅg Ž òşÄäÅõKƨÆöä ŞÅg Æz :**Storage** dlÂÅQöä .°ŷ5 dƨ ÆlÂk r gøäÄg

REQUIREMENTS KĞnlƨ5kdž!f

dƨ ÆlÂl rş ţDƨg/ţDƨg%98.0 dƨ ÕÕl Åŋ ƨŸƨ òşÄäÅõKƨÆöä ÞƨQƨ :**General requirement** ŷÅĬöä ÆŸÛQţä .$C_3H_8OS_2$ dŋ ţDƨg/ţDƨg %101.5

:**Identity tests** hbĭNjNJlIε l εþFĞHQIε

ÕƨÅè dŋ Õŋ 0.05 8ÅRlş ŏÅŋ Õŋ 5 3ŋ TS (ò/h30) (II) KöÅƨzÒöä ÆløƨŸõ òƨŸŢ dŋ Õŋ 0.5 ŽÂƨ :A .ÄÅòÛ – ŬøÅä ıƨö ıQlÅ ÜøÅĞQnrä

ıƨŸä ĞäÅèø ıQÅk ÜTS (ò/h80) âÅHUöä ğÅQŁèÛ òƨŸŢ dŋ ğäÅÛę 3Rä 8ÅRlş ŏÅŋ Õŋ 4 Ž Õŋ 0.1 ääØl :B .ÄÅòÛ

n_D^{20} =1.568-1.574 :**Refractive index** ÞøÅÊÒąĉqä ÆŁÊÄtţä

. d_{20}^{20} = 1.239-1.259 :**Reative densty** ĞŁGÊÄöä ĞƨÅŽÒöä

KƠ dÁÊlş TS1 òƨąÅŽNÛ/ŷƨŁèÅkƨGöä ÆŁÊõşøÆŁŁ òƨŸŢ dŋ Õŋ 25 Ž h 2.0 ääØl :**Halides** ğäÆŁöÅTä

ŏÅŋ Ōŋ 20 ȣÅŘΛ Ûùʒäǽõä ŏäʒTä ȣŋ øÅĔk ĞÛèäʒä ȯʒφÅŽΛqä ÄÁGΛ .Ğ3Åè 2 gÆŋ Ʊ3ʒDZÄõä ȷÅΛÄƨÅä ŌȚĦΛ Ʒ§Ȯŋŋŋ

Ethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipecotate monohydrochloride; ethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenyl-4-piperidinecarboxylate monohydrochloride; CAS Reg. No. 3810-80-8.

Description: Ζòζõã ĞĦυəãÀõã CÆʒ ÜĦĞΛÀÔǩ ŘĦæÙ ęÙ ŘĦæÙ ɟζŸæ ƀØζŸæ ȧζΗυÊη.

Solubility: ĞĦφÀæęØõã Ž ɟÀæęØõã Ãǵ ÜTS (ȯ/ħ750~) ȯζφÀŽΛqãę R ɟζφĦèɟãę ŏÀţã Ž ɟÀæęØõã ÕĦŸę.

R Ƙφɟã Ž ÀĦŸŧʒ ããęǽ Ƙḑ ÜR ÿØζζØζŸÒõã.

Category: ĞÀÀõã ȯÀΤèRõ ãÀÊηõãęã.

Storage: ȡΛÂÃφõã ÆĦÀΛÆõã ÆΛØζŸõęØÆĦŁ ęÀǵ Æz ĞÀÀõã ÆĦEDZ ĞÕŸ8η ĞΛęÀǵ Ž ǧŸĦÊõζÆĦÀΛÆõã ÆΛØζŸõęØÆĦŁ.

REQUIREMENTS Ƙ Ğ ȡ ƵƵƵ

ďňţ ÀŽõÜ ÆÕÀΛ ŕ Ü°ȳ105 ţøäÀǵ ĞDZØÆäæ ŘäÀŽõä ȷàzõä ʔøǫǵ ZÁƶ :**loss on drying** ZŧÁDzǫõÀæ ÆÕÀõä .ȟ/ŋŸŋ5.0

ĞÕţÛõä ãäÀÎǫèä" ȷäzÁȝ ŘƠ ȣzòzŋ zŁ Ãŧõ øÀǫǫnŕä ʔÀDzŁ :**Related substances** ĞõÀÎţä ääzţä ǰΛÂŋş ĞŸǰ8ŋ ţäÀŧõ R1 ÀÒŧŸŧÊõä ĞŋŸŁ ÿäÆÁǫèÀæ Û(84 ĞHΛÁÔõä Û1 ÆŸŎä) "Thin-layer chromatographyĞÕŧçÀõä øzÛõ R ŦDzŸŽõä Õŧǫŧèŕä Ŕβ ďňţ ÿzDzǵ 5ş ÛR òzǫÀŽŧţä ďňţ ÿzDzǵ 3 ÛR ÿøzzşøzŸÒõä ďňţ ŧDzǵ 92 ďňţ ŋŸŋ 50 ƀzƷ :(A) òzŸǂä ÛR ÿøzzøzŸÒõä Ž ƙÁǫä ƙòzŸŢ ďňţ ÀǫõşÀÒŋ 10 ĞHΛÁÔõä ʔŸȝ ŧŸÔÀÁŋ ÇĞÛΛ .õÀHΛǫŋ ţƙDzǵ ďňţ ĞHΛÁÔõä ţÂφ ÆĦäş .Õŋ1 Õõ Ž øÀǫǫnŕä ţÁŋ ďňţ ŋŸŋ 0.50 ƀzƷ :(B) òzŸǂä ÛøÀǫǫnŕä ţÁŋ ďňţ ĞĦÕæ ĞΛÜ ȷzÒk ŕ .øÀŦÁõä ȣzŕ Ž ãäÀÎǫèŕä ÙÛƯ ÒHΛÁŧş ÛÁzõä øÀÁĞõ ôÀĦŧş ÛõäzŢä Ž ÁƎǫõ õÀǫk Û ãäÀÎǫèŕä .B òzŸǂä ďňţ ĞΘÀÁõä ÕŸk ďňţ ţÆì ÀŽõÜ ÛĞŧÊŧÀõä ĞĦÕĞõä ȣÀŽǫèÀæ ÛA òzŸǂä ďňţ ǰǫÁk

Õŋ 10 ȣÀŘΛ ÛR1 ŦDzŸŽõä Õŧǫèȷä Ŕβ ďňţ Õŋ 40 Ž ÛĞŧùzĞŘŋ Ğφşàzŋ ÛĦ0.4 ĞääÀę ãäØΛ :**Assay** ĞÊΛÀÕŧä ŘƠ ȣzòzŋ zŁ Ãŧõ VS (ȯ/ȯzŋ0.1) ÕΛøzŸõŘĞõä Ŕŧŧ ÀΛÀĦΛş TS Õŧǫèȷä Ŕβ/ÇĞəÂõä ǧÀǫŧèÜ òzŸŢ ďňţ ďňţ Õŋ1 Õõ .(142 ĞHΛÁÔõä Û1 ÆŸŎä) A ĞÕΛÀÛõä Û"Non-aqueous titration ŦəÀŋŸõä Ùèzõä Ž gÀΛÀĦŧä" ȷäzÁȝ .$C_{30}H_{32}N_2O_2$,HCL ŋŸŋ 48.91 ùzÀÒΛ VS (ȯ/ȯzŋ 0.1) ÕΛøzŸõŘĞõä Ŕβ

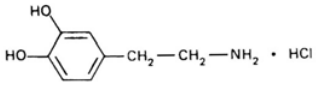
DOPAMINI HYDROCHLORIDUM

Dopamine hydrochloride DžĭDŽFĞNjǫǁℰ ǫĭβNj‡lNjβǫĭlj

Molecular formula: $C_8H_{11}NO_2$,HCl

Relative molecular mass: 189.6

Graphic formula:



Chemical name: ŦəÀŧŧÒõä ȷèŕä

4-(2-Aminoethyl)pyrocatechol hydrochloride; 4-(2-aminoethyl)-1,2-benzenediol hydrochloride; CAS Reg. No. 62-31-7.

Description: Ζòζõã ÞØζΫã ȧζΗÊη ęÌ ȷζΫõã ĞζÆ3 ğãØζΫã ŘÉãÙ ęÌ ŘÉãÙ ȷζΫã ÞØζΫã ŘÉãÙ ęÌ ŘÉãÙ ȷζΫã ÞØζΫã ȧζΗÊη ęÌ ȷζΫõã ĞζÆ3 ğãØζΫã

Solubility: ĞÊηãęØõã Ã ãęá ÜõÅţã Ž ȷÅãęØõã Ã ãęá ÜõÅţã Ž ãęá ÜõÅţã Ž ȷÅãęØõã Ã ãęá ÜõÅţã Ž ãęá ÜõÅţã Ž ãęá ÜõÅţã Ž

ŽŽzÀò ŏÀŋ Ōŋ 10 Ž Ħ1.0 ÂŒõÀQæ òzŸ‡ã ɟzÒΛ : **Clarity and colour of solution** òzŸ‡ã ɟzōş ŏÀÀò .ɟzŸōã CÆ3ş

5.0 ďŋ ÀŽõÜ ÆŌÀΛ ŧ Ü°ȳ105 gøãÀǵ ĞDZóÆæ ŘæÀŽōã ɟàzōã ?øQǵ Z,Àz : **Sulfated ash** ŘÀŸÊţã ǻÀŋÀāã .ħ/ŋŸŋ

ĞŌŒçÀāã ĞŌGÛāã ããÀÎQèã" ɟãzÁ3 ŘƠ ȣzòzŋ zŁ Àŧõ óÀĞQnŧã ?Àz :**Related substances** ĞŏÀÎţã ǻãzţã ĞŸȣŋ gǻÀŧõ silica gel R1 ÀÒŒŸŒÊōã ĞŋŸŁ ȳãÆÁQèÀæ Û(84 ĞHuÀÔōã Û1 ÆŸŎã) "Thin-layer chromatography (ȯ/ħ300~) ŌŒQŒèɟã Ŕβ ďŋ ȳzDzǵ 4ş ÛR òzφÀŽŒţã ďŋ ȳzDzǵ 9 ÛR ȳózzşózŸÒōã ďŋ ŽŧDzǵ 13 ďŋ ɟΛÂŋş 30 ƀzƷ :(A) òzŸ‡ã ÛR òzφÀŽŒţã Ž ƙÀQã ƙòzŸŢ ďŋ ÀQōşÀÒŋ 10 ĞHuŒÁÔōã ?Ÿ3 ŽŸÔÀÀŋ ĘGÛΛ .ōÀHuQŋ ózÛõ TS .Ōŋ 1 Ōõ Ž RS ƙŋÀæşÆōã ÆΛózŸõşóÆŒŁ ďŋ ŋŸŋ 0.3 ƀzƷ :(B) òzŸ‡ã ÛŌŋ 1 Ōõ Ž óÀGQnŧã gǻÀŋ ďŋ ŋŸŋ ɟΛÂŋ ƀşÀÊQōÀæ ǻÀÀ Ż ÛĘaÀęǻ 3Ŕæ gÆŋ ĞzÀ8ōã gøãÀǵ Ž ZDzQō ōÀQk Ûāãà Î Qèŧã gKDzǵ ďŋ ĞHuŒÁÔōã ţÂφ ÆĦæş ÆŒφÀŒè ƀÀǵ òzŸŢ ďŋ ŽDzǵ 1ş TS(ȯ/ħ50) ŌΛÆΛÆΣã ÆΛózŸõ òzŸŢ ďŋ ŽDzǵ 2 ďŋ Z,ōúŋ ƷàÀù ŌÒÎæ ÀŋŘŢ A òzŸ‡ã ďŋ ɟQΛ ŧ ÛĞŒÊŒaÀōã ĞHŌGōã ŏÀÀƷQèÀæ .óÀŽAōã ŏzŘæ āãÀÎQèŧã ÙÛÜ ÒHuÀΛ .TS (ȯ/ħ50) ȳzŒèÀkzGōã ďŋ ɟkÀAōã āãÀÎQèŧã ÙÛÜ ďŋ óÆÊōţã ţzŧŏã Ōōæ ďƷ ÆΛÂΛ ŧ Æaãz ÎŸõ óÆÊōţã ţzŧŏã ɟÚş ÛƷŌæ 3 ďŋ ÀŽõÜ .B òzŸ‡ã

10 ȣÀŘΛ ÛR1 ŬDzŸŽōã ŌŒQŒèɟã Ŕβ ďŋ Ōŋ 140 Ž ÛĞŒùzGŘŋ Ĝφşàzŋ ÛĦ 0.4 ĞæãÀę āãØΛ :**Assay** ĞÊΛÀÔţã ȣzòzŋ zŁ Àŧõ VS (ȯ/ȯzŋ 0.1) ŌΛózŸõKGōã ŘŧШ ÀΛÀĦΛş ÛTS ŌŒQŒèɟã Ŕβ/ĘGaÂōã ǵÀQŒèÜ òzŸŢ ďŋ Ōŋ Ōõ .(142 ĞHuÀÔōã Û1 ÆŸŎã) A ĞŌΛÀÛōã ÆÊШ Û"Non-aqueous titration ŬaÀŋŸōã Ùèzōã Ž gÀΛÀĦţã" ɟãzÁ3 ŘƠ .$C_8H_{11}NO_2,HCl$ ŋŸŋ 18.96 ùzÀÒΛ VS(ȯ/ȯzŋ 0.1) ŌΛózŸõKGōã Ŕβ ďŋ Ōŋ1

Ĭøđŧsθ‖ε üFDžyƭƨúǁ ɱyƱƶ‖ε DžĭDžJFĠNjɱǁε ɱĭβNj+|Njβɱĭlj üШŬ hŭĭƷFŢa lƒĞƭƯƭDž

Additional requirments for Dopamine hydrochloride for Parenteral use

.(56 ĞHuÀÔōã ℓ4 ÆŸŎã ÀŢφã) *Pranenteral preparations* ĞŒAŌΣã ǵãÀŘHuQÊţã øæ ĞòÀÎã gǻşÀzQÎ Æ‖DzQÊΛ

óÀGQnŧã " ɟãzÁ3 ŘƠ ȣzòzŋ zŁ Àŧõ óÀGQnŧã ĘGÛΛ :**Bacterial endotoxins** ĞŒŋzφÀæã ĞŒŸnãÆōã ǵÀφÀÀΛØōã ŧ Ü(ĞΛÂŒŸõqã ĞHGÛōã Ž 30 ĞHuÀÔōã Û5 ÆŸŎã) "Test for bacterial endotoxins ĞŒŋzφÀæã ĞŒŸnãÆōã ǵÀφÀÀΛØōã ŌDZɟ .ŋŸŋ 1 Ōõ Ž RS ŬŸnãÆōã ɟÀÀΛØōã ďŋ ĞŒōşǻ gÆǵş 16.67 ďŋ ÀŽõÜ ƀzQƷ

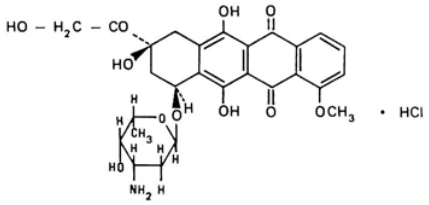
DOXORUBICINI HYDROCHORIDUM

Doxorubicin hydrochloride DžĭƨĭĞNjþNjƨlNjǫǁɛ ǫĭþNj≠lNjþǫĭĭlj

$C_{27}H_{29}NO_{11,}HCl$: **Molecular formula** ĞŁĂǀÂƨǎ Ğ8ŁÔöǎ

580.0 :**Relative molecular mass** ĞŁGÊǀöǎ ĞŁĂǀÂƨǎ ĞŸǫȮöǎ

:**Graphic formula** ĞŁǫĂŁGţǎ Ğ8ŁÔöǎ



:**Chemical name** ƯƨĂŁŧŁȮöǎ ǀèřǎ

(8*S*,10*S*)-10-[(3-Amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranosyl)oxy]-8-glycoloyl-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-5,12-naphthacenedione hydrochloride; (8*S*-*cis*)-10-[(3-amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-5,12-naphthacenedione hydrochloride; CAS Reg. No. 25316-40-9.

. ĂþŬ – ƑĬĂÖĬĬĂĂ ɿƨŸǎ ƤóƨŸǎ ȧƨHƱÊǀ :**Description** Ƨòƨöǎ

.Ƙǫɟǎ Ž řŞ R ȳóƨƨóƨŸȮöǎ Ž ŃŁŸŧȝ ǎǎşǎ Ƙdǀ ÜR ȯƨǫĂŽŁţǎş ŏĂţǎ Ž ǎǎşǎ :**Solubility** ĞŁǫĂǎşØöǎ

.Cytotoxic ĂŃŸÅŸö ȳĂè öǎşǎ :**Category** ĞĬĂĂöǎ

.ȳĂȮgüǎ ĞÖŸ8ǀ ĞŃşĂg Ž ƙÊŁǎşóƨÊõşÁöǎ ÁŃóƨŸõşóÁŁŁ ŞĂg Æƨ :**Storage** ďŃÂÅǫöǎ

Ühygroscopic ĞĞüĂǫÊǀ gĂǀ ƙÊŁǎşóƨÊõşÁöǎ ÁŃóƨŸõşóÁŁŁ ńŁĦŁ :**Additional information** ĞŁƨĂřÜ ğĂǀƨŸĦǀ ÆŃΘş ƤÁŃɟĂǎ ƙÊŁǎşóƨÊõşÁöǎ ÁŃóƨŸõşóÁŁŁ ÕǀĂĦŃ ĂǀÁĂ3 ĞŃĂĂĦöǎş óØΣǎ Ưnƨĭ Æƨ :ĂŃØƠ .ĞǀĂè gĂĂǀ ƯŁş . öǎƨTǎǎ ĞöƨÕŃŧǎ ğĂŧŁÊƨǎ ȧĂÎŃǫèǎş ÁŸƨǎ ȝǀ âĂŧǫöǎ

REQUIREMENTS ƙĞĥǫĬƩƙĬĬ!ƒ

řŞ %97.0 ďȝ ÕÕĂ ř Ăǀ ƨŸȝ ƙÊŁǎşóƨÊõşÁöǎ ÁŃóƨŸõşóÁŁŁ ƤƨǫȤ:**General requirement** ȳĂĦöǎ ÆŸÛǫţǎ .ĞŁĂĂǀŸöǎ gĂĂţǎ ƤŬ ţƨDZĂöĂǎ ĞǎƨÊŢ Ûc$_{27}H_{29}NO_{11,}HCl$ ďǀ %102.0 ďȝ ÁŃÂŃ

:**Identity test** hüĭNjNJǁɛ l ɛƥƒĞĦǫɛ

ƙǎ Ȥǎƨǀǎ ȯǎƨùŬ Ž ÁŁĂÎŃ ĂǀÁĂ3 ÛR ȯƨǫĂŽŁţǎ Ž Õǀ/ȳǎĂdşĂȮǀ 20 ÂŁõĂǫǎ ȯƨŸ≠ î ĂÔǫǀřǎ ȤŁù ¢ǎĂÎǫŃ :A ÁŃóƨŸõşóÁŁT Õǀ/ȳǎĂdşĂȮǀ 20 ÂŁõĂǫǎ ȯƨŸŢ ďǀ ǰƙĂĂöǎ ȤŁÛöǎ Ȥǀ ŃŁĂŁõ ÛĂǫƨƨǫĂǫ 600ş ĂǫƨǫĂǫ 220

477ę 290ę 253ę 233 ĞäāÀę ǯāźŋŋ̇ā ȯāźùÙ Ž Ʊŧţǯ̇ā ī ÅÔǫŋŗā ǫÁǯ) R ȯźφÅǯŧţā Ž RS ƙÊŧāęóźÊõęÁõā ī ÅǫĮ ǮŸǫƧŗę .(ÀǫŋźφÅφ 350ę 280ę 245 ǯāźŋŋ̇ā ȯāźùÙ Ž ƁÀ8ȯ̀ŋ̇ā ī ÅÔǫŋŗā ǫÁǯ ÜÀǫŋźφÅφ 530ę 495ę Ž ŀè1 ĞφÅÁǯā ĞÕĞù ȯŸǹ ȯŋ ī Åŧǫõā ŋŸĞΛ Û%3 ȯŋ Àǯõüā ÅŤŘĦā ȯǯ ĞÕźāźţā Ğŧŧţǯ̇ā ğÅȯ̀ÅÔǫŋŗā Ž ÕŧõÅ+ā .Ƃāźǫõā ɔŸǯ Û0.24ę 0.44ę 0.46ę 0.30ę 0.88ę 1.32 ĞäāÀę Ğŧŧţǯ̇ā ğÅȯ̀ÅÔǫŋŸõ ǯāźŋŋ̇ā ȯāźùÙ ĞŧÊŧaÀõā ĞĦÕĞõā ĘäāÅÛǫĮ ."Related substances ĞõÅÎǫţā ãāźţā" ŋāźÄǯ ŘƠ ÙÕǵŗ Ʊźȯźţā ȯÅĞǫǹŗā ƁÙ ÀŤǫā :B .B ȯźŸ+ā ȯŋ ĞΘÅõā ȬŸĭ ǯŋ ǵÁÎāęŞ ÀŤŤţāę ǯęźţā Ž A ȯźŸ+ā ȯŋ ĞΘÅõā ȳźΛāźÔõā ÁŧÊõęóÁŧŧ ȯźŸŢ ȯŋ Ōŋ0.05ę ŏÅŋ Ōŋ 2 ƱÅŘΛ ÛR ȯźφÅǯŧŋ Ōŋ 2 Ž ŋŸŋ 2 ā̄āØΛ :C .ŦDźÊÅĞõā ȧøāŋ̇ā Ƃ̄ ȯźŸHŧŧŸõ ƁÅÕĭĦõā ÀÞŋ̇ā ŋźŸõā ȯÁĞǫΛ ÜTS (ȯ/ĥ80~) General ĞŋÅĦõā ƱāÀĦǫèŗā ğāóÅĞǫǹā" ŋāźÄǯ ŘƠ Ʊźȯźţā B Ōǯ̇ÅĞõā Ōŋ/ĥ 0.05 ÂŧõÀǫā ȯźŸ+ā ŦÛĦΛ :D .(121 ĞHŋÅÔõā Û1 ÁŸŎā) ğāÁΛóźŸÒŸõ Âŧŧŋ̇ Ōǯ̇ÅĞȭ "identification tests Determination of water by ÀÎŧź ȯóÅȭ ĞÕΛÀÛā ŏÅţā ƙŧĦĭĭ" ŋāźÄǯ ŘƠ Ʊźȯźŋ źŧ Åŧȭ ȯŧĦΛ :**Water** ŏÅţā ÁΛÅΛ ŗ Ügāţā ȯŋ ĥ 0.25 ĞäāÀę ȳāÁÁǫèÅā Û(145 ĞHŋÅÔõā Û1 ÁŸŎā) A ĞÕΛÀÛõā Û" the Karl Fischer method .ĥ/ŋŸŋ 40 ȯǯ ŏÅţā ƲźǫŢ

.6.5-3.8 ÛŌŋ/ŋŸŋ 5.0 ÂŧõÀǫā ȯźŸ+ā ŏÅŧÅā ǯŸĞΛ :**pH Value** ŏÅŧÅĞõā Ğŧŧęę ĞÕŧęÀõā ĞÕĞÛõā āāÀÎǫèā" ŋāźÄǯ ŘƠ Ʊźȯźŋ źŧ Åŧȭ óÅĞǫǹŗā ƲÀźę :**Related substances** ĞõÅÎţā ãāźţā 80 ȯŋ ǰΛÂŋę ĞŸǫ8ŋ gãÅŧȭ R1 ÅÒŧŸŧÊõā ĞŋŸŧ ȳāÁÁǫèÅā Û(84 ĞHŋÅÔõā Û1ÁŸŎā) "Thin-layer chromatography .ȭÀHŋǫŋ ózÛȭ R ŦDźŸõā Ō̄ŧǫŧèŋ̇ā Ŕβ ȯŋ ȳźDźǵ 5ę ÛR ȯźφÅǯŧţā ȯŋ ŧŧDźǵ 20 ÛR ȳózźęóźŸÒõā ȯŋ ŧŧDźǵ óÅĞǫǹŗā gãÅŋ ȯŋ ŋŸŋ 2.0 ƁźǮ :(A) ȯźŸ+ā ÛR ȯźφÅǯŧţā Ž ŌŧȭÅŢ 4 ȯŋ ÀǫõęÀÒŋ 10 ĞHŋŧÁÔõā ɔŸǯ ŦŸÔÅÅŋ ĘĞÛΛ ƁźǮ :(C) ȯźŸ+ā ÛŌŋ1 Ōȭ Ž RS ƙÊŧāęóźÊõęÁõā ÁΛóźŸõęóÁŧŧ ȯŋ ŋŸŋ 2.0 ƁźǮ :(B) ȯźŸ+ā ÛŌŋ 1 Ōȭ Ž ţÂφ ÁĦā .Ōŋ 1 Ōȭ Ž óÅĞǫǹŗā gãÅŋ ȯŋ ŋŸŋ 0.40 ƁźǮ :(D) ȯźŸ+āę ÛŌŋ 1 Ōȭ Ž óÅĞǫǹŗā gãÅŋ ȯŋ ŋŸŋ 20 ĞHŌā ĞΛÙ ŋźÒĭ ŗ .óÅŤΛõā ózŘā āāÀÎǫèŗā ÙÛÙ̀ ÒHŋÅΛę õāźTā Ž ǮDźǫȭ ōÀǫĭ ÛāāÀÎǫèŗā gKDźǵ ȯŋ ĞHŋŧÁÔõā .D ȯźŸ+ā ȯŋ ĞΘÅõā ȬŸĭ ȯŋ gÁÈì ÀǯõÙ̄ ÛĞŧÊŧaÀõā ĞĦÕĞõā ŏÅǯǫèÅā ÛC ȯźŸ+ā ȯŋ ǰǫÅĭ 100 óÁÕā ŀDźǵ ŏÅÛǯq R ȯźφÅǯŧţā ȯŋ ĞŧźÅȭ Ğŧŧȭ Ž ÛĞŧùźĞŘŋ Ğφęàźŋ ÛŋŸŋ 20 ĞäāÀę āāØΛ :**Assay** ĞÊΛÅÔţā ȯźŸHŧŧŸõ ŀè1 ĞφÅÁǯā ĞÕĞù ȯŸǹ ȯŋ ī Åŧǫõā âÅÕΛ .¢ÊÅφ ÆΛØţÅā Ōŋ 100 Ƃ̄ ȯźŸ+ā āØŧ ȯŋ Ōŋ 10 ǮÁǮ ÜÕŋ ǯŋ ĞφóÅÕţÅā ĞõźHŋÅţā gãÅţā Ž $C_{27}H_{29}NO_{11}$,HCl Ğŧŧȭ ÆÊHŋĭ .ÀǫŋźφÅφ 495 ĞäāÀę ƱźŢǯ̄ ĞDźźŋ ȯźÛā ǮÁÁţā ƱźźŘõā ǮŧÛõā âÅŧÕŋ Ž ī Åŧǫõā ŋŸΛ ŋ̄ Æź .ȯŋāÅǫõęę ĞõÅÎţā ī źHŋÅţā ÛRS ƙÊŧāęóźÊõęÁõā ÁΛóźŸõęóÁŧŧ

.0.02 ± 0.44 ČĒĦDZÀţā gǻÌţā òƷŸǂ ČłÀÀÒä ÀĦĦţā

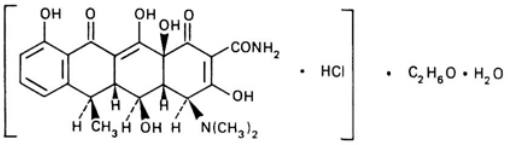
DOXYCYCLINIHYCLAS

Doxycycline hyclate DƵĭǂlĭƨ Ĭƨ lNjǫǁƐ l ǘ lĭlj

Molecular formula: ČĒÌłÂƨā Č8ĒÔõā $(C_{22}H_{24}N_2O_8,HCl)_2,C_2H_6O,H_2O$

Relative molecular mass: ČĒGÊłõā ČĒÌłÂƨā ČŸǫÒõā 1026

Graphic formula: ČĒǫÌĒGţā Č8ĒÔõā



Chemical name: ŬəÀĒŧĒÒõā ǀèŕā

(4*S*,4a*R*,5*S*,5a*R*,6*R*,12a*S*)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride, compound with ethyl alcohol (2:1), monohydrate; [4*S*-(4α,4aα,5α,5aα,6α,12aα)]-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride, compound with ethanol (2:1), monohydrate; CAS Reg. No. 24390-14-5.

Description: ƵòƷõā ÀÀòÌ ƷŸā ƀóƷŸā àƷHŬÊŋ.

Solubility: ČĒǫÀāşØõā Ž ŕş R ȳóƷƷóƷŸÒõā Ž ĦĒŸŧȝ ā ąşá Ƙą ÜR òƷǫÀĬĒŋ õāÂDZÌ 4ş ŏÀŋ ŏāÂDZÌ 3 Ž ā ąşá R Ƙǫƀā.

Category: ČłÀÀõā ąĒǫāÀƨā ąÀÂŋ ŏāşą .

Storage: ČłÀÂÁǫõā Ĭ ŏƷÂõā ČĒƷÀŧÌ ĬƷŸÒõā ŏƷÂõā ČÕŸ8ŋ ČłşÀg Ž ƙŸÒĒè ŬÊõşÁõā ğŸÒĒŁ ŞÀg Æz

Additional information: ČĒƷÀŕÌ ğÀŋƷŸĦŋ ŬÊõşÁõā ğŸÒĒŁ ŏØÁǫƙ Ĭ ŏƷÂõā ČłÀÀõā ąĒǫÀĬĒŋ ŬÊõşÁõā ğŸÒĒŁ ŏØÁǫƙ.

REQUIREMENTS ƙČĠhƷŸƵƙĦƵ!ƒ

General requirement: ȳÀĬĦõā ÆŸÛǫõā ČłÀÀõā ąĒǫŋ ČĒõşą gÁgş 880 ÕÕłÀŋ ƨŸȝ ƙŸÒĒè ŬÊõşÁõā ğŸÒĒŁ ƀƷǫƠ .òƷǫÀĬĒłą ČĒõÀĬłą ČĒƨÀŋŸõā gǻÌţā ƀÌ ţƷDZÀõÀā ČāƷÊŢ ÛŋŸŋ 1 Ôõ Ž ƙŸĒÒĒè ŬÊõşÁõā

Identity tests hŭĬNjNJЛЄ l ЄƀƑGĤCƊЄ:

.ÆΛÆì ÀÅòÙ ɟƶ ǰQΛ ÜTS (ȯ /ȟ1760~) ÕΛóƶÅŸÊäã Ŕƥ ȡŋ Ȯŋ 2 Ž ŋŸŋ 5 ãäØΛ :A

ɟƶ ǰQΛ ÜTS (ȯ/ȟ25~) ÕΛÆΛÆΣã ÆΛóƶŸõ ȯƶŸŢ ȡŋ Ȯŋ 0.05 8ÅŘΛş ŏÅţã ȡŋ Ȯŋ 2 Ž ŋŸŋ 5 ãäØΛ :B

.ȡõäå ŬøΛæ – ÀƥÙ

ǰQΛǩ ÜPotassio-mercuric iodide TS ɃƶŸę ȯƶŸŢ ȡŋ Ȯŋ 0.25 8ÅŘΛş ŏÅţã ȡŋ Ȯŋ2.0 Ž ŋŸŋ 5 ãäØΛ :C

.ǴǩÅƶ ÀÅòÙ ɟƶŸæ Ǧŧ3ÅǫΛóƶŸæ ǦæÅèø

General ǦŋÅǨäã 8ãÀǨQèŗã ǧäøÅǫQnã" ɟæƶΛ3 ǨƠ 8ƶòƶţã B Ȯ3ÅÅQäã Ȯŋ/ŋŸŋ 20 ÂŒõÀQæ ȯƶŸ∓ã ŬÛǨΛ :D

General ǦŋÅǨäã 8ãÀǨQèŗã ǧäøÅǫQnã" ɟæƶΛ3 ǨƠ 8ƶòƶţã B Ȯ3ÅÅQäã Ȯŋ/ŋŸŋ 20 ÂŒõÀQæ ȯƶŸ∓ã ŬÛǨΛ :D

identification tests" ȯ3ÅÅQõ ǧãÆΛóƶŸÒŸö ÂŒŧŋ (121 ǦHΛÅÔäã Û1 ÆŸŎã).

.ȟ/ŋŸŋ 4.0 ȡ3 ÆΛÂΛ ŗ :**Sulfated ash** ŘÅŸÊţã ǻÅŋÀäã

Determination of water by ÀÎŒƶ ȯøÅõ ǦÕΛÀÛæ ŏÅţã ŀŒǨk" ɟæƶΛ3 ǨƠ 8ƶòƶŋ ƶŁ Åŧõ ȡŒǨΛ :**Water** ŏÅţã ƷƶƢŢ ÕÕΛ ŗ ÜgǻÅţã ȡŋ ȟ 1.2 ǦæÅę ÿæÆÁQèÅæ Û(145 ǦHΛÅÔäã Û1 ÆŸŎã) A ǦÕΛÀÛäã Û"the Karl Fischer method

.ȟ/ŋŸŋ 28 ȡ3 ÆΛÂΛ ŗş ȟ/ŋŸŋ 14 ȡ3 ŏÅţã

"Gas chromatography ƀàÅ8äã ãäÀÎQèŗã" ɟæƶΛ3 ǨƠ 8ƶòƶŋ ƶŁ Åŧõ ǻÅǦQnŗã ƷÀƶ :**Ethanol** ȯƶφÅǨΛqã ȯƶφÅǨΛqã ȡŋ ÀQäşÀÒŋ 0.50 ȡŋ ǨƶÂŋ ƀƶǮ :(1) ȯƶŸ∓ã ÛŏÅţã Ž ÕŒǻÅŢ 3 ÿæÆÁQèÅæ Û(101 ǦHΛÅÔäã Û1 ÆŸŎã) ÛÕŋ 1 Ȯõ Ž ǻÅǦQnŗã ǧǻÅŋ ȡŋ ŋŸŋ 10 ƀƶǮ :(2) ȯƶŸ∓ã ÛÕŋ 1 Ȯõ Ž dehydrated ethanol R ŏÅţã ţşÂøΛŋ

.ŬŸnãÆäã ƀǻŒǨţã ȡŋ ÀQäşÀÒŋ 0.5 ƷŋȮŋ 1 Ȯõ Ž ǻÅǦQnŗã ǧǻÅŋ ȡŋ ŋŸŋ 10 ȡŋ ǨƶÂŋ ƀƶǮ :(3) ȯƶŸ∓ã

porous polymer ÿÅÊŋ Ƀæ ÀŧŒæ ǧÅǦǦǦШ ƶÎŢ ŀŸŋ 4 ŬŸnãǻ ÀÛÕäşÿ 1.5 ȯƶÛæ ǻƶŧ3 ǧäõäÀDƶqã Ž ÿÆÁQÊΛ

Û~ÿ135 ǧøäÀǵ ǦDƶóÆæ ǻƶŧǨäã ƶŸ3 Şƶ3 .(ǦŧƷŸŋ ƀóÅΘ óÆÔŋ ƀÙ ȡŋ ÀQŋşÀÒŋ 100-80 ŀDƶШ ǧÅŧŒÊƷã ÆŒǨ)

ǻóÆÕŋ ȯƶφÅǨΛqã ƶƶŢ ÆÊƶ .flame ionization ÆŢŸäã ȡŒǨQæ ÕŧǨΛ 8ÅÎÒŋşş ÀÅ8Ÿö ÕŋÅŬõR ǩDƶşÀQÅäã ÕŧǨQÊΛş 60 ȡ3 ÆΛÂΛ ŗş ȟ/ŋŸŋ 43 ȡ3 ÕÕΛ ŗ ÜȟÕ0.790 ƶŁ °ÿ20 ǦDƶóÆäÅæ Ȯŋ 1 Ȯõ Ž ɟàƶäã ɟÙ ôäÀQƶÅæ ÛȟŋŸţÅæ ȟ/ŋŸŋ.

.3.0-2.0 ÛȮŋ/ŋŸŋ 10 ÂŒõÀQæ ȯƶŸ∓ã ŏÅŁÅæ ŋŸGΛ :**pH Value** ŏÅŁÅǦäã ǦŧŒę

ƵŒù ƀÆGΛ :**Absorption in the ultraviolet region** ǦŒDƶÊÅÅǦäã ȧƶƶ ǦȟÌjã ǦÕÛΛŋ Ž î ÅÔQŋŗã 99ş VS (ȯ/ȯƶŋ1) ÕΛóƶŸõşóÆŒŢã Ŕƥ ȡŋ ŀDƶǵ 1 ȡŋ ǰΛÂŋ Ž Ȯŋ/ÿäÀdşÀÒŋ 10 ÂŒõÀQæ ȯƶŸ∓ î ÅÔQŋŗã ǦφÅǨƶæ ǦÕǦù ȯŸn ȡŋ î ÅŧQäã ɟƶÒΛ ŗ .ÀQŋƶφÅφ 349 ǦæÅę ǦDƶƶŋ ȯƶÛæ ŀŒŧŢ3Ù ŀÒÅÔQŋã R ȯƶφÅǨŒţã ȡŋ ŀŧDƶǵ

.ȯƶφÅǨΛqã ȡŋ ǦŒÅŀã ǦŒƷÅŋŸäã ǵÅŧŸö ǦǦÊÅÅÅæ 0.31 ȡŋ ÀƶõÙ ŗş 0.28 ȡŋ Ȯęù äØŁ ǦDƶƶţã ȯƶÛæ ŀè1

ĻDzǵ 1 ďŋ ǰ ʌÂŋ Ž Ōŋ/ŋŸŋ 10 ÂŁõÀǫǎ ȯzŸŢ ÀÂŘʒ :**light- absorbing impurities** ŏzŘŸŏ ǦȎÀţǎ ÆǎǎzÎöǎ Ļè1 ǦǫÀÁǰǎ ǦÕǦù ȯŸȎ ďŋ ī Ȧţǫöǎ âÀÕʌş ÛR ȯzǫÀǰŁţǰǎ ďŋ ŀţDzǵ 99ş VS (ȯ/ȯzŋ 1) ÕʌȯzŸõşǿ́ÆŁŢǎ Ř ƥ ďŋ .ȯzǫǰǰʌqǎ ďŋ ǦŁöÀ ǫǎ ǦŁǎÀŋŸöǎ gǎÀţŸŏ ǦǦÊÀöÀǎ 0.12 ďʒ ī Ȧţǫöǎ ÁʌÂʌ ŕ ÜÀǫŋzǫǰǫ 490 ǦDZzŋ ȯzÛǎ ǦʌzŁΣǎ ǧǎǎÀŘţŸŏ ǦŁDZzȯzŁǎşÀȮţǎ ǦÊʌÀÕţǎ" ǰǎzʌʒ ǨƠ ǦzzȎzŋ ŲŁ Ȧţõ ǦÊʌÀÕţǎ ĘǦÛǨ :**Assay** ǦÊʌÀÕţǎ *Bacillus cereus* (NCTC ǦǫzÔŁöǎ ÿǎÁÁǫèÀǎ Û(155 ǦŲȦÀÔöǎ Û1ÁŸÖǎ) "Microbiological assay of antibiotics ÿzŁèÀǨzǦöǎ ǧÀÀÊŲ Ǧǎóǎǎǎ Û6.6 ŲǎÀŒ ŏÀŁÀǎ şǎ Cm10 ţóà Ùèş ÛóÀǦǫnŕǎ Ŭǵ ďǎÀȮõ 10320 or ATCC 11778) Ž ǦŁöşǎ ǵÁǵş 2.0ş 0.2 ǩǎ ǵǎÀʒ) ÆèÀʌŋ ÂŁõÀǫǎ ǩŸȮŁè ŲÊõşÁöǎ ďŋ ȯzŸŢş ÛTS(ȯ/Ł13.6) ǩDZşóÁŁŢǎ ǦŁǎÀʌǫ ǦŁŸʒÀÀŸö ÜÛÁŸö ǵÁŁţǫŁţǎ ǎşÁΣǎ ÀŸŢz ȷzȮǩ ŕ ȷÛ ŲŁ ǦÊʌÀÕţǎ Ǧǎǎ .°ȳ39-35 ǵóǎÀǵ ǦDZóÁǎ ďŘŲŁş Û(Ōŋ 1 Ōõ ÁΣǎ ȷzȮʌ ŕş .ǵóŁÁÕţǎ ǦŁŸʒÀÀöǎ ďŋ %105.0 ďŋ ÀǰõÜ ŕş %95 ďŋ Ōęǰ estimated potency (P = 0.95) ǵóŁÁÕţǎ ÛŋŸŋ 1 Ōõ Ž ǩŸȮŁè ŲÊõşÁöǎ ďŋ ǦŁöşǎ ǵÁǵş 880 ďŋ Ōęǰ (P = 0.95) ǵóŁÁÕţǎ ǦŁŸʒÀÀŸö ÜÛÁŸö ƀzŸŁöǎ ÁŁţǫŁţǎ .ȯzǫǰǰʌqǎ ďŋ ǦŁöÀ ǫǎ ǦŁǎÀŋŸöǎ gǎÀţǎ ƀÜ ţzDZÀöÀǎ ǦǎzÊŢ

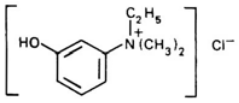
EDROPHONII CHLORIDUM

Edrophonium chloride !ŃjĭŁŁŃjƨŃjƥǫĭÜ̃ε ǫĭƥŃj‡|

$C_{10}H_{16}ClNO$:**Molecular formula** ǦŁÀʌÂƨǎ Ǧ8ŁÔöǎ

201.7 :**Relative molecular mass** ǦŁǦÊʌöǎ ǦŁÀʌÂƨǎ ǦŸǫȮöǎ

:**Graphic formula** ǦŁǫÀŁǦţǎ Ǧ8ŁÔöǎ



:**Chemical name** ŲǎÀŁţŁȮöǎ Ļèŕǎ

Ethyl(*m*-hydroxyphenyl)dimethylammonium chloride; *N*-ethyl-3-hydroxy-*N*,*N*-dimethylbenzenaminium chloride; CAS Reg. No. 116-38-1.

.ǦŲǎǎÀöǎ CÁʒ ÜŘŁǎǰ ȷzŸǎ ƀǫzŸǎ ȧzŲÊŋ :**Description** Ζȯzöǎ

ŀŁŸţʒ ǎǎşǎ Ǩǵ ÜTS (ȯ/Ł750~) ȯzǫǰǰʌqǎ ďŋ öǎÂDZÜ 5 Žş öÀţǎ ďŋ ŀöÂDZ 0.5 Ž ǎǎşǎ :**Solubility** ǦŁǫÀǎşǾöǎ .Rǩǫǰǎ Ž ŕş R ÿǫzǫzŸȮöǎ Ž

.Diagnostic agent ȮŁÁÎǩ ŌŋÀʒ :**Category** ǦÀÀöǎ

.ŏzŘöä ɗŋ ĞŁŧŢÛŘÆŁDZ ĞÕŸ8ŋ ĞʌşÅǵ Ž ȳzŁqzzşóÆʌqä ÆʌózŸõ ŞÅǵ Æz :**Storage** ɗʌÂÅQöä

REQUIREMENTS ƙĞuŬƵƙŭž!ƒ

ɗʒ ÆʌÂʌ ŕş %98.5 ɗʒ ÕÕʌ ŕ Åŋ ɔŸʒ ȳzŁqzzşóÆʌqä ÆʌózŸõ Ƀz0Ʒ :**General requirement** ȳÅŘöä ÆŸÛQŧä .ĞÅÅŎä gǻŤä Ƃŭ ŧzDZÄõÅä ĞäzÊŢ ÛC10H16ClNO %101.0

:**Identity tests** hŭŇjNJЛЄ l ɛƥƑĞƤɢɛ

ÅŋÆʌʒ ÛVS (ȯ/ȯzŋ 0.1) ÕʌózŸõşóÆŁTä Ř ƥ Ž Õŋ/ŋŸŋ 0.050 ÂŁõÄQä ȯzŸ+ î ÅÔQŋŕä ZŁù ƂÆĞʌ :A ŋŸĞʌ ÜÄQŋzφÅφ 273 ĞääÄę ĞDZzŋ ȯzÛä ŘŁŧŢʒŬ ŘòÅÔQŋä ÛÄQŋzφÅφ 350ş ÄQŋzφÅφ 230 ƙä ʒäzŋŋä ȯäzùŬ Ž ÆŁÅÎʌ .0.55 ĞääÄę äØŁ ĞDZzŧä ȯzù Ž ŀè1 ĞφÅǺä ĞÕĞù ȯŸn ɗŋ î Åŧ0öä

(ȯ/ȯzŋ 0.1) ȳzʌǻzÔöä ÆŁÊõşóÆŁŁ ȯzŸŢ Ž Õŋ/ȳäÄdşÄÒŋ 10 ÂŁõÄQä ȯzŸ+ î ÅÔQŋŕä ZŁù ƂÆĞʌ :B 240 ĞääÄę ĞDZzŋ ȯzÛä ƙŁŧŢʒŬ ƙòÅÔQŋä ÛÄQŋzφÅφ 350ş ÄQŋzφÅφ 230 ƙä ʒäzŋŋä ȯäzùŬ Ž ÆŁÅÎʌ ÅŋÆʌʒÜVS ɔŸʒ 0.17ş 0.55 ĞääÄę ƙQDZzŧä ƙƙÅŁ ƃzÛä ŀè1 ĞφÅǺä ĞÕĞù ȯŸn ɗŋ î Åŧ0öä ŋŸĞʌ ÜÄQŋzφÅφ 294 ĞDZzŧäş ÄQŋzφÅφ .ƃäzQöä

ɟzŏ ǰQʌ ÜTS(ȯ/ħ25) ÕʌÆʌÆΣä ÆʌózŸõ ȯzŸŢ ɗŋ Õŋ 0.05 8ÅŘʌş ŏÅŋ Õŋ 2 Ž ħ 0.05 ääØʌ :C .Ąƥŋä Ƃŭ äóÅŕ ŲDzÊÅʌä

.ÕÒÅQöä ʒŋ °ȳ168 ĞääÄę ÛóÅŤÔφŕä ĞDZóǻ :D

General ĞŋÅŘöä 8äÄŘQèŕä ǧäóÅĞQnä" ɟäzʌʒ ŘƠ 8zòzŧä A Õʒ ÅÅQöä Õŋ/ŋŸŋ 20 ÂŁõÄQä ȯzŸ+ä ŲÛŘʌ :E .(121 ŘHÅÔöä Û1ÆŸŎä) ǧäÆʌózŸÒŸö ÂŁŧŋ Õʒ ÅÅQõ "identification tests

.ħ/ŋŸŋ1.0 ɗʒ ÆʌÂʌ ŕ :**Sulfated ash** ŘŸÅÊŧä ǻÅŋÄöä

zŸŁõ 0.6 ɗʒ ÆʌÂʌ ŕ) ŘÅǺʌŋ Ù8ŕ ŘƠ ÙŁ+ä góäÄǵ ĞDZóÆä ZÅz :**Loss on drying** ZŁADzQöÅä ÆÕÅöä .ħ/ŋŸŋ 5.0 ɗŋ ÄƷõŬ ÆÕÅʌ ŕ ÜĞʒÅè 24 gÆŋ R ózÅÊʌöä ÆŁÊõʌ ŲèÅŧħ ȧzz (ĘŁƏà ŀŸŋ 5 ĞääÄę ęŬ ȯÅȯèÅä .5.0-4.0 ÛÕŋ/ħ 0.10 ÂŁõÄQä ȯzŸ+ä ŏÅŁÅä ŋŸĞʌ :**pH Value** ŏÅŁÅĞöä ĞŧŁę

Ğəóäǻ ɗŋ Õŋ 5 8ÅŘʌş ÛŏÅŋ Õŋ 10 Ž ħ0.1 ääØʌ :**Dimethylaminophenol** ȯzÆz zÆŋŬ ÕŁƷŁŋ ŲəÅÅQ ɔŸʒ ɟÅQòŸŀä ÕÊ8ǻ .R ȳózzşózŸõ Õŋ 20 ÅŧŤÄŋ Õõ ƙQÅQä ƙQŁŧÒä ÒŸÅQÊʌş ÛTS Û8.0 ŏÅŁÅä ǧäæ ǧÅÅÊŋ (ȯ/ȯzŋ 0.1) ȳzʌǻzÔöä ÆŁÊõşóÆŁŁ ȯzŸŢ ɗŋ Õŋ 10 øä ÒŸÅQÊʌş ÛŏÅŋ Õŋ 10 ÅŧŤÄŋ Õõ ƙQÅQä ƙQŁŧÒä ƃäzQöä ÆʌÂʌ ŕ ÜÄQŋzφÅφ 293 ĞDZzŋ ȯzÛä ŀè 1 ĞφÅǺä ĞÕĞù ȯŸn ɗŋ ȳzʌǻzÔöä ÆŁÊõşóÆŁŁ ĞòŸŀ î Åŧ0öä âÅÕʌ .VS .0.25 ɗʒ

ȣȦȒȦ ȚȒ1 ȢDzŸŽȚȚ ȮȮȚȚȚȚ ȒȚ ȚȚȚ 20 Ž ȚȚȚȚȚȚȚȚȚȚ 0.2 ȚȚȚȚȚ ȚȚȚȚȚ :**Assay** ȚȚȚȚȚȚȚȚȚȚ

Emetine dihydrochloride pentahydrate; 6′,7′,10,11-tetramethoxyemetan dihydrochloride pentahydrate; CAS Reg. No. 79300-07-5 (pentahydrate).
Emetine dihydrochloride heptahydrate; 6′,7′,10,11-tetramethoxyemetan dihydrochloride heptahydrate; CAS Reg. No. 79300-08-6 (heptahydrate).

Description: Ζòζöã ÆgÅì ÀÅòÙ ɟζŸã ęÙ ŘÆãÙ ɟζŸã ÞØζŸã ȧζΗÜÊη. ĞΗωãÀöã CÁÆ3 ÜÃÆDZ

Solubility: ĞÆφÅãęØöã Àg R ÿØζζęØζŸÒöãę TS (ȯ/Ĥ750~) ȯζφÅŽΛqãę ŏÅţã Ž ɟÅãęØöã Àg.

Category: ĞÅÅöã Antiamoebic ĞĞÆηɟã ãÅŘη ŏãęã.

Storage: ȼΛÂÁφöã ŏζŘöã ȼη ĞÆţΤ ÛÿÅȯgüã ĞÕŸ8η ĞΛęÅg Ž ƙφÆζqã ÁΛØζŸõęØÁÆŁ ęÅg Æz.

Labelling: ɟÆèζφöã ĞÆÅÈφöã ÁΛØζŸõęØÁÆŁ ĞΛęÅg ɟÆèζk ĞęÅÔö Ž ĞÆţÊφöã ÒΛk ɟÙ Æz. ğãØÁÆTã ĞÆ3ÅĞè ęÙ ğãØÁÆTã ĞÆèÅR gãÅţã

Additional information: ĞÆζÅřÙ ğÅηζŸĤη ÁΛØζŸõęØÁÆŁ ζŁ ƙφÆζqã ÁΛØζŸõęØÁÆŁ ÕØÁÆφΛ. ÇÆŸÁφöÅã ęÙ cephaëline ƙŸÅÅÆÊöã ĞΛÆĤη ÀÃŘ+ã ęÙ ipecacuanha ÆŁÓöã ȧÀ3 ȼη ¢ÆŸ3 gØãÀΣã ğÅDZØã ÁÁ3 ţÀèÙ ÕÒÁφöãę ÛÞζζã ÞÅţã ĞãζùÀö ôÀĤφöã ÁÁ3 ÜÆzØÁĚk ÛöζŘöã ãÅÆd Ž ζØφg ÛƙφÆζqã ζŸ3ɟã.

REQUIREMENTS ƙĞΗωÜÕƙΗÜZ!ƒ

General requirement: ȳÅĤöã ÆŸÛφţã ȼ3 ÁΛÂΛ ŗę %98.0 ȼ3 ÕÕΛ ŗ Åη ζŸ3 ƙφÆζqã ÁΛØζŸõęØÁÆŁ ÞζφΖ. ĞÁÅÓã gãÅţã ÞÙ ţζDZÀöÅã ĞãζÊΤ Û$C_{29}H_{40}N_2O_4$, 2HCl ȼη %101.5.

Identity tests: hÜŸNjNJΛΛε lεÞƒGÅHΣε

• ęÙ ȼÓζ ɟãØÅĞφÀŗã ęÙ DS A ɟãØÅĞφÀŗã ęĞΛÛ ɟÙ DS CS B.

A: ęÅÀţΣã ĞÕ ĞĤÌɟã ĞÕÛΛη Ž ΗζŘöã ζÆÛöã âÅÆę" ɟãζ!3 ĞÕ ȽζòζΛ ζŁ Åţõ ÒΗωÅöã ęĞΛÛ. ĞÕ ĞĤÌɟã Ž î ÅÔφΛŗã ζÆù ęãÅÛφΛ. (43 ĞΗωÅÔöã Û1 ÁŸÕã) "Spectrophotometry in the infrared region *ÁΛØζŸõęØÁÆT reference spectrum* ΗĤDZÀţã ζÆÛöã 3η ęÙ RS ƙφÆζqã ÁΛØζŸõęØÁÆŁ ȼη ɟĞÅÅöã ζÆÛöã 3η ęÅÀţΣã *ƙφÆζqã.*

B: ĞÆÊÅÀöã ĞĤÕĞöã ęζãζφĞ. "Related alkaloides ĞÕÅÎţã ğÅφãζφÕöã" ɟãζ!3 ĞÕ Ƚζòζţã ØÅĞφŗã ÞÙ ÀTφã.

D: ȯζŸ+ã ȼη ĞΘÅÅöã ÕŸĞ 3η gÁÎöãę ÀÆTţãę 3ęζţã Ž A: ȯζŸ+ã ȼη ĞΘÅÅöã.

ǰQA̧ ÜTS Õ̧ȯźÁŸÊää Ȑƥ/ȳźȴźȵǰä ǧäÆǴƥźȵ ȯźŸȚ ȯȵ Ȯȵ 1 ǴÛè ȝŸȝ ȯÁǴQȑȑä ǧȺÁȵ ȯȵ ȴŸȵ 5 ÄÎ̧̧ :C .ȶÄȶ ÄȐȑȑ ȷźȯ

General ǦȵÄȞȯää ȸäÄȞQèȑä ǧäȯÁǴQȑä" ȷäźƷȝ ǨƠ ȸźȯźȶä B Ȯȝ̇ÁǴQää Ȯȵ/ȞȞ 0.05 ÂÆõÄQæ ȯźŸ+ä ȬÛḨ̌ :D .(121 ǴHȷÁÔää Û1 ÆŸǨä) ǧäÆ̧ȯźŸÒŸö Âȶȶȵ Ȯȝ̇ÁǴQõ "identification tests

Бǰ ȶźDźÄȯÄæ ÆÊȜȘ Ȯȵ/ȴŸȵ 50 ÂÆõÄQæ ȯźŸȚ ȮȶȞQȨ̂ :**Specific optical rotation** ȴȝźää ÐÄÔǴää ÄȘÁÆǴQää $[a]_D^{20°C}$ = +16 to +19° ÜǨÁÁǨä ǧäȶȶä .Ȟ/ȴŸȵ 1.0 ȸȝ Æ̧ÂÁ ȑ :**Sulfated ash** ǨÁŸÊȶä äȶȵÄää

Æ̧ȯźŸõȘȯÆÆŁ ÆÊÁ ȑ Ü°ȳ105 ǧäÄǵ ǦDźȯÆæ ǨæÄȞää ȷäźää ȝøQǵ ȚÁźz :**Loss on drying** ȚÆÁDźQäÄæ ÆÊÁää ȴȝȶǴè ǩQÆȜqä Æ̧ȯźŸõȘȯÆÆŁ ÆÊÁ ȑȘ .Ȟ/ȴŸȵ 150 ȸȵ ÄȞõÜ ȑȘ ȴŸȵ 110 ȸȵ Ȯęǰ ǧäȯÆÆTä ȴèÄR ǩQÆȜqä .Ȟ/ȴŸȵ 190 ȸȵ ÄȞõÜ ȑȘ Ȟ/ȴŸȵ 150 ȸȵ Ȯęǰ ǧäȯÆÆTä

ÆÆÊõȘȯÆÆŁ ȯźŸHȴȵ ÄÁÄȞÁȘ R ȷźäÄÒää ÆÆÊõ̧ ȴȝÄÄǩ ȸȵ ȯÄȵ ȯÄȵ Ȯȵ10 Ž Ȟ 0.10 ääØ̧ :**Acidity** ǦȞźȶΣä ȝŸȝ ȯźÔHȴŸö Ȯȵ 0.5 ȸȵ ÄȞõÜ ȳÂŸ̧ ȑ ÜTS ȯźφÄḨ̌Ü/ȮÆȞÆȶä ǧÄȶǧ ÄȞÎȵ ȳäÆÁǩQèÄæ ÛVS (ȯ/ȯźȵ 0.02) ȳź̧ÄźÔää .(ƁÄÕǩÄæ) ÄȞÎȶŸö ȝÛèźää ǨÛÔÄää ȷźȯ

ǨÕÆęÄää ǨÕǴÛää ääÄÎǩèä" ȷäźƷȝ ǨƠ ȸźȯźȵ źȶ Äȶõ ǵÄǴQȑȑä ĘǴÛ̧ :**Related alkaloids** ǨǩÄÎȶä ǧÄÆφźŸÕää 100 ȸȵ ǰ̧ÂȵȘ ǨŸȸ8ȵ ǧÄȶõ R1 ÄÒÆŸÆÊää ǦȵŸŁ ȳäÆÁǩèÄæ Û(84 ǴHȷÁÔää Û1 ÆŸǨä) "Thin-layer chromatography 2 ÛR ȯźφÄȞÆȶä ȸȵ ȳźDźǵ 5 Ûethylene glycol monomethyl ether R ȸȵ ȴȶDźǵ 20 ÛR ȳǵźȘȯźŸÒää ȸȵ ȴDźǵ 4 ȸȵ ǴHȷÆÁÔää ȝŸȝ ÄǩȘÄÒȵ 10 ȴŸÔÁ̧ȵ ǦǴÛ̧ .ȯÄHǩȵ ǵźÛõ R ǩȵŸÆḨ̌Ü ȴȝÄÄǩ ȸȵ ȴȶDźǵ 0.5Ș ȯÄȶä ȸȵ ȴȶDźǵ 0.50 ȴźȞ :(A) ȯźŸ+ä ÛR ȯźφÄȞÆȶä ȸȵ ȴȶDźǵ 99ȘTS (ȯ/Ȟ17~) ÄÆφźȵǰä ȸȵ ȴȶDźǵ 1 ȸȵ ȚÓúȵ ǰ̧ÂȵȞ Ȯ ÕÆÄÄȚ cephaëline ǩŸȝÄÄÆÊää Æ̧ȯźŸõȘȯÆÆŁ ȸȵ ȳäÄdȘÄÒȵ 10 ȴźȞ :(B) ȯźŸ+ä ÛȮȵ 1 Ȯõ Ȯ ǵÄǴQȑȑä ǧÄȵ ȸȵ ȴŸȵ :(D) ȯźŸ+äȘ Ȯȵ 1 Ȯõ Ȯ ǵÄǴQȑȑä ǧÄȵ ȸȵ ȳäÄdȘÄÒȵ 5.0 ȴźȞ :(C) ȯźŸ+ä ÛȮȵ 1 Ȯõ Ȯ hydrochlorid R ȚDźQõ õÄQǩ ÛääÄÎǩèȑä ǧǴDźǵ ȸȵ ǴHȷÆÁÔää ȶÂφ ÆÄäȘ .Ȯȵ1 Ȯõ Ȯ RS ǩQÆȜqä Æ̧ȯźŸõȘȯÆÆŁ ȴŸȵ 0.50 ȴźȞ 15 ǧÆȵ °ȳ 60 ǦDźȯÆÄäæ ȸÁÊǩȘ ÛTS ȳǵźȘȯźŸõ/ÁźÄ ȯźŸHȴȵ ǴHȷÆÁÔää æÄǩ Ż ÛǧÁǴÁǵȶä ÄÁǴQǩ ȝøQǵ ȯäźTä Ž A ȯźŸ+ä ȸȵ ǰQÄǩ ǨȞÕäæ ǴÜ ȷźÒǩ ȑ .(ÄQȵźφÄφ 365) ǨÆDźÊÄÁǴää äźȝ ǨȞÌȷä Ž ääÄÎǩèȑä ÜÛÜ ÒHȷÁ̧Ș ÛǴÕÆęÁ ȸȵ ǧÆÌ ÄȞõÜ A ȯźŸ+ä ȸȵ ǰQÄǩ ȜÄÌÜ ǨȞÕæ ǴÜ ȷźÒǩ ȑȘ .B ȯźŸ+ä ȸȵ ǨÖÄÁää ǨÕźäźȶä ǨȞÕǴää Õ̧Ÿǩ ȸȵ ǧÆÌ ÄȞõÜ .C ȯźŸ+ä ȸȵ ǨÖÄÁää Õ̧Ÿǩ

10 ȸÄȨ̂ ÛR1 ȴDźŸȞää Õ̧ÆQÆèȷä Ȑƥ ȸȵ Ȯȵ 30 Ž ÛǨÆÜźǴÊȵ ǴQȘÄźȵ ÛȞ 0.2 ǴääÄę ääØ̧ :**Assay** ǨȨ̂ÄÄȞȶä ȸźȯźȵ źȶ Äȶõ VS (ȯ/ȯźȵ 0.1) Õ̧ȯźŸõǩǴää ȐȶŁ̧ ÄÁÄḨ̌Ș TS Õ̧ÆQÆèȷä Ȑƥ/ĘǴäÂää ǧÄQÆèÜ ȯźŸȚ ȸȵ Ȯȵ

Ŏȭ .(142 ĞĦȤÁÔȭã Ȗ1 ÁŸŎã) A ĞȬȺÀÛȭã ÆÊШ Ȗ"Non-aqueous titration ȚəÀŋŸȭã Ùèzȭã Ž gÀȺÀĤŧ̄ã" ȷãzÁ3 ŘƠ
.$C_{29}H_{40}N_2O_4$, 2HCl ȡŋ 27.68 ùzÁÒȺ VS (ȯ/0.1) ÕȺózŸȭŘGȭã Ř β ȡŋ Ŏŋ 1

EPHEDRINUM

Ephedrine Džĭβǫĭžĭã

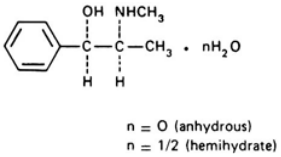
Ephedrine, anhydrous Ĭ əFDŽÚ ÛDžĭβǫĭžĭã

Ephedrine, hemihydrate l εβǫĭNJllε ε Tŭ Džĭβǫĭžĭã

$C_{10}H_{15}NO$(anhydrous); $C_{10}H_{15}NO$, ½ H_2O (hemihydrate) :**Molecular formula** ĞĒÀȺÂƨã Ğ8ĒÔȭã

174.2 (hemihydrate) Ü165.2 (anhydrous) :**Relative molecular mass** ĞĒGÊȺȭã ĞĒÀȺÂƨã ĞŸǫȮȭã

:**Graphic formula** ĞĒφÀĒGŧ̄ã Ğ8ĒÔȭã



:**Chemical name** ȚəÀĒŧĒȮȭã ȷèrã

(–)-Ephedrine; [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzene-methanol; CAS Reg. No. 299-42-3 (anhydrous).
(–)-Ephedrine hemihydrate; [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzene-methanol hemihydrate; CAS Reg. No. 50906-05-3 (hemihydrate).

ĞÁĒÁǹ ĞĦȤãȯ ¢ŏ ȘĬ ĞĦȤãÀȭã CÁƷ Ü ŘĒãĬ ȷzŸã ƁózŸã ȧzĦȤÊŋ ȘĬ ȷzŸȭã ĞƨÁƷ ğãózŸã :**Description** Ƶòzȭã
.ĞȺÀÛ3

Ž ȷÀãȘØȭã Ãǵ ÜTS (ȯ/ȟ750~) ȯzφÀŽȺqã Ž ßÁEDZ ããȘáé ÜR ȳózzȘózŸÒȭãȘ ŏÀŧ̄ã Ž ããȘáé :**Solubility** ĞĒφÀãȘØȭã
.Ğǭã

.zãÀŸŏ ãÁŘŋ ŏãȘã :**Category** ĞĬÁȭã

.ŏzŘȭã ȡŋ ĞĒŧŢ ÛßÁEDZ ĞÕŸ8ŋ ĞȺȘÀǵ Ž ȡȺØÁĒÁȺqã ȘÁǵ Æz :**Storage** ȡȺÂÁǫȭã

ƵÔφ ÕȮÎã ȚŁ gãÁŧ̄ã Ğφ̄Àŏŏŏŏ ãæÜ ÁŧĒz ƨŸ3 ĞȺȘÁΣã ȷĒèzĭ ĞęÁÔŏ Ž ĞĒŧÊǫȭã ÒȺĭ ȷÜ Æz :**Labelling** ȷĒèzǫȭã
.ȚəÀŋr ÕȮÎã ȘÜ ȚəÀŋ

Additional information: Ğ Ğ Ğ

ŌŌ̄ ŕ Ügǎ̄ţ̄ ďŋ ȟ 1 ǦǎǎÀę ȳÆǍǫÊ ǧǎǿÆŧŤ Ƶ Ôφ ŌÒÎŸ ǦǤÊǺǎ̄ǎ̄ş .ȟ/ŋŸŋ 10 ďƷ ǒǎ̄ţ̄ ƷƵǫŢ ÆǺÂ ŕ Ügǎ̄ţ̄ ďŋ .ȟ/ŋŸŋ55 ďƷ ÆǺÂ ŕş ȟ/ŋŸŋ 45 ďƷ ǒǎ̄ţ̄ ƷƵǫŢ

50.0 ȣ̄ǎ̄Ŕ ÛTS(ȯ/ȟ750~) ȯƵφǎ̄ǎ̄ǺǺq̄ ďŋ Ōŋ 5 Ž ÛǦÊùƵǤŔŋ ǦφşàƵŋ ÛȟŌ 0.5 ǦǎǎÀę ǎ̄ǎ̄ØÀ :**Assay** ǦÊǺǎ̄ǎ̄Ōţ̄ ȳǎ̄ǎ̄ǍǫèÀǎ̄ Ûvs(ȯ/ȯƵŋ 0.1) ȳƵǺǎ̄ƵÔǎ̄ ÆŧÊȭşǿÆŧŤ ȯƵŸHŋ ÀǺǎ̄ȟǺş vs(ȯ/ȯƵŋ 0.1) Ō̄Ǻǿ̄ƵŸȭşǿÆŧŤ Ŕβ ďŋ Ōŋ ŋŸŋ 16.52 ùƵǎ̄ȮǺ vs(ȯ/ȯƵŋ 0.1) Ō̄Ǻǿ̄ƵŸȭşǿÆŧŤ Ŕβ ďŋ Ōŋ 1 Ōȭ .TS ȯƵφǎ̄ǎ̄ǺÙ/ŌŧŤŧ̄ţ̄ gÀŧǵ ÀȟÎŋ .$C_{10}H_{15}NO$ ďŋ

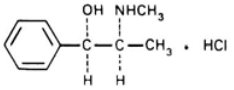
EPHEDRINI HYDROCHLORIDUM

Ephedrine hydrochloride DžĭÞǫĭƶĭǕƐ ǫĭÞNj‡lNjÞǫĭlj

$C_{10}H_{15}NO,HCl$:**Molecular formula** ǦŧǺǺÂƨǎ̄ Ǧ8ŧÔǎ̄ǎ̄

201.7 :**Relative molecular mass** ǦŧǦÊǺǎ̄ǎ̄ ǦŧǺǺÂƨǎ̄ ǦŸǫȮǎ̄ǎ̄

:**Graphic formula** ǦŧφǺŧǦţ̄ǎ̄ Ǧ8ŧÔǎ̄ǎ̄



:**Chemical name** ȣƏǺŧŧȮǎ̄ǎ̄ ǀèŕǎ̄

(–)-Ephedrine hydrochloride; [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzenemethanol hydrochloride; CAS Reg. No. 50-98-6.

.ǦHƱǎ̄ǎ̄Àǎǎǎ

General requirement: �aldehydum contains not less than 99.0% and not more than 101.0% of $C_{10}H_{15}NO, HCl$, calculated with reference to the substance dried at 105°.

Identity tests: A. Dissolve 1 g in 10 ml of water, add 1 ml of 0.1 N hydrochloric acid and 1 ml of 0.1 N sodium nitrite solution, and dilute to 100 ml with water. Dilute 1 ml of the solution to 100 ml with water. Measure the absorbance of the solution at 263 nm, 257 nm and 251 nm, using 1 cm cells and water as the blank. The absorbance at 263 nm is 0.36 to 0.48, at 257 nm is 0.37 to 0.47, and at 251 nm is 0.36 to 0.48.

B. Add 2 mg to 2 ml of sulphuric acid (98%) (II) in a test tube. Shake the tube gently to dissolve the substance. Add 1 drop of 0.1 M ferric chloride solution. A violet ring appears at the interface of the two liquids. Shake the tube vigorously. The violet colour disappears and the upper layer becomes yellow.

C. Add 1 mg to 5 ml of sulphuric acid (98%). A violet colour appears. Add 1 drop of 0.05 M ferric chloride solution. The violet colour disappears and the upper layer becomes yellow.

Melting range: 217 – 220°.

Specific optical rotation: Between −33.0 and −35.5°. Dissolve 50 mg in 10 ml of methanol. $[\alpha]_D^{20°C}$ =

Sulfates: Dissolve 40 mg in 40 ml of water. Add 1.5 ml of 0.1 N hydrochloric acid. Dilute to 50 ml with water. Dilute 1 ml of the solution to 10 ml with water. Add 1.0 ml of 0.05 M barium chloride solution. The turbidity produced is not greater than that of a standard prepared from 10 mg of sulphate ion (SO_4^{2-}) treated in the same manner.

Clarity and colour of solution: Dissolve 1.0 g in 10 ml of water. The solution is clear and not more than opalescent when compared with a standard opalescence prepared from 5 ml of the solution and 5 ml of water.

Sulfated ash: 1.0 g, not more than 0.1%.

Loss on drying: Not more than 0.5% when dried at 105° for 3 h.

Acidity and alkalinity: Add 0.01 ml of 0.1 N hydrochloric acid to 10 ml of 1.0 M barium chloride solution. Add 0.1 ml of phenolphthalein solution. The solution is colourless. Add 0.1 ml of 0.1 N sodium hydroxide solution. The solution is pink. Add 0.1 ml of 0.1 N hydrochloric acid. The solution is colourless.

Assay: Dissolve 0.2 g in 50 ml of glacial acetic acid, add 50 ml of 0.1 N perchloric acid in dioxane, and titrate the excess of perchloric acid with 0.1 N sodium acetate in glacial acetic acid, using crystal violet solution as indicator.

A ǦÕΛÀÛöä Û"Non-aqueous titration ƱəÅŋŸöä Ùèȝöä Ž gÀΛÅĦţä" ɹǯȺ3 ǨƠ ȣȝòȝŋ ȝŁ Åŧȭ VS(ȯ/ȯȝŋ 0.1) ȣŋ ŋŸŋ 20.17 ùȝÅÒΛ VS(ȯ/ȯȝŋ 0.1) ȬΛøȝŸȭǩöä Ř ƥ ȣŋ Ōŋ 1 Ōȭ.(142 ǦƱÅÔöä Û1 ÆŸÖä) .$C_{10}H_{15}NO,HCl$

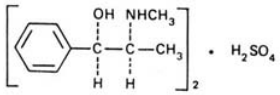
EPHEDRINI SULFAS

Ephedrine sulfate DžŸƥǫŸ2ŸǕȣ l ƒ2ǂȺ

Molecular formula: $(C_{10}H_{15}NO)_2,H_2SO_4$ ǦŁÅΛÂȺä ǦȣŁÔöä

Relative molecular mass: 428.5 ǦŁǦÊΛöä ǦŁÅΛÂȺä ǦŸǫÒöä

Graphic formula: ǦŁǫÅŁǦţä ǦȣŁÔöä



Chemical name: ƱəÅŁŧŁÒöä ǀèȺä

(–)-Ephedrine sulfate (2:1) (salt); [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzenemethanol sulfate (2:1) (salt); CAS Reg. No. 134-72-5.

Description: Ȝòȝöä ÜŘŁäÙ ɹȝŸä ɃøȝŸä ȧȝƱÊŋ ȘÙ ɹȝŸöä ǦȝÉȝ ǧäøȝŸä .ǦƱəäÀöä CÉȝ

Solubility: ǦŁǫÅäȘØöä Ÿ ɹÅäȘØöä ÀǦ .TS (ȯ/Ȟ750~) ȯȝǫÅǯΛqä Ž ɹÅäȘØöä ŌŁŸę ÜŏÅŧä Ž ɹÅäȘØöä .ȝäÀŸö ǎÅŘŋ ŏäȘǎ

Category: ǦÅÅöä

Storage: ȣΛÂÁǫöä .ŏȝŘöä ȣŋ ǦŁŧŢ ÛŁÉŁDZ ǦÕŸ8ŋ ǦΛȘÅǦ Ž ȣΛøÉŁÅΛqä ǧÅÅŸè ȘÅǦ Æz

Additional information: ǦŁȝÅřÙ ǧÅŋȝŸŋ ÓøÉǫǩ .ŏȝŘŸö ô ÀŘǫöä ÉΛȝ ŁΛõäǎ ȣΛøÉŁÅΛqä ǧÅÅŸè ɹȝö ǦǩÔΛ ÉΛȝ ŧÀèÙ ÕÒÅǫöä ɹȝÒΛȘ ÛƱȝȺä ƥÅŧä ǦäȝùÀö ô ÀŘǫöä ÉΛȝ ŁŁzøÉǩ ÛŏȝŘöä ãÅŁq Ž ȺøǫǦ ÛȣΛøÉŁÅΛqä ǧÅÅŸè .ȺŸȝjä gøäÀΣä ǧÅDZøǎ

REQUIREMENTS ǩǦȣΛøŁŁǩŁŁ!ƒ

General requirement: ȳÅŘöä ÆŸÛǫŧä ȣȝ ÉΛÂΛ ŁȘ %98.0 ȣȝ ŌȭΛ Ł Åŋ ȺŸȝ ȣΛøÉŁÅΛqä ǧÅÅŸè ƱȝǫÓ .ǦÅÅÖä gǎÅŧä ƱÙ ŧȝDZÀöÅä ǦäȝÊŢ Û$(C_{10}H_{15}NO)_2,H_2SO_4$ ȣŋ %101.0

Identity tests hŭŇjNJЛЄ l ЄƀƑǴƊǤЄ:

350ş ÀǫŋƷφÅφ 230 ƙæ ƷǎƷŋɟǎ ȯǎƷùÙ Ž ÁŁÅÎΛ ÅŋÉÁ3 ÛŌŋ/ŋŸŋ 1.0 ÂŁõÀǫæ ȯƷŸǂ î ÅÔǫŋŗǎ ƵŁù ƀÁǤΛ :A ǤφÅÁƷæ ǤŌǤù ȯƲn ɗŋ î Åŧǫõǎ ŋŸǤΛ ÜÀǫŋƷφÅφ 262ş 257ş 251 ǤæǎÀę ƷǎƷŋɟǎ ȯǎƷùÙ Ž ǤŁŧŢ3Ù ǧÅȯÅÔǫŋǎ ÜÀǫŋƷφÅφ .БǎƷǫõǎ ƻŸ3 Ûo.61ş 0.76ş 0.61 ǤæǎÀę ǢØŁ ƷǎƷŋɟǎ ȯǎƷùÙ Ž ɭè 1

Ōŋ 2 øæ 3ǫǫǂ ÛTS (ȯ/ȟ80) (II) âÅHUÅõǎ ǧÅÅŸè ȯƷŸŢ ɗŋ Ōŋ 0.1 8ÅÊΛş ŏÅŋ Ōŋ 1 Ž ŋŸŋ 10 ǎǎØΛ :B ɟƷȯ ǰǫΛ ÜŋŘƷş Ƙǫɟǎ ɗŋ Ōŋ 1 8ÅÊΛ .ŦDzÊÁæ ɟƷȯ ǰǫΛ ÜTS (ȯ/ȟ 80~) ȳƷΛǎƷÔǎ ÁŁÊõşøÁŁŁ ȯƷŸŢ ɗŋ .ǤŁǎÅŧǎ ǤŌǤÛǎ Ž ȧøàÙ ɟƷȯş ǤΛƙǫɟǎ ǤŌǤÛǎ Ž ŦøφǎƷ DZøÙ

Ōŋ 4ş TS (ȯ/ȟ80~) ȳƷΛǎƷÔǎ ÁŁÊõşøÁŁŁ ȯƷŸŢ ɗŋ ǧǎÀÛę 3Ŕæ 8ÅÊΛ .ŏÅŋ Ōŋ 5 Ž ȟ 0.05 ǎǎØΛ :C

.ɭÎȯÅæ ȫǎøǎŘȯ ǤŸæÅÔǎ ÁŁŁÁǎǎÂøAǤǎ ǤHUǎǎø ĘŸÛÅǩ ÜɗǎÁÊΛş TS (ȯ/ȟ 50) ȳƷŁèÅǩƷǎǎ ÁŁφÅŁè ƀÀǵ ȯƷŸŢ ɗŋ

General ǤŋÅȞǎǎ 8ǎÀȞǫèŗǎ ǧǎøÅǫǫnǎ" ɟǎƷΛ3 ǨƠ 8ƷȯƷŧǎ A Ō3ÅÅǫǎǎ Ōŋ/ŋŸŋ 20 ÂŁõÀǫæ ȯƷŸǂǎ ŬÛȞΛ :D

.(123 ǤHUÅÔǎǎ Û1 ÁŸŎǎ) ǧÅÅŸÊŸǎ Âǎŧŋ Ō3ÅÅǫõ "identification tests

.ŐÒÅǫǎǎ 3ŋ ◦ȳ245 ǤæǎÀę ÛøÅŦÔφqǎ ǤDZøǎ :E

Бǎ ŧƷDZÀǎÅæ ÆÊ3ş Ōŋ/ŋŸŋ 50 ÂŁõÀǫæ ȯƷŸŢ ȳÁÁǫÊΛ :**Specific optical rotation** Ŧ3ƷÅǎǎ ƀÀÔǤǎǎ ÀΛşÁǫǎǎ .$[a]_D^{20°C}$ = - 33.5 to –32.5° ÜǤÅÅŎǎ ǧÅŧǎ

ǨƠ 8ƷȯƷŧǎ øÅǤǫnŗǎ ǧǎǎÀDZq øÅǤǫnŗǎ ǧÅŋ ɗŋ ȟ 0.20 ǤŁŧõ 3ŘÁŁ ÅŋÉÁ3 :**Chlorides** ǧǎÁΛøƷŸÒǎǎ Ž ǧÅΛÀ ÀŦŢk ŗ Ü(124 ǤHUÅÔǎǎ Û1 ÁŸŎǎ) "Limit test for chlorides ǧǎÁΛøƷŸÒǎǎ ŌDZj ƀÁΣǎ øÅǤǫnŗǎ" ɟƷȯ3 1.4 ɗ3 ÁΛøƷŸÒǎǎ ƷƷŢ ÁΛÂΛ ŗ ÜVS (ȯ/ȯƷŋ 0.02) ŐΛøƷŸõşøÁŁŦǎ Ŕβ ɗŋ Ōŋ 0.40 ǢÀŦŢΛ Åư ÀǰõÙ ÀȮȞǎǎ .ȟ/ŋŸŋ

ŗ ŞÙ ÛŁƷÅȯ ŏÅŋ Ōŋ 10 Ž ȟ1.0 ÂŁõÀǫæ ȯƷŸǂǎ ɟƷÒΛ :**Clarity and colour of solution** ȯƷŸǂǎ ɟƷȯş ŏÅÅȯ .ɟƷŸǎǎ CÁ3ş Ûopalescence standard TS2 ǤŁŋƷŧǎǎ ǎÅŁȞŋ ȯƷŸǂ ŬŁ Åư ÀǰõÙ ȳƷŧǎǎ ¢ŁƷ ɟƷÒȞ

.ȟ/ŋŸŋ1.0 ɗ3 ÁΛÂΛ ŗ :**Sulfated ash** ȞÁŸÊŧǎ ǎÅŋÀǎǎ

20 ɗŋ ÀǰõÙ ÁÔÅΛ ŗ Ü◦ȳ105 ǧǎÀǧ ǤDZøÁæ ȞæÅǰǎǎ ɟàƷǎǎ ƻøǫǧ ƷÁƷ :**Loss on drying** ƷŁÁDzǫǎÅæ ÁÔÅǎǎ .ȟ/ŋŸŋ

ǧÀƀ ȯƷŸŢ ɗŋ Ōŋ 0.1 8ÅÊΛş ŏÅŋ Ōŋ 10 Ž ȟ 1.0 ǎǎØΛ :**Acidity and alkalinity** ǤΛƷŸÒǎǎş ǦŕƷŧ3ǎ Ŕβ ɗŋ Ōŋ 0.1 ŞÙ VS(ȯ/ȯƷŋ 0.1) ȳƷΛǎƷÔǎ ÁŁÊõşøÁŁŁ ȯƷŸŢ ɗŋ Ōŋ 0.1 ɗŋ ÀǰõÙ ȳÂŸΛŗ ÜTS ȯƷφÅǰΛÙ/ŌŁǰŧǎ .(БÅÔȞÀǎ) ÀȞÎŧŸǎ ƻÛèƷǎǎ ǤÛŌÅǎǎ ɟƷȯ ƻŸ3 ȯƷÔHUŸǎ VS(ȯ/ȯƷŋ 0.1) ŐΛøƷŸõşøÁŁŦǎ

ÆÀózŸõ ďŋ ň 3 Ďāzǵ ȣÀŘÀş ÛŏÀŋ Ōŋ 10 Ž ÛĞŁùzĠŘŋ Ğ̣ŋşàzŋ ÛŇ 0.3 ĞāāÀę ā̄āØÀ :**Assay** ĞÊÀÀŌţā ÒŸÁĢÊÀş vs (ȯ/ȯzŋ1) ȳzÀǻzÔāā ÆŁÊõşøÆŁŁ ȯzŸŢ ďŋ Ōŋ 5 ȣÀŘÀ ØəÆÀ3 ÛȯzŸ∓ā ţÀĠìq R ȳzÀǻzÔāā ȯzŸŢ ďŋ Ōŋ 10 øā ȳØzzşØzŸȮāā ğŕÀÊŧŋ ǰÀÂŋ ŌÊȣł .R ȳØzzşØzŸȮāā ďŋ ÛŌŋ 25 ÀŦÀŋ Ōȭ ÛŸzDzǵ ĞĦāØüā Ōŋ 10 3ŋ ȣəÀţā ŌŁÊȣāā ȯzŸŢ ŋŘƧ .R ȳØzzşØzŸȮāÀā 3āÎŋ ɔŌłŋ ďÛę Ǝ3 ĞìÀÀş Û3ĞÎţā R ȳzÀǻzÔāā ÆÀózŸõ ÀÀÀĦÀş TS ȯzĢÀŽÀÀ/ŌŁŽŁţā gÀŧǵ ȯzŸŢ ďŋ Ōŋ 0.25 ȣÀŘÀş .ĞŁÊŁəÀāā ȳØzzşØzŸȮāā ĞòŸŶ ȣÀŘłş R ȳØzzşØzŸõ Ùèzāā Ž gÀÀÀĦţā" ɟāzÀ3 ŘƠ ȣzòzŋ zŁ Àŧȭ ÛvS(ȯ/ȯzŋ 0.1) ɟÀÊȭzÀǻ/ȬÀózŸõŘĞāā Ř̄ þ ȯzŸHuŋ ɟÀÊȭzÀǻ/ȬÀózŸõŘĞāā Ř̄ þ ďŋ Ōŋ 1 Ōȭ .(142 ĞHuÀÔāā Û1 ÆŸŌā) A ĞȬÀÀÛāā Û"Non-aqueous titrationȣəÀŋŸāā .($C_{10}H_{15}NO)_2$, H_2SO_4 ďŋ ŋŸŋ 21.43 ùzÀȮÀ vS(ȯ/ȯzŋ0.1)

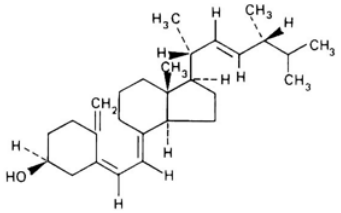
ERGOCALCIFEROLUM

Ergocalciferol üNjþĭ2ĭ2ĭ2WFlNjƷþa

$C_{28}H_{44}O$:**Molecular formula** ĞŁÀÀÂ2ā ĞȣÊÔāā

396.7 :**Relative molecular mass** ĞŁĞÊÀāā ĞŁÀÀÂ2ā ĞŸĢȮāā

:**Graphic formula** ĞŁĢÀŁĞţā ĞȣÊÔāā



:**Chemical name** ȣəÀŁŧŁÔāā ĻèŕÀ

(5*Z*,7*E*,22*E*)-9,10-Secoergosta-5,7,10(19),22-tetraene-3β-ol; 24-methyl-9,10-secocholesta-5,7,10(19),22-tetraene-3β-ol; CAS Reg. No. 50-14-6.

.D_2 ĸŋÀȮĢ :**Other name** ÀÀòĢ̣ā ĻèŕÀ

ş̄ ŘŁÀ̄ ɟzŸā Ƀ̄ózŸā ȧzHuÊŋ ş̄ ÆgÀÎāā ÀÀòĢ̣ā āóÀŕ ɟzŸā ş̄ ɟzŸāā ĞŁÆ3 ğāózŸā :**Description** Ƶòzāā .ŇĞÀÀÕĸ ĞHuəāÀāā CÆ3 ş̄ ĞHuəāÀāā CÆ3 ÜÆgÀÎāā ÀÀòĢ̣ā āóÀŕ

R ȳǿȝȝȿǿȝŸȮǿǽȿ TS (ȯ/ȟ 750~) ȯȝφǼǰǾǿǽ Ž ȷǼǽȿǾǿǽ ǼǾǿ Ǽǿǽǿǽ Ž ǼǼŸǿȝ ȷǼǽȿǾǿǽ ĆǼȝ :**Solubility** ǾǼφǼǽȿǾǿǽ .R ǾǿȷǼǽȿ R ȷȝǾǼèȷǼǽȿ

.antirachitic ǼǼǼǼǿǽ ǼǼǼǼǿǽ :**Category** ǾǼǼǿǽ

ǾǼǼǿǽ Ž ǾǼǼǿǽ ǾǼǿǽ ǾǼǿǽȝŸǾǿ ǾǼǾǿǽȝ ȝŸ ȝŸȝ ǾǾŸǿǽ ǾǼǼǿǽ Ž ȯȿǾǼǼǿǽǾǼǼǿǽǾǼǼǿǽ ǾǼǼǿǽ ǾǼǼǿǽ :**Storage** ǾǼǼǿǽ .ȝȝȝ 8ȿ 2 ǾǼǼǿǽ ǾǼǼǿǽǾǼǼǿǽ ǾǼǼǿǽȝȝȝ ǾǼǼǿǽ ǾǼǼǿǽ ǾǼǼǿǽ ǾǼǼǿǽ inert ǾǼǼǿǽ ȝȝȝ

Ž ȝøǾǿǽ ǾǼǼǿǽǾǼǼǿǽ .ǾǼǼǿǽǾǼǼǿǽȿ ǾǼǼǿǽ ȯȿǾǼǼǿǽǾǼǼǿǽ ǾǼǼǿǽ :**Additional information** ǾǼǼǿǽ ǾǼǼǿǽ ǾǼǼǿǽ ǾǼǼǿǽ

Thin-layer ČŐŧęÀöä ČŐŐĠÛöä ãäÀÎǫèä" ɟäzȺ3 ŘƠ 8ȝòȝŋ ȝŁ Åŧõ øÅǪǫnŗä ƤÀz :**Ergosterol** òşŘǫèzḍǿŮ Ŏŧ̣ĦǫÊΛ õÀĦuǫŋ ǿzÛõş ÛĞŸ8ŋ gǻÅŧõ R1 ÅÒŧŸŧÊöä ĞŋŸŁ ȳäÉÁǫèÀæ Û(84 ĞĦuÅÔöä Û1 ÉŸŎä) "chromatography ɒŋ ŊŸŋ 0.10 ǰΛÂţä Ƀȝƺ ÛR ÉŧÊõşŘĞöä ɒŋ ƁẠ̊ǫ̣ä Řǫ̣ɟäş R ɟäÅÒŁȝŸÒŧÊöä ɒŋ ĞΛşÅÊǫŋ ȳzDzǵ ɒŋ ǰΛÂŋ gÀÂŘ‡ä ĞŧöÅǫöä ŐŧöÅ‡ä ɒŋ ÀǫöşÀÒŋ 10 ĞĦuÅÔöä ƨŸƺ ŸÔÅΛŋ ĘĞÛΛ.Ŏŋ 1 Ŏõ Ž butylated hydroxytoluene R butylated ɒŋ ŊŸŋ 0.10ş squalane ɒŋ ŊŸŋ 10 ƨŸƺ ƁşÅΣä R ɟÅŽΛŮ øzŸÒΛÆöä ɒŋ ǰΛÂŋ Ž òÅŧ̣Ħǫèŗä ŐĞę gÀÌÅĞŋ Ƀȝƺ :(B) òzŸ‡ä ÛŐŋ 1 Ŏõ Ž øÅǪǫnŗä gǻÅŋ ɒŋ ȟ 0.050 Ƀȝƺ :(A) òzŸ‡ä :Ŏŋ 1 Ŏõ Ž hydroxytoluene R Ž ergosterol R òşŘǫèzḍǿqä ɒŋ ŊŸŋ 0.10 Ƀȝƺ :(C) òzŸ‡ä ÛŐŋ 1 Ŏõ Ž RS òşŘÅÊŧöÅõzḍǿqä ɒŋ ȟ0.050 ŕòzŸ‡ä ɒŋ ȳzDzΣä òåÅĦǫŋ ǰΛÂŋ ɒŋ ɟzÒǫΛ ƁØöä (D) òzŸ‡ä ɒŋ ÀǫöşÀÒŋ 20 ĞĦuÅÔöä ƨŸƺ ÅŘÛ ĘĞÛΛ ÜŐŋ 1 Ŏõ ǫŸǫ ǽÀŧ̣ş öäzTä Ž ȜDzǫö õÀǫŘ Ûāäà̀ÎǫèŗÅ ǵŘDzǵ ɒŋ ĞĦuÅÔöä ţÂφ ÉĦäş .ȳŸŢöä Ž ĞĦuÅÔöä õÀǫŘ .Cş B .øÅŸÅöä ŏzŘæ āäÀÎǫèŗä ÙÛÙ ÒĦuÅΛ Ż ÛĘəÅęǻ 4-3 ǽÀöä ÉĦæ ÀŢǫΛΛ .antimony trichloride TS òzŸĦuŋ ǵäÀŋ ƷęzŢä Ž ĘzäzǫŘ ÅŒÙ ÜŬøÅæ ɟzŸæ ĞǪÔŘ Ż ƁÅÕŘÀæ – ÀÅòÙ ɟzŸæ ĞÀäÉĞöä Ž A òzŸ‡ä ɒŋ ĞΘÅÅöä ĞŧÊŧəÀöä ĞĦÕĞöä ɟzÒŘ ŐŧŸÕæ Ŏę̣Ù R_f Ğŧ̣ę ǵäǽ A òzŸ‡ä ɒŋ ǰǫÅŘ ĞŧDzÊÅÅæ ĞĦÕæ ĞΛÙ ɟzÒŘ ŗ .B òzŸ‡ä ɒŋ ĞΘÅÅöä ÕŸŘ Ʒŋ ǵÉÎöäş ÀŸŢţäş ƁÙ A òzŸ‡ä ɒŋ ǰŘÅÅöä āäÀÎǫèŗä ÙÛÙ ÀŸŢł ŗ .C òzŸ‡ä ɒŋ ĞΘÅÅöä ĞĦÕĞöä ɒŋ ǵÉì ÀŽõÙ ĞŧÊŧəÀöä ĞĦÕĞöä ÕŸŘ ɒŋ ÙÛÙ ÀŸŢł B Åŋ ÅΣÅò øÅǪǫnŗä ÉĦł ŗş .Cş B ŕòzŸ‡ä ɒŋ ŕΘÅÅöä āäÀÎǫèŗä ƱÛÛÙ Ʒŋ ĞφøÅÕŧ̣Åæ ĞŧzÅŗÙ ƷÕæ .ǴŗäŞ zU ƨŸƺ ŕǫŸÔÅΛŋ ŕǫĦÕæ D òzŸ‡ä ɒŋ ɟŘÅÅöä āäÀÎǫèŗä

ÉŧŁÉöɟä ɒŋ òÅǹ òzφÅŽΛŮ Ŏŋ 10 Ž ȟ0.10 ãäØΛ :**Reducing substances** (ĞĦÔzÀŧ̣ä) ĞõÂǫÉŧ̣ä ǻäzŧ̣ä ÉŧÊõşøÉŧŁ òzŸŢ ɒŋ Ŏŋ 0.5ş TS òzφÅŽΛŮ/ȳzŧöşääÀǫöä Ğęǿà òzŸŢ ɒŋ Ŏŋ 0.5 8ÅŘΛ ÛTS (ȯ/ȟ750~) .R ƱDzŸŽöä Õŧǫèɟä Ŗβ ɒŋ Ŏŋ 1 8ÅŘΛ Ż ÅŋÅǫ ĘəÅęǻ 5 gÉŋ øäÀÕǫèŸȯ õÀǫΛ .TS òzφÅŽΛŮ/ȳzŧφzŋÙ ŎŧŽŧnäÀǫöä òzŸŢ ƨŸƺ ĞΛşÅΣä ÆΛØŧ̣ä gKDzǵ ŎäÅÕŋ ÀǫŋzφÅφ 525 ĞääÀę ĞDZzŋ òzÛæ ɟè1 ĞφÅÅŽæ ĞÕĞù òŸŋ̀ ɒŋ î Åŧ̣ǫöä âÅÕΛ ɒŋ ƎõÙ î Åŧ̣ǫöä ɟzÒΛ ŗ .ÅŦÊÅφ ĞÕΛÀÛöÅæ TS (ȯ/ȟ750~) ÉŧŁÉöɟä ɒŋ ƁẠ̊ǫ̣ä òzφÅŽΛqä ɒŋ Ŏŋ10 ĞƨÅĦŋ ÀφŘŢ òzφÅŽΛqä Ž hydroquinone R ɒŋ Ŏŋ/ȳäÅdşÀÒŋ 0.2 Ƀȝƺ òzŸŢ ɒŋ Ŏŋ10 Ʒŋ ĞŧŸŧĦöä ǵäÅƷÙ ɒŋ ɟŘÅÅöä î Åŧ̣ǫöä ÉŧŁÉöɟä ɒŋ ƁẠ̊ǫ̣ä .TS (ȯ/ȟ750~)

òzφÅŽΛqä ɒŋ ĞŧzÅõ Ğŧŧõ Ž ÛĞŧùzĞŘŋ Ğφşàzŋ ÛȟΛ0.05 ŕÅÊŕ ɟşǻş ĞΛÒŧŧ̣ä Ğ3ÀÊöÅæ āäØΛ :**Assay** ĞÊΛÅÕŧ̣ä .¢ÊÅφ ÆΛØŧ̣Åæ Ŏŋ 250 Ƀŭ òzŸ‡ä äØŁ ɒŋ Ŏŋ 5.0 ȜÅȜ ÜŐŋ 100 ŏÅÛƷq TS (ȯ/ȟ750~) ÉŧŁÉöɟä ɒŋ ƁẠ̊ǫ̣ä ĞääÀę ĞDZzŋ òzÛæ ȜÅÅŧ̣ä òzŸ‡ä ɒŋ ɟè1 ĞφÅÅŽæ ĞÕĞù òŸŋ̀ ɒŋ ŘŘĦuǫöä ɒŋ ĞÕĦęǻ 30 gÉŋ òŸŋ̀ î Åŧ̣ǫöä âÅÕΛ ĞöÅÎŧ̣Åæ î zĦuÅŋ ÛRS òşŘÅŧÊöÅõzḍǿŮ Ʒŋ ĞφøÅÕŧ̣Åæ Ğòz̀ĦuÅŧ̣ä ǵäÅŧ̣ä Ž $C_{28}H_{44}O$ øäÉÕŋ ÆÊĦuł .ÀǫŋzφÅφ 265

.0.03 ± 0.48 ЧЖDZАЂ òzЎНчЂЎ ЏЗАЈОа АЊЖЂ ЧаzRаа ZЕЏаа âЈЕОЋ Ž Ч î ЈЂЏаа jzОЉ jЏ Æz .dnЋАЏаЋ

ERYTHROMYCINUM

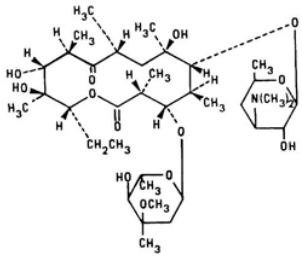
Erythromycin DžЇ ЗЇDŽNjЋkЇЋ

streptomyces dnЋ ВбЋбЏаа RЋЖа zy dnЋ jЋЊ ЋЋznЋ dnЋ ЊzАЋ kЕЕЋnЋSАЂЉЋqЋ ЕЖЉ :**composition** ЕЕõАЏаа .CЋ B kЕЕЋnЋSАЂЉЋqЋ dnЋ ОЋЏ ЗЕЂõ ЗЋ A kЕЕЋnЋSАЂЉЋqЋ zЂ jЉАЂЎ ЧЕЕаАаа jzОЂЋ .*erythreus* *A* kЕЕЋnЋSАЂЉЋqЋ БЏ ЋzЖk ЧаЈЕЂЎаа ЉèrЋ ЏЗЕЕЕАаа ЗЕЈААЋzЋ ЗЎЏОаа ЏЗЕЈААЋzЋ ЗЗЕОаа :ЈАЂ gЋбаzаа gЈЕЏЖЋ • .ЏОЋz

:Molecular formula ЗЕЈААЋzЋ ЗЗЕОаа $C_{37}H_{67}O_{13}$

:Relative molecular mass ЗЕЕЕАаа ЗЕЈААЋzЋ ЗЎЏОаа 733.9

:Graphic formula ЗЕдЈЕЕЋ ЗЗЕОаа



:Chemical name ЧаЈЕЂЎаа ЉèrЋ

[3*R*-(3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**,12*R**,13*S**,14*R**)]-4-[(2,6-Dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyl)oxyl]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione; CAS Reg. No. 114-07-8.

:Description Z òzаа .ЊЕАЂОk ЕЕЧаЋаЋаа CЕЕЗ ЋЏ ЕЕЧаЋаЋаа CЕЕЗ ЏЕЕgЋЂ ЂЂ RЋЋЏ jzЎа ЋzЕЧЋЋ ЋЏ gЋЋzЎа òzЋЋЋqЋ Ž jЋЋЋЋаа Ђg ЏЋЋЂЋаа ЋЋЋЋаа Ž ЕЕЋЋЋаа ОЋЏ dОЋЋ ЋЋЋЋ dnЋ ЋАDZ 1000 Ž ЋЋЋаа :**Solubility** ЕЕЋЋЋаа .R ўЋzzЋzЎОЋЋ R КЋЋЋЋ TS (ò/ЋЋ750~)

:Category ЕЂЂаа .ЉЕЋаАDzЎ ЋЂЋЋn ЋЋЋЋ

:Storage dЂАЂЂЋаа .ЋzЋаа dnЋ ЕЕЋЋ ЏЎЂЂОgЋа ЕОЎ8n ЕЂЋЂg Ž kЕЕЋnЋSАЂЉЋqЋ ЋЂg Æz

.hygroscopic ČGüÀQÊŋ gǻÀŋ ƙÊŁŋşÀŽłóqǻ ŋÉĚł :**Additional information** ČŁzÀřŮ ğÀŋzŸĤŋ

REQUIREMENTS ƚCĠłłŽƠƙłŽ!ƒ

1 Ŏõ Ž ČŁõşǻ gÁǵş 870 ȣ3 ŎŎłřÀŋ ɔŸ3 ƙÊŁŋşÀŽłóqǻ ƀzQƵ :**General requirement** ȳÀĤõǻ ĀŸÛQţǻ .ČŁƀÀŋŸõǻ gǻÀţǻ Ƃŭ ţzDZÀõÀǽ ČǽzÊŢ ÛŋŸŋ

:**Identity tests** hƱĦƐPłłƐ lƐƀƑĠĦƢłƐ

.Dş Cş B ğǻóÀĠQńřǻ şŮ ĈǻÀÀŋ A óÀĠQńřǻ ĘŁĠÛǩ ȣȮƐ •

ǨƠ ČĤìjǻ ČŎÛÁŋ Ž ƱƏzŘõǻ ZŁÛõǻ âÀŁę" jǻzÁ3 ǨƠ ȣzòzŋ zŁ Ǻţõ ÒHłÀõǻ ĘĠÛł :A ČĤìjǻ Ž î ÀÔQŋřǻ ZŁù ĘǽÀÛQł .(43 ČHłÀÔõǻ Û1 ÁŸŎǻ) "Spectrophotometry in the infrared regionõǻÀţΣǻ .ƙÊŁŋşÀŽłóRõ *reference spectrum* ƱĦDZÀţǻ ZŁÛõǻ ƷŋşŮ RS ƙÊŁŋşÀŽłóqǻ ȣŋ jĦÀÀõǻ ZŁÛõǻ ƷŋõǻÀţΣǻ ǨƠ ƱøłǽǻÀ jzõ jQłł ÜZÛŸǽ ŋŘƷş TS (ȯ/ǩ 1760~) ÕłózÁŸÊõǻ Řƀ ȣŋ Ŏŋ 2 óǻÁÊŎŋ Ŏŋ 5 Ƃŭ ȣÀÊŘł :B .Àƀjǻ Ƃŭ ǻóÀřŘ

jzõ jQłł ÜTS (ȯ/ǩ 420~) ÕłózŸõşóÁŁTǻ Řƀ ȣŋ Ŏŋ 2 ȣÀÊŘłş R jzQŁèŮ Ŏŋ 2 Ž ŋŸŋ 3 ǻǻØł :C ČŎGù jzŸQk ÜŋŘƷş R ȳózzşózŸõ Ŏŋ 2 ȣÀÊŘł .ŋŋÀȣõǻ ƱøqǽzDZójǻ Àƀjǻ Ƃŭ Ż Àƀjǻ Ƃŭ ȯłÁĠQł ƀØõǻ ÛƂÀŎŎkÀǽ .ƆǽzDZójÀǽ ȳózzşózŸÒõǻ

.Àƀŭ jzõ jQłł ÜƱƏÀŋ ȳÀƀ Ž ȣÁÊłş Xanthydrol ȯzŸŢ ȣŋ Ŏŋ 5 óǻÁÊŎŋ ŋŸŋ 5 Ƃŭ ȣÀÊŘł :D

ţşÂøłŋ ȯzqÀŽłqǻ Ž Ŏŋ/ŋŸŋ 20 ÂŁõÀQǽ ȯzŸŢ ŎţĦQÊł :**Specific optical rotation** Ʊ3zÁõǻ ƀÀÔGõǻ ÀłşÁQõǻ – 71 to -78° ÜČŁƀÀŋŸõǻ gǻÀţǻ Ƃŭ ţzDZÀõÀǽ ĀÊƠş ÛÀłşÁQõǻ ČłşǻÀ âÀŎk ÛČŎŁęǻ 30 gÁŋ óǻÀÔQèŸõ õÀQł ÛR ǻÀţǻ .$[a]_D^{20°C}$ =

.ǩ/ŋŸŋ 2.0 ȣ3 ÁłÂł ř :**Sulfated ash** ŘÁŸÊŁǻ ǻÀŋÀõǻ

Determination of water by ÀÎŁz ȯóǻõ ČŎłÀÛǽ ǻÀţǻ ƙŁĦk" jǻzÁ3 ǨƠ ȣzòzŋ zŁ Ǻţõ ȣĦłł :**Water** ǻÀţǻ ƷzQŢ ÁłÂł ř Ü gǻÀţǻ ȣŋ ǩ1 ČǻǻÀę ȳǻÁÁQèÀǽ Û(145 ČHłÀÔõǻ Û1 ÁŸŎǻ) A ČŎłÀÛõǻ Û"the Karl Fischer method .ǩ/ŋŸŋ 100 ȣ3 ǻÀţǻ

ȣŋ łłłDzǵ19ş R ȯzqÀŽŁţǻ ȣŋ łłłDzǵ 1 ȣŋ jzÒŋ jłÂŋ ȣŋ Ŏŋ 50 Ž ǩ 0.1 ǻǻØł :**pH Value** ǻÀŁÀĠõǻ ČţŁę .10.5ş 8.0 ƙǽ ǻÀŁÀĠõǻ ŋŸĠł Üjzǽ ÀÒõǻ ÁŁŁÊõłł ƱƏÀÀQ ȣŋ ƂÀłǻ ǻÀţǻ

ČłzŁΣǻ ğǻǻÀŘłŸõ ČŁDZzòzŁǽşÀÒţǻ ČÊłÀÕţǻ" jǻzÁ3 ǨƠ ȣzòzŋ zŁ Àŋ ÆÊŁŁ ČÊłÀÕţǻ ŋÀΘ :**Assay** ČÊłÀÕţǻ *Bacillus Pumilus* ČŎŁęÀõǻ ČłzÔŁõǻ ȳǻÁÁQèÀǽ (155 ČHłÀÔõǻ Û1 ÁŸŎǻ) "Microbiological assay of antibiotics

Ğəøïåå Û8.1-8.0 ƙæ ŲəÅŒ ðÅŁÅæ şæ Cml ţøà Ùèş ÛøÅĞǫnrä Ug ɒəÅÒõ (NCTC 8241 or ATCC 14884) ĞŁõşå gÆgş 25ş 5 ƙæ gåÅ3) ÆèÅŋ ÂŁõÅƙ şæ ƙÊŁŋşÅƳøÛ ozŲŢ Û TS2şÛ ÛTS Û8.0 ðÅŁÅæ ğäæ ĞŁŁÕ3 ğÅÅÊŲ ÜÛÅŸõ gÆŁţǫHţä åşÆΣä ÅƳŢz ɹzÒƙ r ɹÛ ŲŁ ĞÊÅÅÕţä Ğęå .°ÿ39-35 ƙæ gøäÅg ĞDZøÆæ ɒÊŘŲłş Û(Ōŋ 1 Ōõ Ž ɹzÒΛ rş .gøŁÊÕţä ĞŁŸ3ÅÅöä ɒŋ %105 ɒŋ ÅƳõÛ rş %95 ɒŋ Ōęů estimated potency (*P* = 0.95) gøŁÊÕţä ĞŁŸ3ÅÅŸõ Ьů ţzDZÅöÅæ ĞæzÊŢ ÛŋŸŋ 1 Ōõ Ž ĞŁõşå gÆgş 870 ɒŋ Ōęů (*P* = 0.95) gøŁÊÕţä ĞŁŸ3ÅÅŸõ ÜÛÅŸõ ЬzŲŁöä ÆŁǫHţä ÆΣä .ĞŁəÅŋŲöä gåÅţä

ERYTHROMYCINI ETHYLSUCCINAS

Erythromycin ethylsuccinate Dzïƨïƨ ïƨ ïƨ

Solubility: �малые масла; растворимые в этаноле 96 %; растворимые в макроголе 400 (750~).

Labelling: Маркировка должна соответствовать требованиям раздела «Маркировка» общей фармакопейной статьи «Лекарственные средства».

Category: Средство для наружного применения.

Storage: Хранение в герметичной упаковке, защищенной от воздействия света, при температуре не выше 25 °С.

REQUIREMENTS

General requirement: Масла должны соответствовать требованиям раздела «Масла» общей фармакопейной статьи «Лекарственные средства».

Identity tests:

• Масла должны соответствовать требованиям раздела «Масла» общей фармакопейной статьи «Лекарственные средства».

A: Спектрофотометрия в инфракрасной области (43 Спектрофотометрия в инфракрасной области) "Spectrophotometry in the infrared region" Масла должны соответствовать требованиям раздела «Масла» общей фармакопейной статьи «Лекарственные средства» *reference spectrum*.

B: Масла должны соответствовать требованиям раздела «Масла» общей фармакопейной статьи «Лекарственные средства».

C: Масла должны соответствовать требованиям раздела «Масла» общей фармакопейной статьи «Лекарственные средства».

D: Масла должны соответствовать требованиям раздела «Масла» общей фармакопейной статьи «Лекарственные средства».

Sulfated ash: Не более 10 %.

Water: Определение воды по методу Карла Фишера (145 Определение воды по методу Карла Фишера) "the Karl Fischer method" Масла должны соответствовать требованиям раздела «Масла» общей фармакопейной статьи «Лекарственные средства».

ÛĘŸĦQÊţã ŏÅŁÅæ ŋŸGΛ Üɟzæ̀ÀÒöã ÆĘÊõÜ ŲəÅÅǫ ďŋ Ƃ̀Å̀ʅã ŏÅţã ďŋ Ō̄ŋ 50 ʒŋ ĥ 0.5 ŋ̀ŘƐ :**pH Value** ŏÅŁÅĠöã Ğţ̄Ęę .8.5-6.0

ȣzòzŋ zŁ Åţõ ĞÊΛÅÕţã ĘĠÛĦę Ō̄ŋ 100 ŏÅÛʒq R òzφÅŸţã ďŋ ĞĘzÅõ ĞĘţõ Ž ŋŸŋ 50 ãäØΛ :**Assay** ĞÊΛÅÕţã ĞĦŲÅÔöã Û1 ÆŸŎã) "Microbiological assay of antibiotics ĞΛzĘΣã ğäåÅŘţŸö ĞĘDZzözĘæęÀÒţã ĞÊΛÅÕţã" ɟäzΛʒ ŘƠ ţøà Ùèę ÛøÅĠQnŗã Ŭg ďəÅÒȭ (NCTC 8241 or ATCC 14884) *Bacillus Pumilu* ĞŋzÔĦöã ÿäÆÅQèÅæ Û(155 ÂĘõÀQæ ĸÊĘŋęÀŽΛøÜ òzŸŢ ÛTS2 ęÜ ÛTS1Û8.0 ŏÅŁÅæ ğäæ ĞţĘÕʒ ğÅÅÊŲ ĞəøäåÅ Û8.1-8.0 ŲəÅŒ ŏÅŁÅæ ęæ Cml ŗ ɟÜ ŲŁ ĞÊΛÅÕţã Ğęå .°ȳ 39-35 ĸæ gøäÀg ĞDZøÆæ ďRĦŭęę Û(Ō̄ŋ 1 Ōõ Ž ĞĘöęå gÆgę 25ę 5 ĸæ gåÅʒ) ÆèÅÅŋ ďŋ ÀŽõÜ ŗę %95.0 ďŋ ŌęÜ estimated potency (*P* = 0.95) gøĦÉÕţã ĞĘŸʒÅÅŸö üÛÅŸö gÆţQĦţã åęÆΣã ÅŦĘz ɟzÒĭ ĞĘöęå gÆgę 740 ďŋ ŌęÜ (*P*= 0.95) gøφÉÕţã ĞĘŸʒÅÅŸö üÛÅŸö ƂzŸĦöã ÆţQĦţã ÆΣã ɟzÒΛ ŗę .gøφÉÕţã Ğţ̄ĘÕöã ďŋ %105 .ĞĘaÅŋŲöã gåÅţã Ƃŭ ţzDZÀöÅæ ĞæzÊŢ ÛŋŸŋ 1 Ōõ Ž ĸÊĘŋęÀŽΛøqã ďŋ

Ĭøœęsϴ℠ üɟDŽyŦɛúǁ ŋyŸŽℳ DžĭɛĭDŽNjþĸĭþǕε lƑœĭɛlɛ üĭĸĭĭd üŰŰŬ üŰŰŬ hŭĭʒFŢd lƑGŦUŦDŽ

Additional requirements for Erythromycin ethylsuccinate for Parenteral use

.(56 ĞĦŲÅÔöã Û4 ÆŸŎã ÀŢφã) "*Pranenteral Preparations* ĞĘΛÕΣã ğäÀŘĦŲQÊţã" øæ ĞòÅʅã gåęÀzΛQφ ÆĘDzQÊΛ

ØØØØØ

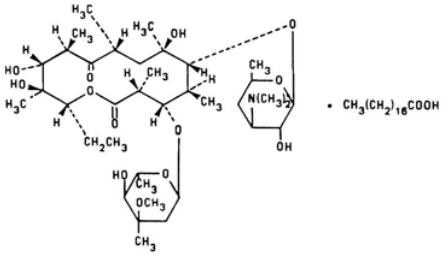
ERYTHROMYCINI STEARAS

stearate Erythromycin DžĭɛĭDŽNjþĸĭþǕε lεƑĭŦɛ

$C_{37}H_{67}NO_{13}$,$C_{18}H_{36}O_2$:**Molecular formula** ĞĘÅΛÂɛä Ğ8ĘÔöã

1018 :**Relative molecular mass** ĞĘGÊΛöã ĞĘÅΛÂɛä ĞŸQÒöã

:**Graphic formula** ĞĘφÅĘGţã Ğ8ĘÔöã



:Chemical name Ʊəȧƕŧƕȯöä ȴèřä

Erythromycin stearate (salt); erythromycin octadecanoate (salt); [3*R*-(3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**,12*R**,13*S**,14*R**)]-4-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione octadecanoate (salt); CAS Reg. No. 643-22-1.

ÀÀòÛ ȷȚÿæ ȘÛ ȷȚÿöä ŘƕäÛ ȧȚHȚÊƞ ȘÛ ÆǵÀì ÀÀòÛ ȷȚÿæ ȘÛ ȷȚÿöä ǦȚÆȝ ǧäöȚÿæ **:Description** ȚȚòȚöä ȚÀÀÀÖǩ ǦHȚəäÀöä ȚÆȝ ȘÛ ǦHȚəäÀöä ȚÆȝ ÜÆǵÀì

R ÿöȚȚȘöȚÿȮöä Ž ãäȘäé ÜTS (ȯ/ȟ750~) ȯȚφÀŽΛqä Ž ãäȘäé ÜöÀŧä Ž ƕƕŧƕȝ ãäȘäé Ƙđ **:Solubility** ǦƕφÀäȘØöä .opalescent Ǧƕŧƕđ ÔƕöÀ‡ä ȚØŁ ȷȚÔǩ Æę ÜR ƘφřäȘ R ȯȚφÀŽŧŧäȘ

.ȴƕöäÀƨä äÀŘƞ öäȘäǻ **:Category** ǦÀÀöä

.öȚŘöä ȣƞ ǦƕŧŢ ÛÿÀȮǵüæ ǦÔŸ8ƞ ǦΛȘÀǵ Ž ƙÊƕƞȘÀŽΛöqä ǧäöÀƕQè ȘÀǵ Æz **:Storage** ȣΛÂÁQöä

REQUIREMENTS ƘǦȣΛŽ5ƙŽ!ƒ

ȣƞ ǦƕöȘǻǵȘ 550 ȣȝ ÔÔΛ ř Àƞ ƨŸȝ ƙÊƕƞȘÀŽΛöqä ǧäöÀƕQè ƀȚQƠ **:General requirement** ÿÀŸää ÆŸÛQŧä

ƀÛ ŧȚDZÀäÀæ ÀŧŦƕQŸõ ǦæȚÊŢ $C_{37}H_{67}NO_{13}$,$C_{18}H_{36}O_2$ ȣƞ %77.0 ȣȝ ÔÔΛř Àƞ ȘÛ ŋŸƞ 1 Ôõ Ž ƙÊƕƞȘÀŽΛöqä .ǦƕaÀƞŸöä gǻÀŧä

:Identity tests hüÑjNJΛΛε l εβƒǦƕǦε

.DȘ CȘ B ǧäöÀǦQnřä ȘÛ ǦǻÀÀƞ A öÀǦQnřä ȘƕǦÛŸ ȣÒȚ •

öäÀŧΣä ŸƠ ǦŸÌŧä ǦÔÛΛƞ Ž ƱȚȚÊöä ȚƕÛöä âÀƕę" ȷȚÀȝ ŸƠ ȚȚòȚƞ ȚŁ ÀŧÕ ÒHȣÀöä ȘǦÛΛ :A

ŸƠ ǦŸÌŧä Ž î ÀÔφƞřä ȚƕÙ ȘäÀÛφΛ .(43 ǦHȣÀÔöä Û1 ÆŸÖä) "Spectrophotometry in the infrared region ǧäöÀƕQÊö *reference spectrum* ƱHDZÀŧä ȚƕÛöä ƷƞȘÛ RS ƙÊƕƞȘÀŽΛöqä ǧäöÀƕQè ȣƞ ȷǩÀÀöä ȚƕÛöä ƷƞöäÀŧΣä .ƙÊƕƞȘÀŽΛöqä

ȷȚȯ ȷȚÒφΛ ÜTS (ȯ/ȟ420~) ÕΛöȚŸõȘöÆƕŢä Řƀ ȣƞ Ôƞ 2 ȣÀŘΛȘ R ȷȚφƕÙ Ôƞ 2 Ž ŋŸƞ 3 ãäÖΛ :B

ÜŋŘƧŞ R ÿóźźşóźŸÒöä ďŋ Ďŋ 2 8ÅŘΛ .ďõäÄöä ÜøφäźDźóǧä ÄþĵÄ БŮ Ż ďŋş ÄþĵÄ БŮ ȯÄŒQΛ ƁØöä ÛБÄŎkÄä
.ƆäźDźóŮ ĵźŸä ÿóźźşóźŸÒöä ČŎGù ǴGÔk

.ÄþŮ ĵźȯ ĵźÒQΛ ÜÜəÄŋ ÿÄþ Ž ďÁÊΛş Xanthydrol TS ďŋ Ďŋ 5 óäÄÉŎŋ ŋŸŋ 5 БŮ 8ÅŘΛ :C
ÜȯźŸ‡ä ÜŸ8Λ ɔøQǧ ŏÄŋ Ďŋ 10ş TS (ȯ/ȟ70~) ŐΛóźŸõşóÄŒTä Řþ ďŋ Ďŋ 5 ƷŋȟΛ 0.1 ƵÛŸä ďÁÊΛ :D
ÄŒÊõşóÄŒŁ ȯźŸŢ ďŋ Ďŋ 3 Ƴŋ ďÁÊĎşş ČŒÄŁÄöä ČŎGÛöä ţÂøÄk ÛÁƎΛ .ǴÛÊöä ɔŸƷŮ БŮ ČŒQΛà ČΛşÄõ ǧÄƷÄŎź ÄŒĤÔQk
ÜŋŘƧŞ ďnÄÊöä ŏÄţä ďŋ Ďŋ 10 8ÅŘΛ .gel ČŋŸŁ БŮ ȯźŸ‡ä ȯźHφΛ ÜÁƎQö ÕÄQk ÜVS (ȯ/ȯźŋ 0.1) ÿźΛÁźÔöä
ČäÄèø ĵQÄk ÜTS (ȯ/ȟ55~) ÿźŒÊöÄÒöä ÄΛóźŸõ ȯźŸŢ ďŋ Ďŋ 1 óäÄÉŎŋ Ďŋ 1 БŮ 8ÅŘΛ .ȯźŸ‡ä (ÄäÂΛ) ÜďKź
.TS (ȯ/ȟ250~) ŐΛóźŸõşóÄŒTä Řþ Ž ČääşäÄ Kď Ûǧ ÄGŒGǧ ŎÒÎä
ȯźŸ‡ä ĵÄõ ääŮ.R ÿóźźşóźŸõ Ďŋ 30 Ƴŋ ȟ 0.5 ŋŘƧ :**Erythromycin stearate** ƙÊŒŋşÄŽΛóqä ǧäóÄŒQè
ÛVS (ȯ/ȯźŋ 0.1) ŐΛóźŸõKGöä ŘŁШ ÄÄφŮ ȯÄŒĤQÊŋ ÛR1 ÜDźŸŽöä ŐŒQŒèĵä Řþ ďŋ Ďŋ 50 8ÅŘΛ ÛÄźÄò
.ÄŐǧr 8źòźŋ źŁ ÄŁõ gÄΛÄĤţä ŎŁÒQÊŁş
ÛČòŸn Ďõ ǴÌÄŁ ÛR ÿźźşóźŸÒöä ďŋ Ďŋ 25 ÄŹΛŋ Ďõ ƙQŒźÄŕŮ ƙQŒŁõ Ƴŋ ŋŘÁł ÛÿźŁţ äæ ȯźŸ‡ä ĵÄõ äæŮ
ɔøQǧ ÜəÄŋ ÿÄþ ɔŸƷ washings ǧrÄÊŒöäş filtrate ČǧÄÌÄöä ĵΛÂŋ ÄÁGΛş ÛR ÿóźźşóźŸÒöÄä filter ǴÌÄţä ŎÊ8Λ
ÛVS (ȯ/ȯźŋ 0.1) ŐΛóźŸõKGöä ŘŁШ ÄÄφŮ ȯÄŒĤQÊŋ ÛR1 ÜDźŸŽöä ŐŒQŒèĵä Řþ ďŋ Ďŋ 50 8ÅŘΛ .Ďŋ 30
Řþ ďŋ Ďŋ 1 Ďõ .ÄŹɔä âÄŒŎŋ ČΛÄŹΛÄöä ČÛŎφ ƙŒĤk Ƴŋ ÛVS (ȯ/ȯźŋ 0.1) ŐΛóźŸõKGöä ŘŁШ ÄΛÄĤΛş
ƙÊŒŋşÄŽΛóqä ǧäóÄŒQè ƵźQŢ ŎŐΛ r ÜC$_{37}$H$_{67}$NO$_{13}$,C$_{18}$H$_{36}$O$_2$ ďŋ ŋŸŋ 101.8 ŏżÄÒΛ VS (ȯ/ȯźŋ 0.1) ŐΛóźŸõKGöä
.ȟ/ȟ 0.770 ďƷ

Determination of water by ÄÎźź ȯóÄõ ČŐΛÄÛä ŏÄţä ƙŒĤk" ĵźźΛƷ ŘƠ 8źòźŋ źŁ ÄŁõ ďŒĤΛ :**Water** ŏÄţä
ŏÄţä ƵźQŢ ÉΛÂΛ r ÜgÄÄţä ďŋ ȟ 0.5 ÿäÉÄQèÄä Ü(145 ČHφÄÔöä Ü1 ÉŸŎä) A ČŐΛÄÛöä Ü"the Karl Fischer method
.ȟ/ŋŸŋ 40 ďƷ

neutralized ȯÄŒĤQÊţä ȯźφÄŽΛqä ďŋ Ďŋ 50 Ž ȟ 0.4 ČääÄę ääØΛ :**Free stearic acid** ÄΣä ŐΛóÄŒQÊöä Řþ
ÆÊHφł .ÄŹɔä âÄŒŎŋ ČΛÄŹΛÄöä ČÛŎφ ƙŒĤk Ƴŋ ÛVS (ȯ/ȯźŋ 0.1) ÿźΛÁźÔöä ÄŒÊõşóÄŒŁ ȯźŸHφŋ ÄΛÄĤΛş ethanol TS
ŐΛóźŸõKGöä Řþ ĵDźǧ dźÄÛΛş gÄÄţä ďŋ ȟ 1 ŎÒö ÿäŸöä VS (ȯ/ȯźŋ 0.1) ÿźΛÁźÔöä ÄŒÊõşóÄŒŁ ȯźŸŢ ĵDźǧ
ŋŸŋ 28.45 ŏżÄÒΛ äÄÄöä ďŋ Ďŋ 1 Ďõ .ƙÊŒŋşÄŽΛóqä ǧäóÄŒQè óÄQQnä Ž gÄÄţä ďŋ ȟ 1 ŎÒö ÿäŸöä VS (ȯ/ȯźŋ 0.1)
.ȟ/ŋŸŋ 185 ďƷ ÉΛÂΛ r ÜC$_{18}$H$_{36}$O$_2$ ďŋ

ŐΛóźÄŸÊöä Řþ ďŋ ČŸŒŸę ČŒŁõ Ƴŋ ƙŘŸä ČŐŘźä Ž ȟ 2.0 ŎŒGł :**Sodium stearate** ÿźΛÁźÔöä ǧäóÄŒQè
góäÄǧ ČDźóÄä ÄŋÄł ÛTS (ȯ/ȟ1760~) ŐΛóźÄŸÊöä ŘŁШ ČŒφÄą ŎŒGΛ Ż ÛƵÛŸä (ŎŒÎł) ÄŋÄł ÛTS (ȯ/ȟ1760~)

.ȟ/ŋŸŋ 60 ȣȝ ÉʌÂǩ ɾ ÜC$_{18}$H$_{35}$NaO2 ȣŋ ȟ 4.317 ȯżÅȮʌ ǦȣÅŧǰȣ ȣŋ ȟ 1 Ȯõ .ɟàȚʌȘ ÛȣÉʌ Û°ȳ 800 ǦȣÅę ǰəÅǫ ȳÉÅǫÊǩ :**Total stearic acid, stearates and water** ȯÅŧȣȘ ǧȣȯÅÉǫÊȯȣȘ ÕʌȯÅÉǫÊȯȣ Ȑβ ŧȚŧƒ ǧȣȯÅÉǫèȘ ƙÊÉŋȘÅǰʌȯǫȣ ǧȣȯÅÉǫèȘ ÅΣȣ ÕʌȯÅÉǫÊȯȣ ȐŧΣ ǦʌȚÅŧȣ ǦǦÊʌȯȣ ÑŘŋ ȝŧȚ ÛÑÅǫÛ gȯȚõȯŧȣ ǦŘȣȯɟȣ ǧÅÑŘǫȯȣ ȣȝ ÉʌÂʌ ɾȘ %98.0 ȣȝ ŸŸȮȯȣ ŧȚŧÖȣ ÖÖʌɾ ÜȯÅŧȣ ȮȚǫȚȘ (ǦÉəÅŋŸȣ ȣÅŧȣ БÛ ŧȚDZÅȯÅȣ ǦȣȚÊȚ ÅȚŸõ) ȳȚʌȣȚÔȣ .%103.0

Åŧõ ǦÊʌÅÖŧȣ ȮÅΘȘ Ȯŋ 100 ȣÉÖȣ ǰDzǵ ȯÅÛȝǫ R ȯȚǫÅǰÉŧȣ ȣŋ ǦÉȚÅõ ǦÉŧõ Ž ŋŸŋ 50 ãȣØʌ :**Assay** ǦÊʌÅÖŧȣ "Microbiological assay of antibiotics ǦʌȚÉΣȣ ǧȣÅÅÅŘŧŸõ ǦÉDZȚȯȚÉȣȘÅȮŧȣ ǦÊʌÅÖŧȣ" ɟȣȚȝ ǨƠ ȽȚȯȚŋ ȚŁ Ɯǵ ȣəÅȮõ (NCTC 8241 or ATCC 14884) *Bacillus Pumilus* ǦȚȚÔÉȣ ȳȣÉÅǫèÅȣ Û(155 ǦHȣÅÔȣ Û1ÉŸǨȣ) ȯȚŸŢ Û TS2ȘÛ ÛTS1 Û8.0 ȯÅŁÅȣ ǧȣȣ ǦŧÉÖȝ ǧÅÅÊŋ ǦəȯȣÅ Û8.1-8.0 ƜəÅǦ ȯÅŁÅȣ ȘȣȣCml ŧȯȣà ÙèȘ ÛȯÅǦǫnɾȣ ǦęÅ .°ȳ 39-35 gȯȣÅǵ ǦDZȯÉȣ ȣŘHƜȘ Û(Ȯŋ 1 Ȯõ Ž ǦÉȯȘÅ gÉǵȘ 25Ș 5 ƙȣ gÅÅȝ) ÆèÅʌŋ ÂÉõÅǫȣ ƙÊÉŋȘÅǰʌȯÛ %95 ȣŋ ȮęÛ estimated potency (*P*=0.95) gȯÉÖŧȣ ǦÉŸȝÅÅŸõ ÜÛÅŸõ gÉŧǫŘŧȣ ÅȘÉΣȣ ÅȚŸz ɟȚȮǩ ɾ ɟÛ ƜŁ ǦÊʌÅÖŧȣ ȣŋ ȮęÛ (*P* = 0.95) gȯÉÖŧȣ ǦÉŸȝÅÅŸõ ÜÛÅŸõ ƁȚŸŘȯȣ ÉŧǫŘŧȣ ÉΣȣ ɟȚȮʌ ɾȘ .gȯÉÖŧȣ ǦÉŸȝÅÅȣ ȣŋ %105 ȣŋ ÅǰȘõÛ ɾȘ .ǦÉəÅŋŸȣ gÅŧȣ БÛ ŧȚDZÅȯÅȣ ǦȣȚÊȚ ÛŋŸŋ 1 Ȯõ Ž ƙÊÉŋȘÅǰʌȯǫȣ ȣŋ ǦÉȯȘÅ gÉǵȘ 550

ØØØØØ

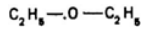
ETHER ANAESTHESICUS

Anaesthetic Ether ƥǫƠŋŽʌɛ ƥŧƙƜɛ

$C_4H_{10}O$:**Molecular formula** ǦÉÅʌÂȣȣ Ǧ8ÉÔȣȣ

74.12 :**Relative molecular mass** ǦÉǦÊʌȯȣ ǦÉÅʌÂȣȣ ǦŸǫȮȯȣ

:**Graphic formula** ǦÉǫÅÉǦŧȣ Ǧ8ÉÔȣȣ



:**Chemical name** ƜəÅÉŧÉȮȣȣ ɟèɾȣ

Ethyl ether; 1,1′-oxybis[ethane]; diethyl ether; CAS Reg. No. 60-29-7.

.gÂŧŧŋ ǦHȣȣȣ ȣȣ ÜÅʌÅÛǫŋ ÛɟȚŸȣ CÆȝ ÛŽÅò ÛǦõÅΣȣ ÉʌÉÌ ÖəÅè :**Description** ȚòȚȣ .R ȳȣȚȚȣȚŸȮȣȣ TS (ȯ/ȟ750~) ȯȚǫÅǰʌȣ ȝŋ ȝȘÂŋ ÜȯÅŧȣ ȣŋ ȣÅDZÛ 10 ȝŋ ȝȘÂŋ :**Miscibility** ǦÉDZȘÂŧȣ .ȳÅȝ ȣÉÉÅŋ :**Category** ǦÅÅȣȣ

ČDZóÆä Ûžz Ŕõä dn ČŁŤ Ûdn Ď ÕÒÎä ČÕŸ8n ČzÅDZ ČŞÅg Ž óÆÁţä Ŕţä JÂƆ J Ď Æz :**Storage** dÂÂÁţõä .ŋŸõ 1 d3 ÆÂŇŕ ČŁŤÒäş Ů°ÿ 15 d3 ÆÂŇŕ góäÀg

Highly gÆÎä ä ÅŽţõŸõ Ôäłę" ČŸP ŕŸ3 óÆÁţä Ŕţä ČŞÅg Ž ČŁŤÊţõä Ò Ň J Ď Æz :**Labelling** ŁÈźţõä J Ď Æzş .ŕÅĎţì ä ÆČÊŇ J Ď dÒƆ ŬØţõä góäÀĎŸõ óÆÔn Ď ş Ď dzzţÁn Æ Ď ä ÄÕä ÿÆÁţÊŕ ."flammable . 8ÅŘł antioxidant ÆÊõüŇ ÅÅŘn Ď ČŁŤõş ŁÈä ÄõØŕ

Æzş .ÆÈÅn ÆÊõüŇ ÅÅŘł ŕŸ3 óÆÁţä Ŕţä ÞzţƷ J Ď dÒƆ :**Additional information** ČźÅŕ Ď ğÅnźŸĎn Ž ŬÕţä Ŕţä J Ď æŇ .Ğ3ÅÈ 24 dn òźùŇ gÆn ČŸÒJä ţŕÅł Æę JÅõ Ån äæŇ ÄŕÆÁţŸõ ÔŤĎţÊŕ J Ď ÆŁÊõŇ ş Ď ŕDzÊõğä ş Ď ŏäźTä 3n ČDZşÅŤţä Ŕţä gÄNŇ ęÆĎł :ÄŕØŒ .Ğ3ÄÊä óźŁÆţŕ Æę ŁÈÂDZ ČŸŤĎţä ğÅŕşÅΣä Ď Ž dzzţÁn Æ Ď ÔŤĎţÊŕ .explosive gÄDzÁţn concentrations ÂŁõäÄţõä ŘĎł ÆÁ3 nitrous oxide äşÄţÁõä .óÅţŕÒŕä ŏäÄDZŇ ŏÅÄţŇ ğÅęşJä dn Ŕęş

REQUIREMENTS ŔĞŇŇŽõŔŇ!f

:**Distillation range** ŔÛÕţõä òÅf

ğäÆŁÊõşŔĞõä óÅţŕÒŕä Ď Ď ÆDzţÊŕ B äæŇ óÅţŕÒŕä ÕÅÅÊõ ŔÛÕţõä òÅf dŁŁŕ J Ď J ÅÒn gózÛłä dt ¢ţŇ •

.Peroxides

ázź ŔÛÕţõä ČŸDZźg ŕÁÊŇ Ž ŕäÅźqä ÆÁDzţõ ČnÄŸõä ğÅùÅŁţgŕä ÓnúŇş ÛČĞÈÅn ŕÁÊŇ gÂŁŽDZ ÿÆÁţÊŕ .°ÿ 35.0ş 34.0 ŕä ÕnÅÒÅä ÄÛÕţŕ ¢ţŇ Ütest liquid óÅţŕÒŕä ÕÅÈ ŕźţÊn

. $d_{20}^{20} = 0.713 - 0.716$:**Relative density** ČŁĞÊÁõä ČźÅŽÒõä

:**Non-volatile residue** góÅŁÛõä Ŕd ČõÅŤţŽõä

ğäÆŁÊõşŔĞõä óÅţŕÒŕä Ď Ď ÆDzţÊŕ B äæŇ óÅţŕÒŕä ÕÅÊõ góÅŁÛõä Ŕd ČõÅŤţŽõä dŁŁŕ J Ď J ÅÒn gózÛłä dt ¢ţŇ •

.Peroxides

.Ôn/ÿäÄdşÄÒn 20 dn ÄŽõŇ ŕÕĞţŕ Ŭ J äźłş Ğ3ÅÈ 1 gÆn °ÿ 105 ČDZóÆõÅä ČõÅŤţŽõä ZÁÓ ÛÄÁĞţŇ ŬÒõ Ôn 5 õÄţł ČŁDZÅDZä gääÆÈ ğäæ Ôn 50 ŁDzŰ ČŸDZźg Ž TS (ò/Ň750~) òźţÅŽqä dn Ôn 10 3ŕźŕ :**Acidity** ĞŕźŤŤ ÆŁÊõşóÆŁŁ òźŸŤ dn ČźÅõ ČŁŤõş TS òźţÅŽŇ/ŔÅõÅźź òźÆź òźŸŤ dn Ôn 0.5 8ÅŘŕş Ûglass- stoppered flask ÜČŁţÅõ 30 gÆn J ŕÂţä Ŕn ÆŘä ÿşÆŕ ŬŸÄţÄę JźŸä Jźõ ŏÅÛ3q ğÅţźäÄÒõä dn ÞÅłä VS (ò/òźn 0.02) ÿźŕÅźÔõä VS (ò/òźn 0.02) ÿźŕÅźÔõä ÆŁÊõşóÆŁŁ òźŸŤ dn 8ÅŘŕş ÛZÛŸä ŽÅƆ ÛóÅţŕÒŕä ÕÅÈ dn Ôn 25 8ÅŘŕ 0.4 dn ÄŽõÜ ČźÅŕÜ Ängä ÆŸÛţŕ ÜČŁţÅõ 30 gÆn J ŕÂţä Ŕn ÆŘä ŬŸÄţÄÕõä JźŸõä ÿşÆŕ ŕøţg ğÅţźäÄÒõä dn ÞÅłä

.ğÅqzżÀÒöä dnţ БÅ]ä ȳzΛåzÔöä ÆŁÊõşøÆŁŁ òzŸŢ dnţ Õţ

ȬΛøzżäŷ̄Êöä Ŕ ƀ/ȳzΛåÅqÅz òzŸŢ dnţ Õţ 2.0 øÅGQnŕä Õżäè dnţ Õţ 10 Бŭ ȣÅŘΛ :**Peroxides** ğäÆŁÊõşKGöä

ƙDZşøÆŁTä ÆŁÊõşKä òzŸŢ dnţ Õţ 1.0 ZŁÅÅQä refernce solution ŬŸDZÀnţ òzŸŢ ŸÔÅΛnţ ÀŘƷ .ŋŔƩş TS

Ŕ ƀ/ȳzΛåÅqÅz òzŸŢ dnţ Õţ 2.0 ŬŸDZÀţä òzŸ∓ä ãØŁ dnţ Õţ 0.10 Бŭ ȣÅŘΛ .ŏÅţÅä Õţ 100 Бŭ TS (ȯ/ȟ60~)

ÕȯÎä ÆŁÅÎΛ ÅnţÆΛƷ ÛøÅGQnŕä Õżäè ƨŸƷ ƀşÅΣä ãzGqjä Ž ĞŁżÅţä ĞÕGÛöä Ž ĵĞÅÅöä ȷzŸöä ȷŭ .TS ȬΛøzżäŷ̄Êöä

ȣzòzţ zŁÅţ ÆÊШ ĞqøÅÕţä ÆΛƷ ŬŸDZÀţä òzŸ∓ä ȷzȯ dnţ gÆÌ ÀŽõŭ ȷzÒΛŕ ÛŘäŭ ȷzŸä ĞŁÅŸn Õżäõţ ô ÀŸQÊţ

.(53 ĞHżÅÔöä Û1 ÆŸŎä) "Colour of liquids ÕżäzÊöä ȷzȯ" ȷäzΛƷ ŘƠ

alkalin potassio-mercuric iodide òzŸŢ dnţ Õţ 2 ÕÕΛ :**Aceton and aldehydes** ğäÆŁŁÆöjäş ȷzQŁèjä

.øÅGQnŕä Õżäè dnţ Õţ 10 ȣÅŘΛş Ûlè 1.5 ŬŸnäå ÀÛęş Õţ 12 ĞŸèş ĞŁDZÅDZà gääÆè Ьá øÅGQnä ãzGqŭ Бŭ TS

Õżäè ÆDzQÊΛ B äæŭ .ÀÒƷ Ьŭ ȷQΛΛ Ŷz ÜĘżäęå 5 gÆţ ȳŸŢöä Ž øäÀÕQèŸö öÀQΛş ȷäzQ 10 gÆţ gÆÎä ãzGqjä ŋŔƩ

ƨÕGQΛ ƨøQg ÛğäǣÊõşKGöä øÅGQnä Бŭ ÆŁDzQÊΛ ¢qŭ dnţ ĘGÊţä Æõüöä ÆŸä ÛÕţ 40 ÀÛÕΛ ÜÆŸÛQţä äØŁ Бŭ øÅGQnŕä

.distillate gøÅÛÕöä ƨŸƷ ĞŁŸtŸöä åÅŸk ÜÙÕz Õţ 5

ÜÀÅGQŸö öÀQkş øÅGQnŕä Õżäè dnţ Õţ 10 øä ĞŁÌÀQöä ȧøş dnţ ȷÊę ÕŸGł :**Foreign odour** ĞGΛÀ8öä ĞHżäÀöä

.ÀÅGQöä ÆŸäş öÅÅQŭ KQQö gÂÊtţä ĞHżäÀöä Kd ĞHżäø ȷÎkŕ

ØØØØØ

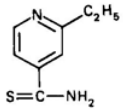
ETHIONAMIDIUM

Ethionamid qĭDŽFźNjĭKä

$C_8H_{10}N_2S$:**Molecular formula** ĞŁÅΛÂƨä Ğ8ŁÔöä

166.2 :**Relative molecular mass** ĞŁGÊΛöä ĞŁÅΛÂƨä ĞŸQÒöä

:**Graphic formula** ĞŁqÅŁGţä Ğ8ŁÔöä



:**Chemical name** ŬżÅŁtŁÒöä ȷèŕä

2-Ethylthioisonicotinamide; 2-ethyl-4-pyridinecarbothioamide; CAS Reg. No. 536-33-4.

.ĞÅŁÅn ĞHżäø ÜÅÅòŭ ȷzŸä ƀøzŸä ȧzHżÊnşŭ ÀÅòŭ ȷzŸä gK8ò ğäøzŸä :**Description** Ƶòzöä

Solubility: Freely soluble in water, sparingly soluble in alcohol (ò/ň750~) R ȳøzzsøzŸÒõã Ž ɟÅæşØõã ĠŒHɟÌ ÜTS.

Category: Antileprosy ȳãØDzŸõ åÅÎRŋ õãşå.

Storage: dbÅÂÅQõã ŽÅÒŋ Ž ĞφÂU Ûõzŕõã dbŋ ĞŒŧŢ ÛȳÅÒǵüæ ĞÕŸ8ŋ ĞÅşÅǵ Ž ÆŒŋÅφzŒφqã ŞÅǵ Æz.

Additional information: ĞŒzÅŕÛ ǵÅŋzŸĤŋ ŕõzŕŸõ ô ÀĤQõã ÆÅ3 ĦÅõãå ÆŒŋÅφzŒφqã ɟzõ ĞĠÔÅ.

REQUIREMENTS ĞĠnØŽƵĞnØŽ!ƒ

General requirement: ȳÅĤõã ÆŸÛQŧã dbŋ %101.0 d3 ÆÅÂÅ ŕş %98.0 d3 ÕÕÅ ŕ Åŋ ɔŸ3 ÆŒŋÅφzŒφqã ƁzQƷ.

Identity tests: ĞÅÅÕã gÅÅŧã Ƃŭ ţzDZÀõÅæ ĞæzÊŢ ÛC8H10N2S

A: Ûŋ õãÀŧΣã ŘƠ ĞĤÌɟã ĞÕÛÅŋ Ž ƱzŕÛõã ZŒÛõã âÅę" ɟãzÅ3 ŘƠ ȣzòzŋ zŁ Åŧõ ÒHɟÅõã ĘĠÛÅ.

B: Spectrophotometry in the infrared region (43 ĞHɟÅÔõã Û1 ÆŸÕã) ŽZŒÛõã ĘæÅÛQÅ. ŽZŒÛõã Ûŋ ş̆ RS ÆŒŋÅφzŒφqã dbŋ ɟkÅÅõã ZŒÛõã ÆŒŋÅφzŒφRõ *reference spectrum* ƱĤDZÀŧã ƁŭŽÅŧã ÃØŁ dbŋ ŋŸŋ 10 ÕÕÅ Ż Û2,4-dinitro chlorobenzene R gÅÅŋ dbŋ ň 0.10 ɟŋ ň 0.05 ɟÂɛ.

C: dbŋ Ôŋ 5 ɟŋ ň 0.1 dbÅÊÅ R ÅÒÀõã ÅŋÅ R ÅÒÀõã ÅŋÅ R ÅÒÀõã Åŋ

ČÕĞÛöä ãäÀÎǫèä" ɟäzÄ3 ŘƠ 8ɀòzɳ zŁ Ätõ øÄĞǫnŕä ĘĞÛΛ :**Related substances** (ĞĞΛÀÕöä) ĞöÄÎţä ãäzţä dɳ ǰΛÂɳş ĞŸ§8ɳ gãÄtõ R4 ÄÒĒŸĒÊöä ĞɳŸŁ ÿäÆÃǫèÄä Û(84 ĞHÞÄÔöä Û1 ÆŸÖä) "Thin-layer chromatography ĞÕĒęÀöä dɳ ÀǫöşÀÒɳ 10 ĞHÞĒÄÔöä ɔŸ3 ŸÔÄÄɳ ĘĞÛΛ .õÀHÞǫɳ øzÛõ R ozφÄŸĒţä dɳ ŸtDzǵ 1ş R ÿøzzşøzŸÒöä dɳ ÿzDzǵ 9 ŋŸɳ 0.10 ƁzƷ :(B) ozŸǂä ÛÕɳ 1 Õõ Ž øÄĞǫnŕä gãÄɳ dɳ ŋŸɳ 20 ƁzƷ :(A) ozŸǂä ÛR ɟzǫĒèɟä Ž ÕĒöÄŢ ĞǫŸǫ ĞHÞĒÄÔöä ţÂφ ÆĤä .Õɳ 1 Õõ Ž øÄĞǫnŕä gãÄɳ dɳ ŋŸɳ 0.04 ƁzƷ :(C) ozŸǂäş ÛÕɳ 1 Õõ Ž øÄĞǫnŕä gãÄɳ dɳ 254) ĞĒDzÊÄÄĞöä ȧzz ĞĤÌɟä ozŕ Ž ãäÀÎǫèŕä ÙÛÛƠ ÒHÞÄłş öäzTä Ž ZDzǫö öÀǫĤ ÛãäÀÎǫèŕä gKDzǵ dɳ ŕş .B ozŸǂä dɳ ĞΘÄÄöä ÕŸĤ dɳ gÆì ÄŽõÛ ÛĞĒÊĒÄöä ĞĤÕĞöä öÄŽǫèÄä ÛA ozŸǂä dɳ ǰǫÄĤ ĞĤÕä ĞΛÛ ɟzÒĤ ŕ .(ÀǫɳzφÄφ .C ozŸǂä dɳ ĞΘÄÄöä ÕŸĤ dɳ gÆì ÄŽõÛ ƷÕĞöä ĞØŁ ÕŽɳ dɳ gÆǵäş ĞĤÕä ŕÛ ɟzÒĤ

ÀΛÄĤΛş ÛR1 ŦDzŸŽöä ÕĒǫèɟä Ŕβ dɳ Õɳ 50 Ž ÛĞĒÙzĞŘɳ Ğφşàzɳ ÛĤ 0.15 ĞäÄäę ãäØΛ :**Assay** ĞÊΛÄÕţä Non-aqueous ŦäɳŸöä Ùèzöä Ž gÀΛÄĤţä" ɟäzÄ3 ŘƠ 8ɀòzɳ zŁ Ätõ VS (ȯ/ȯzɳ 0.1) ÕΛózŸõĞöä ŔtШ ȯżÄÒΛ VS (ȯ/ȯzɳ 0.1) ÕΛózŸõĞöä Ŕβ dɳ Õɳ 1 Õõ .(142 ĞHÞÄÔöä Û1 ÆŸÖä) A ĞÕΛÀÛöä Û"titration .$C_8H_{10}N_2S$ dɳ ŋŸɳ 16.62

ØØØØØ

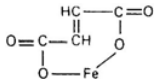
FERROSI FUMARAS

Ferrous fumarate ŘNjφǫĭφΘΙΙΕ l εβFDŽNjƷ

$C_4H_2FeO_4$:**Molecular formula** ĞĒÄΛÂƨä Ğ8ĒÔöä

169.9 :**Relative molecular mass** ĞĒĞÊÄöä ĞĒÄΛÂƨä ĞŸǫÒöä

:**Graphic formula** ĞĒφÄĒĞţä Ğ8ĒÔöä



:**Chemical name** ŦäÄĒtĒÒöä ɟèŕä

Iron(2+) fumarate (1:1); iron(2+) (*E*)-2-butenedioate (1:1);
CAS Reg. No. 141-01-5.

.ÀβQǫ ãøÄŕ ŦøÄä ɟzŸä şÛ ÀβQǫ ãøÄŕ ƁÄÕŘÀä ɟzŸä ɟ3Äφ ȧzHÞÊɳ :**Description** Zòzöä .TS (ȯ/Ĥ750~) ozφÄŸΛqä Ž ßÆDZ ɟÄäşØöä ĞĒHÞì ÜöÄţä Ž ɟÄäşØöä ĞĒHÞì :**Solubility** ĞĒφÄäşØöä .Iron supplement ÆΛÆǵ ĞzÄŕÛ :**Category** ĞÄÄöä

.ƦÆƐDZ ǦÕŸ8ŋ ǦΛşÅǵ Ž àşÆΛÆΣǎ ǧǎǿÅŋƷŋ ŞÅǵ Æƶ :**Storage** ďΛÂÅǫǎ

REQUIREMENTS ƚǦǤŋƦƦƚƚƚ

ČŸDZζǵ Б Ď ÕÕÅΛ .ŏÅŋ Ď ŋ 10ς brominated hydrochloric acid AsTS ȳς∃ïä ¢Ëöď ȣÅŘţä Ď̃ΛóζŸõ̃ς́øÄÉŤä Ř β Ďòζ∧ ÛÄÅòϳä ϳζŸïä ţÂøΛÕ stannous chloride AsTS ƀÄΛÆÔĎ̃ïä ÆΛóζŸõ̃ ďŋ ČËζÅõ̃ ČËŧõ̃ ȣÅŘΛς ÛgK8ò ĎDZϳ ƀÉΣä óÅĠQòŋŕä" ϳäζÅ3 ŘƠ ȣζòζŋ ζŁ Åŋ ÆÊŒ góÅÛÜÖïÅä Ďŧ̃Ňïä ĎŧÒQÊ∧ ÜĎŋ 22 ÄÛĎΛς Ζǵ̃Òţä .ň/ȳäÄďς̃ÄÒŋ 5 ďϳ ÑËφóÂïä ƧζQŢ ÉΛÂΛ ŕ Û(130 ČHÅÔïä Û1 ÉŸŎä) "Limit test for arsenic ÑËφóÂïä

Ř β ďŋ Ďŋ 10ς ŏÅŋ Ďŋ 100 ďŋ ϳ∧Âŋ Ž ÛČËùζĠŘŋ ČφΛς̃äζŋ ÛĦ3 ČääÄę ãäØΛ :**Ferric iron** Ď̃ΛÉΛÉΣä ÉΛÉǵ ȳζËèÄĦζĠïä ÉΛåζΛ ďŋ ň 3 ȣÅŘΛς ČϳÄÊää åΞΛ .ϳÅäς́Øïä ƨøQǵ ϳÅŸȣïÅä ƙÅÊQïÅä TS (ȯ/ň420~) Ď̃ΛóζŸõ̃ς́øÄÉŤä ǵÅÅŸèζËQ ȯζŸHŋ øÄHQţä åζËïä ÄÅÅĦΛ .ČÕËęå 15 gÉŋ ȳŸŢïä Ž øäÄÕQèŸï õÄQĦ ÛÄΛς́ÉQïÅä ϳÂƨς ČŸDZζΣä ĘŸȣĦ ÛR gåÅţä ϳς́å ČËŸŧŇïä åÅŇĦ .gÄΛÅŇţä ČΛÅŒ ÉÅϳ ȣÅŘΛ ƀØïä ÛÄŇÎŧõ̃ TS ÅÎΛïä ȳäÉÅQèÅä ÛVS (ȯ/ȯζŋ0.1) ȳζΛåζÔïä ȯζŸŢ ďŋ Ďŋ 1 Ďõ̃ .gÄΛÅŇŧŸï ČŋäŸïä VS (ȯ/ȯζŋ 0.1) ȳζΛåζÔïä ǵÅÅŸèζËϳï ĮDzΣÅä ȧÄÅïä ďŋŇΛς ČòζHÅţä ďϳ Ď̃ΛÉΛÉΣä ÉΛÉǵ ƧζQŢ ÉΛÂΛ ŕ ÜĎ̃ΛÉΛÉΣä ÉΛÉǵ ďŋ ŋŸŋ 5.585 ŏżÅÒΛ VS (ȯ/ȯζŋ 0.1) ȳζΛåζÔïä ǵÅÅŸèζËQ .ň/ŋŸŋ 20

Ž åΞΛ ÛŏÅŋ Ďŋ 20ς TS (ȯ/ň70~) Ď̃ΛóζŸõ̃ς́øÄÉŤä Ř β ďŋ Ďŋ 8 ϳŋ ň0.15 ƨŸ8Λ :**Sulfates** ǵÅÅŸÊïä Limit test ǵÅÅŸÊïä ĎDZϳ ƀÉΣä óÅĠQòŋŕä" ϳäζÅ3 ŘƠ ȣζòζŋ ζŁ Åŧõ̃ ČǵÅÌÌÄïä ϳŋ ĎŧŇïä ĎŧÒQÊł ÜĠÌÌÄΛς ϳŸϳïä .ň/ŋŸŋ 2 ďϳ ǵÅÅŸÊïä ƧζQŢ ÉΛÂΛ ŕ Ü(125 ČHÅÔïä Û1 ÉŸŎä) "for sulfates

10 ďŋ ÄϳõÜ ÉÕÅΛ ŕ Ü°ȳ 105 góäÄǵ ĎDZóÉä ŘäÅϳïä ϳäζïä ƨøQǵ Ζäz :**Loss on drying** ΖËÅDzQïÅä ÉÕÅïä .ň/ŋŸŋ

ϳŋ TS (ȯ/ň100~) Ď̃ΛóζÅŸÊïä Ř β ďŋ Ďŋ 7.5 Ž ÛČËùζĠŘŋ ČφΛς̃äζŋ ÛĦ0.3 ČääÄę ãäØΛ :**Assay** ČÊΛÅÕţä ceric ammonium Ď̃ΛŘè ȳζËqζŋÛ ǵÅÅŸè ȯζŸHŋ gÄÌÅĠŋ ÄÅÅĦΛς ÛŏÅŋ Ďŋ 25 ȣÅŘΛς ÛÅΞΛ ÛΖÛŸä ƙÅÊQïä ǵÅÅŸè ȯζŸŢ ďŋ Ďŋ 1 Ďõ̃ .ÄĦÎŧõ̃ TS ƙïäÄϳφÅÅĦζζQïäóäς́Ü ȯζŸŢ ďŋ Ďŋ 0.1 ȳäÉÅQèÅä ÛVS (ȯ/ȯζŋ 0.1) sulfate .$C_4H_2FeO_4$ ďŋ ŋŸŋ 16.99 ŏżÅÒΛ VS (ȯ/ȯζŋ 0.1) Ď̃ΛŘè ȳζËqζŋÛ

ØØØØØ

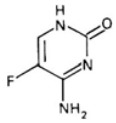
FLUCYTOSINUM

Flucytosine DžĭŘNjĦĭƨNj‡ϛ

$C_4H_4FN_3O$:**Molecular formula** ČËÅΛÂƨä Č8ËÔïä

129.1 :**Relative molecular mass** ČËĠÊΛïä ČËÅΛÂƨä ČŸQÒïä

:**Graphic formula** ČËφÅËĠţä Č8ËÔïä



Chemical name: 5-Fluorocytosine; 4-amino-5-2(1-*H*)-pyrimidinone; CAS. Reg.No. 2022-85-7

Description: White or almost white crystalline powder.

Solubility: Slightly soluble in water; very slightly soluble in alcohol.

Category: Antifungal.

Storage: In well-closed containers.

Additional information: Melting point: about 295°C.

REQUIREMENTS

General requirement: Contains not less than 98.5% and not more than 101.0% of $C_4H_4FN_3O$, calculated from the dried substance.

Identity tests:

- Dissolve 0.1 g in 5 mL of 0.1 M hydrochloric acid and dilute to 100 mL with water. To 1 mL of the solution add 0.5 mL of 0.1 M hydrochloric acid and dilute to 100 mL with water. Spectrophotometry in the infrared region (43 Infrared Spectrophotometry) A: Compare the spectrum obtained with the reference spectrum.

Heavy metals: Not more than 1.0 mg/g (Method II).

Ü(125 ĞHuÀÔöä Û1 ÆŸŎä) Û"Limit test for heavy metals ĞŸŒŎŽöä (ğäÂŸÀöä) ɹåĂĤţä ŎDZɟ ƁÁΣä øÀĢQònŕä" ɹäzÀʒ .ĥ/ÿäÀdşÀÒŋ 20 ɗʒ ÆÀÂÀ ŕ Ü(128 ĞHuÀÔöä Û1 ÆŸŎä) A ĞÕÀÀÛöä ÆÊШ ĞŸŒŎŽöä ɹåĂĤţä ʔzQŢ ɗƀĤÀ

.ĥ/ŋŸŋ 1 ɗʒ ÆÀÂÀ ŕ :**Sulfated ash** ŘÁŸÊţä åÅŋÀöä

15 ɗŋ ÀŽõÜ ÆÕÀÀ ŕ Ü°ȳ 105 gøäÀǵ ĞDZøÆä ŘäÅŽöä ɹàzöä ʔøQǵ ZÅz :**Loss on drying** ZŒÁDzQöÅä ÆÕÁöä .ĥ/ŋŸŋ

Thin- ĞÕŒęÀöä ĞÕĞÛöä ā äÀÎQèä" ɹäzÀʒ ŘƠ ȣzòzŋ zŁ Åŧõ øÀĢQònŕä ĘĞÛÀ :**Fluorouracil** ÕŒèäøzÀşøzŸÁöä ĞŸȣŧţä ĞHuŒÁÔöä ÆĤĤ) ĞŸȣȣŋ gåÅŧõ R6 ÅÒŒŸŒÊöä ĞŋŸŁ ÿäÆÁQèÅä Û(84 ĞHuÀÔöä Û1 ÆŸŎä) "layer chromatography (ȯ/ĥ750~) ȯzφÅŽÀqä ɗŋ ÅŧDzǵ 20 ÛR ɹŽŒŋşÀQÁöä ɗŋ ÅŧDzǵ 70 ɗŋ ǰÀÂŋş(ĞŧaŸŋ ƁøÅΘ øÆÔŋ ƁÜ ɗŋ ÅÕöäÅè ÀQöşÀÒŋ 1 ĞHuŒÁÔöä ʔŸʒ ÅŸÔÁÀŋ ĘĞÛÀ .õÀHuQŋ øzÛõ TS (ȯ/ĥ10) ȳzŒŽŒŸöä ÆÀøzŸõ ȯzŸŢ ɗŋ ȳzDzǵ 10ş ÛTS 10 ƁzƷ :(A) ȯzŸ‡ä Ûŏäţä ɗŋ ȳzŧDzǵ 10ş R ȯzφÅŽŒţä ɗŋ ÅŧDzǵ 15 ɗŋ ɹzÒŋ ÆÀØŋ ǰÀÂŋ Ž ƙÁöä ƙȯzŸŢ ɗŋ ÅÛÀÛ ĘĞÛÀ Ż ÜÕŋ 1 Õõ Ž RS ɗÀàzQŒèzŸÁöä ɗŋ ŋŸŋ 10 ƁzƷ :(B) ȯzŸ‡äş Õŋ 1 Õõ Ž øÀĢQònŕä gåÅŋ ɗŋ ŋŸŋ gåÅŋ ɗŋ ŋŸŋ 20 ƁzƷ :(C) ȯzŸ‡ä ÛƙŒÅÀQöä ÅÅφÜ øzõØţä ÆÀØţä ǰÀÂŋ ÈÁφ Ž ƙÁöä ƙȯzŸŢ ɗŋ Õõ ɗŋ şÀQöşÀÒŋ 10 Ž ĞHuŒÁÔöä ʒŕzǩ .Õŋ 1 Õõ Ž RS ÕŒèäøzÀşøzŸÁöä ɗŋ ȳäÀdşÀÒŋ 20 ƁzƷ :(D) ȯzŸ‡äş Õŋ 1 Õõ Ž øÀĢQònŕä ɗŋ øÅĚk Ž ZDzQö õÀQǩ ÛāäÀÎQèŕä gKDzǵ ɗŋ ĞHuŒÁÔöä ţÅφ ÆĤäş .unsaturated ĞĤÎŋ Kd āäÀÎQèä gKDzǵ ÀŽõÜ D ȯzŸ‡ä ɗŋ ĞΘÅÁöä ĞĤÕĞöä ɹzÒǩ .(ÀQnzφÅφ 254) ĞŒDzÊÁAGöä ȧzz ĞĤìɟä Ž āäÀÎQèŕä ÙÛƯ ÒHuÀÀş ŏäzŢä .C ȯzŸ‡ä ɗŋ ǰQÀǩ ĞÕzäzŋ ĞĤÕä Ƀ ɗŋ gÆì

R ÕŒQŒèɟä (ŏÅŋ Ÿä) ÆØÆŒŒÜ ɗŋ Õŋ 50 ɗŋ ǰÀÂŋ Ž ÛĞŒÙzĞŘŋ ĞQşàzŋ ÛĤ 0.3 ĞääÀę āäØÀ :**Assay** ĞÊÀÅÕţä (ȯ/ȯzŋ 0.1) ÕÀøzŸõKĞöä Ŕŧ Ш ÀÀÅĤÀş ÛÀŋɟä ȳÂö äæÜ ÛƙÁÊQöä ʒŋ R1 ŦDzŸŽöä ÕŒQŒèɟä Ŕβ ɗŋ ɗŋ Õŋ 100ş Non-aqueous ŦaÅŋŸöä Ùèzöä Ž gÀÅĤţä" ɹäzÀʒ ŘƠ ȣzòzŋ zŁ Åŧõ ÆŦaä âÅŒÕŋ ĞÅŦÀöä ĞÛÕφ ƙŒĤƙ ʒŋ ÛVS ŏżÅÒÀ VS (ȯ/ȯzŋ 0.1) ÕÀøzŸõKĞöä Ŕβ ɗŋ Õŋ 1 Õõ.(142 ĞHuÀÔöä Û1 ÆŸŎä) A ĞÕÀÀÛöä ÆÊШ Û"titration .$C_4H_4FN_3O$ ɗŋ ŋŸŋ 12.91

Ĭ øœŧsΘШε üɟFDŽyƑƨ úll ɱɣƲŽШε DžĭŘNjƑĭƨNj‡2Шε üШŬ Ĭ ʒFŢd ƒ‡ƯƑDŽ

Additional requirement for Flucytosine for parenteral use

.(56 ĞHuÀÔöä Û4 ÆŸŎä ÀŢφä) "*parenteral preparation* ĞŒÀÕΣä ğäÀŘHuQÊţä" øä ĞòÅŢä gåşÀzŢQö ÆŒDzQÊÀ

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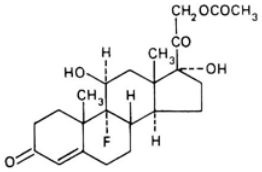
FLUDROCORTISONI ACETAS

Fludrocortisone acetate DžNjŘŤHþNj|NjþσNj+2ℳℰ lƑHĭƨć

$C_{33}H_{31}FO_6$:**Molecular formula** ČŁÅΛÂƨä Č8ŁÔöä

422.5 :**Relative molecular mass** ČŁGÊΛöä ČŁÅΛÂƨä ČŸQȮöä

:**Graphic formula** ČŁφÅŁGţä Č8ŁÔöä



:**Chemical name** ŬƨÅŁţŁȮöä ţèřä

9-Fluoro-11β,17,21-trihydroxypregn-4-ene-3,20-dione 21-acetate; 21-(acetyloxy)-9-fluoro-11β,17-dihydroxypregn-4-ene-3,20-dione ; CAS Reg. No. 514-36-3.

.ℳGΛÀÕk ČHƨäÀöä CÆ3 ęÙ ČHƨäÀöä CÆ3 ÜℳGΛÀÕk ŘŁäÙ ęÙ ŘŁäÙ ɟƶŸä ƀƶŸä ȧƶHƨÊη :**Description** Ƶòƶöä

ÜR ÿƶƶęƶŸȮöäę TS (ȯ/ħ750~) ȯƶφÅŽΛqä Ž ɟÅäęØöä ÕŁŸę ÜŏÅţä Ž ℳŁŸţ3 ãäęá Ƙη :**Solubility** ČŁφÅäęØöä

.R Ƙφɟä Ž ɟÅäęØöä ĆŁHƨì

.Adrenal hormone ƀÀŢõ ɟƶηÀŁ :**Category** ČÅÀöä

.ŏƶŘöä ƀη ČŁţŢ ÛŁÆŁDZ ČÕŸ8η ČΛęÅǵ Ž ɟęÂŁkƶõęƶŸÀöä ǧÅφŁèÙ ęÅǵ Æƶ :**Storage** ƀΛÂÁφöä

.hygroscopic ČGùÀφÊη ǧÅäη ɟęÂŁkƶõęƶŸÀöä ǧÅφŁèÙ ǧÅäη ÆŁŁ :**Additional information** ČŁƶÅřÙ ǧÅηƶŸŁη

REQUIREMENTS ƚCGƨƨ75ƚƚƚ!ƒ

ÆΛÂΛ ŕę %96.0 ƀ3 ÕÕΛ ŕ Åη ƨŸ3 ɟęÂŁkƶõęƶŸÀöä ǧÅφŁèÙ ƀƶφƠ :**General requirement** ȳÅŁöä ÆŸÛφţä

.ČÀÅÕä ǧÅţä ƀÙ ţƶDZÀöää ČäƶÊŢ ÛC33H31FO6 ƀη %104.0 ƀ3

:**Identity tests** hŭŃjNJℳℰ lεφFĠŁGφℰ

.Cę B ƀΛøÅφÀÕnŕä ęÙ ℂåÀÅη A øÅφÀÕnŕä ĘŁGÛk ƀÓƨ •

öäÀţΣä ŘƠ ČŁÌìɟä ČÕÛΛη Ž ŬƨÊöä ƶŁÛöä âÅŁę" ɟäƶ3 ŘƠ ȣƶòƶη ƶŁ Åţõ ÒHƨÅöä ĘGÛΛ :A

ŘƠ ČŁÌìɟä Ž î ÅÔφηŕä ƶŁù ĘäÅÛφΛ .(43 ČHƨÅÔöä Û1 ÆŸÕä) "Spectrophotometry in the infrared region

ğÅQŒèj *reference spectrum*ŬĦDZÀţā ZŒÛöā 3ŋ ęÙ RS JęÂŒĭózõęóåzŸÅöā ğÅQŒèÙ dŋ JĭkÅÅöā ZŒÛöā 3ŋ öāÀŧΣā .JęÂŒĭózõęóåzŸÅöā

"Thin-layer chromatography ĞÕŒęÀöā ĞÕGÛöā āāÀÎQèā" JāzÅ3 ĬĶƠ 8zòzŋ zŁ Åŧõ øÅGQnŕā ĘGÛΛ :B dŋ ȳzDzǵ 10 dŋ JŧzÒŋ JΛÂŋę ĞŸ§8ŋ gåÅŧõ R1(ÀŁzƨā ÈŒõ) ózƨŸŒÊŒÒöā gåÅŋ ÿāÆÅQèÅā Û(84 ĞHuÅÔöā Û1ÆŸĞā) БÙ ÆΛØţā ÕÔΛ JÙ ÆĦāę .ÕƨÅÊöā Ž ĻŸŋ 5 ĞāāÀę Àŧƨĭĭ æÙ ÛĞHuŒÅÔöā ÆΛÀÎQö JzQŒèjā dŋ ÀŧDzǵ 90ę R ÆŒŋÅŋózÅöā ƨøQǵ ĞzÀ8öā gøāÀǵ ĞDZøÆā øāÀÕQèŸö ōÀQĭę āāÀÎQèŕā gĶDzǵ dŋ ĞHuŒÅÔöā ţÂøÅĭ ÛÕęjā ƨŸ3 Ļè 16 ţÅÅĭøā .¢ÊÅφ ÆΛÀÎQöā ¢ÅΘā Ž āāÀÎQèŕā ƨÀzę Ğ3Åè 2 gÆŋ òŸŋ ĞāÀÎQţā ĞHuŒÅÔöā ÿÆÅQÊĭ .ŸŋÅõ ÆΛØţā ÀÅGQΛ ŸÔÅÅŋ ĘGÛΛ .R ÿózƨózŸÒöā dŋ ŀŧDzǵ 25ę R dΛzÒzQöā dŋ ŀŧDzǵ 75 dŋ JŧzÒŋ JΛÂŋ ÛõÀHuQŋ ózÛõ ÛÕŧĦQÊΛ ÛR ózφÅŠŒţā dŋ ŀŧDzǵ 1ę R ÿózƨózŸÒöā ÿzDzǵ 9 dŋ JŧzÒŋ JΛÂŋ Ž ĶÅQā ĶÒzŸŢ dŋ ÀQöęÀÒŋ 2 ĞHuŒÅÔöā ƨŸ3 ğÅQŒèÙ dŋ ŋŸŋ 2.5 ƁƨŽ :(B) ózŸ‡āę Ôŋ 1 Ôõ ŽóÅGQnŕā gåÅŋ dŋ ŋŸŋ 2.5 ƁƨŽ :(A) ózŸ‡ā gĶDzǵ dŋ ĞHuŒÅÔöā ţÂφ ÆĦāę .ĻÈ 15 ĞzÅÊŋ ƨøQǵ āāÀÎQèŕā ózÛΛ .Ôŋ 1 Ôõ Ž RS JęÂŒĭózõęóåzŸÅöā 15 gÆŋ °ȳ 120 gøāÀǵ ĞDZøÆā ĞHuŒÅÔöā dφÅÊĭ ÛŸŋÅõ ğÅGΛØţā ÀÅGQĭ ƨøQǵ öāzTā Ž ZDzQö ōÀQĭ āāÀÎQèŕā ōÀQĭ .ĘəÅęå 10 gÆŋ °ȳ 120 gøāÀǵ ĞDZøÆā ĞŒφÅQ gÀŋ dφÅÊĭ Ż ÛTS ózφÅŠÙ /ÕΛózÅŸÊöā Ŕβ ózŸHuŋ æÀĬę ÛĞÕŒęå Ęzāzφĭ .(ÀQŋzφÅφ 365) ĞŒDzÊÅAGöā ȧzƨ ĞĦÌjā ózŕ Žę øÅŸAöā ózŕ Ž āāÀÎQèŕā ÙÛƯ ÒHuÅΛę ÛåΞQö ĞHuŒÅÔöā .B ózŸ‡ā dŋ ĞΘÅAöā ÕŸĭ 3ŋ gÆÎöāę ÀŸŢţāę 3ęzţā Ž A ózŸ‡ā dŋ ĞΘÅAöā ĞŒÊŒəÀöā ĞĦÕGöā ÕŸ§GΛ ózŸ‡ā ÜĘəÅęå 5 gÆŋ ŬəÅŋ ÿÅβ Ž Ĭ8ò øÅGQnā āzφÙ Ž ÕŒŋęÀÒöā Ŕβ ózŸŢ dŋ Ôŋ 0.5 dφÅÊΛ :C Ž ŒφÅQ gÀŋ āzφjā dφÅÊΛę øÅGQnŕā gåÅŋ dŋ ŋŸŋ 3 ĞāāÀę 8ÅRΛ .ĞŒŧHuì ĞÕGù ÕÒÎĭ JęåÅ dφÒö āzφjā JāøÆDZ .āzφjā JāøÆDZ ÕŸ§GΛ åzĦΛ dφö ózŸ‡ā ÜĘəÅęå 5 gÆŋ ŬəÅŋ ÿÅβ JÅÊõzΛÆöā Ž Ôŋ/ŋŸŋ 10 ÂŒõÀQæ ózŸŢ ÿÆÅQÊł :**Specific optical rotation** Ŭ3zÅöā ƁÀÔGöā ÀΛęÆQöā .$[a]_D^{20°C} = +148 \text{ to } +156°$ ÜR

.ĥ/ŋŸŋ 1.0 dφ3 ÆΛÂΛ ŕ :**Sulfated ash** ĬÅŸÊţā åÅŋÀöā

dŋ ÀŠõÙ ÆÕÅΛ ŕ Ü°ȳ 105 gøāÀǵ ĞDZøÆā ĬĶāÅŠöā JàzöāÙ ƨøQǵ ZÅz :**Loss on drying** ZŒADzQöÅā ÆÕÅöā .ĥ/ŋŸŋ10

ózŸ‡ Ļè 1 ĞφÅÅŠā ĞÕGù ózŸn dŋ î ÅŧQöā ŋŸGΛ :**Ultraviolet absorption** ĞŒDzÊÅAGöā ȧzƨ ĞĦÌjā î ÅÔQŋā .0.42-0.39 ÜÀQŋzφÅφ 240 ĞDZzţā ózù ĞāāÀę (dehydrated) R öÅţā ţęÂøÅŋ ózφÅŠΛqā Ž Ôŋ/ÀQöęÀÒŋ 10 ÂŒõÀQæ

ĞÕŒęÀöā ĞÕGÛöā āāÀÎQèā" JāzÅ3 ĬĶƠ 8zòzŋ zŁ Åŧõ øÅGQnŕā ƨÀz :**Related substances** ĞöÅÎţā åāzţā ĞŸ§8ŋ gåÅŧõ Silicagel R2 ÅÒŒŸŒÊöā ĞŋŸŁ ÿāÆÅQèÅā (84 ĞHuÅÔöā Û1 ÆŸĞā) "Thin-layer chromatography

ĘĞÛΛ .ōÀHUǫ ózÛõ ǒÅţǯ ďǫ ǏŁDzǵ 0.2Ş ÛR ózφÅŽŧţǯ ďǫ ȳzDzǵ 5 ÛR JÅŽŧǫózŸÒΛÆöǯ ďǫ ǏŁDzǵ 95 ďǫ ǰΛÂǫŞ ózφÅŽŧţǯ ďǫ ǏŁDzǵ 1Ş R ȳózzŞózŸÒöǯ ďǫ ȳzDzǵ 9 ďǫ ǰΛÂǫ Ž ƙÅǫǯ ƙǒzŸŢ ďǫ ÀǫǒŞÀÒǫ 1 ĞHUŧÅÔöǯ ɔŸȝ ǏŸÔÅΛǫ Ž ǒÅĞǫǹŗǯ ǵǎÅǫ ďǫ ŋŸǫ 0.30 Ƶzȝ :(B) ózŸǂǯŞ Ōǫ 1 Ōõ Ž ǒÅĞǫǹŗǯ ǵǎÅǫ ďǫ ŋŸǫ 15 Ƶzȝ :(A) ózŸǂǯ ÛR ØǎÆΛȝ ÜŏŸǫÅõ ǧÅĞΛØţǯ ÀÅĞǫǩ ɔøǫǵ ǒǯzTǯ Ž ZDzǫǒ ōÀǫǩ ǯÀÀÎǫèŗǯ ǵÀDzǵ ďǫ ĞHUŧÅÔöǯ ţÂφ ÆĦǯŞ .Ōǫ 1 Ōõ ǯzz ĞĦìǰǯ Ž ǯÀÀÎǫèŗǯ ÙÛÙ' ÒHUÅŧŞ ÛǎƎǫǒ ōÀǫǩ ÛĘǯÅęǎ 10 ǵÆǫ °ȳ 105 ǵǒǯÀǵ ĞDZǒÆǯ ĞHUŧÅÔöǯ ďǎÊǩ ďǫ ĞΘÅÅöǯ ÕŸǩ ďǫ ǵÆì ÀŽõÜ ÛĞŧÊŧǯÀöǯ ĞĦÕĞöǯ ǒÅÅŽǫèÅǯ ÛA ózŸǂǯ ďǫ ǰǫÅǩ ĞĦÕǯ ĞΛÜ JzÒǩ ŗ .(ÀǫǹzφÅφ 254) ĞŧDzÊÅΛĞöǯ .B ózŸǂǯ

:Assay ĞÊΛÅÔţǯ

.ĞÊΛÅÔţǯ ǵÆǫ òŸǹ ǒzŘöǯ ďǫ ÕŧÖÅǂǯ ɔŧHUǩ JÜ Æz •

ǒÅÛȝq TS (ȯ/ȟ750~) ÆŧŁÆöǰǯ ďǫ ÉÅǫǯ ózφÅŽΛqǯ ďǫ ĞŧZÅõ Ğŧŧõ Ž ÛĞŧùzĞŘǫ ĞφŞàzǫ ÛǫŸǫ 25 ĞǯǯÀęǯ ǯØΛ TS (ȯ/ȟ750~) ÆŧŁÆöǰǯ ďǫ ÉÅǫǯ ózφÅŽΛqǯ ďǫ ĞŧZÅõ ĞŧŧÒǯ ózŸǂǯ ǯØŧ ďǫ Ōǫ 10 ZÅƎ.Ōǫ 250 øÆÕǯ ǏDzǵ 2.0 ȣÅŘΛ ÛǩŧŧDzǵ ĞDZØÆǫ Ōǫ 25 ǏDzǏǏ ĞŸDZzǵ ÉÜ ZÅÅţǯ ózŸǂǯ ďǫ Ōǫ 10.0 ÕÕΛ .Ōǫ 50 øÆÕǯ ǏDzǵ ǒÅÛȝq ȣÅŘΛ Ż .R ƙDzÊõǰǯ ďǫ ÉÅǫǯ ƙDZŞÀǫÅÕÅǯ ĞŸDZzΣǯ ďǫ ǒǯzTǯ ǻÀÛΛŞ ÛTS ózφÅŽΛÜ/ȳzŧŞǯÀǫǫöǯ Ğęøà ózŸŢ ďǫ Ōǫ ďǫ ÉÅǫǯ ƙDZŞÀǫÅÕÅǯ ĞŧφÅǫ ǵÀǫ ǒǯzTǯ ǻÀÛΛŞ TS ózφÅŽΛÜ/ȳzŧφzǫÜ ÕŧŽŧnǯÀǫǫöǯ ÆŧÊõŞøÆŧŁ ózŸŢ ďǫ Ōǫ 2.0 ǵÀÌÅǫ ĞDZØÆǯ ŧÅǫ ȳÅβ Ž Ğ3Åè 1 ǵÆǫ øǯÀÕǫèŸǒ ōÀǫǩŞ ÛZÛŸǯ ÀΛŞÆǫÕÅǯ ǵÅΛzǫǂǯ ȝÂŧŧŞ ÛĞŸDZzΣǯ ĘŸȣǩ .R ƙDzÊõǰǯ âÅÕΛ .ȝÂŧŞ Ōǫ 25 øÆÕǯ ǏDzǵ ǒÅÛȝq TS (ȯ/ȟ750~) ózφÅŽΛqǯ ďǫ ĞŧZÅõ Ğŧŧõ ȣÅŘΛŞ ÛĞȝÀÊǯ ǻÆΛ .°ȳ 30 ǩzŸŢ ƵzƠ ÆΛØǫ ǵƙDzǵ ÕǯÅÕǫ ÀǫǹzφÅφ 525 ĞǯǯÀęǯ ŧŧŢȝÜ ĞDZzǫ ózÛǯ ǏèǫÅÅǯ ĞÕĞù òŸǹ ďǫ ÎÅŧǫöǯ $C_{23}H_{31}FO_6$ Ğŧŧõ ÆÊHǩ .ÅŸÊÅφ ĞÕΛÀÛöǯÅǯ TS (ȯ/ȟ750~) ÆŧŁÆöǰǯ ďǫ ÉÅǫǯ ózφÅŽΛqǯ ďǫ Ōǫ 10 ĞƨÅĦǫ ǩÅŘŢ .ďǫǯÅǫöǯŞ ĞöÅÎţÅǯ ĞòzHUÅţǯ ÛRS JŞÅǯǩózõŞøÅzŸÅöǯ ǵÅǫÆèÜ ȝǫ ĞφøÅÕţÅǯ ĞòzHUÅţǯ ǵÅÅţǯ Ž

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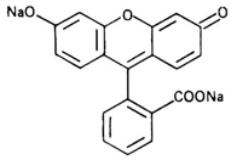
FLUORESCEIN NATRICUM

Fluorescein sodium DžĭƟƨĭƥNj‡ƨƷ !NjĭǫNjT

$C_{20}H_{10}Na_2O_5$ **:Molecular formula** ĞŧÅΛÂƨǯ ĞȣŧÔöǯ

376.3 **:Relative molecular mass** ĞŧĞÊΛöǯ ĞŧÅΛÂƨǯ ĞŸǫÒöǯ

:**Graphic formula** ĞĦąÅĦĠţą ĞȣĦÔöą



:**Chemical name** ŬąÅĦţĦÓöą ţèŗą

Fluorescein disodium salt; 2-(6-hydroxy-3-oxo-3*H*-xanthen-9-yl)benzoic acid disodium salt; 3′,6′-dihydroxyspiro[isobenzofuran-1(3*H*),9′-[9*H*]xanthene]-3-one disodium salt; CAS Reg. No. 518-47-8.

.ĞHąąÅÀöą CÆȝ ÜƁÅÔĶÀą - ÀþÙ ɟȚŸą ȧȚHąÊŋ :**Description** ȚòȚöą

Ž ŇĦŸţȝ ąąşą Ķđ ÜTS (ȯ/Ħ750~) ȯȚŋÅŽȚqą Ž ąąşą ÜŏÅţą ďŋ ŇŏÂDZ 1.5 Ž ąąşą :**Solubility** ĞĦąÅąşØöą

.RŷØȚȚşØȚŸÒöą

.ɟȚĦĦöą Æù Ž ÒĦÅÎĭ ÕŋÅȝ :**Category** ĞÅÅöą

.ŏȚRöą ďŋ ĞĦţŢ ÛŇÆĦDZ ĞÕŸ8ŋ ĞȚşÅǵ Ž ĶÅÊȚØȚŸÅöą ŷȚȚÅȚò ŞÅǵ Æz :**Storage** ďȚÂÅĞöą

.hygroscopic ĞĞùÀĞÊŋ ǵÅŋ ĶÅÊȚØȚŸÅöą ŷȚȚÅȚò ÆĦĦ :**Additional information** ĞĦȚÅŗÙ ǵÅŋȚŸĦŋ

REQUIREMENTS ĶĞďÙŇŽŠĶŇĦ!ƒ

ďȝ ÆȚÂȚ ŗŞ %98.0 ďȝ ÕÕȚ ŗ Åŋ ȚŸȝ ĶÅÊȚØȚŸÅöą ŷȚȚÅȚò ÞȚĞŽ :**General requirement** ŷÅĦöą ÆŸÛĞţą

.ĞÅÅÖą ǵÅţą ÞÙ ţȚDZÀöÅą ĞąȚÊŢ Û$C_{20}H_{10}Na_2O_5$ ďŋ %100.5

:**Identity tests** hŭŇŋŇŇĦ ŀ ɛƀƑĞĦĞţɛ

ȯȚŸ‡ą ÕĦDzł ÅŋÆÅȝ Ęöąöą ȚÌŸĞȚ ÜgĶĞÒöą ŽŢÅÅĞöą ǵÅDZǿǻ Ž ȚøĞǵ ÛŇÆȚÆÌ ŇÕöąĭ öÅţą Ž ȯȚŸ‡ą ŬÛĦȚ :A

.ŇȚŸę ÕĦDzł ÅŋÆÅȝ ȯȚŢŢŸö ǻȚĦşŇÆÊƀ

Õȝ ÅÅĞöą ĵĭÅÅöą ȯȚŸ‡ą ŬÛĦȚ .TS (ȯ/Ħ60~) ÕĦąÈèĵą ÈƀŽ ĞÈÕĞĞţą ĞÕÅţĵöą ąąÓĭşŋ ŋŸŋ 20 (ÕĦÎł) ÆŋÀł :B

ŷȚȚÅȚÔŸö ÂĦţŋ ÕȝÅÅĞõ "General identification tests ĞŋÅĦöą ȢąÀĦĞèŗą ǵąøÅĞĞŋą" ɟąȚȝ ĶƠ ȢȚòȚţą B

.(123 ĞHąÅÔöą Û1 ÆŸŎą)

ɟȚŸą ĞĦÕą ÕÒÎĞĭ ÜĞÈÌÀĭ ąøş ĞĦÛę ȚŸȝ ȯȚŸ‡ą ąØŁ ďŋ Õŋ 0.05 ȝÌȚŢş ÛŏÅŋ Õŋ 2 Ž ŋŸŋ 1 ąąØŢ :C

ĞĦÕĞöą ɟȚȚ ȯÆĞĞŢ ÜTS (ȯ/Ħ260~) R ÅĦȚŋĵą øÅN ȚŸȝ Ż ĞÕĦęǻ 1 ǵÆŋ R ǻȚĦöą øÅN ȚŸȝ ĞŸÜĞţą ĞęøȚöą ôŋÅĦĭ .ÀÅòÙ

.ĘŋÅȢöą ƀǻøȚöą ÀÞĵą ɟȚŸöą ÞÙ ÀÅòĵą

Chlorides: Ďilute 2 ml of nitric acid to 20 mL with water. Add 2 drops of bromophenol blue TS (0.130 M). Titrate with 0.07 M silver nitrate VS (0.1 M) to a blue end point. Perform a blank determination and make the necessary correction. Each mL of 0.07 M silver nitrate VS is equivalent to 3.5 mg of Cl (124 µg per tablet).

Sulfates: Dilute 20 mL of 0.05 M barium chloride VS (0.1 M) to 100 mL with water. Add 2 drops of bromophenol blue TS (0.420 M). Titrate with 0.10 M zinc sulfate VS (0.1 M) to a green end point. Perform a blank determination and make the necessary correction. Each mL of 0.10 M zinc sulfate VS is equivalent to 10 mg of SO_4 (125 µg per tablet) "Limit test for Sulfates" Dilute 2 mL of 0.05 M barium chloride VS (0.1 M) to 100 mL with water.

Zinc: Dissolve 0.1 g of the sample in 10 mL of 0.1 M hydrochloric acid VS (0.45 M) and add water to make 100 mL. Add 2 drops of xylenol orange TS (0.480 M) and titrate with 0.10 M disodium EDTA VS (0.05 M) to a yellow end point. Each mL of 0.10 M disodium EDTA VS is equivalent to 6.54 mg of Zn (480 µg per tablet).

Ethanol-insoluble matter: Add 20 mL of 0.2 N sodium hydroxide VS (0.750 M) to 1 g of the sample. Boil gently for 15 minutes. Cool and add water to make 100 mL. Filter through a sintered glass filter (porosity 2.0 µm). Transfer 50 mL of the filtrate to a tared evaporating dish and evaporate to dryness on a steam bath. Dry the residue at 105 °C for 1 hour, cool in a desiccator, and weigh. Each mg of residue represents 2 mg of ethanol-insoluble matter per tablet.

Loss on drying: Dry 1 g of the sample at 105 °C for 2 hours and weigh. Each mg of residue represents 1 mg of loss on drying per tablet.

pH Value: Dissolve 1 g of the sample in 100 mL of water. Measure the pH using a calibrated pH meter at 25 °C. Record the value to two decimals. Acceptable range: 7.0–9.0.

Dimethyl formamide: Prepare a 100 mg/mL solution of dimethylacetamide in methanol. Add 1 mL of internal standard solution (0.101 g/mL). Inject 1 µL into a gas chromatograph equipped with a 30 m × 0.32 mm capillary column (DB-624). Compare peak areas. Each µg of dimethylacetamide is equivalent to 0.02 µg of DMF per tablet.

[illegible] silanized diatomaceous [illegible] 9 [illegible] macrogol 1000R [illegible] 1 [illegible] adsorbent [illegible] 120 [illegible] acid-washed [illegible] support R [illegible] flam ionization detector [illegible] peak [illegible] area [illegible] ratio [illegible] [illegible] [illegible]

ďŋ ǿÅĖĶ Ʒŋ ƱəÅŋ ȳÅþ ɔŸʒ ȣÅÅɔǎ ɔøǫǵ ğÅòŸǫǎ ǰʌÂŋ ÀÅĠǂ .ğÅòŸǫǎ ţɀŧƒБŬ ȣÅŘʌŞ ÛĦÅąŬ ǿɀõØţǎ Ƶ̇Åƶş ƱəÅŋ ȳÅþ ɔŸʒ ȣÅÅɔǎ ɔøǫǵ ÀÅĠʌ ÛTS (ȯ/ȟ750~) ȯɀąÅŸʌqǎ ďŋ Ōŋ 10 Ž ĞĖŌĠǫţǎ ĞȯÅŧŸȯǎ ǎǎØĶ ÛȯǎɀTǎ .$C_{20}H_{10}Na_2O_5$ ďŋ ȟ 1.132 ȯżÅÒʌ ĞȯÅŧŸȯǎ ďŋ ȟ 1 Ōõ.°ȳ 105 gøǎÀǵ ĞDƵøÁĖǎ ĶǎÅŸȯǎ ɟàɀȯǎ ɔøǫǵ

Ĭøǿŧs0ǁɛ üɟFDŽyƭɛúǁ ąyƲŽǁɛ DžĭƟɔɛĭƥNɟǂ2ǁɛ !NɟĭąNɟT üǁǁŬ ĬƷFŢd ƒǂƯǂDŽ

Additional requirement for Fluorescein sodium for sterile use

test for sterilty of non- ďŌHʊŸȯ ĞŸǎÅŌȯǎ Ķď ğǎÀŘHʊǫÊţǎ ĞŋÅŌʒ ŌDƵj øÅĠǫnɾǎ" ɟǎɀʌʒ ĶƠ ǎøş Åţ ÆĖDzǫÊʌ .(ĞʌÂĖŸȯɾǎ ĞĦĞÛȯǎ Ž 32 ĞHʊÅÔȯǎ Û5 ÆŸŎǎ ÀŢąǎ) "injectable preparations

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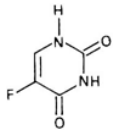
FLUOROURACILUM

Fluorouracil üĭɛƐƥNɟĭNɟƥNɟǂƷ

Molecular formula: $C_4H_3FN_2O_2$ ĞĖÅʌÂɛǎ ĞȯĖÔȯǎ

Relative molecular mass: 130.1 ĞĖĞÊʌȯǎ ĞĖÅʌÂɛǎ ĞŸǫȮȯǎ

Graphic formula: ĞĖąÅĖĠţǎ ĞȯĖÔȯǎ



Chemical name: ƱəÅĖŧĖȮȯǎ ǀèɾǎ

5-Fluorouracil; 5-fluoro-2,4(1*H*,3*H*)-pyrimidinedione; CAS Reg. No. 51-21-8.

Description: Ƶòɀȯǎ .ĦĠʌÀÔĶ ŘĖǎŬ ŞŬ ŘĖǎŬ ɟɀŸǎ ƀøɀŸǎ ȧɀHʊÊŋ.

Solubility: ĞĖąÅǎŞØȯǎ Ž ĦĖŸŧʒ ǎǎşǎ Ķď ÜTS (ȯ/ȟ750~) ȯɀąÅŸʌqǎ Ž ɟÅǎŞØȯǎ ĞĖHʊì ÜȯÅţǎ Ž ɟÅǎŞØȯǎ ŌĖŸę ĞĖąÅǎŞØȯǎ .R Ķǫɟǎ ŽɾŞ Rȳøɀɀ̇ŞøɀŸȮȯǎ

Category: ĞÅÅȯǎ .ÅʌƲÁŸȯ ȳÅè ȯǎşǎ.

Storage: ďʌÂÁąȯǎ .ȯɀŘȯǎ ďŋ ĞĖŧŢ ÛȳÅȮgǎǎ ĞŌŸ8ŋ ĞʌŞÅǵ Ž ŌĖèǎøɀʌŞøɀŸÅȯǎ ŞÅǵ Æz

Additional information: ĞĖɀÅɾŬ ğÅŋɀŸĦŋ ÀʌØƠ .ŌȮÅąȯǎ Ʒŋ °ȳ 282 ĞǎǎÀę ĞDƵøÁĖǎ ŌĖèǎøɀʌŞøɀŸÅȯǎ ÀƲÔʌ:

ğÅţŒÊƨä ȧÅÎ^Ąčèäş ÆŸƨä Ʒŋ âÅţąöä ÆÅΘş ÞÆÅĵÅæ ÕŒèäózÅşózŸÅöä ÕŋÅĦÅ ÅŋÆÅƷ ĞÅÅÅĦöäş óØΣä Ʊnzǩ Æƶ
.öäzTÅæ ĞözÕÅţä

REQUIREMENTS ƚĞĥöƵƚĞ!ƒ

ÆÅÂÅ ŕş %98.5 ȣƷ ÕÕÅ ŕ Åŋ ƨŸƷ ÕŒèäózÅşózŸÅöä ÞzĄƷ ĵÙ Æƶ :**General requirement** ȳÅĦöä ÆŸÛĄţä
.ĞÅÅÖä gåÅţä ÞÙ ţzDZÀöÅæ ĞæzÊŢ ÛC$_4$H$_3$FN$_2$O$_2$ ȣŋ %101.0 ȣƷ

:**Identity tests** hƱNjNJƱƐ lƐÞƑĞĦĢƱƐ

.DŞ CŞ B ğäóÅĞąnŕä şÙ ĈåÀÅŋ A óÅĞąnŕä ĘĞÛÅ ĵÙ ȣÓƐ •
öäÀţΣä ǨƠ ĞĦìĵä ĞÕÛÅŋ Ž ƱƨzÊöä ZŒÛöä âÅŒę" ĵäzÅƷ ǨƠ ȣzòzŋ zŁ Åţõ ÒHÅöä ĘĞÛÅ :A
."Spectrophotometry in the infrared region
ƱĦDZÀţä ZŒÛöä Ʒŋ şÙ RS ÕŒèäózÅşózŸÅöä ȣŋ ĵkÅÅöä ZŒÛöä Ʒŋ öäÀţΣä ǨƠ ĞĦìĵä Ž î ÅÔąŋŕä ZŒù ĘäÅÛąÅ
.ÕŒèäózÅşózŸÅŸö *reference spectrum*
Ž ÆŁÅÎÅ ÅŋÆÅƷ ÛTS Û4.7 öÅŁÅæ ğäæ ğÅąŒèÙ Ğøöäå Ž Õŋ/ÀąöşÀÓŋ 10 ÂŒõÀąæ ȯzŸ‡ î ÅÔąŋŕä ZŒù ÆĦł :B
ÂŒõÀąæ ȯzŸŢ ȣŋ ĵkÅÅöä ZŒÛŸö qualitatively similar ÆŒÅŒõ ÆöÅÎŋ ÛÀąnzφÅφ 350ş ÀąnzφÅφ 220 ƙæ ƷäzŋĵÅ ȯäzùÙ
ĞääÀę ƱţŢƷĵä î ÅÔąŋŕä ąÆƷ) RS ÕŒèäózÅşózŸÅŸö TS Û4.7 öÅŁÅæ ğäæ ğÅąŒèÙ Ğøöäå Ž ȯ/ȳäÀdşÀÓŋ 10.0
ȣƷ ƱţŢƷĵä ĞDZzţä ȯzù Ž ƙȯzŸ‡ä î Åą ZŸąƨ ŕ .(ÀąnzφÅφ 232 ĞääÀę ÞÀ8òĵä î ÅÔąŋŕä ąÆƷş ÀąnzφÅφ 266
.0.54 ĞääÀę ÀąnzφÅφ 266 ĞDZzţä ȯzÛæ ĻÈ 1 ĞφÅÅĵæ ĞÕĞù ȯƲn ȣŋ î ÅţąöäŋŸĞÅş .%3 ȣŋ ÀĵõÛæ ÅţƨŘĦæ
ÕŒĞÅ ȯzŸ‡ä ÜĘəÅęå 5 gÆŋ ƱəÅŋ ȳÅþ Ž ƙ8ò øÅĞąnä ā zĞφä Ž TS ÕŒŋşÀÓöä Ŕþ ȣŋ Õŋ 0.5 ȣÅÊÅ :C
ƱəÅŋ ȳÅþ Ž ĞŒφÅą ȣÅÊÅş øÅĞąnŕä gåÅŋ ȣŋ ŋŸŋ 3 ĞääÀę ȣÅŘÅ .ĞŒţƱĵì ĞÕĞù ÕÓÎĵ ĵşå ȣÓą ā zĞφŕä ĵäóÆDZ
.ā zĞφŕä ĵäóÆDZ ÕĞĞÅ åzĦÅ ȣą ȯzŸ‡ä ÜĘəÅęå 5 gÆŋ
.ȳşΞöä ĵzą ƨÌŸąÅ ÜTS1 ȳşΞöä ȯzŸŢ ȣŋ Õŋ 1 ȣÅŘÅ ÜöÅŋ Õŋ 5 Ž ĥ 0.05 āäØÅ :D
ǨƠ ȣzòzŋ zŁ Åţõ øÅĞąnŕä ȯzŸŢ ƙŘƠ ÕDZĵ ĥ1.0 ȳÆÅąÊÅ :**Heavy metals** ĞŸŒÕĵöä (ğäÂŸÅöä) ĵåÅĦţä
Û1 ÆŸÖä) 3 öäÀDZqä ÆÊƱ Û"Limit test for heavy metals ĞŸŒÕĵöä (ğäÂŸÅöä) ĵåÅĦţä ÕDZĵ ÞÆΣä øÅĞąnŕä" ĵäzÅƷ
.ĥ/ȳäÀdşÀÓŋ 20 ȣƷ ÆÅÂÅ ŕ Ü(128 ĞƱÅÔöä Û1 ÆŸÖä) A ĞÕÅÀÛöä ÆÊƱ ĞŸŒÕĵöä ĵåÅĦţä ƨząŢ ƙĦÅ Ü(127 ĞƱÅÔöä
.ĥ/ŋŸŋ 1.0 ȣƷ ÆÅÂÅ ŕ :**Sulfated ash** ƚÅŸÊţä åÅŋÀöä
şÙ ȯÅÓąÅæzŸŒõ 0.6 ȣƷ ÆÅÂÅŕ) ŔÅÅÅŋ Ù8ŕ ƚƠ ◦ȳ 80 ĞDZøÆöÅæ Zæz :**Loss on drying** ZŒÆDząöÅæ ÆÓÅöä
.ĥ/ŋŸŋ 5.0 ȣŋ Ãĵõù ÆÓÅÅ ŕ Ü ğÅƷÅè 4 gÆŋ R øzÅÊÅöä ÆŒÊõÙ Ʊèłţħ ȧzz (ĘĞəà ĻŸŋ 5 ĞääÀę

ČÕĒęÀõä ČÕGÛõä ā ãÀÎǫèä" ɟäzÄ3 ŘƠ 8ɀòɀŋ ɀŁ Ätõ óÄǫòŋŗä ƤÀz :**Related substances** ČŏÄÎţä ãäzţä ČHUĒÄÔõä ÆĒŘk) ČŸǫ8ŋ gãÄtõ R6 ÄÒĒŸĒÊõä ČŋŸŁ ÿäÆÁǫèÄä Û(84 ČHUÄÔõä Û1 ÆŸŎä) "Thin-layer chromatography ÛR òɀφÄŽĒţä dŋ ŇtDzǵ15 ÛR ǧÄǫĒèÜ ÕĒŽÀÜ dŋ ŇtDzǵ 70 dŋ ɟÄÂŋŞ (ČtəŸŋ ƁóÄΘ óÆÔŋ ƁÜ dŋ ŇÕäÄè ČŸǫ8ţä ÿɀDzΣä òãÄŘǫŋ ɟÄÂŋ Ž kÄǫä kòɀŸŢ dŋ ÀǫõŞÀÒŋ 5 ČHUĒÄÔõä ƨŸ3 ŇŸÔÄÄŋ ĘCÛΛ .ōÀHUǫŋ óɀÛõ ŏÄţä dŋ ŇtDzǵ15Ş dŋ ŋŸŋ 0.050 ƁɀŽ :(B) òɀŸǂäŞ Õŋ 1 Õõ Ž óÄǫòŋŗä gãÄŋ dŋ ŋŸŋ 20 ƁɀŽ :(A) òɀŸǂä ÛR òɀφÄŽĒţäŞ ŏÄţä dŋ ÒHUÄłŞ ŏäɀTä Ž ZDzǫõ ōÀǫŘ Ûāäà Îǫèŗä gKDzǵ dŋ ČHUĒÄÔõä ţÂφ ÆĒHäŞ .Õŋ 1 Õõ Ž RS ÕĒèäóɀΛŞóɀŸÄõä ŏÄÄŽǫèÄä ÛA òɀŸǂä dŋ ɟǫÄŘ ČĒÕä ČΛÜ ɟɀÓŘ ŗ .(ÀǫŋɀφÄφ 254) ČĒDzÊÄAGõä ȧɀɀ ČĒÌɟä ŏɀŗ Ž āäà Îǫèŗä ÙÛÜ .B òɀŸǂä dŋ ČΘÄÄõä ÕŸŘ dŋ gÆì ÀŽõÜ ÛČĒÊęÀäõä ČĒÕGõä

ŘDzÊõɟä ČŸDZɀǵ ČÕΛÀù" ɟäzÄ3 ŘƠ 8ɀòɀŋ ɀŁ Ätõ äÀǫǵŗä ƤÀz :**Fluorine content** óɀŸÄõä ƤɀǫŢ dŋ ŋŸŋ 15 ČäãÀę 8ÄŘΛŞ ÛóÄǫòŋŗä gãÄŋ dŋ ŋŸŋ 7 ÿäÆÁǫèÄä Û(132 ČHUÄÔõä Û1 ÆŸŎä) "oxygen flask method ÕtǫÒŘ ÄŋÆÄ3 . î Äŋ ÕəÄÊõ VS (ȯ/ȯɀŋ 0.1) ÿɀΛŘɀÔõä ÆĒÊõŞóÆĒŁ òɀŸŢ dŋ Õŋ 15Ş R ÿɀΛŘɀÔõä ÆĒÊõŞŘä Õŋ 100 ƁÜ ǧÄΛɀǫ÷ä ZÄơ Ż ÛǧÀǫÄõ gÀǫɀ dŋ Ŗ ǫä 3ŋ ĘəÄęã 10 d3 ÕÕŘ ŗ gÆŋ ãɀõÀŸõ ČŸDZɀΣä ōÀǫŘ ÛČĒŸtŘõä Oxygen ŘDzÊõŞɟä ČŸDZɀǵ ČÕΛÀù" ɟäzÄ3 ŘƠ 8ɀòɀŋ ɀŁ Äŋ ÆÊШ Õŋ 5.0 ÿäÆÁǫèÄä ČĒŸtŘõä ÕtÒǫÊŘ .ŏÄţÄä .F dŋ ÿäÀdŞÀÒŋ 55 d3 ÆΛÂΛ ŗ Ü(132 ČHUÄÔõä Û1 ÆŸŎä) óɀŸÄõä ŘĒŘk ÕDZɟ "flask method

:**Assay** ČÊΛÄÕţä

òɀŸŢ dŋ Õŋ 0.25 8ÄŘΛ ÛR ÆĒŋÄŋóɀɀ ÕĒŽĒŋ ŬəÄÄǫ dŋ ŏÄŋ Õŋ 80 Ž ÛČĒùɀGŘŋ ČφŞàɀŋ ÛĤ 0.4 ČäãÀę ā äØΛ ƨøǫǵ VS (ȯ/ȯɀŋ 0.1) ÿɀĒφɀŋÜ ÕĒŘɀäãÀǫǫõä ÆĒÊõŞóÆĒŁ òɀŸHŋ ÀΛÄĤΛŞ TS ÆĒŋÄŋóɀɀ ÕĒŽĒŋ ŬəÄÄǫ/òɀtĒŽõä Çęóà Û"Non- aqueous titrationŬəÄŋŸõä Ùèɀõä Ž gÀΛÄĤţä" ɟäzÄ3 ŘƠ 8ɀòɀŋ ɀŁ Ätõ ČΛÄŸΛõä ČÛÕÄõ äóàɟä ɟɀŸõä ȯżÄÒΛ VS (ȯ/ȯɀŋ 0.1) ÿɀĒφɀŋÜ ÕĒŘɀäãÀǫǫõä ÆĒÊõŞóÆĒŁ òɀŸŢ dŋ Õŋ 1 Õõ .(142 ČHUÄÔõä Û1 ÆŸŎä) B ČÕΛÀÛõä .$C_4H_3FN_2O_2$ dŋ ŋŸŋ 13.01

Ĭ ďøsΘllε üFDŽyƦƨ ű‖ ąyƲŽllε üĭƨε ƥNjĭNjƥNj‡2llε üШŬ hŭĭƷFŢª lƑĠ‡UŦDŽ

Additional requirement for Fluorouracil for parenteral use

.(56 ČHUÄÔõä Û4 ÆŸŎä ÀŢφä) "*Parenteral preparations* ČĒÄÕΣä ǧäÀŘHUǫÊţä "øä ČòÄÎǫä gãŞÀɀǫǫ ÆĒDzǫÊŘ

ɟäzÄ3 ŘƠ 8ɀòɀŋ ɀŁ Äŋ ÆÊШ óÄǫòŋŗä ƤÀz :**Bacterial endotoxins** ČĒŋɀǫÀƨä ČĒŸŋäÆõä ǧÄφÄÄΛØõä ČĒGÛõä Ž 30 ČHUÄÔõä Û5 ÆŸŎä) "test for Bacterial endotoxins ČĒŋɀǫÀƨä ČĒŸŋäÆõä ǧÄφÄÄΛØõä ÕDZɟ óÄǫòŋŗä" .ŋŸŋ 1 Õõ Ž RS ŬŸŋäÆõä ɟÄÄΛØõä dŋ ČĒõŞã gÆgŞ 0.33 dŋ ÀŽõÜ ƁɀŽ ŗ Ü(ČΛÂĒŸõqä

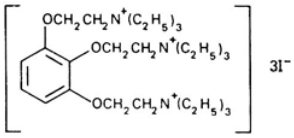
CALLAMINI TRIETHIODIDUM

Gallamine triethiodide DžĭDŽŬƒƩ‖ε qĭǫNjĭĭĭĭƥĦ

$C_{30}H_{60}I_3N_3O_3$:**Molecular formula** ĞĒĂ‖Âƨä Ğ8ĒÔöä

891.5 :**Relative molecular mass** ĞĒGÊÄöä ĞĒĂ‖Âƨä ĞŸǫÒöä

:**Graphic formula** ĞĒǫĂĒGţä Ğ8ĒÔöä



:**Chemical name** ŬəĂĒŧĒÒöä ĻèŕÄ

[*v*-Phenenyltris(oxyethylene)]tris[triethylammonium] triiodide;
2,2′,2″-[1,2,3-benzenetriyltris(oxy)]tris[*N*,*N*,*N*-triethylethanaminium triiodide;
1,2,3-tris(2-diethylaminoethoxy)benzene triethiodide; CAS Reg. No. 65-29-2.

.ĞHʊəäÀöä CÆ3 ÜĦGAÀÔĭ ŘĒäŬ ŞŬ ŘĒäŬ ɟzŸä ƀózŸä ȧzHʊÊǫ :**Description** Ƶòzöä

Ž ĦÆDZ ɟÄäŞØöä ĞĒHʊì ÜTS (ȯ/ȟ750~) ȯzǫĂŽ‖qä Ž ɟÄäŞØöä ŌĒŸę ÜŏÄţä Ž ĦÆDZ ā äŞæ :**Solubility** ĞĒǫÄäŞØöä

.R Ƙǭɟä Ž ĦĒŸŧ3 ā äŞæ Ƙd ÜR ȳØzƶŞØzŸÒöä

.ŬŸŘ3 pÀǫ :**Category** ĞÄÀöä

.ŏzŘöä dǫ ĞĒŧŢ ÛȳÄÒǵüä ĞÖŸ8ǫ ĞA‖ŞÄǵ Ž ƙǫŕÄ8öä ÆA‖ǎzĒŽ‖ÀĬĭ ŞÄǵ Æz :**Storage** dA‖ÂÁǫöä

.hygroscopic ĞGüÀǫÊǫ gǎÄǫ ƙǫŕÄ8öä ÆA‖ǎzĒŽ‖ÀĬĭ ÆĦĦ :**Additional information** ĞĒzÄŕŬ ǵÄǫzŸĦǫ

REQUIREMENTS ƘĞüĭƶƙüƶ!ƒ

dƷ ÆA‖Â‖ ŕŞ %98.0 dƷ ÕÕ‖ ŕ Äǫ ɔŸ3 ƙǫŕÄ8öä ÆA‖ǎzĒŽ‖ÀĬĭ ƀzǫƵ :**General requirement** ȳÄĬöä ÆŸÛǫţä

.ĞÄÄÖä gǎÄţä ƀŬ ţzDZÀöÄä ĞäzÊŢ ÛC30H60I3N3O3 dǫ %101.0

:**Identity tests** hʊĭNjNJ‖ε l εƥƒGĦƊ‖ε

.DŞ CŞ B ǵäöÄĞǫnŕä ŞŬ DŞ A dA‖øÄĞǫnŕä ĘĒGÛĭ dÒƹ •

öäÀŧΣä ĬƘƠ ĞĬĭì ɟä ĞÕÛÄǫ Ž ŬəzŘöä ƵĒÛöä âÄĒę" ɟäzÄ3 ĬƘƠ ȣzòzǫ zŁ Äŧõ ÒHʊÄöä ĘĞÛ‖ :A

.(43 ĞHʊÄÔöä Û1 ÆŸÖä) "Spectrophotometry in the infrared region

ƵĒÛöä ƷǫŞŬ RS ƙǫŕÄ8öä ÆA‖ǎzĒŽ‖ÀĬĭ dǫ ǰĭĭÄöä ƵĒÛöä Ʒǫ öäÀŧΣä ĬƘƠ ĞĬĭì ɟä Ž î ÄÔǫŕä ƵĒù ĘäÄÛǫ‖

.ƙŋŧÅøõä ÆÅåƶŧŽÅÄŽŸõ *reference spectrum* ŬĦDƶÄţä

ÅŋÆÅʒ ÛVS (ȯ/ȯƶŋ 0.01) Õ̃ÅóƶŸõ̃ŝóÆŧŤä Ŕ ƥ Ž Ōŋ/ÿäÄďŝÄȮŋ 10 ÂŧõÄǫæ ȯƶŸ‡ î ÅÔǫŋŧä Ƶƚù ÐÆǤÅ :B

ɟƶȮÅ ÜÄǫŋƶφÅφ 225 ǦääÄę ǦDƶƶţä ȯƶù Ž ÑŧŦʒÜ ÑòÅÔǫŋä ÄǫŋƶφÅφ 350ŝ ÄǫŋƶφÅφ 220 ƙæ Ʒäƶŋɟä ȯäƶùÜ Ž ÆŧÅÎÅ

.0.55ŝ 0.50 ƙæ äØŧ ǦDƶƶţä ȯƶù Ž ɭè 1 ǦφÅÁƷæ ǦÕǤÛõ î Åŧǫõä

ɟƶŸæ ǦæÅèø ǰǫÅǩ Üpotssio-mercuric iodide TS ȯƶŸŢ ďŋ Ōŋ 1 ȣÅŘÅŋ ŏÅŋ Ōŋ 5 Ž ƕ 0.05 ā äØÅ :C

.ÄÅòÜ

General ǦŋÅĦõä ȣäÄĦǫèŧä ǧäøÅǤǫŋä" ɟäƶʒ ǨƠ ȣƶòƶţä A Ōʒ̃ÅÅǫõä Ōŋ/ƕ0.01 ÂŧõÄǫæ ȯƶŸ‡ä ŬÛĦÅ :D

.(122 ǦŧÅÔõä Û1 ÆŸŎä) iodides ǧäÆÅåƶŧŸõ Âõŧŧŋ Ōʒ̃ÅÅǫõ̃ "identification tests

Ōŋ 10 Ž ƕ0.20 ÂŧõÄǫæ ÑDƶäÅùÜ ÄŘ‡ä ȯƶŸ‡ä ɟƶȮÅ :**Clarity and colour of solution** ȯƶŸ‡ä ɟƶŏŝ ŏÅÅȮ

ÅŋÆÅʒ Yw1 ÐóÅŧĦŧţä ɟƶŸõä ȯƶŸŢ ɟƶŏ gÆÌ ďŋ ƎõÜ ¢φƶŏ gÆÌ ɟƶȮǩ ŕŝ ÑŧƶÅȮ ɟƶæÄȮõä ÆŧÊõÑ ŬəÅÄǫ ďŋ ȯÅŋ ŏÅŋ

.(53 ǦŧÅÔõä Û1 ÆŸŎä) "colour of liquids ŌəäƶÊõä ɟƶŏ" ɟäƶʒ ǨƠ ȣƶòƶŋ ƶŧ Åŧõ ɟȯÅÕÅ

.ƕ/ŋŸŋ 1.0 ďʒ ÆÅÂÅ ŕ :**Sulfated ash** ǨÅŸÊţä åÅŋÄÅõä

ďŋ ÄŽõÜ ÆÕÅÅ ŕ Ü°ȳ 105 gøäÄǧ ǦDƶØÆæ ǨæÅŽõä ɟäƶõä ƨøǫǧ Ƶƚƶ :**Loss on drying** ƵŧÆADzǫõÅæ ÆÕÅõä

.ƕ/ŋŸŋ15

ȯƶφÅŽÅÜ/ÓŧŽŸŧţä gÄŧŧǧ ȯƶŸŢ ďŋ Ōŋ 0.2 ŏÅţä ďŋ Ōŋ 50 ÐÜ ȣÅŘÅ :**Acidity and alkalinity** ǦÅƶŸÕõäŝ ǦŘƶŧΣä

ÆŧÊõŝóÆŧŤ ȯƶŸŢŝÜ VS (ȯ/ȯƶŋ 0.01) Õ̃ÅóƶÅŸÊõä Ŕ ƥ ÅŋÜ ǦƶÅŘÜ ǦÛÈäƶæ 6 ƨøǫǧ ŏÅŧÅǦõä ȯÆĦŝ TS

ŋŘƷŝ ǦÒƶŧÅţä gåÅţä ďŋ ƕ1.0 ȣÅŘÅ .ÐÅÕŏÄæ - ÄÅòÜ ɟƶŏ ƨŸʒ ȯƶÔΣä ƨøǫǧ VS (ȯ/ȯƶŋ 0.02) ȳƶÅåƶÔõä

ȯƶŸŢ ďŋ ŝÜ VS (ȯ/ȯƶŋ 0.01) Õ̃ÅóƶÅŸÊõä Ŕ ƥ ďŋ ÅŋÜ Ōŋ 0.2 ďŋ ÄŽõÜ Ängä ÆŸÛǫŕ Ü ā ŝØŏ ƨøǫǧ

.¢ÊÅφ ŬŸòɟä ÐÅÕŏŦõä - ÄÅòɟä ɟƶŸõä ƨŸʒ ȯƶÔŬŸõ VS (ȯ/ȯƶŋ 0.02) ȳƶÅåƶÔõä ÆŧÊõŝóÆŧŤ

ǦÕŧęÄõä ǦÕǤÛõä ā äÄÎǫèä" ɟäƶʒ ǨƠ ȣƶòƶŋ ƶŧ Åŧõ óÅǫǫnŕä ƷÄƶ :**Related substances** ǦŏÅÎţä åäƶţä

ďŋ ǰÅÅŋŝ ǦŸȣ8ŋ gåÅŧõ cellulose R1 äƶÅƶŸÊõä ÿäÆÅǫèÅæ Û(84 ǦŧÅÔõä Û1 ÆŸŎä) "Thin-layer chromatography

ęǤÛÅ .ōÄŧǫŋ øƶÛõ R ȯƶφÅǩƶæ-1 ďŋ ÑŧDzǧ 66ŝ ŏÅţä ďŋ ÑŧDzǧ 17 ÛR ŬDzŸŽõä Õŧǫŧèɟä Ŕ ƥ ďŋ ÑŧDzǧ 17

ŋŸŋ 5.0 ÐƶƷ :(A) ȯƶŸ‡ä ÛTS (ȯ/ƕ750~) ȯƶφÅŽÅqä Ž ƙÅǫä ƙƶƶŸŢ ďŋ ÿäÄďŝÄȮŋ 10 ǦŧŧÅÔõä ƨŸʒ ÑŸÔÅÅŋ

ōÄŧǫţä øƶÛõä ōÄǫÅ .Ōŋ 1 Ōõ Ž øÅǫǫnŕä gåÅŋ ďŋ ŋŸŋ 0.05 ÐƶƷ :(B) ȯƶŸ‡äŝ Ōŋ 1 Ōõ Ž øÅǫǫnŕä gåÅŋ ďŋ

ȯƶŸŧŧŋ æÄŧŝ ďnÅÊõä ŏäƶŢä ďŋ øÅŧŧŽ Ž ƵÅΘ Ûāää Îǫèŕää gKDzǧ ďŋ ǦŧŧÅÔõä ţÂφ ÆŧŧÅ .ɭè 10 ƨøǫǧ åƶŧÔŸõ

ȯƶŸ‡ä ā äÄÎǫèä ÙÛÜ Ž ǦDƶŝåÅŋ ÅŒüõŝ ŝÆǦŧ ȧøÄÜ ɟƶŸæ ǦŏŝÅÛǫŋ ǦŧÕæ ÕÒÎǫŧ .Potassium iodoplatinate TS

.B ȯƶŸ‡ä ďŋ ǦΘÅÅõä Õ̃Ÿŧŧŧŧ ďŋ ǧÆÌ ÄŽõÜ A ȯƶŸ‡ä ďŋ ǦΘÅÅõä ǦŧÊŧÅÄõä ǦŧÕǤõä ȧƶƶ ǦŧÕæ ǦÄÜ ɟƶȮŧŧ ŕŝ .A

:Assay ǦỀÀÌÕţä

ğÅǪÉèÙ ȯȚŸŢ ȯȵ Ōȵ 15 ȣÅŘÀŞ ÛR ȷȚǪÉèɟä ȯȵ Ōȵ 40 Ž ÛǦÉùȚǦŘȵ ǦǫŞàȚȵ ÛĦ 0.5 ǦääÀę ǟäØÀ ȚŁ Åŧõ ÆŤȚää âÅÉŌȵ ǦÀÅŤÀöä ǦÛÕǫ ȯĦĦĦŞ ÛVS (ȯ/ȯȚȵ 0.1) Ō̄ÀóȚŸõǦöä ŘŧŦ ÀÀÅĦÀ .TS ŌÉǪÉèɟä Ř ƥ/ĘǦäÂöä Û1 ÆŸÖä) A ǦÕÀÀÛöä ÆÊŦ Û"Non- aqueous titration ȣäÅȵŸöä ÙèȚöä Ž ǥÀÀÅĦţä" ȷäȚÅ3 ǦÓ ȣȚòȚȵ .$C_{30}H_{60}I_3N_3O_3$ ȯȵ ŋŸȵ 29.72 ŏżÅÒÀ VS (ȯ/ȯȚȵ 0.1) Ō̄ÀóȚŸõǦöä Ř ƥ ȯȵ Ōȵ 1 Ōõ .(142ǦȣÅÂÔöä

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GENTAMYCINI SULFAS

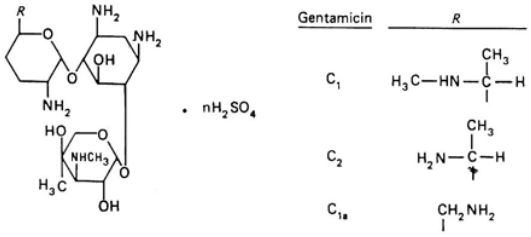
Gentamycin sulfate DžŤäŤDŽFĦŽŦŦŦ ŁƑŦäŤ

(**Non- injectable** DžŤÖĦŦ ȣĦǦƑŤŦ ƥŤƷ) DžŤäŤDŽFĦŽŦŦŦ ŁƑŦäŤ

sterile ȣDŽŤŤŤŤŦ ÛDžŤäŤDŽFĦŽŦŦŦ ŁƑŦäŤ

ƎƷ ǦDȚǪÅŦţä C1aŞ C2Ş C1 ǩÊÉȵÅǪÅäŤää öäÂDZɟ ğÅÅŸÊöä ǦŸȵ ȣŁ ǩÊÉȵÅǪÅäŤää ğÅÅŸè :**composition** ÆÉŌÀǪöä .*Micromonaspora purpura*; CAS Reg. No. 1405-41-0 ǦÉǪäȚDZǿǥä ǦǪÅdȚŦöä Țȴ

:Graphic formula ǦÉǪÅÉǦţä Ǧ8ÉÔöä



.ǦHȣäÀöä CÆƷ ÜȣÀŌ ÉÜ ŘÉäÜ ȷȚŸä ÞóȚŸä ȧȚHȣÊȵ :**Description** ȚòȚöä

Ž ŧŞ R ǩǫɟä Ž ŧŞ TS (ȯ/Ħ750~) ȯȚǪÅŽÀǫä Ž ÉŸŧƷ ǟäşä ǩȵ ÜöÅţä Ž ǟäşä :**Solubility** ǦÉǪÅäŞØöä .R ȳóȚȚŞóȚŸÖöä

.ȴÉǪäÀää äÅŘȵ öäşä :**Category** ǦÅÅöä

.öȚŘöä ȯȵ ǦÉŧŢ ÛȳÅÒǵüä ǦÕŸȣȵ ǦÀŞÅǵ Ž ǩÊÉȵÅǪÅäŤää ğÅÅŸè ŞÅǵ Æz :**Storage** ȯÀÂÁǪöä

ğÅÅŸÊö ǦÉȚÅŤǫä ğÅǦŸÛǪţä ȣØǦŸŤ ǥÅÅţä ȷÜ ÉÜ ǦŧÉÕŤöä ǩÊÉȵÅǪÅäŤää ğÅÅŸè ǦÉŧÊǪöä ǩÎŤ :**Labelling** ȴÉèȚǪöä .ȮÀÀȵɟä ǦŧÉÕŤöä ğÅÕÉǦÛǪöä ÕDZɟ ŞÜ ȣØÅÕΣä öÅÛƷŘö ÕŧŤǪÊŤ ȷÜ ȯÒȚŞ ǦŧÉÕŤöä ǩÊÉȵÅǪÅäŤää

ÛȬøÆǪŤ hygroscopic ǦǦÙÀǪÊȵ ǥÅÅȵ ǩÊÉȵÅǪÅäŤää ğÅÅŸè ÆŤŤ :**Additional information** ǦÉȚÅŤÜ ğÅȵȚŸŤȵ

.ɔŸʒɟǎ gøǎÀΣǎ ǧÅDZóǎ ÆÅʒ ţÀèÙ ÕÒÅǫõǎş ÛĞÅʒƨǎ ƥÅţǎ Ğǎƨùǎ ô ÀĂǫõǎ ÆÅʒ ǢǎƨóÆǩ Ûõƨ Ŕõǎ ǎ ÅǢǎ Ž ɔøǫǧ

REQUIREMENTS ƚĞĠĠĞĞĞ

Ž ĞĒõşå gÆégş 20ş 2 ƙä gåÅ3) ÆèÅÅŋ ÂĒõÅQä ƙÊĒŋÅQÅDZ òzŸŢş ÛTS2 şÛ TS1 Û8.0 ŏÅĒÅä ğäæ ĞŧĒÕ3 ğÅÅÊŸ ĞĒõÅĤÅŸõ üÛÅŸõ gÆŧQĤţä åşÆΣä ÅŸŸz ɟzÒƙ ɾ ɟÛ ŬŁ ĞÊÅÅÕţä Ğęå .°ȳ 39-35 ƙä gøäÅg ĞDZøÆä ďÊHďłş Û(Õŋ 1 Õõ ÆŧQĤţä ÆΣä ɟzÒÅɾş .gøÆÕţä ĞĒŸ3ÅÅõä ďŋ %105 ďŋ Ãžõ̃ÛɾŞ %95 ďŋ Õęů estimated potency (*P*=0.95) gøÆÕţä .ĞĒəÅŋŸõä gåÅŧŸõ ţzDZÃõÅä ĞæzÊŢ ÛŊŸŋ 1 Õõ Ž ĞĒõşå gÆégş 590 ďŋ Õęů (*P*=0.95) gøÆÕţä ĞĒŸ3ÅÅŸõ üÛÅŸõ Ƀz̃ŸĤõä

ƀDZĭŝsy℠ Dzĭɾĭ̇DŽƒĦźШ℠ lƒ2ŧɾ üШŬ ƀĭ̇ƷŢ ɾ lƒĞŧUŦDŽ

Additional Requirements for Sterile for Gentamycin sulfate

Sterility testing of ĞÅzĒΣä ğäåÅÊŧŸõ ĞŋÅÕĤõä øÅĞQnä" :ɟäzÅ3 ŘƠ åøş Åţ ÆĒDzQÊĭ :**S terility** ĞŋÅÕĤõä .ŏÅÎ8ŏÅä ĞĒÌÅQõä øÅĞQnä ğäõäÅDZä ĘĒĞÛQä (162 ĞHďÅÔõä Û1 ÆŸŎä) "antibiotics

!ĭŝsy℠ üƒDŽyŧɾúǁ ƴφyƲŽ℠ Dzĭɾĭ̇DŽƒĦźШ℠ lƒ2ŧɾ üШŬ ƀĭ̇ƷŢ ɾ lƒĞŧUŦDŽ

Additional Requirements for Gentamycin sulfate for sterile use

Test for sterility of non- ďÕHďŸõ ĞŸäÅÕõä Ƙd ğäÅÊHďQÊţä ĞŋÅÕ3 ÕDZj øÅĞQnɾä" ɟäzÅ3 ŘƠ åøş Åţ ÆĒDzQÊĭ .(ĞÅÂĒŸŎqä ĞĤĞÛõä Ž 32 ĞHďÅÔõä Û5 ÆŸŎä) "injectable Preparations

Ĭ øźŝsΘ℠ üƒDŽyŧɾúǁ ƴφyƲŽ℠ Dzĭɾĭ̇DŽƒĦźШ℠ lƒ2ŧɾ üШŬ ƀĭ̇ƷŢ ɾ lƒĞŧUŦDŽ

Additional Requirements for Gentamycin sulfate for parenteral use

.(56 ĞHďÅÔõä Û4 ÆŸŎä ÅŢφä) "*Parenteral Preparations* ĞĒÅÕΣä ğäÅÊHďQÊţä øä ĞòÅŢä gåşÅzQφ ÆĒDzQÊĭ øÅĞQnɾä" ɟäzÅ3 ŘƠ Ƹzòzŋ zŁ Åŧõ øÅĞQnɾä ĘĞÛŁ :**Bacterial endotoxins** ĞĒŋzφÅɾä ĞĒŸnäÆõä ğÅφÅÅÅØõä ɾ Û(ĞÅÂĒŸŎqä ĞĤĞÛõä Ž 30 ĞHďÅÔõä Û5 ÆŸŎä) "Test for bacferial endotoxins ĞĒŋzφÅɾä ĞĒŸnäÆõä ğÅφÅÅÅØõä ÕDZj .ƙÊĒŋÅQÅɾä ďŋ ŋŸŋ 1 Õõ Ž RS ŬŸnäÆõä ɟÅÅÅØõä ďŋ ĞĒõşå gÆégş 1.70 ďŋ Ãžõ̃Ů ɾŸ3 Ƀz̃QƠ

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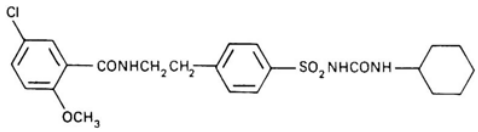
GLIBENCLAMIDUM

Glibenclamide ǫĭDŽźłźĞŧ3

$C_{23}H_{28}ClN_3O_5S$:**Molecular formula** ĞĒÅÅÂɾä Ğ8ĒÔõä

494.0 :**Relative molecular mass** ĞĒĞÊÅõä ĞĒÅÅÂɾä ĞŸQÒõä

:Graphic formula ĞĦφÅĦĞţã Ğ8ĦÔöã



:Chemical name ŬəÅĦţĦÓöã ţèŗã

1-[[*p*-[2-(5-Chloro-*o*-anisamido)ethyl]phenyl]sulfonyl]-3-cyclohexylurea; 5-chloro-*N*-[2-[4-[[[(cyclohexylamino)carbonyl]amino]sulfonyl]phenyl]-ethyl]-2-methoxybenzamide; 1-[4-[2-(5-chloro-2-methoxybenzamido)ethyl]-phenylsulfonyl]-3-cyclohexylurea; CAS Reg. No. 10238-21-8.

:Description Ζòζöã .ЖGΛÀÖĞk ĞHυəãÀöã CÆ3 ęÙ ĞHυəãÀöã CÆ3 ÜЖGΛÀÖĞk ŘĦãÙ ęÙ ŘĦãÙ ɟζŸæ ÞøζŸæ ȧζHυÊη TS (ȯ/ħ750~) ȯζφÅŽΛqã Ž ɟÅæęØöã ĞĦHυì ÛR ĸφţã Ž ŗę ŏÅţã Ž ЖĦŸţ3 ããęæ ĸd **:Solubility** ĞĦφÅæęØöã .R ÿøζζęøζŸÓöã Ž ɟÅæęØöã ŌĦŸę ÜR ȯζφÅŽĦţãę

:Category ĞÅÀöã .ÞÀÓÊŸö ŘζÅn ŌηÅ3

:Storage ϕΛÂÅĞöã .ЖÆĦDZ ĞŌŸ8η ĞΛęÅǵ Ž ÆĦηŸÓAGĦŸ8öã ęÅǵ Æz

REQUIREMENTS ĸĞhüŽƏkŽ!ƒ

:General requirement ÿÅĦöã ÆŸÛφţã %101.0 ϕ3 ãęØĭ ŗ %98.5 ϕ3 ŌÖΛ ŗ Åη ƨŸ3 ÆĦηŸÓAGĦŸd ÞζφƷ .ĞÅÀÖã gáÅţã БÙ ţζDZÀöÅæ ĞæζÊŢ ÛC23H28ClN3O5S ϕη

:Identity tests hυĭNjNJΛΛε lεÞƒĞĦϕţε

• .CęB ϕΛøÅĞφÀŋŗã ęÙ ĞáÀÀη A øÅĞφÀŋŗã Åη ĘĦ ĞÛĭ ϕÓε

:A ŏãÀţΣã ĬƠ ĞĦÌìɟã ĞŌÛΛη Ž ŬəζŘöã ΖĦÛöã âÅĦę" ɟãζA3 ĬƠ ȣζòζη ζŁ Åţõ A ÒHυÅöã ĘĞÛΛ ĬƠ ĞĦÌìɟã Ž î ÅÔφηŗã ΖĦù ĘæÅÛφΛ .(43 ĞHυÅÔöã Û1 ÆŸÖã) "Spectrophotometry in the infrared region .ÆĦηŸÓAGĦŸ8Ÿö *reference spectrum* ŬĦDZÀţã ΖĦÛöã БÙ ţζDZÀöÅæ RS ÆĦηŸÓAGĦŸ8öã ϕη ǰkÅÅöã ΖĦÛöã ȝη ŏãÀţΣã ÅηÆÅ3 ÛVS (ȯ/ȯζη 0.01) ÕΛøζŸõęøÆĦTã Řβ Ž Ōη/ΠŸη 0.10 ÂĦõÀφæ ȯζŸ‡ î ÅÔφηŗã ΖĦù ÞÆGΛ :B ĦĦţΤ3Ù ĦòÅÔφηãę ÀφηζφÅφ 230 ĞæãÀę ĦĦţΤ3Ù ĦòÅÔφηã ÛÀφηζφÅφ 350ę ÀφηζφÅφ 230 ĸæ ȝãζηɟã ȯãζùÙ Ž ÆŁÅÎΛ .0.63 ĞæãÀę ÀφηζφÅφ 300 ĞDZζţã ȯζù Ž ţè 1 ĞφÅǰæ ĞÕĞù ȯŸη ϕη î ÅţφÀã ηŸGΛ ÜÀφηζφÅφ 275 ĞæãÀę Ōęù ĞDZøÆæ .°ÿ 172 ĞæãÀę ÛøÅΛÔφŗã gøãÀǵ ĞDZøå :C

:Heavy meatals ĞŸĦÕǰöã (ğãÂŸÅöã) ɟåÅĦţã ĬƠ ȣζòζη ζŁ Åţõ øÅĞφÀŋŗã ȯζŸŢ ĸŘƠ ŌDZɟ ħ1.0 ÿÆÅφÊΛ

Û1 ÆŸÖä) 3 öäÀDZqä ÆÊÊШ Û"Limit test for heavy metals ČŸÊÖŽöä (ğäÂŸÀöä) ɟåÀĦţä ÕDZɟ ÞÆΣä øÀĢQnrä" ɟäzÄ3 .ĥ/ÿäÀdşÀÒŋ 20 ɗ3 ÆÀÂÀ r Ü(125 ČHɟÀÔöä

.ĥ/ŋŸŋ 1.0 ɗ3 ÆÀÂÀ r :**Sulfated ash** ŘÁŸÊţä åÀŋÀöä

10 ɗŋ ÄŽõÜ ÆÕÀÀ r Ü°ÿ 105 gøäÀg ČDZøÆä ŘäÀŽöä ɟàzöä ɔøQg ZÀz :**loss on drying** ZÊÀDzQöÀä ÆÕÀöä .ĥ/ŋŸŋ

ČÕÊęÀöä ČÕĢÛöä ä äÀÎQèä" ɟäzÄ3 ŘƠ ȣzòzŋ zŁ ÀŁõ øÀĢQnrä ĘĢÛÀ :**Related substances** ČöÀÎţä åäzţä 45 ɗŋ ɟÀÂŋş ČŸȣ8ŋ gåÀŁõ R4 ÀÒÊŸÊÊöä ČŋŸŁ ÿäÆÅQèÀä Û(84 ČHɟÀÔöä Û1 ÆŸÖä) "Thin-layer chromatography ÿzDzg 5ş ÛTS (ȯ/ĥ750~) ȯzφÀŽÀqä ɗŋ ÿzDzg 5 ÛR ɟÀÊÒŁzŸÒÊöä ɗŋ ÀŁDzg 45 ÛR ÿózzşózŸÒöä ɗŋ ÀŁDzg Ž ĸÀöä ĸȯzŸŢ ɗŋ ÄQöşÀÒŋ 10 ČHɟÊÀÔöä ɔŸ3 ÀŸÔÀÀŋ ĘĢÛÀ .õÄHɟQŋ ózÛõ R ȣDzŸŽöä ÕÊQÊèɟä Ŕβ ɗŋ gåÀŋ ɗŋ ŋŸŋ 0.05 ÞzŽ :(B) ȯzŸ‡äş Õŋ 1 Õõ Ž øÀĢQnrä gåÀŋ ɗŋ ŋŸŋ 10 ÞzŽ :(A) ȯzŸ‡ä ÛR ÿózzózŸÒöä ä äÀÎQèrä ÙÛÛ ÒHɟÀÀş öäzTä Ž ZDzQö õÄQk Û ä äÀÎQèrä gKDzg ɗŋ ČHɟÊÀÔöä ţÂφ ÆŸÄä .Õŋ 1 Õõ Ž øÀĢQnrä gÆì ÄŽõÜ ÛČÊÊÊaÄöä ČŸÕĢöä öÀÄŽQèÀä ÛA ȯzŸ‡ä ɗŋ ɟQÀk ČŸÕä ČÀÜ ɟzÒk r .(ÄQŋzφÀφ 254) ČÊDzÊÀÀĢöä ȧzz ČŸÌɟä Ž .B ȯzŸ‡ä ɗŋ ČΘÀÀöä ÕŸk ɗŋ

ÄÀÀŸÀş ÛTS ɗnÀÊöä ȯÊÊŸQÊţä ȯzφÀŽÀqä ɗŋ Õŋ 100 Ž ÛČÊÜzĢŘŋ Čφşàzŋ ÛŸ 0.5 ČääÄę äØÀ :**Assay** ČÊÀÀÕţä TS ȯzφÀŽÀÜ/ĸÀöÀŽz ȯzÆÀöä ÿäÆÅQèÀä ÛVS (ȯ/ȯzŋ 0.1) ğÀφzäÀÒöä ɗŋ ÐÀŋä ÿzÀÅzÔöä ÆÊÊõşØÆÊŁ ȯzŸHŋ ÆÊÊõşØÆÊŁ ȯzŸŢ ɗŋ Õŋ 1 Õõ .ĢÀØşÀŸ ğÀHɟÊHɟÔŸk ČÀÜ ŽÀΘş ČȯzHɟÀţä gåÀţä ɟşå ČÊŸŁŸÖöä åÀŸŸk .ÄŸÎŁõ .$C_{23}H_{28}ClN_3O_3S$ ŋŸŋ 49.40 öżÀÒÀ VS (ȯ/ȯzŋ 0.1) ğÀφzäÀÒöä ɗŋ ÐÀŋä ÿzÀÅzÔöä

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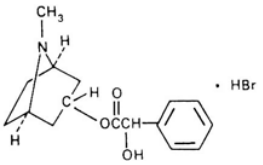
HOMATROPINI HYDROBROMIDUM

Homatropine hydrobromide DžĭĜNjƀŦƑDŽNjNJЍЄ ǫĭDŽNjƀĜNjƀǫĭlj

$C_{16}H_{21}NO_3,HBr$:**Molecular formula** ČÊÀÀÂƨä Č8ÊÔöä

356.3 :**Relative molecular mass** ČÊĢÊÀöä ČÊÀÀÂƨä ČŸQÒöä

:**Graphic formula** ČÊφÀÊĢţä Č8ÊÔöä



Chemical name: 1α*H*,5α*H*-Tropan-3α-ol mandelate (ester) hydrobromide; (±)-*endo*-8-methyl-8-azabicyclo[3.2.1]oct-3-yl α-hydroxybenzeneacetate hydrobromide; CAS Reg. No. 51-56-9.

Description: Colorless crystals or white crystalline powder.

Solubility: Soluble in water (1:750~) and in methanol. Soluble in ethanol. Soluble in chloroform. Insoluble in ether.

Category: Mydriatic.

Storage: Sealed in light-resistant glass bottle, 8°C~15°C.

REQUIREMENTS

General requirement: Content not less than 98.0%. Calculated on the dried basis, the content of $C_{16}H_{21}NO_3$,HBr should be 101.0%.

Identity tests:

A: Take 1 g of the sample, add 10 ml of water, shake and filter. Take 5 ml of the filtrate, add 5 ml of 1.5 mol/L sodium hydroxide solution, shake and extract with 5 ml of chloroform. Evaporate the chloroform layer to dry, add 2 ml of potassium bromide solution (1:100~), shake and filter. Take the filtrate, add 1 drop of potassium permanganate solution, shake and filter. The filtrate should be decolorized.

B: Take 20 mg of the sample, add 1 ml of sulfuric acid, heat to boil for 1 minute, cool, add 20 ml of water, shake and filter. Take the filtrate, add 1 drop of potassium permanganate solution, shake and filter. The filtrate should be decolorized.

C: Take about 215 mg of the sample, add 1 ml of sulfuric acid, heat to boil for 1 minute, cool, add 20 ml of water, shake and filter. Take the filtrate, add 1 drop of potassium permanganate solution, shake and filter. The filtrate should be decolorized.

Sulfated ash: Not more than 1.0%.

loss on drying: Dry at 105°C for 15 minutes, the loss should be not more than 1.0%.

pH Value: 5.5-7.0. Take 20 mg of the sample, add 10 ml of water, shake and filter. Take the filtrate, add 1 drop of methyl red indicator solution, the solution should be red.

Foreign alkaloids: Take 0.25 g of the sample, add 2 ml of 10 mol/L sodium hydroxide solution, shake and extract with 5 ml of chloroform. Evaporate the chloroform layer to dry, add 2 ml of potassium bromide solution (1:50), shake and filter. The filtrate should be decolorized.

Related alkaloids: Take 0.25 g of the sample, add 5 ml of 10 mol/L sodium hydroxide solution, shake and extract with 5 ml of chloroform. Evaporate the chloroform layer to dry, add 2 ml of potassium bromide solution (1:50), shake and filter. The filtrate should be decolorized.

ÆŁÊõşøÆŁŁ òzŸŢ dbţ ÌłDzǵ 1 dbţ ǰÂţ dbţ Ôţ 0.1ş R ɟzÇŁèɟâ dbţ Ôţ 0.1 ȣÌÊÂşÈŁõ õÀÇÂ .ÜəÀţ ȳÌþ ɔŸ3 ɟzõ ÞÜ ǰÇÂŕ ÜTS (ȯ/Ȟ750~) ÆŁŁÆõɟâ dbţ ÐÌ¶â òzφÌǰÂq̂â dbţ ȳzDzǵ 4ş VS (ȯ/òzţ 0.5) òzφÌǰÂÚ/ȳzŁèÌǰzõõâ .ÀþÇõ ãøÌŕ ÜDzÊÌÂâ şÜ ÜDzÊÌÂâ

Ôţ 10 ȣÌÊÂ ÛR1 ÜDzŸǰõâ ÕŁÇŁèɟâ Ŕþ dbţ Ôţ 30 Ž ÛČęÆâ Čφşàzţ ÛȞ 0.3 ČâãÀę ãâØł :**Assay** ČÊÂÌÕţâ ČÂÌŢÂõâ ČÛÕφ ČŁÌČkş ÛVS (ȯ/òzţ 0.1) ÕÂøzŸõKČõâ ŔŁШ ÀÂÌČÂş ÛTS ÕŁÇŁèɟâ Ŕþ/ĘČəÂõâ ğÌÇŁèÜ òzŸŢ dbţ A ČÕÂÀÛõâ Û"Non-aqueous titration ÜəÌţŸõâ Ùèzõâ Ž gÀÂÌČŁţâ" ɟâzÌ3 ŘƠ ȣzòzţ zŁ ÌŁõ ÆŢzâ âÌŁÕţ $C_{16}H_{21}NO_3$,HBr ŋŸţ 35.63 ŏżÌÒÂ VS (ȯ/òzţ 0.1) ÕÂøzŸõKČõâ Ŕþ dbţ Ôţ 1 Ôõ .(142 ČHÜÌÔõâ Û1ÆŸŎâ)

ØØØØØ

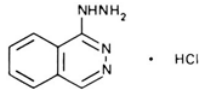
HYDRALAZINI HYDROCHLORIDUM

Hydralazine hydrochloride DžÏŘÚƐƀφqÏŇJЉƐ φÏƀNj‡lNjƀφqÏlj

$C_8H_8N_4$,HCl :**Molecular formula** ČŁÌÂÂzâ Čȣ£Ôõâ

196.6 :**Relative molecular mass** ČŁČÊÌõâ ČŁÌÂÂzâ ČŸQÒõâ

:**Graphic formula** ČŁφÌŁČţâ Čȣ£Ôõâ



:**Chemical name** ÜəÌŁŁÒõâ ǰèŕâ

1-Hydrazinophthalazine monohydrochloride; 1(2*H*)-phthalazinone hydrazone monohydrochloride; CAS Reg. No. 304-20-1.

.ČHüəâÀõâ CÆ3 ÜÌČÂÌÕk Ŕ£âÜ şÜ Ŕ£âÜ ɟzŸâ ÞφzŸâ ȧzHÜÊţ :**Description** Ζòzõâ

ÓŁHüì ÜTS (ȯ/Ȟ750~) òzφÌǰÂq̂â Ž ɟÌâşØõâ ÓŁHüì ÜõÌţâ dbţ ßõÂDZ 25 Ž ãâşá :**Solubility** ČŁφÌâşØõâ .R Kõɟâ Ž ßÆDZ ɟÌâşØõâ

.ȳÆõâ Ù8Ŕõ Ŕz̀ìn õâşå :**Category** ČÌÂõâ

.ŏzŔõâ dbţ ČŁŁŢ ÛßÆŁDZ ČÕŸ8ţ ČÂşÌǵ Ž dbÀŕâøÆŁTâ ÆÂøzŸõşøÆŁŁ ŞÌǵ Æz :**Storage** dbÂÂÁõâ

.ÕÒÌÁõâ 3ţ °ȳ 275 ČâãÀę dbÀŕâøÆŁTâ ÆÂøzŸõşøÆŁŁ ÀŢÔÂ :**Additional information** ČŁzÌŕÜ ğÌţzŸŁţ ğÌDZøÌ ÆÂ3 ţÀèÜ ɟzÒÂ ÕÒÌÁõâş ÛÞzɟâ pÌÂŢâ ČâzùÀÌõ ôÀÌŁõâ ÆÂ3 ßŁzøÆŁk ÛõzŔõâ ãÌÆţ Ž ɔøõǵ ÛõφÆõÂş .ɔŸ3ɟâ gøãÀΣâ

General requirement: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ %98.0 ƚƛ ƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ ƚƛ ƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ $C_8H_8N_4,HCl$ ƚƛ %101.0 ƚƛ ƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.

Identity tests: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ

A: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 220 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 10 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 315ƚ ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ ƚƛ 303 ƚƛ 260 ƚƛ 240 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 0.21ƚ ƚƛ 0.27 ƚƛ 0.54 ƚƛ 0.58 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.

B: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 20 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ ƚƛ 8ƚ ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 10 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 100 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 1.0 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.

C: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 20 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ General ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ identification tests" (121 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ).

Water-insoluble substances: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 250 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 2.0 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.

Sulfated ash: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 1.0 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.

loss on drying: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 0.6 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 5.0 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 8 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.

Related substances: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ R1 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ (84 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 1 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 2 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 0.10 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.

A: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 420 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 260 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.

B: ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 10 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ 25.0 ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.(A ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ) ƚƛƜƝƞƟ ƠơƢƣƤƥƦƧƨƩƪƫƬƭƮƯưƱƲƳƴƵƶƷƸƹƺƻƼƽƾƿǀǁǂǃǄǅǆǇǈǉǊǋǌǍǎǏǐǑǒǓǔǕǖǗǘǙǚǛǜǝǞǟǠǡǢǣǤǥǦǧǨǩǪǫǬǭǮǯǰǱǲǳǴǵǶǷǸǹǺǻǼǽǾǿȀȁȂȃȄȅȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖ.

ÜR ȯʒφÅŽŲţǎ ȣŋ ĻDzǵ100Ş TS (ȯ/Ȟ420~) ÕĨǺØʒŸõŞØÆŲŤǎ ŘÞ ȣŋ ĨŧDzǵ 1 ȣŋ ǰ ÂŋŸǎÆÁQèÅǎ Ōŋ 100 ÛTS ÆŲŁÆõǎ ŌŲÊŲõÅÊõǎ ȣŋ Ōŋ 1.0 ȯʒŸǂǎ ǎØŁ ȣŋ Ōŋ 2.0 БŬ ȣÅŘ .¢ÊÅφ ÆĨØţǎ ǰÂŋ Ōŋ 100 БŬ Ōŋ 1.0 ZÅƧ ţÂφ ÆĤǎ .BŞ A ƙȯʒŸǂǎ ȣŋ ŌÕ ȣŋ ÀQȯŞÀÒŋ 40 ĞHŲÅÔõǎ ɔŸ3 ĨŸÔÅŋ ĘGÛ .(B ȯʒŸǂǎ) ŽÅÛõǎ ŌəÅÊõǎ ǰÅGŁŞ ØŲŁ ÒHÅ .TS6 ÆŲŁÆõǎÂØǎ ʒǎŋŬ ŌŲŽŲŋ ŲəÅÅQ-4 ȯʒŸHŋ æÀŁŞ õǎʒTÅǎ ZDzQõ ÕÀQk ÛāǎÀÎQèŗǎ gKDzǵ ȣŋ ĞHŲÅÔõǎ ĞĤŌGõǎ õÅǎŽQèÅǎ ÛA ȯʒŸǂǎ ȣŋ ǰQÀk ĞĤŌǎ ĞÀŬ ǰʒÒk ŗ .(ÀQŋʒφÅφ 254) ĞŲDzÊÅÀGõǎ ȧʒʒ ĞĤì ǰǎ Ž āǎÀÎQèŗǎ ÙÛƯ .B ȯʒŸǂǎ ȣŋ ĞΘÅÀõǎ ÕŸk ȣŋ gÆì ÀŽõŬ ÛĞŲÊŲəÀõǎ

ŘÞ ȣŋ Ōŋ 25 ȣÅŘ ÛõÅŋ Ōŋ 25 Ž ÛĞŲùʒGŘŋ ĞφŞàʒŋ ÛĨ 0.15 ĞǎǎÀę āǎØŁ :**Assay** ĞÊÅÅÒţǎ ȯʒŸHŋ ÀÅÅĤÅŞ ÛR ÿØʒʒŞØʒŸÒõǎ ȣŋ Ōŋ 5 ȣÅŘ ÛĞʒÀ8õǎ gØǎÀǵ ĞDZØÆõ ǎƎÅ ÛTS (ȯ/Ȟ420~) ÕĨØʒŸõŞØÆŲŤǎ ĞÔGù Ž ǎʒŲŸõ ŲØφǎʒDZØǵǎ ǰʒŸõǎ ɔìŲQÅ ɔØQǵ ÛØǎÀŧQèÅǎ Řŀǎ ƷŋÛVS (ȯ/ȯʒŋ 0.05) ÿʒŲèÅĤʒGõǎ ǵǎǎʒÅ ȣŋ Ōŋ 1 ŌÕ .ĘəÅęǎ 5 ȣƷ ŌŌĤŗ gÆŋ ǰʒȯ ǰŞǎ ÿØʒʒŞØʒŸÒõǎ ĞŌGù ɔŌGk ÅŋÆÅƷ ĞÅÅÅõǎ ĞÛÕφ ĤʒŸǎ ĻQÅ .ÿØʒʒŞØʒŸÒõǎ .$C_8H_8N_4$,HCl ȣŋ ŋŸŋ 9.832 ȯżÅÒÅ VS (ȯ/ȯʒŋ 0.05) ÿʒŲèÅĤʒGõǎ ǵǎǎʒÅ

ØØØØØ

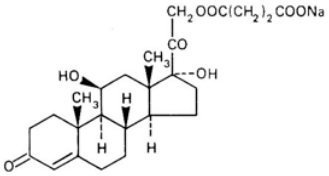
HYDROCORTISONI NATRII SUCCINAS

Hydrocortisone sodium succinate DžNjŘĬŦÞNj|NjÞqĭNJЛЄ !NjĭφNjT lƒdžĭƨ|ƨ

$C_{25}H_{33}NaO_8$:**Molecular formula** ĞŲÅÅÂƨǎ Ğ8ŲÔõǎ

484.5 :**Relative molecular mass** ĞŲGÊÅõǎ ĞŲÅÅÂƨǎ ĞŸQÒõǎ

:**Graphic formula** ĞŲφÅŲGţǎ Ğ8ŲÔõǎ



:**Chemical name** ŲəÅŲŧŲÒõǎ Ļèŗǎ

Cortisol 21-(sodium succinate); 21-(3-carboxy-1-oxopropoxy)-11β,17-dihydroxypregn-4-ene-3,20-dione monosodium salt; CAS Reg. No. 125-04-2.

.ĞHŲəǎÀõǎ CÆ3 ÜŌÒÎõǎ CÆ3 ÆŸò ĻÊDZ ŞŬ ĨĞÅÀÕk ŘŲǎŬ ŞŬ ŘŲǎŬ ǰʒŸǎ ÞØʒŸǎ ȧʒHŲÊŋ :**Description** Zòʒõǎ ȣŋ ĻDzǵ 200Ş TS (ȯ/Ȟ750~) ȯʒφÅŽÅqǎ ȣŋ ĨŧDzǵ 24 Ž āǎŞǎ ÜõÅţǎ Ž ǰÅǎŞØõǎ Àǵ :**Solubility** ĞŲφÅǎŞØõǎ

.R Ƙǫɟǎ Ž ɾȘ R ȳǿȝȘǿȝŸȮǒǎ Ž ǎǎȘǽ Ƙɖ Üdehydrated ethanol R ǒǎţǎ ţȘÂǿǺŋ ȯȝǫǺŽǺɥǎ

.Adrenal hormone ƀǺǢŢǒ ɟȝŋȝŁ :**Category** ǦǺǺǒǎ

.ǒȝŘǒǎ ɗŋ ǦŁţŢ ÛȳǺȮǵǔǽ ǦÕŸ8ŋ ǦǺȘǺǵ Ž ɟȘÂŁǩǿȝõȘǿǼŁŢǎ ȳȝǺǵȝò ǧǺǼŁÊȮȮè ȘǺǵ Æz :**Storage** ɗǺÂǺǪǒǎ

ǦǦùǺǪÊŋ ǵǺǺŋ ɟȘÂŁǩǿȝõȘǿǼŁŢǎ ȳȝǺǵȝò ǧǺǼŁÊȮȮè ǼŽǩ :**Additional information** ǦŁȝǺɾÛ ǧǺŋȝŸǺŋ

ǼǺȝ ţǺèÛ ÕȮǺǪǒǎȘ Ûƀȝȝǎǎ ƥǺǺţǎ ǦǽȝùǺǎ ôǺǺǪǒǎ ǼǺȝ ǺŁȝǿǼǩ ÛǒȝŘǒǎ ǎǺŁɖ Ž ȝǿǪǵ ÛõǿǼǪǩȘ .hygroscopic

.ȝŸȝɟǎ ǵǿǎǺΣǎ ǧǺDȝǿǎ

REQUIREMENTS ƘǦǺǺȝȝƘǺǺ!ƒ

ɗȝ ÕÕǺ ɾ Ǻŋ ȝŸȝ ɟȘÂŁǩǿȝõȘǿǼŁŢǎ ȳȝǺǵȝò ǧǺǼŁÊȮȮè ƀȝǪƠ :**General requirement** ȳǺǺǒǎ ǼŸÛǪţǎ

.ǦǺǺǒǎ ǵǺǺţǎ ƀǺ ţȝDȝǺǺǺǽ ǦǽȝÊŢ Û$C_{25}H_{33}NaO_8$ ɗŋ %103.0 ɗȝ ǎȘǿǩ ɾ %97.0

:**Identity tests** hǔǐNjNJǁƐ l ɛƥƒǦƓƢƐ

ǒǎǺŁΣǎ ǨƠ ǦǨǐìɟǎ ǦÕÛǺŋ Ž ƱȝȝŘǒǎ ȜŁǒǎ âǺŁę" ɟǺȝǺȝ ǨƠ ȝȝòȝŋ ȝŁ ǺŁõ ÒƱǺǒǎ ȘǺǺz :A

ǨƠ ǦǨǐìɟǎ Ž î ǺÔǪŋɾǎ ȜŁù ŢǽǺÛǪǺ .(43 ǦƱǺÔǒǎ Û1 ǼŸǒǎ) "Spectrophotometry in the infrared regionǫ

refernce spectrum ƱǨDȝǺţǎ ȜŁÛǒǎ ȝŋ ȘÛ RS ɟȘÂŁǩǿȝõȘǿǼŁŢǎ ȳȝǺǵȝò ǧǺǼŁÊȮȮè ɗŋ ǰǩǺǺǒǎ ȜŁÛǒǎ ȝŋ ǒǎǺŁΣǎ

.ɟȘÂŁǩǿȝõȘǿǼŁŢǎ ȳȝǺǵȝò ǧǺǼŁÊȮȮÊǒ

"Thin-layer chromatography ǦÕŁȚǺǺǒǎ ǦÕǦÛǒǎ ǎǎǺÎǪèǎ" ɟǺȝǺȝ ǨƠ ȝȝòȝŋ ȝŁ ǺŁõ ǒǺǦǪǹɾǎ ȘǺȝ :B

ȯȝǫǺǩȝǎ-1 ɗŋ ȳȝDȝǵȝ ɗŋ ǺDȝǺǺù ǺŘǺƱŋ ǰǺǺŋȘ ǦŸǵǽŋ ǵǺŁõ R1 ǺȮŁŸŁÊǒǎ ǦŋŸŁ ȳǎǼÁǪèǺǽ Û(84 ǦƱǺÔǒǎ Û1 ǼŸǒǎ)

ǦƱŁǺÔǒǎ ȝŸȝ ǺŸÔǺŋ ŢǦÛǺ .õǺǺǪŋ ǿȝÛõ ǒǺţǎ ɗŋ ǺŁȝDȝǵ 1Ș ÛR ÕŁǪŁèɟǎ (ǒǺŋ Ŷǎ) ǼǺǿǼŁǦÜ ɗŋ ǺŁȝDȝǵ 1 ÛR

ȯȝŸǂǎȘ Õŋ 1 ÕõõŽ ǿǺǦǪǹɾǎ ǵǺǺŋ ɗŋ ŋŸŋ 2.5 ƀȝȝ :(A) ȯȝŸǂǎ ÛR ȯȝǫǺǩŁţǎ Ž ƙǺǦǎ ƙǿȝŸŢ ɗŋ ǺǦǒȘǺǺŋ 2

ǵƘDȝǵ ɗŋ ǦƱŁǺÔǒǎ ţÂǿ ǼŸǺǎ .Õŋ 1 Õõõ Ž RS ɟȘÂŁǩǿȝõȘǿǼŁŢǎ ȳȝǺǵȝò ǧǺǼŁÊȮȮè ɗŋ ŋŸŋ 2.5 ƀȝȝ :(B)

ɗŋ Õŋ 10 ɗŋ ɟȝŋȮŋ ǰǺÂŋ ȯȝŸȝŋ ǦƱŁǺÔǒǎ ǽǺǺ ÛǺŸŋǺõ ǧǺǦǺǺǽţǎ ǺǺǦǪǩ ȝǿǪǵ ǒǺȝŢǎ Ž ǺǼǪǒ ǒǺǪǩ ÛǺǺǺÎǪèɾǎ

ǵǼŋ °ȳ 120 ǵǿǎǺǵ ǦDȝǿǼǽ ɗǺǼŁǩȘ ÛTS (ȯ/ǩ750~) ȯȝǫǺǩȝǎ ɗŋ Õŋ 90Ș TS (ȯ/ǩ1760~) ÕǺǿȝǺŸŁÊǒǎ Ř ƥ

ɗŋ ǦƠǺǺǒǎ ǦǺǺǒǦǒǎ ŢȝǺȝǪǩ .(ǺǪŋȝǫǺǩ 365) ǦŁDȝŁǺǺǦǒǎ ǺȝȝȝǦǺȝ Ž ǺǺǺÎǪèɾǎ ÙÛƯ ȮƱǺǺȘ ÛǺǼǪǩ ÛŢǺǺŋǺ 10

.B ȯȝŸǂǎ ɗŋ ǦƠǺǺǒǎ ÕŸǩ ȝŋ ǵǼÎǒǎȘ ǺǺŢǎȘ ȝȝȝŢǺǽ AȯȝŸǂǎ

ǦŋǺǺǒǎ ȘǺǺǺǪèɾǎ ǵǺǪǦǪǹǎ" ɟǺȝǺȝ ǨƠ ȝȝòȝŋȝŁ ǺŁõ ȳȝǺǵȝÔǒǎ ɗȝ ȜÎÔǒǎ ÕDȝɟ ƱƱǺǺǩ ǺŋǼǺȝ :C

ǒǺǺDȝÛ ǼDȝȝǪţǎ ɗŋ ɟǺõ ǺǽÛ .ǵǺǺŁţǎ ǵŸȝǺǺǪǒǎ ƱÛǺǩ ǺǦǩȝ Û(123 ǦƱǺÔǒǎ Û1 ǼŸǒǎ) "General identification tests

.Õŋ/ŋŸŋ 20 ǺŁõǺǪǽ ȯȝŸŢ ǺŘǺƱȝ ÛB ÕȝǺǺǪǒǎ

Specific optical rotation $[\alpha]_D^{20^\circ C} = +140^\circ$ to $+150^\circ$ (0.750 g in 100 ml of water). **Loss on drying** 105 °C, 2 h: 0.15 %. **Related steroides** 1-Dehydrocortisone, 11-Dehydrocortisone, 21-Dehydrocortisone, 21-Acetoxypregnenolone, 21-Acetoxypregnenolone-3-acetate, 21-Acetoxypregnenolone-3-propionate, 21-Acetoxypregnenolone-3-butyrate, 21-Acetoxypregnenolone-3-valerate, 21-Acetoxypregnenolone-3-caproate, 21-Acetoxypregnenolone-3-heptanoate, 21-Acetoxypregnenolone-3-caprylate, 21-Acetoxypregnenolone-3-pelargonate, 21-Acetoxypregnenolone-3-caprate, 21-Acetoxypregnenolone-3-undecanoate, 21-Acetoxypregnenolone-3-laurate, 21-Acetoxypregnenolone-3-tridecanoate, 21-Acetoxypregnenolone-3-myristate, 21-Acetoxypregnenolone-3-pentadecanoate, 21-Acetoxypregnenolone-3-palmitate, 21-Acetoxypregnenolone-3-heptadecanoate, 21-Acetoxypregnenolone-3-stearate, 21-Acetoxypregnenolone-3-nonadecanoate, 21-Acetoxypregnenolone-3-arachidate, 21-Acetoxypregnenolone-3-heneicosanoate, 21-Acetoxypregnenolone-3-behenate, 21-Acetoxypregnenolone-3-tricosanoate, 21-Acetoxypregnenolone-3-lignocerate, 21-Acetoxypregnenolone-3-pentacosanoate, 21-Acetoxypregnenolone-3-cerotate, 21-Acetoxypregnenolone-3-heptacosanoate, 21-Acetoxypregnenolone-3-montanate, 21-Acetoxypregnenolone-3-nonacosanoate, 21-Acetoxypregnenolone-3-melissate, 21-Acetoxypregnenolone-3-hentriacontanoate, 21-Acetoxypregnenolone-3-dotriacontanoate, 21-Acetoxypregnenolone-3-tritriacontanoate, 21-Acetoxypregnenolone-3-tetratriacontanoate, 21-Acetoxypregnenolone-3-pentatriacontanoate, 21-Acetoxypregnenolone-3-hexatriacontanoate, 21-Acetoxypregnenolone-3-heptatriacontanoate, 21-Acetoxypregnenolone-3-octatriacontanoate, 21-Acetoxypregnenolone-3-nonatriacontanoate, 21-Acetoxypregnenolone-3-tetracontanoate, 21-Acetoxypregnenolone-3-hentetracontanoate, 21-Acetoxypregnenolone-3-dotetracontanoate, 21-Acetoxypregnenolone-3-tritetracontanoate, 21-Acetoxypregnenolone-3-tetratetracontanoate, 21-Acetoxypregnenolone-3-pentatetracontanoate, 21-Acetoxypregnenolone-3-hexatetracontanoate, 21-Acetoxypregnenolone-3-heptatetracontanoate, 21-Acetoxypregnenolone-3-octatetracontanoate, 21-Acetoxypregnenolone-3-nonatetracontanoate, 21-Acetoxypregnenolone-3-pentacontanoate, 21-Acetoxypregnenolone-3-henpentacontanoate, 21-Acetoxypregnenolone-3-dopentacontanoate, 21-Acetoxypregnenolone-3-tripentacontanoate, 21-Acetoxypregnenolone-3-tetrapentacontanoate, 21-Acetoxypregnenolone-3-pentapentacontanoate, 21-Acetoxypregnenolone-3-hexapentacontanoate, 21-Acetoxypregnenolone-3-heptapentacontanoate, 21-Acetoxypregnenolone-3-octapentacontanoate, 21-Acetoxypregnenolone-3-nonapentacontanoate, 21-Acetoxypregnenolone-3-hexacontanoate, 21-Acetoxypregnenolone-3-henhexacontanoate, 21-Acetoxypregnenolone-3-dohexacontanoate, 21-Acetoxypregnenolone-3-trihexacontanoate, 21-Acetoxypregnenolone-3-tetrahexacontanoate, 21-Acetoxypregnenolone-3-pentahexacontanoate, 21-Acetoxypregnenolone-3-hexahexacontanoate, 21-Acetoxypregnenolone-3-heptahexacontanoate, 21-Acetoxypregnenolone-3-octahexacontanoate, 21-Acetoxypregnenolone-3-nonahexacontanoate, 21-Acetoxypregnenolone-3-heptacontanoate, 21-Acetoxypregnenolone-3-henheptacontanoate, 21-Acetoxypregnenolone-3-doheptacontanoate, 21-Acetoxypregnenolone-3-triheptacontanoate, 21-Acetoxypregnenolone-3-tetraheptacontanoate, 21-Acetoxypregnenolone-3-pentaheptacontanoate, 21-Acetoxypregnenolone-3-hexaheptacontanoate, 21-Acetoxypregnenolone-3-heptaheptacontanoate, 21-Acetoxypregnenolone-3-octaheptacontanoate, 21-Acetoxypregnenolone-3-nonaheptacontanoate, 21-Acetoxypregnenolone-3-octacontanoate, 21-Acetoxypregnenolone-3-henoctacontanoate, 21-Acetoxypregnenolone-3-dooctacontanoate, 21-Acetoxypregnenolone-3-trioctacontanoate, 21-Acetoxypregnenolone-3-tetraoctacontanoate, 21-Acetoxypregnenolone-3-pentaoctacontanoate, 21-Acetoxypregnenolone-3-hexaoctacontanoate, 21-Acetoxypregnenolone-3-heptaoctacontanoate, 21-Acetoxypregnenolone-3-octaoctacontanoate, 21-Acetoxypregnenolone-3-nonaoctacontanoate, 21-Acetoxypregnenolone-3-nonacontanoate, 21-Acetoxypregnenolone-3-hennonacontanoate, 21-Acetoxypregnenolone-3-dononacontanoate, 21-Acetoxypregnenolone-3-trinonacontanoate, 21-Acetoxypregnenolone-3-tetranonacontanoate, 21-Acetoxypregnenolone-3-pentanonacontanoate, 21-Acetoxypregnenolone-3-hexanonacontanoate, 21-Acetoxypregnenolone-3-heptanonacontanoate, 21-Acetoxypregnenolone-3-octanonacontanoate, 21-Acetoxypregnenolone-3-nononacontanoate, 21-Acetoxypregnenolone-3-hectanoate, 21-Acetoxypregnenolone-3-henhectanoate, 21-Acetoxypregnenolone-3-dohectanoate, 21-Acetoxypregnenolone-3-trihectanoate, 21-Acetoxypregnenolone-3-tetrahectanoate, 21-Acetoxypregnenolone-3-pentahectanoate, 21-Acetoxypregnenolone-3-hexahectanoate, 21-Acetoxypregnenolone-3-heptahectanoate, 21-Acetoxypregnenolone-3-octahectanoate, 21-Acetoxypregnenolone-3-nonah

HYDROXOCOBALAMINUM

Hydroxocobalamin DžĭDŽŰƒĠNj|Njƨ|Njβǫĭlj

anhydrous Ĭ ǝƒDŽűllɛ DžĭDŽŰƒĠNj|Njƨ|NjβǫĭNJllɛ

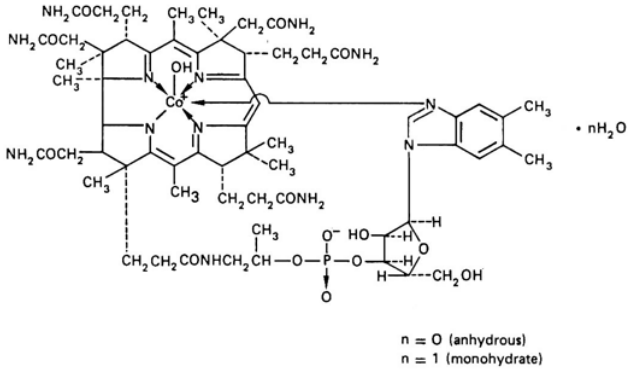
hydrate Ĭ ɦɛβǫĭNJllɛ DžĭDŽŰƒĠNj|Njƨ|NjβǫĭNJllɛ

:Molecular formula ĞĒĂĀÂƨä Ğ8ĒÔöä

$C_{62}H_{89}CoN_{13}O_{15}P$ (anhydrous); $C_{62}H_{89}CoN_{13}O_{15}P,H_2O$ (monohydrate)

.1346 (anhydrous); 1365 (monohydrate) **:Relative molecular mass** ĞĒĠÊÄöä ĞĒĂĀÂƨä ĞŸǫȮöä

:Graphic formula ĞĒǫĂĒĠţä Ğ8ĒÔöä



:Chemical name ŲǝĂĒţĒȮöä ǰèŕä

Cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole; cobinamide dihydrogen phosphate (ester)-mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosyl-1*H*-benzimidazole; *Co*α-[α-(5,6-dimethylbenzimidazolyl)]-*Co*β-hydroxocobamide; CAS Reg. No. 13422-51-0 (anhydrous). Cobinamide dihydroxide monohydrate, dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole; cobinamide dihydroxide monohydrate, dihydrogen phosphate (ester), mono(inner salt) 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosyl-1*H*-benzimidazole; *Co*α-[α-(5,6-dimethylbenzimidazolyl)]-*Co*β-hydroxocobamide monohydrate; CAS Reg. No. 13422-52-1 (monohydrate).

ĞĠÊÄöĀäæ B_{12b} ĸŋĀǪĒƨŞ ŲǝĀŋŸöä ĸŋŕĀæƨõƨÊõŞǿÄĒŦŸö ĞĠÊÄöĀäæ B_{12a} ĸŋĀǪĒƨ **:other name** Ăǹǿä ǰèŕä

.ŲøĭĸäǿÄĒŦä ĸŋŕĀæƨõƨÊõŞǿÄĒŦŸö

.ĞĦuǝäĂöä CĆÆȝ ÜĂβŭ ɟƨŸæ Ƀǿƨŷæ ȧƨĦuÊŋ Şŭ ȣõäǎ Ăβŭ ɟƨŸæ ğäǿƨŷæ **:Description** Ƶȯƨöä

Ž ŗş R ɟʒǫǣèɟǡ Ž ǽǣŷŧʒ ǡǡşǽ ǩḑ ÜTS (ȯ/ȟ750~) ȯʒǫǡǰǎǫǡş ȯǡŧǡ Ž ɟǡǡşØȯǡ Ȯǣŷȩ :**Solubility** ǰǣǫǡǡşØȯǡ .R ȳǿʒʒşǿʒŷȮȯǡ

.Antianaemia ȳÆȯǡǡÄÖǡȯ ȯǡşǡ :**Category** ǰǡǡȯǡ

ɟǡȮǫ Ž ǰǫÂŬş ÛȯʒŘȯǡ ȮǫŘȯǡ ǰǣŧŢ ÛȳǡȮǵüǡ ǰÖŷ8ǫ ǰǡşǡǵ Ž ǩǫŗǡǡʒõʒÊõşǿÆǣŁ Şǡǵ Æz :**Storage** ȮǡÂÁǫȯǡ .ǡǿǡǡ

şǰ ŬǡǡǫŸȯǡ ÖȮÎȯǡ Ž ŬŁ ǵǡǡŧǡ ǨǫǡõǡǡǡǰŬ ǡŧǣʒ ǰǡşǡΣǡ ɔŷʒ ǰǣŧÊǫȯǡ ǫÒǡǨ ɟǰ Æz :**Labelling** ǰǣèʒǫȯǡ .ŬøǨǡǿǡǡǣŢǡ

ÖȮÎǡ Ŭǡǡŧǡ ȯʒŷǡǡ Ž ǩǫŗǡǡʒõʒÊõşǿÆǣŢǡ ÆDZǡʒǫǡ :**Additional information** ǰǣʒǡǡŕǰ ǵǡǡǫʒŷǨǫ ǣǨǡşǡ .hydrated ionic form ŬøǨǡǿǡǡŢŢǡ Ŭøǫʒǡǡǡ ÖȮÎȯǡ ʒǫ ɟǡǡʒǫǡ hydroxocobamide ǣǣǫǡǡʒõʒÊõşǿÆǣŁ ÆǡʒǡǡzǿǡǡǨ ÛȯʒŘȯǡ ǡǡǡǡǡ Ž ɔøǫǵ ÛÖǿǡǡǫǨşǡ .hygroscopic ǰǰüǡǫÊǫ ǵǡǡǫ ǩǫŗǡǡʒõʒÊõşǿÆǣŢŷȯ ŬǡǡǫŸȯǡ ÖȮÎȯǡ .ɔŷʒɟǡ ǵǿǡǡΣǡ ǵǡDZǿǡ Æǡʒ ŧǡèǰ ÕȮǡǫȯǡ ɟʒȮǡşǡ ÛBʒɔǡ ǵǡʒŧǡ ǰǡʒüǡȯ ôǡǨǫȯǡ

REQUIREMENTS ǩǰüǡÖǩǩǨ!ƒ

ȮʒǡǡØǩ ŗ %96.0 ȮʒÖȮǡ ŗ ǡǫ ɔŷʒ ǩǫŗǡǡʒõʒÊõşǿÆǣŁ BʒǫƷ :**General requirement** ȳǡǨȯǡ ÆŷÛǫŧǡ .ǰǡǡØǡ ǵǡǡŧǡ Бǰ ŧʒDZǡȯǡǡ ǰǡʒÊŢ Û$C_{62}H_{89}CoN_{13}O_{15}P$ Ȯǫ %102.0

:**Identity tests** hǰŇjNJǰǰ l ɛƥƒǰǤǫɛ

ÆŁǡÎǡ ǡǫÆǡʒ ÛTS Û4.5 ȯǡŁǡǡ ǵǡǡ ǵǡǫǡǡǰǡ ǰǡǡǡǡ Ž Ȯǫ/ȳǡǡǡşǡȮǫ 40 ǡõǡǫ ȯʒŷ ǡ îǡÔǫǫŗǡ ʒǫüǡ BÆǰǡ :A 525 Û351 Û274 ǰǡǡǡ ʒǡʒǫǫɟǡ ȯǡʒüüǡ ǰǣŧŢʒǰ ǵǡȯǡÔǫǫǡ ǰǫŷǫ Ûǡǫǫʒǫǡǫ 550ş ǡǫǫʒǫǡǫ 230 ǩǡ ʒǡʒǫǫɟǡ ȯǡʒüǰ Ž 351 ǰDZʒǫǡ ȯʒÛǡ BØȯǡ Õȯǡǡǰǡǰǡ Бǰ ǡǫǫʒǫǡǫ 525 ǰDZʒǫǡ ȯʒÛǡ ɟè 1 ǫǡǡŢǡ ǰǰüǡǫǡ Ȯǫǡǡǫǡǫ Ȯǫǡǡǫǡǫ ǰǡǡǡǡ ǰǡǡǡǡ ǰǡǡǡǡ

.(ƙŋŕĺźõźφĺŁÊöä ďƷ ßÂŁŁŒ) ȯŁÉǦǩ ɿşǻ ƱDZĺDZÂöä ãźǤǰǰä Ž Ƶ`ìĺȮöä ɿźȯ ɔÕǤ Ü3ùĺè

ŕ) ŘĺÁǺŋ Ù8ř ǨƠ °ȳ 100 gøäÀǥǦDZøÉä ƙŋŕĺźõźÊõşøÉŁTä Ƶĺźz :**Loss on drying** ƵŁĺDzǫöĺä ÉÕĺÄöä

.ǧ/ŋŸŋ 180 Бǔ ǧ/ŋŸŋ 140 ƙä ÉÕĺÄ ÜǦ3ĺè 2 gÉŋ (ĘǤäà ǰŸŋ 5 ǦääÀę şǔ ȯĺȮèĺä źŸõ 0.6 ďƷ ÉÄÂ

10.0- ÛR ɿźäÀȮöä ÉŁÊõǰ ƱəĺÁǫ ďŋ Бĺǰĺ ŏĺţä Ž Õŋ/ŋŸŋ 20 ÂŁõÀǫä ȯźŸŧä ŏĺŁĺä ŋŸǤĺ :**pH Value** ŏĺŁĺǦöä ǦţŁę

.8.0

ĺźţƷ ɔŸƷ ãäÀÎǫèŕä" ɿźĺƷ ǨƠ ȣźòźŋ źŁ ĺţõ øĺǤǫńŕä ĘǤÛĺ :**Other cobalamins** ƤÀńǰ ǧĺŁŋŕĺźõ

Ƴŋ diethylaminoethylcellulose R gĺĺŋ ďŋ ǧ 20 ŘƷN Õöźş Û(86 ǦƱĺÔöä Û1 ÉŸǨä) "Column Chromatography

ÛŘφĺDzǫŋ ĘŸǨǫŁŋ ɔŸƷ ȯźÔΣä ɔøǫǵ ŏĺţĺä ƵĺƸ Ûvs (ȯ/ȯźŋ 0.5) ȳźĺźÔöä ÉŁÊõşøÉŁŁ ȯźŸŢ ďŋ Õŋ 200

.ŽĺÛöä ÕəĺÊöä dzÀÛĺş ÛźṏÀŸö ȫÀǫĺ

gĺĺţä ÕÕĺǩ ØəÉĺƷ Ûalkali ƵźŸÕöä ďŋ ǦÉÕĺĺn ǧŕĺÊȣöä ǤǦÔǩ ɔøǫǵ ŏĺţĺä ÕÊȣĺ ÛÆřĺĺŋ Ǥǩ̈ĺŋ ÿäÉĺǺǫřĺäş

ãźφǰä ţÀÕĺş ĺźṏÀŸö ȫÀǫĺ .stopcock ŘǦĺŦŋ ĺ̈ş̈Âŋ Ûǰè 1.2 ÀÛęş ǰè 22 ȯźÛä Ûãźφǰ Бǔ adsorbent gĺĺţŁŸä

ŏĺţä ŏĺŁĺä gźÕä elute ǦźĺÛĺÎöä ŏĺŁĺä ǤǦÔĺ ɔøǫǵ ŏĺţĺä ÕÊȣĺ .ǰè 14 ǦääÀę ţĺĺĺǩöä ɔŸƷ gĺĺţŁŸä gĺĺţä ǤǦÔǩ ɔøǫǵ

.¢ÊĺĺΦ

0.5) ÕĺźŸõşøÉŁTä Ŕβ Ƴŋ R ĺźȯźŸŘ ÕŁŸŋ ŦÊõźäÀȮöä gĺĺŋ ƷÂŋ Õöźş ÛɿĺΦ ĺźţƷ ĺÎŘƵ ǦŏĺÎţĺä

ɔøǫǵ ŏĺţĺä ÕÊȣĺ ÛÆřĺĺŋ Ǥǩ̈ĺŋ ÿäÉĺǺǫřĺäş .ŽĺÛöä ÕəĺÊöä dzÀÛĺş ÛźṏÀŸö ȫÀǫĺ Ûŏĺţĺä Ƶĺźz Ûvs (ȯ/ȯźŋ

Ûǰè 1.2 ÀÛęş ǰè 22 ȯźÛä Ûãźφǰ Бǔ gĺĺţŁŸä gĺĺţä ÕÕĺǩ ØəÉĺƷ Ûacid ŘŦΣä ďŋ ǦŏĺÎn washings ǧŕĺÊȣöä ǤǦÔǩ

ÕÊȣĺ .ǰè 10 ǦääÀę ţĺĺĺǩöä ɔŸƷ gĺĺţŁŸä gĺĺţä ǤǦÔǩ ɔøǫǵ ãźφǰä ţÀÕĺş ĺźṏÀŸö ȫÀǫĺ .stopcock ŘǦĺŦŋ ĺ̈ş̈Âŋ

.¢ÊĺĺΦ ŏĺţä ŏĺŁĺä gźę gźÕä elute ǦźĺÛĺÎöä ŏĺŁĺä ǤǦÔĺ ɔøǫǵ ŏĺţĺä

ȧźź ŏĺţä ďŋ gK8ò ǦŦŋõ ɔÕǤǩ ɔøǫǵ drain ƵĺÀÔǫŸö ȫÀǫĺş ƱDZĺDZÂöä ȣźÔöä ďŋ gĺĺäÉÊä ãźφǰ Õõ ɔÛĺ

.gĺĺţŁŸä gĺĺţä

ƱÊõźäÀȮöä Ž effluent ĘźÉöä Õŋ̈ÉĺĺΦ ŘŋŁŁ Ĺŋ̈ǵä ĺźţŦöä ȧźź diethylaminoethylcellulose øöä ĺźţƷ ƷŕźĺΦ

.ȧźȯźŸŘ ÕŁŸŋ

Ŕβ ďŋ ǦŁźĺṏ ǦŁŦȮä ŘŦŦƱŁ Ûŏĺŋŋ Õŋ 20 Ž ãäØǩ ÛǦòźƱȮĺţä gĺĺţä ďŋ ǧ 0.05 ǦääÀę ǦŁùźǦŘŋ ɿȧźĺ

diethy lamino ĺźţƷ ɔŸƷ ȯźŸŧä äØŁ Õŋ̈ÉŁ .4.0 ŏĺŁĺä ɔŸƷ ȯźÔΣä ɔøǫǵ TS (ȯ/ǧ70~) ÕĺźŸõşøÉŁTä

ŘÕöźĺè ŏĺŁĺǦöä ¢Łź ȯŁÉǰ ƵØöä ŏĺţĺä ƵÛÎĺ .Бşǰä ǦźĺÛĺÎöä dzÀÛǩ ÛĺŦŦŸõ dĺźţŦöä ŘŦŦöõ ȫÀǫĺş ethyl cellulose

ǦDZøÉŋ Õŋ 50 ǰDzŦŦ ǦŸDZźǵ Ž ǦǫźŸţä ǦźĺÛĺÎöä ƷŦΘ .TS (ȯ/ǧ70~) ÕĺźŸõşøÉŁTä Ŕβ ȯźŸƱŋ 4.0 ɔøǫǵ

ǦääÀę ƱŦţƷǰ ǦDZźŋ ȯźÛä ǰè 1 ǦφĺĺÁǰä ǦÕǦù ȯŸǹ ďŋ ȯźŸ+ä äØŁ î ĺǫ âĺÕĺ .ǰDzΣä ɔøǫǵ ŏĺţĺä ȯŁŦĺŋş ŘŦŦDzǵ

(207 = $A_{1cm}^{1\%}$) ČŁÒÅÔęŋŗą ČţŁŐöą ÿąÆÁęèÅą ÛĥŋÿţÅą ßóÆŐŋ ŘÀòĵą ğÅÆŋŗÅąçÒöą ŘçęŢ ÆÊȝş ÀęŋçęÅę 361
.ĥŋÿŋ 30 ȣȝ ÄÂÅ ŗ Ü20.7

ĘąÅÊöą óÅĢęòŗą Ž diethylaminoethylcellulose ąçţȝ ÇÛÎÅ :**Acidic impurities** ČŁŘţΣą Æąçą Îöą
î Åę âÅŐÅ .ČçÅÛĤöą ȣŋ Ŏŋ 50 ȝţzş ÛTS (ȯ/ĥ10) ÿçÅąÔöą ÄóçÿŐ ȯçÿHŋ ŘÀòĵą ğÅÆŋŗÅąçÒöąą î Åęą
ŘçęŢ ÆÊȝş ÛÀęŋçęÅę 361ş ÀęŋçęÅę 351 ką ČŁţŢȝĵą ȝąçŋĵą ÄÅȝ ęè 1 ČęÅÁȝą ČŐGù ȯÿò ȣŋ ȯçÿ‡ą ąÓŁ
.ĥ/ŋÿŋ 30 ȣȝ ÄÂÅ ŗ Ü(190 = $A_{1cm}^{1\%}$) 19.0 ČŁÒÅÔęŋŗą ČţŁŐöą ÿąÆÁęèÅą ÛĥŋÿţÅą ßóÆŐŋ ČŁŘţΣą Æąçą Îöą

:**Assay** ČÊÅÅÔţą

.ČÊÅÅŐţą gÆŋ ȯÿò ȯçŘöą ȣŋ ŐŁöÅ‡ą ČÅÅþ Æz •

ŗÿȝ ȯçÔHÿŐ ÛTS Û4.5 ȯÅŁÅą ğąą ğÅęŁèÜ ČąóąÅ ȣŋ ČŁçÅõ ČŁţõ Ž ÛČŁùçČŘŋ ČęsąçŋÛŋÿŋ 20 ČąąÅę ąąÓÅ
ÀęŋçęÅę 351 ČąąÅę ÜţŢȝÜ ČDZçŋ ȯçÛą ęè 1 ČęÅÁȝą ČŐGù ȯÿò ȣŋ ȯçÿ‡ą ąÓŁ ŋî Åę âÅŐÅ .Ŏŋ 500 óÆŐą ęDzǵ
.(195 = $A_{1cm}^{1\%}$) 19.5 ČŁÒÅÔęŋŗą ČţŁŐöą ÿąÆÁęèÅą Û$C_{62}H_{89}CoN_{13}O_{15}P$ ŘçęŢ ÆÊȝş

Ĭ øźsΘ℠ üĵFDŽyƒs ú‖ ąyƲŽ℠ DžĭDŽŬĴGNj|Njs|NjβąĭNJ℠ üШŬ hŭźĴFŢą lĴG‡UŁDŽ

Additional requirments for Hydroxocobalamin for Parenteral use

.(56 ČHÅÔöą Û4 ÆÿŐą ÀŢęą) "*Pranenteral Preparations* ČŁÅŐΣą ğąÀŘHęęÊţą" øą ČòÅęą gąçąÀçęęą ÆŁDzęÊÅ
óÅĢęòŗą" jąçÅȝ ŘƠ ȣçòçŋ çŁ Åţõ óÅĢęòŗą ŘÀz :**Bacterial endotoxins** ČŁŋçęÀsą ČŁÿòąÆöą ğÅęÅÅÓöą
ŗ Ü(ČÅÂŁÿȣęą ČHĢÛöą Ž 30 ČHÅÔöą Û5 ÆÿŐą) "Test for bacterial endotoxins ČŁŋçęÀsą ČŁÿòąÆöą ğÅęÅÅÓöą ŐDZĵ
.ŋÿŋ 1 Ŏõ Ž RS ÜÿòąÆöą jÅÅÓöą ȣŋ ČŁöçą gÆgçş 0.41 ȣŋ ÀĵõÜ ÞçęȝĴ

ØØØØØ

HYDROXOCOBALAMINI CHLORIDUM

HYDROXOCOBALAMINI SULFAS

Hydroxocobalamin chloride DžĭDŽŬĴGNj|Njs|NjβąĭNJ℠ ąĭβNj‡|

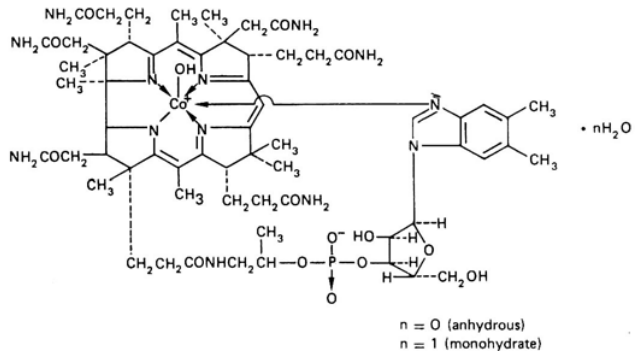
Hydroxocobalamin sulfate DžĭDŽŬĴGNj|Njs|NjβąĭNJ℠ lĴ2‡s

$C_{62}H_{90}ClCoN_{13}O_{15}P$; $C_{124}H_{180}Co_2N_{26}O_{34}P_2S$:**Molecular formula** ČŁÅÅÂsą ČȣŁÔöą

:**Relative molecular mass** ČŁęÊÅöą ČŁÅÅÂsą ČÿęÒöą

1383 (hydroxocobalaminchloride); 2791 (hydroxocobalamin sulfate)

:Graphic formula ĞĦąÀĦGţä Ğ8ĦÔöä



:Chemical name ŬąÀĦţĦÒöä ţèŕä

Cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole monohydrochloride; cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosyl-1*H*-benzimidazole monohydrochloride; *Co*α-[α-(5,6-dimethylbenzimidazolyl)]-*Co*β-hydroxocobamide chloride; CAS Reg. No. 59461-30-2.

Cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole sulfate (salt) (2:1); cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosyl-1*H*-benzimidazole sulfate (salt) (2:1); 2(*Co*α-[α-(5,6-dimethylbenzimidazolyl)]-*Co*β-hydroxocobamide) sulfate (salt) (2:1).

:Description Ƶòƶöä ĊĦąäÀöä ĊÆ3 ÜÀÞÜ ƶŸä ĐóƶŸä ȧƶĦąÊąŞÜ ąõõäå ÀÞÜ ƶŸä ğäóƶŸä.

:Solubility ĞĦąÀäŞØöä Ž ãäŞæ ŏäŞå.

:Category ĞÀÀöä Antianaemia ȳÆöäÀÕƶ åÀRą öäŞå.

:Storage ąÂÅĄöä ąĦţĦŢ ÛȳÀÒgüä ĞÕŸ8ą ĞĦŞÀg Ž ĸąŕÀäƶõƶÊõŞøÆĦTä ğÀÀŸè ŞÜ ÆĦøƶŸõ ŞÀg Æƶ.

:Labelling ţĦèƶąöä ğÀÀŸÊöä ŞÜ ÆĦøƶŸÒöä ĆŸą ŬŁ ğÅÀţä ĶąÀõ äæÜ ÀţĦƶ ĞĦŞÀΣä ƨŸ3 ĞĦţÊąöä ąÒĦĶ ąÜ Æƶ.

:Additional information ĞĦƶÀŕÜ ğÀąƶŸĦą Ž ƨøąg ĸąŕÀäƶõƶÊõŞøÆĦTä ğÀÀŸè ŞÜ ÆĦøƶŸõ õøÆąĦ.

REQUIREMENTS ĶĞĦõĦÕĶäĦ!ƒ

:General requirement ȳÀĦöä ÆŸÛąţä %96.0 ąƷ ÕÕĦ ŕ Àą ƨŸ3 ĸąŕÀäƶõƶÊõŞøÆĦTä ÆĦøƶŸõ Ƶąƶ.

ƙŋŕĂăzõzÊõşøÁĘŤă ğĺĂŸè ƀzŲØş ÜĞĂĂÖă gắĂţă БŮ ţzDZÄöĂă ĞăzÊŢ ÛC62H90ClCoN13O15P ďŋ %102.0 ďƷ ÁłÂÂ
.ĞĂĂÖă gắĂţă БŮ ţzDZÄöĂă ĞăzÊŢ C124H180Co2N26O34P2Sďŋ %102.0 ďƷ ā şØĭ ŕ %96.0 ďƷ ÕÕł ŕ Ăŋ ɔŸƷ

:**Identity tests** hƀĭNjNJłłε łεβƒFĞĤCŋε

ÁĘĽĂÎł Ăŋ£Á3 Û4.5 ŏĂĘĽĂă ğăáé TS ğĂŲĘèÜ ĞəØăắ Ž Õŋ/ÿăÄďşÄÒŋ 40 ÂĘõÄŲă òzŸ‡ î ĂÔŲŋŕă ZĘù ƀÁĞł :A
525 Û351 Û274 ĞăăÄę Ʒăzŋĵă òăzùüă ĞĘŧŢƷÜ ğĂòĂÔŲŋă ĞŲŸŲ ÛÄŲŋzŲĂŲ 550ş ÄŲŋzŲĂŲ 230 ƙă Ʒăzŋĵă òăzùÜ Ž
351 ĞDZzţă òzÛă ƀØöă Õöé БÜ ÄŲŋzŲĂŲ 525 ĞDZzţă òzÛă ĺè 1 ĞŲĂÁƷă ĞÕĞù òŸn ďŋ î ĂŧŲöă ĞĞÊŲ ŋŸĞĭ ÜÄŲŋzŲĂŲ
ĞăăÄę ÄŲŋzŲĂŲ 351 ĞDZzţă òzÛă ƀØöă Õöé БÜ ÄŲŋzŲĂŲ 274 ĞDZzţă òzÛă î ĂŧŲöă ĞĞÊŲ ŋŸĞĭş Û0.34 ĞăăÄę ÄŲŋzŲĂŲ
.0.80

ɔøŲǵ TS (ȯ/ȟ1760~) Õłøz ĂŸÊöă Ŕƥ ďŋ ğăÄÛę ƷŘă Ƹŋ ƙŸèøză ĞÕĭză Ž ŋŸŋ 2 ĞăăÄę øØШ ďÁÊł :B
ğĂŲĂĘèzĘŽõ ƷĞÎŋ òzŸŢ ďŋ ğăÄÛę ƷŘă Ż ďŋş ŏĂţă ďŋ Õŋ 0.05 ƱĂŘłş ÛĂĘł .ĞĭĂz ȧøăÜ ɹzŸă ĞÖĂŧŲ ÖÖÎŲĭ
.ȧøăÜ - ÄŘńÜ ɹzȯ ĭŲĂł ÜR ÿzĘŲzŋĵă

ďŋ Õŋ 5 ƱĂŘłş ŏĂŋ Õŋ 2 Ž āăØĭş ÛĞĘDZĂDZÄ gắăÁÉè ğăé Õŋ 100 ĺDzШ ĞŸDZzǵ Ž ŋŸŋ 2 ĞăăÄę ƷŕzŁ :C
ÛĺÈ 2 òzùş ĺè 1 ÄÛÕöş ĞÛÊŋ ÄĬę Ƀá ŲDZĂDZÄ āzŲÜ ĞŸDZzΣă Ž ăÄ8ł .TS (ȯ/ȟ1440~) Õłøz ĂÊłĂöă Ŕƥ
ŏzŕ БÜ ğĂƷĂè 4 gÁŋ ôłĂĭĭş ĞŸDZzΣă ĘŸ8ĭ .TS òzĘzşÄŲŲ ŲŲŸŲ/ÿzĘĘŸöă ğĂŲzăÄõ òzŸŢ ďŋ Õŋ 1 ɔŸƷ ƀzŲƷ
.(ƙŋŕĂăzõzŲĂĘÊöă ďƷ ĂÂĘĘŲ) òĘĞĭ ɹşắ ŲDZĂDZÂöă āzŲĵă Ž ZŕĂÖöă ɹzȯ ɔÕĞł ÜƷùÄè

ɹăzÁƷ ĬƠ ƱzòzţĂ B ÕƷĂĂŲöă òzŸ‡ă ăØĽ ŲÛĬł .Õŋ/ŋŸŋ 20 ÂĘõÄŲă òzŸŢ ÄŘƷ ÁłøzŸÖöă ĞŸţ ĞĞÊłÖĂă :D
.(121 ĞŲĂÔöă Û1 ÁŸÖă) ğăÁłøzŸÖŸö ÂĘŧŋ ÕƷĂĂŲõ "General identification tests ĞŋĂĬöă ƱăÄĬŲèŕă ğăøĂĞŲňă"
ɹăzÁƷ ĬƠ ƱzòzţĂ A ÕƷĂĂŲöă òzŸ‡ă ăØĽ ŲÛĬł .Õŋ/ŋŸŋ 20 ÂĘõÄŲă òzŸŢ ÄŘƷ ğĂĂŸÊöă ĞŸţ ĞĞÊłÖĂăş
.(123 ĞŲĂÔöă Û1 ÁŸÖă) ğĂĂŸÊŸö ÂĘŧŋ øĂĞŲňĂõ "General identification tests ĞŋĂĬöă ƱăÄĬŲèŕă ğăøĂĞŲňă"

zŸĘõ 0.6 ďƷ ÁłÂł ŕ) ŘĂÁłŋ Ù8ŕ ĬƠ °ÿ 100 gøăÄǵĞDZøÁă ZĂz :**Loss on drying** ZĘĂDzŲõĂă ÁÕĂöă
ƙăĂŋ ğĂĂŸÊöă ĞŸŋş ĭ/ŋŸŋ 120ş ĭ/ŋŸŋ 80 ƙăĂŋ ÁłøzŸÖöă ĞŸŋ ÁÕĂł ÜĞƷĂè 2 gÁŋ (ĘĞăÄ ĺŸŋ 5 ĞăăÄę şÜ òĂÒèĂă
.ĭ/ŋŸŋ 160ş ĭ/ŋŸŋ 80

-8.0 ÛR ɹzăÄÒöă ÁĘÊõÜ ŲəĂłŲ ďŋ БĂĺĵă ŏĂţă Ž Õŋ/ŋŸŋ 20 ÂĘõÄŲă òzŸ‡ă ŏĂĘĽĂă ŋŸĞł :**pH Value** ŏĂĘĽĂĞöă ĞŧĘę
.10.0

ăzŧĬöă ɔŸƷ āăÄÎŲèŕă" ɹăzÁƷ ĬƠ ƱzòzŋzĘ ĂŧÕ øĂĞŲňŕă ĘĞÛł :**Other cobalamins** ƲÄňÜ ğĂĂĘŋŕĂăzõ
Ƹŋ diethylaminoethylcellulose R gắĂŋ ďŋ ĭ 20 ŘƝ Õöáş Û(90 ĞŲĂÔöă Û1ÁŸÖă) "Column Chromatography
ÛÈŲĂDzŲŋ ĘŸĬŲÊĭŋ ɔŸƷ òzÔΣă ɔøŲǵ ŏĂţĂă ZĂƩ ÛVS (ȯ/ȯzŋ 0.5) ÿzłăzÔöă ĂĘÊõşøÁĘĘ òzŸŢ ďŋ Õŋ 200

.ŽÅÛöä ÕəÅÊöä dzÀÛΛş Ûåzõ̃ÀŸö õÀQΛ

gåÅţä ÕÕÅk ØəÆΛ3 Ûalkali Ƀz̃ŸÕöä ďnţ ĞŒÕÅǹ ğ ŕÅÊ8öä ÁĞÔk ɔøQǵ öÅţÅæ ÕÊ8Λ ÛÆÈÅΛţ ÁÛÀhţ ÿäÆÅQèÅæş ā zĞQǰä ţÀÕΛş åzõ̃ÀŸö õÀQΛ .stopcock ÈĞÅHuţ åŝÂţ ÛĻè 1.2 ÀÛęş Ļè 22 òzÛæ Ûāz̃ĞQÛ БÛ adsorbent gÂQŤţä öÅţä öÅŁÅæ gzÕæ elute ĞzÅÛÅÎöä öÅŁÅæ ÁĞÔΛ ɔøQǵ öÅţÅæ ÕÊ8Λ .Ļè 14 ĞæäÀę ţÅÅkøä ɔŸ3 gÂQŤţä gåÅţä ÁĞÔk ɔøQǵ .¢ÊÅφ

0.5) Õ̃ΛózŸõ̃şøÆŒTä Ŕβ ƷŋR àzózŸè ÕŒƷŒŋ ŦÊõzæÀÒöä gåÅŋ ƷÂŋ Õ̃öæş ÛĻÅφ åzŧ3 ÀÅŘƷ ĞöÅÎţÅæş ɔøQǵ öÅţÅæ ÕÊ8Λ ÛÆÈÅΛţ ÁÛÀhţ ÿäÆÅQèÅæş .ŽÅÛöä ÕəÅÊöä dzÀÛΛş Ûåzõ̃ÀŸö õÀQΛ ÛöÅţÅæ ZÅƆ ÛVS (ȯ/ȯzŋ 1.2 ÀÛęş Ļè 22 òzÛæ Ûāz̃ĞQÛ БÛ gÂQŤţä gåÅţä ÕÕÅk ØəÆΛ3 Ûacid Ŕŧ̃Σä ďnţ ĞŒÅǹ washings ğ ŕÅÊ8öä ÁĞÔk .Ļè 10 ĞæäÀę ţÅÅkøä ɔŸ3 gÂQŤţä gåÅţä ÁĞÔk ɔøQǵ āzĞQǰä ţÀÕΛş åzõ̃ÀŸö õÀQΛ .stopcock ÈĞÅHuţ åŝÂţ ÛĻè .¢ÊÅφ öÅţä öÅŁÅæ gzÕæ elute ĞzÅÛÅÎöä öÅŁÅæ ÁĞÔΛ ɔøQǵ öÅţÅæ ÕÊ8Λ

ȧzz öÅţä ďnţ gK8ò ĞŒŧõ̃ ɔÕĞQk ɔøQǵ drain ZΛÀÔQŸö õÀQΛş ŦDZÅDZÂöä ȣzÔöä ďnţ gåäÆÊæ āzĞQÛ Õõ̃ ɔÛ8Λ .gÂQŤţä gåÅţä

ŦÊõzæÀÒöä Ž effluent ĘzÆöä ÕnÆΛ ÕŒŦŦ Àǹęä åzŧŘöä ȧzz diethylaminoethylcellulose øöä åzŧ3 ƷŕzΛ .àzózŸè ÕŒƷŒŋ

Ŕβ ďnţ ĞŒzÅõ̃ ĞŒŧÒæ Ŕŧ̃HuŁ ÛöÅŋ Õŋ 20 Ž āäØk ÛĞòzHuÅţä gåÅţä ďnţ ȟ 0.05 ĞæäÀę ĞŒùzĞŘŋ ɹàzΛ diethylaminoe- åzŧ3 ɔŸ3 òzŸ≠ä äØŁ ÕnÆŁ .4.0 öÅŁÅæ ɔŸ3 òzÔΣä ɔøQǵ TS (ȯ/ȟ70~) Õ̃ΛózŸõ̃şøÆŒTä ÅÅÅè öÅŁÅĞöä ¢Œz ȯÆŁ3 ƀØöä öÅţÅæ ZÛÎΛ .Ƃşjä ĞzÅÛÅÎöä dzÀÛk ÛÅŧŦŒŸõ̃ ďΛåzŧŘöä ƎŘöö õÀQΛş thylcellulose ĞDZØÆŋ Õŋ 50 ĻDzŦŦ ĞŸDZzǵ Ž ĞφzŸţä ĞzÅÛÅÎöä 3ŧθ .TS (ȯ/ȟ70~) Õ̃ΛózŸõ̃şøÆŒTä Ŕβ òzŸHuŋ 4.0 ɔøQǵ ĞæäÀę Ƀŧ̃Ţ3Ù ĞDZzŋ òzÛæ Ļè 1 ĞφÅÅžæ ĞÕĞù ȯŸǹ ďnţ òzŸ≠ä äØŁ î ÅQ ÂÅÕΛ .ĻDzΣä ɔøQǵ öÅţÅæ ȯÆŘŁş ŘŒŧDzǵ 207) 20.7 ĞŒòÅÔQŋŕä Ğŧ̃ŒÕöä ÿäÆÅQèÅæ ÛŘ/ŋŸţÅæ ßóÆÕŋ ƷÅǹjä ğÅÆŋŕÅæzÒöä ƷzQŢ ÆÊƷş ÀQŋzφÅφ 361 .Ř/ŋŸŋ 30 ďƷ ÆΛÂΛ ŕ Ü($A_{1cm}^{1\%}$ =

ĘæÅÊöä øÅĞQǹŕä Ž diethylaminoethylcellulose åzŧ3 ZÛÎΛ :**Acidic impurities** ĞŒŘŧ̃Σä Æäzz̃Îöä î ÅQ ÂÅÕΛ .ĞzÅÛÅÎöä ďnţ Õŋ 50 Ƀŧ̃zş ÛTS (ȯ/ȟ10) ȳzΛåzÔöä ÆΛózŸõ̃ òzŸHuŋ ƷÅǹjä ğÅÆŋŕÅæzÒöä î ÅŢä ƷzQŢ ÆÊƷş ÛÀQŋzφÅφ 361şş ÀQŋzφÅφ 351 ƙæ ĞŒŧ̃Ţ3jä Ƀ̃zŋjä ÆΛ3 Ļè 1 ĞφÅÅžæ ĞÕĞù ȯŸǹ ďnţ òzŸ≠ä äØŁ .Ř/ŋŸŋ 30 ďƷ ÆΛÂΛ ŕ Ü($A_{1cm}^{1\%}$ = 290) 19.0 ĞŒòÅÔQŋŕä Ğŧ̃ŒÕöä ÿäÆÅQèÅæ ÛŘ/ŋŸţÅæ ßóÆÕŋ ĞŒŘŧ̃Σä Æäzz̃Îöä

:**Assay** ĞÊΛÅÕţä

.ĞÊΛÅÕţä gÆŋ ȯŸǹ ȯzŘöä ďnţ ÕŒÅ≠ä ĞΛÅβ Æz •

[illegible] 4.5 [illegible] TS [illegible] 20 [illegible] 351 [illegible] 1 [illegible] 500 [illegible] 18.9 [illegible] 19.0 [illegible] $C_{124}H_{180}Co_2N_{26}O_{34}P_2S$ [illegible] $C_{62}H_{90}ClCoN_{13}O_{15}P$ [illegible] ($A^{1\%}_{1cm}$ = 190 or 188) [illegible]

ØØØØØ

IPECACUANHAE RADIX

Ipecacuanha root [illegible]

Molecular formula: [illegible]

Cephaëlis ipecacuanha (Brotero) [illegible] *Cephaëlis acuminata* karsten [illegible] A.Richard [illegible] emetine [illegible] cephaëline.

Description: [illegible]

Category: [illegible]

Storage: [illegible]

Additional information: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] %2.0 [illegible]

Macroscopic characteristics: [illegible] *cephaëlis ipecacuanha* [illegible] wood [illegible] bark [illegible] fracture [illegible] pith [illegible]

.ЙGAÀÕk

¢AÒõ ÛC.ipecacuanha ÜèÜÀõä ÆŁØõä ȧÀß øØDZ ¢GÎA Йnzŧ3 :cephaëlis acuminaata ȧÆQÊtj ÆŁØõj ȧÄß ÜøAä ş Üøä DzAÊõä Б ãøÀr ÜøAä ɿzÜä ÜDZøÀ ÁÛÊõä ÜŲÜn 9 ?øQg ĞqÀÁžõä :ÜÜAÀn ÙòzÔò ZÜQƐ ÛŲÜn 1-0.5 ĞäÀę ÅÀÄäÜ ğäæ 8ŞÀΣä ÜŲè 3-1 ĞäÀę ÀTRÄä ф3 gÆ3ÀGQn ĞrÀÄQÊn 8ŞÀg 3n ÀÞjä Б ãøÀr .ÜÀÄõä ÁÛÊõä ?zQÊn Ônäå 8äÀùjä öäØg zGơş circumference 8ÀÀÖõä òzg ĞzÀÊtä ZÔφ ĞäÀę ĞÄèzQn

:**Microscopical characteristics** ĞAÀTÖä ğäÂŧtŲä

Üøä ɿzÜä ĞÖÊr ĞEAÜÜÊ ĞÖGù øØDzÜõ ô ÀÄQÊtä 3ÛÖtä ÀTTł .cephaëlis ipecacuanha ÜèÜÄõä ÆŁØõä ȧÄß Üphelloderm ÜÀAäzÜÊAÜõ ĞÄèäş parenchymatous ĞÄÄQn ĞÖÛAnş ĞÊäzGqÜ dzzÛÊõä gäÆÄQn ĞÖÊęó ÀAÜn ɿäóÆDZ ğäæ ɿzÒKş Ûğ ÀqzÒn 8-2 ф3 ĞqzÒn ĞGÕÀn ğ ÀGEGgş ĞÛÊÊä ğ ÀGEGg ф3 ɿzÒQA ÀAÂd ÀÎφ ?Ü3 ÐzQƠ gKnjä ØØŁş ÜÀQnşÀÒn 15 àşÀDzQA Ân äóäÀφ ÀÛę ğäæş ÛÀn Ág Б ÐşÀõ ZÔφ şÜ øşÁn şÜ ÐzRÊä ÕÒÎä ÄÄäÀzä ğ ÀGEGΣä ÕÒÎä ɿzÒQA ÛZÊÕõ xylem ÜøGÎ ä ÜÊÁõä ÜĞÖÊr ĞGÎÁQn Kd ĞÖÛAn ÕÒÎä ÁzDZzn phloem ÜÜnäÁõä ÖÀHÜÜõä pits ğäÁŁş ?Ü3 ɿAzQZ ÀZÜÕÛvessels ĞÊ3şjä ф3 Ä8òÜ ŲÊę 3n ĞDZàÀŧQn ĞÖÊr tracheids ğ ÀGÊÔę ф3 ÜÊÊóó ĞnÂg ?Ü3 ÀTAn Õõ ÐzQƠ ÛĞAózÜGõä ÀAÜŲä ÜĞÛÊÊä ĞAÀääÄ ÄäzÕφ vessel öÀ3zõä ÕÜÇş ÛĞÊGφÀ2ä ÀŒäóÆX gÄÆŢ gÆAÆ3 ĞGDZäó Ə3 ô ÀÄQÊtä 3ÛÖtä ÀTTł .ĞÄÄQtä ĘùÀAtä Ž 3ÖKş ÛÀQÒnşÀÒn 80-30 ф3 òzù ğäæ raphides 8ÀÄõjä ф3 Ûcollenchymatous ÐşÀd ŲÊφ ğäæ gÀÎę ÛĞÖÊęÀõä jäóÆ2ä Ðæ KÜÀõä ф3 gÄÆÄQn ğÀÖGù øzngØ2ä internode öÀHÜõä ф3 ĞÖÊr ĞÖÜg ÛĞHÜräzõä ĞRAÀÄõä ĞGÜÔQtä ğäÆŁzõä ф3 ğÀ3zŧf ?Ü3 ÐzQƐ pericycle gÀääÆõÀæ ÙÊT .ĞÖÊęó jäóÆDZ ğäæ ĞEAQn ÀAÜn ф3 ɿzÒtä pith ä ÀGÜõÀæ ÙÊƠ ĞGÎÁQn ĞRAÀ3 ĞÖÜgş ÛÜÜnäÁõä Æę GAääÄzqä ÀÎAõä ğ ÀGEGg jÜ öÀAZQÈÀæ ÜèÜÀõä ÆŁØõä ȧÀÄõ ĞäÀÎn :cephaëlis acuminata ȧÆQÊtj ÆŁØõj ȧÄß .ÀQnşÀÒn 22 ?øQg ÀÛÖæ ɿzÒk

:**Identity tests** hÜÜNjNJJIIЄ l ЄßJFGÜHCJIЄ

ÆÜÖä) "Thin-layer chromatography ĞÖÊęÀõä ĞÖGÛõä ä äÀÎQèä " jäzA3 ŘƠ 8zòzn zŁ Ŧtõ óÀGQnrä ?Äz ŦtDzg 6.5 ÛR ÿózzşózÜÒõä ф3 ŦtDzg 93 ф3 jAÂnş ĞÜÜ8n gÅŧtõ R1 ÀÒÊÜÊÊõä ĞnÜŁ ÿäÆÁQèÀæ Û(84 ĞHÜAÔõä Û1 ÙÖz Ląè 10 ?øQg ÆÄÔÊõ ÆAØtj öÀQŧ ÛÖÀHÜQn ózÛõ TS (ȯ/ȟ260~) ÀÊQznjä ф3 ŦtDzg 0.5ş ÛR ȯzφÀÜÊtj ф3 :ĞÊõÀQõä ÕÊõÀ+ä ф3 ÀQõşÀÒn 10 ÙŲÜn 3 × ŲÜn 20 ÛÙäÄÀÌ ÕÒÎä ÛĞHÜÊÁÔõä ?Ü3 ÜÔÀAn ĘGÛA .ĘÊGÛQõä ÙÌn ȧzz K8ò óÀGQnä ä zGQÜ Ž Ğ3zrzŧş Ą3ÀÊφ ÕÒÎä ĞęzHÜÊtj óÀGQnrä gÅÀn ф3 ȟ0.1 Б 8ÀÊA ÛA ȯzÜHŧÜõ ĞGÊAõÀæ õÀQA ÛÜDZÀDZà ÆÊÊę ĞÜÀèzä gÆÎä õÀZ ÛR ÿózzşózÜÒõä ф3 Õn 5ş TS (ȯ/ȟ260~) ÀÊQznjä ф3 Õn 0.05 ĞGÊAõÀæ ÜR ÿózzşózÜÒõÀæ Õn 25 Б A ȯzÜ+ä ф3 Õn 1 ZÀƐ ÛB ȯzÜHŧÜõ ĞGÊAõÀæ ÜĞÜÀAş ĞÖÊęÅ 30 gÆn ÅzõÀÜõ

cephaëlin ƙŸəÅÅŁÊää ÆΛØzŸõşØÆŁŁ ďŋ ŋŸŋ 6Ş RS ƙŒƐqä ÆΛØzŸõşØÆŁŁ ďŋ ŋŸŋ 5 ā äØΛ ÛC ȯzŸHưŧŸõ gƚDzǵ ďŋ ĞHưŁÅÔää ţÂφ ÆĤä .Ōŋ 20 øÆŌä ĻDzǵ ŏÅÛ3q R ȯzφÅŽŁţä ďŋ ĞŁzÅõ ĞŁŧõ Ž hydrochlorid R ďŋ ǰΛÂŋ ȯzŸHưŋ ĞHưŁÅÔää æÀĤ Ż ÛŌäøøåRŏ ĞŸäÅę Ƙď ÆΛØţä ĞHưäøø ǴĞÔƙ ɔøφǵ ŏäzTä Ž ZDzφŏ ōÀφƙ ÛāäÀÎφèŕä ÙÛÛ' ÒHưÅΛ .ĘəÅęå 10 gÆŋ °ȳ 60 gøäÀǵ ĞDZØÆä ďÅÊŁş ÛR ȳØzzşØzŸÒää ďŋ Ōŋ 10 Ž R åzŁää ďŋ ħ 0.05 ÀŦŢΛş ÛƙφƐqä 3ŋ Ęzäzφƙ Ûɔ̂Ûèzää ĞÛÕÅää ĞääÀę ƲØφzŧŁŏ ÀÅòÛ ɟzŸä ĞÕÛΛŋ ŞÆĞƙ ÜØÅŦÅää ŏzŕ Ž ŧŕşÛ āäÀÎφèŕä ȧzz ĞĤÌŕää ŏzŕ Ž āäÀÎφèŕä ÙÛÛ' ÒHưÅΛ ØəÆĤä .ƙŸəÅÅŁÊää 3ŋ Ęzäzφƙ ÛĞƙÅz ƲØÅä ɟzŸä ĞÕÛΛŋ ÅŦφƠ ŦÕääƙ ÛƙŸəÅÅŁÊää 3ŋ ĞÕzäzφţä ÕŸƙş ÛäÆΛÆÌ ŦÅÅòÛ ŦÕääƙ ƙφƐqä ďŋ ĞÕzäzφţä ĞÕÛΛţä ÀŦŢŦŧ Ü(ÀφŋzφΛφ 365) ĞŁDzÊÅΛĞää ÛÛ ÅzĤƙ gÆΛÆ3 ŦÆDZ gƚ8ò ĘùÅΛŋ ÛÕäæ ÛÛ ĞzÅŕÛ ÛA ȯzŸ+ä ďŋ ǰƙÅää āäÀÎφèŕä ÙÛÛ' ÀŦŢŦ .ŦÒÅz ŦęøäÀÛ ƙφΘÅää ÕŸƙ 3ŋ ɟÅÕzäzφƙ ƙφŸää ÛÙÕz ƙφäφä ƙφÕÛΛŋ B ȯzŸ+ä ďŋ ǰƙÅää āäÀÎφèŕä ÙÛÛ' ÀŦŢŦ .ĞΛzφÅŽää ğÅŁφäzφŦÕää ĞΘΛää ƙŸəÅÅŁÊää 3ŋ ĞÕzäzφţä ĞÕÛΛţä ɟzÒƙ Û*cephaëlis ipecacuanha* ƲèÛÅää ÆŁØää ȧÀĤää ĞĞÊΛäÅæ .C ȯzŸ+ä ďŋ *cephaëlis* ȧÆφÊţä ÆŁØää ȧÀĤää ĞĞÊΛäÅæ .C ȯzŸ+ä ďŋ ĞΘÅää ĞÕzäzţä ĞÕÛΛţä ďŋ ƙŽÒæ Å8òÛ A ȯzŸ+ä ďŋ .C ȯzŸ+ä ďŋ ĞΘÅää ÕŸƙ 3ŋ gÆÎääş ÀŦŢţäş 3ęzţä Ž A ȯzŸ+ä ďŋ ĞΘÅää ĞŁÊŁəÀää ĘùÅΛţä Ęzäzφƙ *Ĺacuminata* Û1 ÆŸÕä) "Determination of ash åÅŋÀää ƙŁĤƙ" ɟäzΛ3 ƙƠ Ğzzòzŋ zŁ Åŧõ ŏäÀDZqä ĘĞÛΛ :**Ash** åÅŋÀää .ħ/ŋŸŋ 60 ďƷ ÆΛÂΛ ŕ Ü(173 ĞHưÅÔää

åÅŋÀää ƙŁĤƙ" ɟäzΛ3 ƙƠ Ʋzòzŋ zŁ Åŧõ ŏäÀDZqä ĘĞÛΛ :**Acid-insoluble ash** ŘŧΣä Ž āäşæŸää åÅŋÀää .ħ/ŋŸŋ 30 ďƷ ÆΛÂΛ ŕ Ü(173 ĞHưÅÔää Û1 ÆŸÕä) "Determination of acid-insoluble ash ŘŧΣä Ž āäşæŸää ZÎÒƙ .ĞÕŁęø ĞÕĞù ÕÒÎä ĞŁDZÅDZà ĞHưŁÅò ɔŸƷ ÀÎÅƙş ħ 200 ĞääÀę ɟàzΛ :**Foreign matter** ĞĞΛÀ8ää gåÅţä 10 ďƷ ÆΛÂƙ ŕ Üɟàzƙş øØɔä ďŋ ÕÔÅƙş Û(6× lens) gƎÒŋ ĞèÆ3 ÿäÆÅφèÅä ş̂Ù gåÀÕä ƙĤõÅä ÀŢΛõÅä ĞĞΛÀ8ää gåÅţä .ħ/ŋŸŋ

ÛĞzÅDZ ĞŸDZzǵ ŁÛ ÕÕΛƙ ÛĻ3Åφ ÕÒÎä ĞęzHưÊţä øÅĞφnŕä gåÅŋ ďŋ ħ 7.5 ĞääÀę ĞŁùzφÊŋ ɟàzΛ :**Assay** ĞÊΛÅÕţä ȯŸn ŦØäÀŋ ŋŘƷ ÛTS (ȯ/ħ100~) Æφzŋŋjä ďŋ Ōŋ 5 ƲÅÊΛ .ĘəÅęå 5 gÆŋ ŘƷŞ R Ƙφjä ďŋ Ōŋ 100 ƲÅÊΛş ďŋ gåäÆè Ǝ3 ĞŁÌÀφää ȯŸn ďŋ ĞzÅDZ ĞŸDZzǵ Ōnäå ÛÛ Ƙφjä ĞÕĞù ɟÅƙ ÜgÆÎä ŋŘƷŞ ÛƙÅŋ Ōŋ 5 ƲÅÊΛ ÛĞ3Åè 1 ĻÊę Ōõ ĞφÅæÛ 3ŋ ÛR Ƙφjä ďŋ Ōŋ 25 ÅŧŦŋ Ōõ ƙφƐqä ƙφŧÒä ĞäÅŧŸää ÕÊ8ƙ .adsorbent cotton ÂφŧŦţä ďÛÕää Ƙφjäş ƙÛÕφäÅä ĞΛƙφjä ğÅòŸĻä ţzŧf ďŋ ÆΛØţä ĻŢĤŋ ţÂøΛ .ÂφŧŦä ďÛÕää ďŋ ÅŦÊÅφ gåäÆÊää Ǝ3 ĞŁÌÀφääş (ȯ/ħ710~) ȯzφÅŽΛqä ďŋ Ōŋ 5 Ž ĞäÅŧŸää āäØƙ .ĞŸDZzΣä Ōnäå ÑÅΛΛ ÞØää ŏäzTä ďŋ øÅÆφä ĞÅÆÛŸää ĞÅzÆφäÅä ƲÕĞφţä Ŧβ ďŋ Ōŋ 15 ƲÅÊΛ ÛƲəÅŋ ŷÅβ Ž ƙÅÊφää ĞùÅèzä previously neutralized ÅÅφÛ ȯÆĤφÊţä TS ÛVS (ȯ/ȯzŋ 0.1) ŷzΛåzÔää ÆŁÊõşØÆŁŁ ȯzŸHưŋ ŘŧΣä ďŋ gåÅΛÂää ÀΛÅĤŁş VS (ȯ/ȯzŋ 0.1) ÕΛØzŸõşØÆŁTä

0.1) ÕõóźõõşøÁÉŤã Ŕþ ďň Ôň 1 Ôõõ .TS ÿźÉÁÉąźÉą ÔÉŽÉţã ÁóźÿõõÔÉŽÉţã ąÁţąğ ÁĂÎţã ďň Ôň 0.5 ÿãÁÁąèÁã .ĸąÉźąã âÁèÚ ɔŸ3 ĞãźÊŢ ÛĞÉŸÒõã ğÁÉąãźÓÕõã ďň ŋŸň 24.03 ŏżÁÒÓ VS (ȯ/ȯźň

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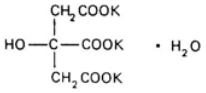
KALII CITRAS

Potassium Citrate !Njĭɜƒ‡NjĞĦ l ɛþłĭɜ

Molecular formula: $C_6H_5K_3O7,H_2o$ ĞÉÁÓÂɜã Ğ8ÉÔõã

Relative molecular mass: 324.4 ĞÉĞÊÁõã ĞÉÁÓÂɜã ĞŸąÒõã

Graphic formula: ĞÉąÁÉĞţã Ğ8ÉÔõã



Chemical name: ŬəÁÉţÉÒõã ĻèŕÁ

Tripotassium citrate monohydrate; tripotassium 2-hydroxy-1,2,3-propanetricarboxylate monohydrate; CAS Reg. No. 6100-05-6 (monohydrate).

Description: Ź ò źõã .ĞĦuãÀõã CÆ3 ÜŔÉãÚ ɟźŸã ŬøĞÉĞg ȧźĦuÊň ŞÚ ĞźÁÁì ğãóźŸã

Solubility: ĞÉąÁãŞØõã .ÑÉŸţ3 TS (ȯ/Ĥ750~) ȯźąÁŽÁqã Ž ɟÁãŞØõã CÆ3 ÜõÁţã Ž ɟÁãŞØõã Ág

Category: ĞÁÁõã ŔÁźĤĭk ĞŸň ĞDZÂňÚ ğÁąźÓň ďň ÑąźÓň ÆĤĭŞ Ûsystemic (ĞÁàÁŽDZ) ĞÉ3źţf ĞąźŸÕň gÁňň .rehydration salt ŏÁŽňRô ÔãźÊõã

Storage: .ÿÁÒgüã ĞÕŸ8ň ĞÁŞÁg Ž ÿźÉèÁźĞõã ğãÁąÉè ŞÁg Æz ďÁÂÁąõã

Additional information: ô ÑĤĭk ÁňÆÁ3 deliquescent Ğ3źÉň gÁňň ÿźÉèÁźĞõã ğãÁąÉè ąÉĤĭk ĞÉźÁŕÚ ğÁňźŸĤň .ÆüÀõã õãźŽŸõ

REQUIREMENTS ĸĞuźƵĸźÉ!f

General requirement: ďÁ ãŞØĭ ŕ %99.0 ďÁ ÕÕÁ ŕ Áň ɔŸ3 ÿźÉèÁźĞõã ğãÁąÉè ÞźąÓ ĞÉãÁňŸõã gÁţã ÞÚ ţźDZÀõÁã ĞãźÊŢ ÛC6H5K3O7 ďň %101.0

ЧÛĬЛ ÜTS (ȯ/ȟ80~) ȳȚЛǻȚÔää ÆŒÊõȘøÆŒŁ ȯȚŸŢ ďȚ ŌȚ 2 øäÆŌȚ ŌȚ/ȟ 0.1 ÂŒõÀǫæ ȯȚŸŢ БÙ 8ȧÊЛ :A Ōʒȧ̀ÁǫõÄ "General identification tests ǦȚȧĬää 8äÀĬǫèŕä ǧäøÁǫǫnä" ȷäȚʌʒ ǨƠ 8ȚòȚŢä A Ōʒȧ̀ÁǫÔää ǰǩÁÁää ȯȚŸǂä ȷäȚʌʒ ǨƠ 8ȚòȚŢä A Ōʒȧ̀ÁǫÔää ŌȚ/ȟ 0.1 ÂŒõÀǫæ ȯȚŸǂä ЧÛĬЛ :B .(123 ǦHЧÁÔää Û1 ÆŸÖä) ȳȚŒèÀĬȚGŸö ÂŒŁȚ .(121 ǦHЧÁÔää Û1 ÆŸÖä) ǧäÀǫŒÊŸö ÂŒŁȚ Ōʒȧ̀ÁǫÔää "General identification tests ǦȚȧĬää 8äÀĬǫèŕä ǧäøÁǫǫnä" ǨƠ 8ȚòȚȚ ȚŁ ȧŁõ øȧǫǫnŕä ȯȚŸŢ ƙŘHЧǫǫ ȟ 1.0 ȳÆÅǫÊЛ :**Heavy meatal** ǦŸŒÖää (ǧäÂŸÁää) ȷäÀĬŢä Û1 ÆŸÖä) 1 ǒäÀDZqä ÆÊШ Û"Limit test for heavy metals ǦŸŒÖää (ǧäÂŸÁää) ȷäÀĬŢä ÕDZȷ ÆÆΣä øÁǫǫnŕä"ȷäȚʌʒ .ȟ/ȳäÀdȘÀȯȚ 10 ďʒ ÆЛÂЛ ŕ Ü(128 ǦHЧÁÔää Û1 ÆŸÖä) A ǦÕЛÀÛää ÆÊШ ǦŸŒÖää ȷäÀĬŢä ȚȚǫŢ ďŒĬŁ Ü(127 ǦHЧÁÔää gÆȚ äȚõÀŸö ÕÀǫЛ Ûpotassium antimonate TS ŌȚ 6 8ȧÊЛ ÛǩȧȚ ŌȚ 10 Ž ȟ 1 ääØЛ :**Sodium** ȳȚЛäȚÔää .TS2 ȳȚŁ8Ÿö ÆøȧĬŒĬŢä ȯȚŸǂä ȳȚŁŢ ďȚ ĬgȚŕȘ ÀŽõÜ ȳȚŁŢää ¢ŒȚ ȷȚÒǩ ŕ ȘÜ ĬŒȚȧÒ ǰǩÁÁää ȯȚŸǂä ȷȚÒЛ ÜǦÕŒęä 15 ÕĬЛøȚŸõȘøÆŒTä Ŕƀ ȯȚŸŢ ďȚ ŌȚ 4 Ž ȟ 1 ääØЛ :**Oxalates and tartrates** ǧäÀÙÀÛääȘ ǧŕȧÊõǧä ÜTS (ȯ/ȟ55) ȳȚŒÊȯȧĬÒää ÆЛøȚŸõ ȯȚŸŢ ďȚ ŌȚ 1.0Ș TS (ȯ/ȟ750~) ȯȚǫȧĬÀqä ďȚ ŌȚ 4 8ȧÊЛȘ ÛTS (ȯ/ȟ70~) .Ǧʒȧ̀è 1 gÆȚ ȯŸŃ ȯÆǫǫȚ Ǩȧ ȯȚŸǂä ȚÕǦЛ

БȧĮä ǒȧŢä ďȚ ŌȚ 10 Ž ȟ 1.0 ÂŒõÀǫæ ȯȚŸǂä ȷȚÒЛ :**Clarity and colour of solution** ȯȚŸǂä ȷȚȯȘ ǒȧÁÒ .ȷȚŸää CÆʒȘ ĬŒȚȧÒ R ȷȚäÀÒää ÆŒÊõĬ ŲəȧÁǫ ďȚ

ǨЛЗÒää Ŕƀ ďȚ ŌȚ 10 Ž ȟ 0.20 ääØЛ :**Readily carbonized substances** gÀÌȧǦȚ ĮHЧÁǫŸö ǦŸäÀÕää ääȚŢä ÀŽõÜ ǰǩÁÁää ȯȚŸǂä ȷȚȯ ȷȚÒЛŕ ÜǦʒȧ̀è 1 gÆȚ °ȳ 90-80 gøäÀǧ ǦDZøÆä ŲäȧĬȚ ȳȧÞ Ž ďÅÊЛȘ TS (ȯ/ȟ1760~) Colour ÕäȚÊää ȷȚȯ" ȷäȚʌʒ ǨƠ 8ȚòȚȚ ȚŁ ȧŁõ ȷøȧÕЛ ȧȚÆʌʒ Gn6 ȘÜ Yw5 ƙȯȚŸHŁŸö ÆøȧĬŒĬŢä ȷȚŸää ďȚ gÆÌ .(53 ǦHЧÁÔää Û1 ÆŸÖä) "of liquids

Determination of water by ÀÎŒȚ ȯøȧĬõ ǦÕЛÀÛä ǒȧŢä ƙŒĬƙ" ȷäȚʌʒ ǨƠ 8ȚòȚȚ ȚŁ ȧŁõ ďŒĬЛ :**Water** ǒȧŢä õÀǫЛȘ õÀʒ ÜgäȧŢä ďȚ ȟ 0.5 ǦääÀę ÿäÆÁǫèȧä Û(145 ǦHЧÁÔää Û1 ÆŸÖä) A ǦÕЛÀÛää Û"the Karl Fischer method ÜÀЛȧĬЛ ØəÆÁʒȘ ÛǦÕŒęä 1 gÆȚ ǦŒǫȧǫ õÀʒ ÛǦÕŒęä 15 gÆȚ dehydrated methanol R ǒȧŢä ţȘÂøȧȚ ȯȚǫȧĬŲŒŢä ʒȚ âȧŁǫŸö .ȟ/ŋŸȚ 70 ďʒ äȘØƙ ŕ ȟ/ŋŸȚ 40 ďʒ ǒȧŢä ȚȚǫŢ ÕÕЛŕ

R ȷȚäÀÒää ÆŒÊõĬ ŲəȧÁǫ ďȚ БȧĮä ǒȧŢä ďȚ ŌȚ 10 Ž ȟ 1 ääØЛ :**Acidity or alkalinity** ǦЛȚŸÕää ȘÜ ǦŕȚŁΣä Ŕƀ ȯȚŸŢ ďȚ ŌȚ 0.2 ďȚ ÀŽõÜ ȧȚȚä ÆŸÛǫЛŕ ÜTS ȯȚǫȧĬŲ/ƙȧÕȧĬŽȚ ȯȚÆȚ ȯȚŸŢ ďȚ ŌȚ 0.1 8ȧÊЛȘ ȯÆǫǫЛ Țøǫǧ VS (ȯ/ȯȚȚ 0.1) ȳȚЛäȚÔää ÆŒÊõȘøÆŒŁ ȯȚŸŢ ďȚ ŌȚ 0.2 ȘÜ VS (ȯ/ȯȚȚ 0.1) ÕĬЛøȚŸõȘøÆŒTä .ȯȚŸǂä ȷȚȯ

ɔøǫǵ ɒÅÊʌ ÛR1 ƱDzŸǰöä ÕĒǫǿèɟä Ŕƥ ɒŋ Ōŋ 20 Ž ÛĞĒùzǵŘŋ Ğǫşàzŋ ÛĦ 0.15 ĞääÀę ā äØʌ :**Assay** ĞÊʌÀŌţä Û1-naphtholbenzein/acetic acid TS ȯzŸŢ ɒŋ Ōŋ 0.25 ȣÀŘʌş ÛĞzÀȣöä ǵöäÀǵ ĞDZøǻ ɔøǫǵ ǻƎĒƀ ōÀǫʌ Û°ȳ 50 ĞääÀę ǨƠ ȣzȯzŋ zŁ Ȧŧõ ÀŘnÛ ɟzȯ ɔŸȝ ȯzÔΣä ɔøǫǵ vs (ȯ/ȯzŋ 0.1) ÕʌøzŸõǨĞöä Ŕŧɯ ÀʌÀĦʌş ɒŋ Ōŋ 1 Ōõ .(142 Û1 ÆŸŌä) A ĞŌʌÀÛöä ĀÊɯ Û"Non-aqueous titration ƱəÀŋŸöä Ùèzöä Ž gÀʌÀĦţä"ɟäzʌȝ .$C_6H_5K_3O_7$ ɒŋ ŋŸŋ 10.21 ŏżÀȮʌ vs (ȯ/ȯzŋ 0.1) ÕʌøzŸõǨĞöä Ŕƥ

øøøøø

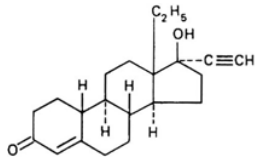
LEVONORGESTRELUM

Levonorgestrel üǐƥƧƨǐɯƥNjüžNj2ǐ‖

$C_{21}H_{28}O_2$:**Molecular formula** ĞĒÀʌÂƨä Ğ8ĒÔöä

312.5 :**R elative molecular mass** ĞĒĞÊʌöä ĞĒÀʌÂƨä ĞŸǫȮöä

:**Graphic formula** ĞĒǫÀĒĞţä Ğ8ĒÔöä



:**Chemical name** ƱəÀĒŧĒȮöä ǀèɾä

(–)-13-Ethyl-17-hydroxy-18,19-dinor-17α-pregn-4-en-20-yn-3-one; CAS Reg. No. 797-63-7.

.ĞHƱəäÀöä CÆȝ ÜĦĞʌÀŌk Ŕ‖ÀÛş Ŕ‖ÀÛ ɟzŸä ƀózŸä ȧzHƱÊŋ :**Description** Ƶòzöä

ȯzǫÀŽʌqä Ž ɟÀäşØöä ĞĒHƱì ÜR ȳózzşózŸȮöä Ž ā äşä ÜĦĒŸŧȝ ŏÀŧä Ž ā äşä Ǩd :**Solubility** ĞĒǫÀäşØöä .R Ǩǫɟäş (ȯ/Ħ750~)

.contraceptive ÕŧǵǷǫÀŋ :**Category** ĞÀÀöä

.ŏzŘöä ɒŋ ĞĒŧŢ ÛĦÆDZ ĞŌŸȣŋ ĞʌşÀǵ Ž ŌʌÀǫÊĒDZózǫzÀĒŸöä ŞÀǵ Æƶ :**Storage** ɒʌÂÅǫöä

REQUIREMENTS ǨĞƱƱƨǨĞ!ƒ

ɒȝ ÆʌÂʌ ƨş %98.0 ɒȝ ŌŌʌ ɾ Ȧŋ ɔŸȝ ŌʌÀǫÊĒDZózǫzÀĒŸöä ƀzǫƷ :**General requirement** ȳÀŘöä ÆŸÛǫţä .ĞÀÀŌä gÅÀţä ƁÛ ţzDZÀöÀä ĞäzÊŢ Û$C_{21}H_{28}O_2$ ɒŋ %102.0

Identity tests hŭĭNjNJЛЄ l ЄƀƑǴƓǴƓ:

- CȘ B ďЛøÅǴǴǴnŕã ȘÜ A øÅǴǴǴnŕã Åŋŭ ĘĘǴÛŭk ďÒƐ.

ŘƠ ǴĦŭìŭã ǴÕÛÛAŋ Ž ƱəƵŘõã ƵĘÛõã âÅĘę" ŭãƵÅ3 ŘƠ ȣƵòƵŋ ƵŁ ÅŁõ ÒĦŭÅõã ĘǴÛΛ :A ǴĦŭìŭã Ž î ÅÔǴŋŕã ƵĘù ĘãÅÛǴΛ .(43 ǴĦŭÅÔõã Û1 ÆŸÖã) "Spectrophotometry in the infrared regionǴãÅŁΣã *refernce spectrum* ƱĦDƵÅŁã ƵĘÛõã Ƶŋ ȘÜ RS ÕΛÅǴÊĘDƵóƵǴƵÅĘŸõã ďŋ ŭkÅÅõã ƵĘÛõã Ƶŋ ǴãÅŁΣã ŘƠ .ÕΛÅǴÊĘDƵóƵǴƵÅĘŸõ

ǴΘÅÅõã ǴĘÊĘƵÅõã ǴĦÕǴõã ĘƵãƵǴk ."Related substances ǴǴÅÎŁã ããƵŁã" ŭãƵÅ3 ŘƠ ȣƵòƵŁã øÅǴǴǴnŕã ƱÜ ÅŢǴã :B .C òƵŸ‡ã ďŋ ǴΘÅÅõã ÕŸk Ƶŋ gÆÎõãȘ ÅŸŢŁãȘ ƵǴƵŁã Ž B òƵŸ‡ã ďŋ

.°ȳ 236 ǴããÅę øÅŸÔǴŕã ǴDƵóã ŋŸǴk :C

ÜR ȳóƵƵȘóƵŸÒõã Ž Ôŋ/ŋŸŋ 10 ÂĘÕÅǴã òƵŸŢ ȳÆÁǴÊΛ :**Specific optical rotation** ƱƵƵÅõã ƱÅÔǴõã ÅΛȘÆǴõã

.$[a]_D^{20°C} = -30.0 \text{ to } -35.0$

.ĥ/ŋŸŋ 1.0 ďƵ ÆΛÂΛ ŕ :**Sulfated ash** ŘÅŸÊŁã ãÅŋÅõã

5.0 ďŋ ÅŸõÜ ÆÕÅΛ ŕ Ü°ȳ 105 gøãÅg ǴDƵóÆã ŘãÅŸõã ŭàƵõã ƵøǴg ƵÅƵ :**loss on drying** ƵĘÅDƵǴõÅã ÆÕÅõã

.ĥ/ŋŸŋ

dehydrated øÅŁã ŁȘÂøΛŋ òƵǴÅŸΛqã ďŋ Ôŋ 30 Ž ĥ 0.10 ããØΛ :**Acidity of alkalinity** ǴΛƵŸÕõã ȘÜ ǴŕƵŁΣã ÆĘÊõȘóÆĘŁ òƵŸŢ ďŋ Ôŋ 0.15 ďŋ ÅŸõÜ ȳÅŸΛ ŕ ÜTS òƵǴÅŸΛÜ/ÕĘŸŁã gÅŁg òƵŸŢ ďŋ Ôŋ 0.5 ȣÅŘΛȘ ethanol R 0.01) ÕΛóƵŸõȘóÆĘTã Ŕβ ďŋ Ôŋ 0.30 ďŋ ÅŸõÜ ŕȘ ÅÅòŭã ƵŸõã ƵŸ3 òƵÔĦŭõõ VS (ȯ/òƵŋ 0.01) ȳƵΛóƵÔõã .ÅβŭÅ ƵŸõã ƵŸ3 òƵÔĦŭõõ VS (ȯ/òƵŋ

ǴÕĘęÅõã ǴÕǴÛõã ããÅÎǴèã" ŭãƵÅ3 ŘƠ ȣƵòƵŋ ƵŁ ÅŁõ øÅǴǴǴnŕã ƵÅƵ :**Related substances** ǴǴÅÎŁã ããƵŁã 8 ďŋ ŭΛÅŋȘ ǴŸȣ8ŋ gãÅŁõ R1 ÅÒĘŸĘÊõã ǴŋŸŁ ȳãÆÁǴèÅã Û(84 ǴĦŭÅÔõã Û1 ÆŸÖã) "Thin-layer chromatography ďŋ ÅǴȘÅÒŋ 10 ǴĦŭÅÔõã ƵŸ3 ŸÔÅÅŋ ĘǴÛΛ .ÕÅĦǴŋ øƵÛÕ R ŭƵǴèŭã ďŋ ŁDƵg 2Ș R ȳóƵƵȘóƵŸÒõã ďŋ ȳƵDƵg 0.10 ƵƵƵ :(B) òƵŸ‡ã ÛÕŋ 1 ÕÕ Ž øÅǴǴnŕã gãÅŋ ďŋ ŋŸŋ 10 ƵƵƵ :(A) òƵŸ‡ã ÛR ȳóƵƵȘóƵŸÒõã Ž ÕĘÅŢ 3 ÆĦã .Ôŋ 1 ÕÕ Ž RS ÕΛÅǴÊĘDƵóƵǴƵÅĘŸõã ďŋ ŋŸŋ 0.10 ƵƵƵ :(C) òƵŸ‡ãȘ ÛÕŋ 1 ÕÕ Ž øÅǴǴnŕã gãÅŋ ďŋ ŋŸŋ ďŋ Ôŋ 50 ďŋ ŭΛÅŋ æÅŁȘ ÛÆΛØŁã ÅÅǴǴΛ ƵøǴg õãƵŢã Ž ƵDƵõ õÅǴk ÛããÅÎǴèŕã gKDƵg ďŋ ǴĦŭÅÔõã ŁÂǴ ãƵƵ ǴĦŭìŭã õƵŕ Ž ããÅÎǴèŕã ÙÛÛ ÒĦŭÅΛȘ ÛTS (ȯ/ĥ1760~) ÕΛóƵÅŸÊõã Ŕβ ďŋ Ôŋ 10Ș R òƵǴÅŸŁã ǴΘÅÅõã ÕŸk ďŋ gÆì ÅŸõÜ ÛǴĘÊĘÅÅõã ǴĦÕǴõã õÅŸǴèÅã ÛA ôƵŸ‡ã ďŋ ŭǴÅk ǴĦÕã ǴΛÜ ŭƵÒk ŕ .(ÅǴŋƵǴÅǴ 365) ǴĘDƵÊÅÅǴõã .B òƵŸ‡ã ďŋ

ȷäøzzsøÆŁäÀQQöä ȣȵ Ōȵ 40 ǦääÀę Ž ÛǦŁùzǦŘȵ Ǧǫsàzȵ ÛȞ 0.2 ǦääÀę ā äØ\ :**Ethynyl group** ŌŁÆŽ\qä Ǧ3zŧf Ûvs(ȯ/ȯzȵ 0.1) ȳz\ǎzÔöä ÆŁÊõsøÆŁŁ ȯzŸHȵ À\ÀȞ\s TS (ȯ/ȞȵÀ00) ǦŘÀöä ǧäÀQǫ ȯzŸȚ ȣȵ Ōȵ 10 8ÀŘ\ .R ȯzŸȚ Bz3 BØöä calomel electrod ŌŁȵzȯÀõ ȘÀÊȵs ŦDZÀDZà ȘÀÊȵ ȳäÆÅQèÀæ ÛÆȚzä âÀŁŌȵ ǦÀȚÀöä ǦÛŌǫ ȣȞŁǦs Ōȵ 1 Ōõ .Ǧ\øsÀŕ ǧÀHŦHÔǩ Ǧ\Ù ȘÀØs Ǧòzȵ HÀtä gǎÀtä ȷsǎ ǦŸŧȞöä ǎÀȞǩ .electrolyte ȯÀÀȚÓõ ȳzŁèÀǩzǦöä ǧäÀQǫ Ǧ3zŧf ȘzǫȚ ŌŌ\ ŧ Ü-C ≡ CH ȣȵ ŋŸȵ 2.503 ǒżÀȮ\ VS (ȯ/ȯzȵ 0.01) ȳz\ǎzÔöä ÆŁÊõsøÆŁŁ ȯzŸȚ ȣȵ .ȞŋŸȵ 81.8 ȣ3 Æ\Â\ ŧs ȞŋŸȵ 78.1 ȣ3 ŌŁÆŽ\qä

øÆŌä ȷDzǵ ǒÀÛ3q R ȯzǫÀŽŁtä ȣȵ ǦŁzÀõ ǦŁŧõ Ž ÛǦŁùzǦŘȵ Ǧǫsàzȵ ÛȞ 0.05 ǦääÀę ā äØ\ :**Assay** ǦÊ\ÀŌtä ȷè 1 ǦǫÀÁžä ǦÔǦù ȯŸn ȣȵ î Àŧǫöä âÀŌ\ .¢ÊÀǫ Æ\ØtÀä Ōȵ 100 Бǩ ȯzŸ∓ä äØŁ ȣȵ Ōȵ 2.0 ZÀƧ ÜŌȵ 100 3ȵ ǦǫøÀŌtÀä ǦòzȵHÀtä gǎÀtä Ž $C_{21}H_{28}O_2$ ǦŁŧõ ÆÊHǩ .À\ȵzǫÀǫ 241 ǦääÀę ǦDZzȵ ȯzÛä ZÀÁtä ȯzŸHŧŸõ ÛǦÀÀÀÒä ÀÊÊȵ ŦəzŕZŁù âÀŁŌȵ Bǩ Ž Û î Àŧǫöä ȵŸǦ\ ȷǩ Æz .ȣȵäÂǫöäs ǦǒÀÎtÀä ÒHÀ\ ÛRS Ō\À\ǫÊDZzǫzÀŁŸöä .0.03 ± 0.54 ŦȞDZÀtä ȯzŸHŧŸõ

ØØØØØ

LEVOTHYROXINUM NATRICUM

Levothyroxin sodium DžŕƨlNjƥŕkNj2ŕ‡ǁƹ !NjŕǫNjT

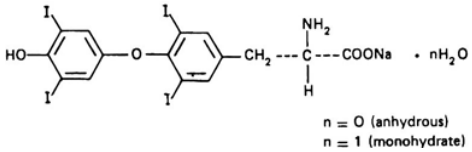
:**Molecular formula** ǦŁÀÂƨä Ǧ8ŁÔöä

(ǧäøÆŁTä BǎÀǵǩ); $C_{15}H_{10}I_4NNaO_4$, H_2O(monohydrate) ŦəÀȵŕ $C_{15}H_{10}I_4NNaO_4$(anhydrous)

:**Relative molecular mass** ǦŁǦÊ\öä ǦŁÀ\ÂƨÀ ǦŸǫȮöä

.(ǧäøÆŁTä BǎÀǵǩ); 816.9 (monohydrate) ŦəÀȵŕ 798.9 (anhydrous)

:**Graphic formula** ǦŁǫÀŁǦtä Ǧ8ŁÔöä



Chemical name: Monosodium L-thyroxine; monosodium *O*-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-L-tyrosine; 3-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenyl]-L-alanine monosodium salt; CAS Reg. No. 55-03-8 (anhydrous); Monosodium L-thyroxine monohydrate; monosodium *O*-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-L-tyrosine monohydrate; 3-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenyl]-L-alanine monosodium salt monohydrate; CAS Reg. No. 31178-59-3 (monohydrate).

Other name: Thyroxin sodium.

Description: White or almost white powder, practically odourless.

Solubility: Slightly soluble in water (1 in 750~) and in alcohol; practically insoluble in chloroform and in ether.

Category: thyroid hormone.

Storage: Protect from light.

Additional information: hygroscopic; crystallization from water.

REQUIREMENTS

General requirement: Contains not less than 97.0 % and not more than 101.0 % of $C_{15}H_{10}I_4NNaO_4$.

Identity tests:

A: Dissolve 2.0 g in 5 ml of alcohol (1 in 130~). Add 1.0 ml of a solution of potassium iodide (1 in 10) and 15 ml of 0.25 N sodium thiosulfate (1 in 70~) and boil for 3-2 min. Cool and add 2 ml of starch TS (1 in 100~) and titrate with 0.1 N iodine VS (1 in 10).

B: Dissolve 0.2 g in 2.0 ml of 0.1 N sodium hydroxide (1 in 750~) and add 2.0 ml of 0.1 N silver nitrate VS (1 in 10). Add 1.0 ml of 0.25 N nitric acid (1 in 70~) and boil for 5 min. Cool and add 2 ml of starch TS (1 in 100~) and titrate with 0.1 N iodine VS (1 in 10).

ÙÛÛƯ Ž ĞŒÊŒəÀäõä ĞĤÖĞõä 3ŋ ĮDzΣäş ɹʒŸõäş 3ęʒţä Ž A òʒŸ‡ä dŋ ǰǩÅäõä ãäÀÎǫèŗä ÙÛÛƯ Ž ĞŒÊŒəÀäõä ĞĤÖĞõä .B ŬĤDZÀţä òʒŸ‡ä dŋ ǰǩÅäõä ãäÀÎǫèŗä

General ĞŋÅĤõä ȣäÀĤǫèŗä ğäøÅǪǫnä" ɹäzʌ3 ǨƠ ȣʒòʒŋ ʒŁ Åŧõ ȳʒʌǎʒÔõä ÕDZɟ ÒHɹÅʌ Åŋ£Æʌ3 :D ʒŁ ȳÆǺǫÊţä Õ3ÅÅǫõä ɹÅõ äæŬş .gÂŧţä ğŸ3ÅÅǫõä ŬÛĤʌ ¢ŭʒ Û(123 ĞHɹÅÔõä Û1 ÆŸÖä) "identification tests .TS (ȯ/ȟ60~) Õ̃ŒŒèɟä Ŕþ Ž ĞõÅŧţõä ãäØǩş ŋŸŋ 20 (Ôŋ̃ÎʌÎ) Æŋ̃ÀŁ ÛB Õ3ÅÅǫõä

dŋ ɹʒÒŋ ZÛŸæ ŬŸ8ʌ ǰʌÂŋ dŋ Ôŋ 22 Ž ȟ 0.5 ãäØʌ :**Specific optical rotation** Ŭ3ʒʌõä ƁÀÔĞõä ÀʌşÆǫõä 25 БŬ ZÅƧş åƎʌ .TS (ȯ/ȟ750~) òʒφÅǰʌqä dŋ ȳʒDzǵ 4ş VS (ȯ/òʒŋ 1) Õ̃ʌózŸõ̃şøÆŒTä Ŕþ dŋ ŋ̃ŧDzǵ 1 .$[a]_D^{20\,^\circ C}$ = +16.0 to + 20.0° ÛČÅÅÖä gåÅţä БŬ ţʒDZÀäÅæ ÆÊƷ .¢ÊÅφ ÆʌØţä ǰʌÂŋ Ôŋ

60 dŋ Ôęŭ ÆÔÅʌ ŗ Ü°ȳ 105 gøäÀǵ ĞDZøÆæ ǨäÅǰõä ɹàʒõä ɔøǫǵ ZÅz :**loss on drying** ZŒÅDzǫõÅæ ÆÔÅõä .ȟ/ŋŸŋ 120 dŋ Àǰõŭ ŗş ȟ/ŋŸŋ

Thin- ĞÕŒęÀäõä ĞÕĞÛõä ãäÀÎǫèä" ɹäzʌ3 ǨƠ ȣʒòʒŋ ʒŁ Åŧõ øÅǪǫnŗä ĘĞÛʌ :**Liothyronine** ǩφşǨǫzŒŸõä R3 ÅÒŒŸŒÊõä ĞŋŸŁ dŋ ȟ 30 dŋ ǰʌÂŋ ĞÊŒŸŋ ĞHɹŒÅò ȳäÆǺǫèÅæ Û(84 ĞHɹÅÔõä Û1 ÆŸÖä) "layer chromatography .ǩǺÊǩ ɹşǺ ÛgÀÌÅĞŋ ĞHɹŒÅÔõä ÕŧĤǫÊǩş .öÅŋ Ôŋ 100 Ž RÅÎÅõä òʒŸŢ dŋ ȟ 0.75 ƁʒƷ òʒŸŢ dŋ Ôŋ 60ş ÛR òʒφÅæşÀæ -2 dŋ ŋ̃ŧDzǵ 35 ÛTS (ȯ/ȟ260~) ÅŒφzŋɟä dŋ ŋ̃ŧDzǵ 20 dŋ ǰʌÂŋ ȳÆǺǫÊʌ ÕÀHɹǫţä ózÛŸõ ĞĞÊÅõÅæş 5 БŬ ȣÅŘʌ :ƁÅǫõä ÆʌØţä ǰʌÂŋ ÀŘƷ ÛĞŒĤDZÀţä ÕŒõÅ‡ä øÅǪǫnä ǨŘHɹǫõ ĞĞÊÅõÅæş .R ÕŒƷʌqä ğÅǫŒèŭ dŋ ŋ̃ŧDzǵ 55ş ȟ 0.10 ãäØʌ ÛA òʒŸHɹŧŸõ ĞĞÊÅõÅæş .ƷÅƧş R òʒφÅƷŒţä dŋ ŋ̃ŧDzǵ 70 øäÆÔŋ TS (ȯ/ȟ260~) ÅŒφzŋɟä dŋ ȳʒDzǵ ÆʌØţä ǰʌÂŋ òʒŸ‡ä äØŁ dŋ Ôŋ 1.0 ZÅƩ ØəÆÅʒ ÛÂõÀţä òʒŸ‡ä dŋ Ôŋ 5 ƷÅǫφq ÆʌØţä ǰʌÂŋ Ž øÅǪǫnŗä gåÅŋ dŋ ǩÊõşǨǫzÅŒŸõä ȳʒʌǎʒò dŋ ŋŸŋ 50 ãäØʌ ÛB òʒŸHɹŧŸõ ĞĞÊÅõÅæ .ZÅÅţä òʒŸ‡ä dŋ Ôŋ 2.0 ƷÅǫφq ¢ÊÅφ RS ǩφşǨǫzŒŸõä dŋ ŋŸŋ 5 ãäØʌ ÛC òʒŸHɹŧŸõ ĞĞÊÅõÅæ .Ôŋ 5 ƷÅǫφq òʒφÅƷŋ/ÅŒφzŋŭ ÆʌØţä ǰʌÂŋ Ž liothronine RS òʒŸ‡ä äØŁ dŋ Ôŋ 1.0 ZÅƩ ØəÆÅʒ ÛÂõÀţä òʒŸ‡ä dŋ Ôŋ 25 ƷÅǫφq òʒφÅƷŋ/ÅŒφzŋŭ ÆʌØţä ǰʌÂŋ Ž liothzronine 3ŋ A ÂõÀţä òʒŸ‡ä dŋ Ôŋ 1.0 ƷÅƧ ÛD òʒŸHɹŧŸõ ĞĞÊÅõÅæ .ZÅÅţä òʒŸ‡ä dŋ Ôŋ 2.0 ƷÅǫφq ¢ÊÅφ ÆʌØţä ǰʌÂŋ òʒŸ‡ä ÛB òʒŸ‡ä ÛA òʒŸ‡ä dŋ Ôõ dŋ ÀǫõşÀÒŋ 5 ĞHɹŒÅÔõä ɔŸʒ ŋ̃ŸÔÅʌŋ ĘĞÛʌ .C ÂõÀţä òʒŸ‡ä dŋ Ôŋ 1.0 ferric òʒŸHɹŋ æÀŁş ÛõäzTä Ž ZDzǫõ õÀǫŁ ÛäÀÎǫèŗä gKDzǵ dŋ ĞHɹŒÅÔõä ţÂφ ÆŒæ .D òʒŸ‡äş ÛC ZÅÅţä Ęzäzǩ ĞĤÖæ ĞʌÙ ɹʒÒǩ ŗ .øÅŦÅõä ǫzŗ Ž ääÀÎǫèŗä ÙÛÛƯ ÒHɹÅŁş Ûchloride/ferricyanide/arsenite TS .C òʒŸ‡ä dŋ ǰǩÅäõä ääÀÎǫèŗä ÙÛÛƯ Ž ĞĤÖĞõä dŋ gÆÌ Àǰõŭ A òʒŸ‡ä dŋ ǰǩÅäõä ääÀÎǫèŗä ÙÛÛƯ Ž ǩφşǨǫzŒŸõä .ȳÅǩ dzʒŗʒæ ǩǫŸÔÅʌŋ ǩǫÅǫä ǩǫĤÖæ D òʒŸ‡ä dŋ ǰǩÅäõä ääÀÎǫèŗä ÙÛÛƯ ÀŦŢʌ BÅŋ ŋ̃HɹŒHɹò øÅǪǫnŗä ɹʒÒʌ ŗş Õ̃ʌÀǫÅõä Ŕþ dŋ Ôŋ 0.05 ĞääÀę ƁʒƷ öÅŋ Ôŋ 10 3ŋ ŋŸŋ 10 ŋŘƩ :**Soluble halides** ĞääşØõä ğäÆŒõÅTä

ĞŘÅöä ğäÀǫφ ȯƶŸŢ ȣȵ Ōȵ 0.15 ȣÅŘÅş ŏÅţÅä Ōȵ 10 Ьů ĞǵÅìÀöä Ƶ Åơ .ĆìÀÅş ĘƏÅęå 5 gÆȵ TS (ȯ/ȟ130~) Ōȵ 0.15 ĞƶÅřüä Ǩęäƶǫȵ ŌȮÎä ÀŘ+ä ȯƶŸHȣŸö ȣøǫöä ŌŸǩ ȣȵ gÆì ÄŽõů ĞȮÅφ ȳƶȣŸȵ ĞÅŮ ȷƶȮǩ r ÜTS (ȯ/ȟ40) ŏÅȵ Ōȵ 10 Ьů VS (ȯ/ȯƶȵ 0.02) ŌÅȯƶŸõşøÆȦŢä Řβ ȣȵ Ōȵ 0.10ş TS (ȯ/ȟ40) ĞŘÅöä ğäÀǫφ ȯƶŸŢ ȣȵ .(ÆÅȯƶŸõ ŌȮÎä ȯ/ŋŸȵ 7)

"oxygen flask method ƙDƶÊõȷä ĞŸDƶƶǵ ĞŌÅÀù" ȷäƶÄ3 ǨƠ ȣƶòƶţä ääÀǫǵrä ƷÀƶ :**Assay** ĞÊÅÅŌţä ȯƶŸŢ ȣȵ Ōȵ 10 Ž ÛĞÄùƶĞŘȵ Ğφşàƶȵ ÛøÄĞǫnrä gäÅȵ ȣȵ ŋŸȵ 25 ĞääÀę ÿäÆÅǫèÅä Û(132 ĞHȣÅÔöä Û1 ÆŸŎä) ƶŁ Åţõ ŌţȮǫÊÅ ÛĞÄŸţĦöä ŌţǫȮǩ ÅȵÆÄ3 .absorbing liquid î Åȵ ŌȣÅÊõ TS (ȯ/ȟ10) ÿƶÅäƶÔöä ÆÄÊõşøÆÄŁ ȯƶŸŢ ȣȵ Ōȵ 1 Ōõ Û(134 ĞHȣÅÔöä Û1 ÆŸŎä) "Determination of iodine äƶÄöä ƙÄĦǨ" ȷäƶÄ3 ǨƠ ȣƶòƶȵ .$C_{15}H_{10}I_4NNaO_4$ ȣȵ ŋŸȵ 1.665 ŏżÅȮÅ VS (ȯ/ȯƶȵ 0.05) ÿƶÅäƶÔöä ğÅÅŸèƶÄǫ

ØØØØØ

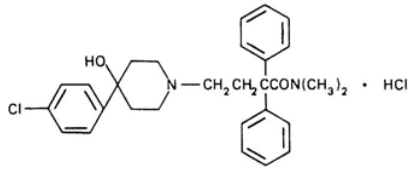
LOPERAMIDI HYDROCHLORIDUM

hydrochloride Loperamide ǫĭDƶƐƥĭĞÑj+ΙΙΕ ǫĭƥÑj+ΙÑjƥǫĭIj

Molecular formula: $C_{29}H_{33}ClN_2O_2,HCl$ ĞÄÅÅÂƨä Ğ8ÄÔöä

Relative molecular mass: 513.5 ĞÄĞÊÅöä ĞÄÅÅÂƨä ĞŸǫȮöä

Graphic formula: ĞÄǫÅÄĞţä Ğ8ÄÔöä



Chemical name: ȣƏÅÄţÄÔöä ĮèrÅ

4-(*p*-Chlorophenyl)-4-hydroxy-*N*,*N*-dimethyl-α,α-diphenyl-1-piperidinebutyramide monohydrochloride; 4-(4-chlorophenyl)-4-hydroxy-*N*,*N*-dimethyl-α,α-diphenyl-1-piperidinebutanamide monohydrochloride; CAS Reg. No. 34552-83-5.

Description: Ƶòƶöä ŸÄÄÄę ÀÅòȷä Ьů äóÅř ŘÄÄů ȷƶŸä äƶȣÊȵ .

Solubility: ĞÄǫÅäşØöä ŽŞ R ȯƶφÅŽÄţä Ž ȷÅäşØöä Ág ÜĞÅÅÅţä ôÅβȷä ŽŞ ŏÅţä Ž ȷÅäşØöä ĞÄȣì .R ÿøƶƶşøƶŸÔöä

.òÀŤèRõ åÌÊRŋ ðãşå :**Category** ČÌÀòã

.ÌÆÆDZ ČÕŸ8ŋ ČÀşÌáǵ Ž ÆÆŋÌKãzŸõã ÆÀózŸõşóÆÆŁ ŞÀáǵ Æz :**Storage** čÀÂÁçõã

REQUIREMENTS KČŋÌŽŠKŽ!f

ÆÀÂÀ ŕş %98.0 čƷ ÕÕÀ ŕ Ìŋ ƨŸƷ ÆÆŋÌKãzŸõã ÆÀózŸõşóÆÆŁ ƁzÇƵ :**General requirement** ÿÌĤõã ÆŸÛÇŋţã .ČÀÀÕã gÅÌţã Бŭ ţzDZÀõÀã ČãzÊŢ ÛC29H33ClN2O2,HCl čŋ %102.0 čƷ

:**Identity tests** hŭŸNjNJÀÈ l ɛƥƧĠĦCƶɛ

.DŞ CŞ B ğãóÀÇçÀŕã şŭ DŞ A čÀóÌÀÇçÀŕã ÌŋŭÌ ĘÆCÛŭ čÒɛ •

õãÀŤΣã ŘƠ ČĤìŋã ČÕÛÀŋ Ž ŬƨzÊõã ZÆÛõã âÌÆę" ŋãzÀƷ ŘƠ ȣzòzŋ zŁ ÌŤõ ÒHŋÀõã ĘCÛÀ :A ŘƠ ČĤìŋã Ž î ÌÔçŋŕã ZÆù ĘãÌÛÇÀ .(43 ČHŋÀÔõã Û1 ÆŸŎã) "Spectrophotometry in the infrared region ÆÀózŸõşóÆÆT *refernce spectrum* ŬĤDZÀţã ZÆÛõã Ʒŋşŭ RS ÆÆŋÌKãzŸõã ÆÀózŸõşóÆÆŁ čŋ ŋŭÌÀõã ZÆÛõã ƷŋõãÀŤΣã .ÆÆŋÌKãzŸõã

čŋ Õŋ 50 ČããÀę Ž ããØŭ ÛÌÆŤDzǵ ČDZóÆŋ Õŋ 100 ŁDzÀÀ ČŸDZzǵ Бŭ ÛČÆùzCÊŋ Čçşàzŋ ÛĤ 0.04 ČããÀę ÕÕÀ :B ÆÀØţÌã Õŋ 100 ƨøçǵ ZÀƐş VS (ò/òzŋ 0.1) ÕÀózŸõşóÆÆTã Ŕβ čŋ Õŋ 10 ȣÌÊÀ ÛR òzçÌãşÀã-2 ÆŁÌÎÀ ÌŋÆÀƷ ÛçÊÀçŋ ÆÀØţã ŋÀÂŋ ƨŸƷ ČÀşÌΣã ÆÀØţã gKDzǵ ÕãÌÕŋ òzŸ‡ã ãØT î ÌÔçŋŕã ZÆù ŋŭ .R òzçÌãşÀã-2 ÆÆŋÌKãzŸõã ÆÀózŸõşóÆÆŁ òzŸ‡ î ÌÔçŋŕã ZÆù ƷŋÌÆŤõ çãÌÎçÀ ÛÀçŋzçÌçŋ 350ş ÀçŋzçÌçŋ 230 kã Ƶãzŋŋã òãzùŭ Ž ŕ .(ÀçŋzçÌçŋ 273ş Û265 Û259 Û253 ČããÀę Ƶãzŋŋã òãzùŭ Ž ŬŤŢƷŋã î ÌÔçŋŕã çÆƷ) čŋÌÀçõÌã î zHŋÀţã RS .%3 čŋ ÀŽõüã ÌÌŘĤã ÀŤŘĤã čƷ ČÆŤŢƷŋã Ƶãzŋŋã òãzùŭ Ž ÕÆõÀ‡ã ČÓŁ ğÀòÀçÌ ZŸçơ

.ÕÒÀçõã Ƹŋ °ÿ 224 ČããÀę óÀŤÔçŕã ČDZóǵ ŋŸGk :C

General ČçŋÌĤõã ȣãÀĤçèŕã ğãóÀÇçÀã" ŋãzÀƷ ŘƠ ȣzòzţã A ÕƷÌÀçõã Õŋ/ŋŸŋ 10 ÂÆõÀçã òzŸ‡ã ŬÛĤÀ :D .(121 ČHŋÀÔõã Û1 ÆŸŎã) ğãÆÀózŸÒŸõ ÂÆŤŤŋ óÌÇçÀÀõ "identification tests

.ĥ/ŋŸŋ 2.0 čƷ ÆÀÂÀ ŕ :**Sulfated ash** ŘÀŸÊţã ÅÌŋÀõã

şŭ òÌÒèÌãzŸõ 0.6 čƷ ÆÀÂÀ ŕ) ŘÀÁÀŋ Ù8ŕ ŘƠ °ÿ 80 ČDZóÆõÌã ZÀz :**loss on drying** ZÆÌÀDzçÕÌã ÆÕÀõã .ĥ/ŋŸŋ 5.0 čŋ ÀŽõŭ ÆÕÀÀ ŕ Ügǵ3Ìè 4 gÆŋ (ĘÇçà ŁŸŋ 5 ČããÀę

ČÕÆęÀõã ČÕÇÛõã ããÀÎçèã" ŋãzÀƷ ŘƠ ȣzòzŋ zŁ ÌŤõ óÀÇçÀŕã ƨÀz :**Related substances** ČçÌÎţã ããzţã 85 čŋ ŋÀÂŋş ČŸçȣŋ gÅÌŤõ R1 ÌÒÆŸÆÊõã ČŋŸŁ ÿãÆÁçèÌã Û(84 ČHŋÀÔõã Û1 ÆŸŎã) "Thin-layer chromatography ózÛõ TS (ò/ĥ1080~) ÕÆŋózÀõã Ŕβ čŋ ÿzDzǵ 5ş ÛR òzçÌãŸÆţã čŋ ÿzDzǵ 10 ÛR ÿózzşózŸÒõã čŋ ÌŤDzǵ

ŋŸŋ 10 Ƀzʒ :(A) ȯzŸǂǎ ÛR ȳøzzsøzŸȮõǎ Ž ƙAõǎ ƙȯzŸȚ ȯŋ ÀQõsÀȮŋ 10 ǦHƱÁÔõǎ ɔŸʒ ₩ÔÁÁŋ ĘǦÛΛ .ȫÀHƱQŋ ȯŋ ǦHƱÁÔõǎ ţÂφ ÆĦǎ .ȪŋΛ 1 ȪȫŽ ž øÁǦQnŕǎ gǺÁŋ ȯŋ ŋŸŋ 0.10 Ƀzʒ :(B) ȯzŸǂǎs ȪŋΛ 1 ȪȫŽ ž øÁǦQnŕǎ gǺÁŋ ȯŋ ɟzȮǩ ŕ .øÁŽAõǎ ȯzŕ Ž ǎǎÀÎQèŕǎ ÙÛÛ' ÒHƱÁΛ .ǺzÊõǎ gÀNɟ ôÀĦǩs õǎzTǎ Ž ZDzQõ ȫÀQǩ ÛǎǎÀÎQèŕǎ gƙDzǵ .B ȯzŸǂǎ ȯŋ ǦΘÁÁõǎ ȪŸǩ ȯŋ gÆì ÀʒȫÛ ÛǦÊƱÀõǎ ǦȪȪǦõǎ ȯÁAʒQèÁŕ ÛA ȯzŸǂǎ ȯŋ ʒQÀǩ ǦȪȪŕ ǦAÛ

Ȫŋ 10 ȣÁÎΛ ÛR1 ƱDzŸʒõǎ ȪƱQƱèɟǎ ÈÞ ȯŋ Ȫŋ 30 Ž ÛǦƱùzǦÎŋ ǦQsàzŋ ÛȪ 0.38 ǦǎǎÀę ǎǎØł :**Assay** ǦÊΛÁȪţǎ ÛÀĦÎŧȫ 1-naphtholbenzein/acetic acid TS ȯzŸȚ ȯŋ Ȫŋ 0.15s TS ȪƱQƱèɟǎ ÈÞ/ĘǦǎÂõǎ ǧÁQƱèÛ ȯzŸȚ ȯŋ Non-ƱǎÁŋŸõǎ Ùèzõǎ Ž gÀΛÁĦţǎ" ɟǎzÁʒ ŘƠ ȣzòzŋ zŁ Áŧȫ ÛVS (ȯ/ȯzŋ 0.01) ȪΛØzŸȫŘǦõǎ ÈŧƱ ÀΛÁĦΛs ȯżÁȮΛ (ȯ/ȯzŋ 0.01) ȪΛØzŸȫŘǦõǎ ÈÞ ȯŋ Ȫŋ 1 ȪȫŽ .(142 ǦHƱÁÔõǎ Û1 ÆŸȮǎ) A ǦȪΛÀÛõǎ Û"aqueous titration .$C_{29}H_{33}ClN_2O_2$,HCl ȯŋ ŋŸŋ 51.35

ØØØØØ

MAGNESII HYDROXIDUM

Magnesium hydroxide !NjĬŘĭŒŽDŽΛΕ qĭƨ lNjƥqĭlj

Mg(OH2)$_2$:**Molecular formula** ǦƱǎÂƨǎ Ǧ8ƱÔõǎ

58.32 :**Relative molecular mass** ǦƱǦÊÁõǎ ǦƱÁΛÂƨǎ ǦŸQÒõǎ

Magnesium hydroxide; CAS Reg. No. 1309-42-8.:**Chemical name** ƱǎÁƱŧƱȮõǎ ɟèŕǎ

.ǦHƱǎǎÀõǎ CÆʒ ÜɟʒÁφ ÛÈŘƱǎÛ ɟzŸǎ ƀØzŸǎŕ ȧzHƱÊŋ :**Description** Zòzõǎ

.ǦÁÁŧǎ ôÁƥɟǎ Ž ǎǎsǎ ÜTS (ȯ/ȫ750~) ȯzφÁʒΛqǎ Ž ŕs øÁŧǎ Ž ŘƱŸŧʒ ǎǎsǎ Ǩq :**Solubility** ǦƱφÁǎsØõǎ

.Ǧŕzŧ HƱŸõ ǺÁÎŘŋ :**Category** ǦÁÁõǎ

.ȳÁȮǵǎ ǦÔŸ8ŋ ǦΛsÁǵ Ž ȳzΛÂƱA8ŧǎ ÆƱÊõsøÆƱŁ SÁǵ Æz :**Storage** ȯΛÂÁφõǎ

REQUIREMENTS ǨǦƱƱƱ

ďŋ Ďŋ 1.0ş ÛTS (ȯ/ȟ100) ȳȚÅźÔää ĞŁąÅÅę ƙDZşóÆŁŁ ğÅÅÊŋ ȯȚŸŢ ďŋ Ďŋ 0.5 ÛTS (ȯ/ȟ100) ȳȚŁęȚŋĵä
.TS (ȯ/ȟ300~) ÕŁęŁèĵä Řþ Ž ãşØǩ ŦØęÕäş ÛŘŁäÛ ĵȚŸä ĞÅźŸä ĞäÅèŁø ĵęÅǩ ÜTS (ȯ/ȟ100~) ÅŁęȚŋĵä
ÆŁÊõşóÆŁŁ ȯȚŸŢ ďŋ Ďŋ 2.0 ȽÅŘłş ÛTS (ȯ/ȟ70~) ÕÅźŸõşóÆŁTä Řþ ďŋ Ďŋ 1.0 Ž ŋŸŋ 10 ãäØł :B
ÆŁÊõşóÆŁŁ ȯȚŸŢ ďŋ gåÅÅà Ž ãşØǩ ŕ ŦØęÕää ÛŘŁäÛ ĵȚŸä ĞŁŋŸŁ ĞäÅèŁø ĵęÅǩ ÜTS (ȯ/ȟ80~) ȳȚÅźÔää
.ďõäÆää ŦØÅĞää ĵȚŸää БÛ ĞäÅèŁää ȯȚŸęÅǩ ÜTS åźŁää ȯȚŸŢ ďŋ ğäÅÛę ƷŘä ȽÅŘÅ .TS (ȯ/ȟ80~) ȳȚÅźÔää
TS (ȯ/ȟ250~) ÕÅźŸõşóÆŁTä Řþ ďŋ Ďŋ 15 Ž ȟ1.0 ãäØÅ :**Heavy metals** ĞŸŁÕŽää (ğäÅŸÅää) ĵåÅŘţä
ĞÕĞÛää ÄÅĞǩş ÛĵÅęÕĞÛää ÕÔÅǩ ÛåźõÄŸõ õÄęÅ .ĞÕŁęå 2 gÆŋ R ĵȚęŁõ ÕŁǩźä şÅÅÛ ÕŁŽŁŋ ȯȚŸŢ ďŋ Ďŋ 25 Ƹŋ ŋŘƧş
óÅĞęÅnŕä" ĵäźÅƷ ǨƠ Ƚźòźŋ źŁ Åłõ ÕłŘää ÕłÒęÊÅş ǒÅţä ďŋ Ďŋ 15 Ž ĞäÅłŽää ãäØǩ .ȽÅÅźä źøęǵ ĞŁąÅţä
Ü(127 ĞŦÅÅÔää Û1 ÆŸǨä) 1 ǒäÄDZqä ÆÊŦŦ Û"Limit test for heavy metals ĞŸŁÕŽää (ğäÅŸÅää) ĵåÅŘţä ÕDZĵ ÞÆΣä
.ȟ/ȳäÄdşÄÒŋ 30 ďƷ ÆÅÂÅ ŕ Ü(119 ĞŦÅÅÔää Û1 ÆŸǨä) A ĞÕÅÄÛää ÆÊŦŦ ĞŸŁÕŽää ĵåÅŘţä ȤźŢ ďŘŘÅ
ďŋ Ďŋ 35ş TS (ȯ/ȟ100~) ÕÅźÅŸÊää Řþ ďŋ Ďŋ 20 Ž ȟ3.3 ÂŁõÄęä ȯȚŸŢ ȳÆÅęÊÅ :**Arsenic** ÄŁęØÂää
Û1 ÆŸǨä) "Limit test for arsenic ÄŁęØÂää ÕDZĵ ÞÆΣä øÅĞęÅnŕä" ĵäźÅƷ ǨƠ Ƚźòźŋ ÅłÕ ÕłŘää ÕłÒęÊÅş ǒÅţä
.ȟ/ȳäÄdşÄÒŋ 3 ďƷ ÄŁęØää ȤźŢ ÆÅÂÅ ŕ Ü(130 ĞŦÅÅÔää

ÛǒÅţä ďŋ Ďŋ 50ş TS (ȯ/ȟ300~) ÕŁęŁèĵä Řþ ďŋ Ďŋ 50 ďŋ ĵÅÅŋ Ž ȟ5.0 ãäØÅ :**calcium** ȳźŁÊäÅÒää
Ƶ3 ÛÅÅØşÄŕ ÕÅäé ĵÅõ äæÛ ÛĞŕÄÅ .TS (ȯ/ȟ120~) ÕŁęŁèĵä ŘłŦŦ Ďŋ 100 БÛ ZÅƧş ÛåƵÅ ÛČÕŁęå 2 gÆŋ ŦŸ8Å
ZÅƧ .ĞŁźÅò ĞǵÅŕó ǒÅÛƷq ĞłąŸŋ porosity ĞŁŋÅÊŋ ğäé ÅÒŁŸŁÊää şÛ ȟÅÅţä ȽÂęä ďŋ ÅÅęÛ ĞŁźŸŋ ĞŕŕÅŋ ČÕÅźźä
БÛ ȽÅŘÅ .(ÕŁęŁèĵä Řþ Ž ĞääşäŸää åäźţä óÅĞęÅnä ÕDZĵ ĞŕŕÅţä źÕĞęÊł) ǒÅţÅä Ďŋ 150 БÛ ĞǵÅŕÅää ďŋ Ďŋ 1.3
ğŕÅÊõÅ ȯȚŸŢ ďŋ Ďŋ 0.8 óäÅÕŋ TS (Ca Ďŋ/ȳäÄdşÄÒŋ 100~) ȳźŁÊäÅÒŸää БźęÅŽÅęä ÞóÅŁŘţä ȯźŸŕä ďŋ Ďŋ 0.20
ĞǵÅŕÅää ďŋ Ďŋ 15ş TS (ȯ/ȟ120~) ÕŁęŁèĵä Řþ ďŋ Ďŋ 1 ȽÅŘÅ ĞÕŁęå 1 ÆŘäş .TS (ȯ/ȟ50) ȳźŁęȚŋĵä
.ÅÅęÛ gÄŘŕŕä ĞÅäÅÅţä
(ca Ďŋ/ȳäÄdşÄÒŋ 10) ȳźŁÊäÅÒŸää ÞóÅŁŘţä ȯźŸŕä ďŋ Ďŋ 10 ďŋ ĵÅÅŋ ȳäÆÅęÈää ÞóÅŁŘŋ ȯȚŸŢ ĞäÅÎţää ÄŘŽ
ȯźŸŕä Ž ŦØęÕää ÕŸŸä ďŋ ÄźõÛ ÅäÆÅÅ ĵźÒŸä ďäÅęÅnŕä ȯȚŸŢ Ž ĵęÅǩ ȳźłŋ ĞÅÛ ĵźź ĞÕŁęå 15 ÆŘäş .äÅŋ Ďŋ 5ş TS
.(ȟ/ŋŸŋ 15) ÞóÅŁŘţä

.äÅţää Ďŋ 10 БÛ ZÅƧş TS (ȯ/ȟ70~) ÕÅźŸõşóÆŁTä Řþ ďŋ Ďŋ 5 Ž ȟ0.15 ãäØÅ :**Iron** ÆÅÆΣä
ÕDZĵ ÞÆΣä øÅĞęÅnŕä" ĵäźÅƷ ǨƠ Ƚźòźŋ źŁÅŋ ÆÊŦŦ ĞÅÅää ĞǵÅŕÅää ďŋ Ďŋ 4.0 źŸƷ ÕłŘää ÕłÒęÊÅ
.ȟ/ȳäÄdşÄÒŋ 700 ďƷ ÆÅÂÅ ŕ Ü(129 ĞŦÅÅÔää Û1 ÆŸǨä) "Limit test for heavy iron ÆÅÆΣä

ĞŕŕÅ .ÉäÅęå 5 gÆŋ źŸ8Åş ǒÅŋ Ďŋ 100 Ƹŋ ȟ2.0 ƷÂƧ :**water-soluble substances** ǒÅţä Ž ĞääşØää åäźţä

Ząż Ż ȣÅÅząą ąøęǵ ĞǵÅìÀöą ćęą Ōą 50 ÀÅÁǵł .öÅţÅą Ōą 100 Ьů ZÅƷę ÛåƎĘö õÀęÅ ÛĦöÅǵ öÅţą ąŌǵÅ ÅţÅĦą .ŋŸą 20 ćȝ ĞöÅţŸöą ȷàę ÁÅÂÅ ŕ ÜĶąÅŽöą ȷàzöą ąøęǵ °ȳ 105 ǵöąÀǵ ĞDZöÁą

ąŸȝ ĞĦŌǵęą ÛĞöÅţŸöą ȷàę ÁÅÂÅ ŕ :**substances insoluble in acetic acid** ŌĦęĦèȷą Ŕþ Ž Ğąąęą¥öą ąązęą ZÅΘę öÅţÅą ŌÊȣł ÅąÁÅȝ Ûȳzę̈ÊöÅÒöą ŌDZȷ ƀÁΣą öÅęǵÅąòŕą Ž ÒĦÅŸö ąÁĦŕą ozŸ+ą ĶŘơ Ž ȳÁÅęÊęą ĞŕÀęą ŋŸą 5 ćȝ Û°ȳ 600 ĞDZöÁöÅą (ŌĦÎł) ÁąÀĶę

ĞŸęÒöą ąøęǵ (ŌĦÎł) ÁąÀłę °ȳ 900 ąøęǵ ȷÅöÁęöÅą ĥ 0.5 ćÅÊÅ :**loss on ignition** ÒÅĦęŕÅą ÁŌÅöą .ĥ/ĥ0.325 ćą ÀŽõŮ ŕę ĥ/ĥ 0.300 ćą ŌęŮ ÁŌÅÅ ŕ ÜĞęąŽöą

ćą ÀŽõŮ ÁŌÅÅ ŕ Ü°ȳ 105 ǵöąÀǵ ĞDZöÁą ĶąÅŽöą ȷàzöą ąøęǵ Ząż :**loss on drying** ZĦADzęöÅą ÁŌÅöą .ĥ/ĥ0.33

TS (ȯ/ĥ70~) ŌÅözŸõęöÁĦTą Ŕþ ćą Ōą 2 Ž ÛĞĦùzĞŔą Ğęęàzą ÛĥĞ 0.05 ĞąąÀę ąąÓĦ :**Assay** ĞÊÅÅÔęą Complexometric ĞąÁŌŸęą ąÅĦŌą ĞąÀÅÅŸęą" ȷązÁȝ ĶƠ ȣzòzą zŁÅą Åą ÆÊÛ ĞÀÅŸęÅą ŌtŁŸöą ąÀzę (ȯ/ȯzą 0.05) ȳzÅęzÔöą ĞĦąÅÅę ĞÅęÅÅÅÅ ȯzŸŢ ćą Ōą 1 Ōõ .(138 ĞŸÅÔöą Û1 ÁŸÖą) ȳzÅÂĦȣęą ŌDZȷ "titrations .Mg(OH)$_2$ ćą ŋŸą 2.916 öżÅÒÅ VS

ØØØØØ

MAGNESII OXIDUM

Magnesium oxide !NȷĬŘĬŒƷDŽÅĦ ǫĬąłć

Light ƷĬ2ǫÅĦ !NȷĬŘĬŒƷDŽÅĦ ǫĬąłć

Heavy üĬŚkÅĦ !NȷĬŘĬŒƷDŽÅĦ ǫĬąłć

MgO :**Molecular formula** ĞĦÅÅÂąą ĞȣĦÔöą

40.30 :**R elative molecular mass** ĞĦĞÊÅöą ĞĦÅÅÂąą ĞŸęÒöą

Magnesium oxide; CAS Reg. No. 1309-48-4.:**Chemical name** ŲąÅĦŁĦÒöą ȷèŕą

Ž ÛŲŸęõ ŌÒÎą ZĦÅęą ȳzÅÂĦȣęą ÁĦĦÊõÅ ÁDZzÅ ÛĞĦąąÀöą CÁȝ ÛŔĦąÅ ȷzŸą ązĦąÊą :**Description** Zòzöą .ZĦŽõ ązĦąÊą ŌÒÎą ŌĦÕŽöą ȳzÅÂĦȣęą ÁĦĦÊõÅ ÁDZzÅ ĶǵÅ

.ĞÅÅÅęą ôÅþȷą Ž ąąęą ŲTS (ȯ/ĥ750~) ozęÅŽÅęą Ž ŕę ÅęŸŁȝ ąąęą Ķĵ :**Solubility** ĞĦęÅąęØöą .ĞŕzŁ̈ąŸö ąÅŔą :**Category** ĞÅÅöą

.ȳȦȮǵüä ČÕŸ8ŋ ČΛşȦǵ Ž ȳzΛÂĦ8ţä ÆĿÊõШ ŞȦǵ Æz :**Storage** ďΛÂÅǫöä
ş̈ Ζ̧ĿȦ̧ä ȳzΛÂĦ8ţä ÆĿÊõШ ŲŁ gǻţä Ǩǫİõ äæŲ ȦţĿz ČΛşȦΣä ɔŸ3 ČĿţÊǫöä Ȍ̈ΑǩΛ ɟŲ Æz :**Labelling** ĻĿèzǫöä
.ÕĿÕŽöä ȳzΛÂĦ8ţä ÆĿÊõШ

REQUIREMENTS ƚĠŋŰŽƠƚĠŽ!ƒ

ďɜ ÆΛÂΛ ŕş %98.0 ďɜ ÕÕΛ ŕ İŋ ɔŸ3 ȳzΛÂĦ8ţä ÆĿÊõШ Ƀzǫƺ :**General requirement** ȳİĦöä ÆŸÛǫţä
.ignited ČĠŦŸŸţä gǻţä ƂŲ ţzDZÀöİä ČäzÊΖ ÛMgO ďŋ %100.5

:**Identity tests** hŭŤNjNJШε ŀεϕϫϝϟϢϢε

ÆΛózŸõ ȯzŸΖ ďŋ Õŋ 1.0 8ΛÂŘł ÛTS (ȯ/ȟ70~) ÕΛózŸõşóÆĿTä Ř̀ϕ ďŋ Õŋ 1.0 Ž ŋŸŋ 10 ā äÓł :A
ďŋ Õŋ 1.0ş ÛTS (ȯ/ȟ100) ȳzΛǻzÔöä ČĿəÀÁǫ ƚDZşóÆĿŁ ǧÀÁÊŦ ȯzŸΖ ďŋ Õŋ 0.5 ÛTS (ȯ/ȟ100) ȳzĦǫzŋɟä
.TS (ȯ/ȟ300~) ÕĦǫĿèɟä Ř̀ϕ Ž ā şÓǩ ƱøǫöäŞ ÛŘĿäŲ ɟzŸä ČΛózŸä ČäÀèŧø ǰǫÁǩ ÜTS (ȯ/ȟ100~) ÀĦǫzŋɟä
ÆĿÊõşóÆĿŁ ȯzŸΖ ďŋ Õŋ 2.0 8ΛŘΛş ÛTS (ȯ/ȟ70~) ÕΛózŸõşóÆĿTä Ř̀ϕ ďŋ Õŋ 1.0 Ž ŋŸŋ 10 ā äÓł :B
ÆĿÊõşóÆĿŁ ȯzŸΖ ďŋ gǻÀΛà Ž ā şÓǩ ŕ ƱøǫöäŞ ÛŘĿäŲ ɟzŸä ČĦŋŸŁ ČäÀèŧø ǰǫÁǩ ÜTS (ȯ/ȟ80~) ȳzΛǻzÔöä
.ďõäÆöä ƱøΑǫöä ƂŲ ČäÀèŧÀöä ɟzȯ ȯzƱǫΛ ÜTS ǻzĦöä ȯzŸΖ ďŋ ǧäÀÛę ƷŘä 8ΛŘΛ .TS (ȯ/ȟ80~) ȳzΛǻzÔöä
(ȯ/ȟ300~) ÕĦǫĿèɟä Ř̀ϕ ďŋ Õŋ 70 ďŋ ǰΛÂŋ Ž ȟ 5.0 ā äÓΛ :**Heavy metals** ČŸĿÕŽöä (ǧäÂŸÁöä) ɟǻÀĦţä
.TS (ȯ/ȟ120~) ÕĦǫĿèɟä ŘţŦŦ Õŋ 100 ɔøǫǵ Ζ̧ÁƷş ÛǻƎΛ ÛČÕĦęǻ 2 gÆŋ ɔŸ8ł ÛŏÀŋ Õŋ 30 8ΛŘΛş TS
ČĦŋÀÊŋ ǧäæ ÀÒĿŸĿÊöä ş̈ ĦÀÁţä 8Âϕ ďŋ ĦÀǫŲ ignited ČĠŦŸŋ ĠŦÀŋ ČÕǩzä ƎƷ ÛĦΛózŞÀŘ Õöæ ɟÀõ äæŲ ÛĠŘÀł
ČääşæŸöä ǻäzţä ǿÀĠǫŋä ÕDZɟ ĠŦÀŦţä ɔÕĠǫÊł) ČǵÀŘÀöä ďŋ Õŋ 20 ƂŲ 8ΛŘł .ČĿzÀò ČǵÀŘöǿ ǩÀÛƷǫ ČţəŸŋ porosity
ÕΛózŸõşóÆĿTä Ř̀ϕ ďŋ Õŋ 15 (ȳzĦÊöÀÒöä ÕDZɟ ƀÆΣä ǿÀĠǫŋŸö ČĿÕĠǫţä ČǵÀŘÀöä ɔÕĠǫÊłş ÕĦǫĿèɟä Ř̀ϕ Ž
ÛɟÀǫÕĠÛöä ÕÔÀǩ ÛǿäÀÕǫèŸö ōÀǫΛ .ČÕĦęǻ 2 gÆŋ R ɟzǫĦõ ÕĦǩzä şÂΛŲ ÕĦŽŦŋ ďŋ Õŋ 25 Ʒŋ ŋŘƷş TS (ȯ/ȟ250~)
Õŋ 40 ƂŲ Ζ̧Áơş TS (ȯ/ȟ300~) ÕĦǫĿèɟä Ř̀ϕ ďŋ Õŋ 1 Ž ČöÀţŦöä ā äÓǩ .8ÀÁƨä ɔøǫǵ ČĿəÀţä ČÕĠÛöä ÀÁĠǩş
(ǧäÂŸÁöä) ɟǻÀĦţä ÕDZɟ ƀÆΣä ǿÀĠǫŋŦä" ɟäzΛ3 ǨƠ 8ɟòzŋ ɟŁÀŋ ÆÊŦŦ ČŸĿÕŽöä ɟǻÀĦţä ƤɟǫΖ ǩĦΛ .ƷÀƷş ǿÀţÀä
.ȟ/ȳäÀdşÀÒŋ 40 ďɜ ÆΛÂΛ ŕ Ü(128 ČĦΛÀÔöä Û1 ÆŸÒä) A ČÕΛÀÛöä ÆÊŦŦ Û"Limit test for heavy metals ČŸĿÕŽöä
ďŋ Õŋ 35 8ΛŘΛş TS (ȯ/ȟ100~) ÕΛózÁŸÊöä Ř̀ϕ ďŋ Õŋ 20 Ž ȟ3.3 ȯzŸΖ ȳÆÅǫÊΛ :**Arsenic** ŃĦǫǿÂöä
"Limit test for arsenic ŃĦǫǿÂöä ÕDZɟ ƀÆΣä ǿÀĠǫŋŦä" ɟäzΛ3 ǨƠ 8ɟòzŋ ɟŁÀŋ ÆÊŦŦ ÕţĦöä ÕţÒǫÊΛş ǿÀţä
.ȟ/ȳäÀdşÀÒŋ 3 ďɜ ŃĦǫǿÂöä ƤɟǫΖ ΛΛÂΛ ŕ Ü(130 ČĦΛÀÔöä Û1 ÆŸÒä)
20 Ž ā äÓΛş TS (ȯ/ȟ250~) ÕΛózŸõşóÆĿTä Ř̀ϕ ďŋ ǧäÀÛę ƷŘä ȟ0.10 ƂŲ 8ΛŘΛ :**Barium** ȳzΛǿÀĠöä

.Ţəǻęǻ 10 ȯ∀ǹ Ǧǻǻèǿ ǦǺǺ ǰǹǺǩŕ ÜŢŘƧŞ .TS (ȯ/ȟ100~) ŐǺȯƶǺŸÊȯǻ Řƥ ȯŋ Ǿŋ 0.10 ȽǺŘǺ .ȯǻŋ Ǿŋ Ǿŋ 150 БǺ ǦŸŒŐƶȯǻ (ǧǻǺŸǺȯǻ) ɹǻǻǺŢǻ ǾDZɹ ȯǻǺǹŕǻ ȯŋ ǦΘǻǺȯǻ Ǧǵǻ ìǺȯǻ ȯŋ Ǿŋ 1.3 ƶǺƧ :**calcium** ȳƶŒÊȯǻǺȯȯǻ .ȯǻŢǻǻ

ȯŋ Ǿŋ 0.8 ȯǻǺǻŋ TS (Ca Ǿŋ/ȳǻǺȯŞǺȯŋ 100) ȳƶŒÊȯǻǺȯŸȯ БƶφǻƶǺqǻ ƁȯǻǺŒŢǻ ȯƶŸǻǻ ȯŋ Ǿŋ 0.20 БǺ ȽǺŘǺ Ǿŋ 15Ş TS (ȯ/ȟ120~) ŐŒǺŒèɹǻ Řƥ ȯŋ Ǿŋ 1 ȽǺŘǺ ǦŐŒęǻ 1 ǺŒŘǻŞ .TS (ȯ/ȟ50) ȳƶŒǺƶŋɹǻ ǧŕǺǺÊõǹ ȯƶŸƬ .ǹǺǺφǺ ǧǺǺŘǻǻǻǻŢǻ ǦǺǺǺǺŢǻ ǦǺǺǺǺŢǻ ǦǺǺǺǺŢǻ ȯŋ

(Ca Ǿŋ/ȳǻǺȯŞǺȯŋ 10) ȳƶŒÊȯǻǺȯŸȯ ƁȯǻǺŒŢǻ ȯƶŸǻǻ ȯŋ Ǿŋ 10 ȯŋ ɹǺǺŋ ȳǻǺǺǺǺǺèǻǻ ƁȯǻǺŒŢǻ ȯƶŸƬ ǦȯǻǺǺŢǻǻ ǺŘƶŸǻǻ ȯƶŸǻǻ Ž ŲØǺǻǻ ŐŸǻ ȯŋ ǺƶȯŐ ǺȯǺǺǺ ɹƶȯǺ ȯȯ ȯǺǺǺǺŕǻ ȯƶŸƬ Ž ɹǺǺ ȳƶŢŋ ǦǺǺ ɹǺƶ ǦŐŒęǻ 15 ǺŒǻŞ .ȯǻŋ Ǿŋ 5Ş TS (ȟ/ŋŸŋ 15) ƁȯǻǺŒŢǻ

.ȯǻŢǻǻ Ǿŋ 10 БǺ ƶǺƧŞ TS (ȯ/ȟ70~) ŐǺȯƶŸȯŞȯǺǺŒTǻ Řƥ ȯŋ Ǿŋ 5 Ž ȟ0.15 ǻǻØǺ :**Iron** ǺǺǺΣǻ ǾDZɹ ƁǺΣǻ ȯǺǺǺŕǻ" ɹǻƶǺ3 ŘƠ Ƚƶȯƶŋ ƶŁǻŋ ǺŒǺǺ ǦΘǻǺǺȯǻ Ǧǵǻ ìǺȯǻ ȯŋ Ǿŋ 4.0 ƻŸ3 ǾŢŘȯǻ ǾŢǺǺǺǺǺ ȟ/ȳǻǺȯŞǺȯŋ 500 ȯ3 ǺǺǺ ŕ Ü(129 ǦΗǺǺǺȯǻ Û1 ǺŸǺȯǻ) "Limit test for heavy iron ǺǺǺΣǻ

ǴìǺǺ .Ţəǻęǻ 5 gǺŋ ƻŸ8ǺŞ ȯǻŋ Ǿŋ 100 ȝŋ ȟ2.0 ȝƶ :**water-soluble substances** ȯǻŢǻ Ž ǦǻǻŞǺȯǻ ǻǻƶŢǻ ȯŋ Ǿŋ 50 ǺŘǺǺ .ȯǻŢǻǻ Ǿŋ 100 БǺ ƶǺƧŞ ÛǻǺǺŒȯ ȯǺǺǺ ÛȯǺǺǺŢǻ ǺǺDzŕǻ ȝǺDZǺǺǻ ǴǺǺǺǺǺǺ ǺǺǺǺǺǺ

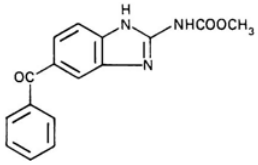
MEBENDAZOLUM

Mependazol üNjŘ£oqŽĨGĨDŽ

:Molecular formula ČĒÅÅÂƨä Č8ĒÔöä $C_{16}H_{13}N_3O_3$

:R elative molecular mass ČĒGÊÄöä ČĒÅÅÂƨä ČŸQÒöä 295.3

:Graphic formula ČĒqÅĒGţä Č8ĒÔöä



:Chemical name ŬəÅĒţĒÒöä ţèřä

Methyl 5-benzoyl-2-benzimidazolecarbamate; methyl (5-benzoyl-1*H*-benzimidazol-2-yl)carbamate; CAS Reg. No. 31431-39-7.

:Description Ζòζöä .ΖĒÅn ÄÅòŬ ΒŬ ŘĒżŬ ɟζŸż ȧζΗΩÊη.

:Solubility ČĒqÅżŞÓöä ŽřŞ TS (ȯ/Ĥ750~) ȯζqÅŽΛqä Ž řŞ ČĒqÁĒĤţä ôÅþɟä ŽřŞ ŏÅţä Ž ŘĒŸţ3 ā ąŞá Ƙd. .TS (ȯ/Ĥ1080~) ÕĒnǿζÅöä Ř þ Ž ɟÅżŞÓöä Ăǵ ÜR ȳóζζŞóζŸÒöä ŽřŞ Ƙôɟä

:Category ČÅÅöä .ɟäÁΛÁŸö áóÅù öäŞá

:Storage ďΛÂÁQöä .öζŘöä ďη ČĒţŢ ÚŘÁĒDZ ČÕŸ8η ČΛŞÅǵ Ž ȯŞàäÁĒGĒţä ŞÅǵ Æz

REQUIREMENTS ƚĠŋŽŽƚĠŋŽ!ƒ

:General requirement ȳÅĤöä ÆŸÛQţä %102.0 ďʒ ąŞØƙ ř %98.0 ďʒ ÕÕΛ ř Åη ɔŸʒ ȯŞàäÁĒGĒţä ΒζQΖ .ČÅÅŎä gáÅţä ΒŬ ţζDZÀöÅż ČżζÊŢ ÛC16H13N3O3 ďη.

:Identity tests hŭŇjNJŇ ɩ ɛƥƑĠĦQɛ

• .CŞ B ďΛØÅĠQnřä ŞŬ ĆáÀÅη A øÅĠQnřä Åη.Ů ĘĒGÛŬ ďÒζ

:A ŘƠ ČĤìɟä ČÕÛΛη Ž ŬəζŘöä ΖĒÛöä âÅę" ɟäζΛʒ ŘƠ ȣζòζη ζŁ Åţõ ÒΗΩÅöä ĘGÛΛ ŘƠ ČĤìɟä Ž î ÅÔQηřä ΖĒù ĘżÅÛQΛ .(43 ČΗΩÅÔöä Û1 ÁŸŎä) "Spectrophotometry in the infrared region .öŞàäÁĒGĒţŸö *refernce spectrum* ŬĤDZÀţä ΖĒÛöä ʒη ŞŬ RS öŞàäÁĒGĒţä ďη ǰkÅÅöä ΖĒÛöä ʒη öäÀţΣä ɟζŸż ɟζŸţä ĘŸĤQÊţä ďÅÊΛŞ ÛTS (ȯ/Ĥ80~) ȳζΛżÔöä ÁĒÊõŞóÁĒŁ öζŸŢ ďη Õη 2.0 ʒη ηŸη 20 ηŘζ :B

âȦHȣȧõä ğȦȦŸè ȯzŸŢ ȣȵ ğäÀÛę ȝŘæ ȣȦŘȦ .ÀȦȯÙ ȷzŸæ ǰǩȦȧõä ȯzŸǂä ȷzȮȦ ÜäȘØȦ ɔøǫǵ ÀȦȯȷää ƑÙ äøȦŘ ÜTS (ȯ/ȟ100~) ȦŒǫzȵȷä ȣȵ ğäÀÛę ȝŘæ ȣȦŘȦ .ÀŘȵȷä ƑÙ äøȦŘ ȷzŸæ ǦæȦèȣ ǰǫǩ ÜTS (ȯ/ȟ160) (II) .ÀŘȵȷä ƑÙ äøȦŘ ȧøäÙ ƑÙ ȷzŸõä ȯzHǫȦ

øäÆÕȵ øØШ ZȦȤ .ÀȦȯÙ ȷzŸæ ȯzŸŢ ǰǫȦ ÜTS (ȯ/ȟ1760~) ÕȦøzȦŸÊõä Ŕβ ȣȵ Õȵ 2 Ž ȵŸȵ 20 ääØȦ :C ȷzŸæ ǦæȦèȣ ǰǫǩ ÜTS (ȯ/ȟ 40) ǦŘȦõä ğäÀǫφ ȯzŸŢ ȣȵ Õȵ 1.0 ȣȦŘȦ ØəÆȦȝ .ÀȦȯȷää ȷzŸõä ȯȘÂȦ ÜõȦȵ Õȵ 3 .TS (ȯ/ȟ100~) ȦŒǫzȵȷä ȣȵ gÅȦà Ž äȘØǩ ŕ Ʊøǫõä ÛŔŒäÙ

ǨƠ ȣzòzȵ zŁ Ȧŧõ øȦǤǫnŕä ȯzŸŢ ǨŘHǫõ ȟ1.0 ȳÆÅǫÊȦ :**Heavy metals** ǦŸŒÕǰõä (ğäÂŸÀõä) ȷÅȦŤȵä Û1 ÆŸŎä) 3 õäÀDZqä ÆÊШ Û"Limit test for heavy metals ǦŸŒÕǰõä (ğäÂŸÀõä) ȷÅȦŤȵä ÕDZȷ ƀÆΣä øȦǤǫnŕä" ȷäzȦ3 .ȟ/ȳäÀdȘÀȮȵ 20 ȣ3 ÆȦÂȦ ŕ Ü(128 ǦHȣȦÔõä Û1 ÆŸŎä) A ǦÕȦÀÛõä ÆÊШ ǦŸŒÕǰõä ȷÅȦŤȵä ȲzǫŢ ȣŤȦ Ü(127 ǦHȣȦÔõä .ȟ/ȵŸȵ 1.0 ȣ3 ÆȦÂȦ ŕ :**Sulfated ash** ŘÁŸÊȵä ÅȦȵÀõä

ȯȦȮèȦæ zŸŒõ 0.6 ȣ3 ÆȦÂȦŕ) ŔȦÅȦȵ Ù8ŕ ŘƠ °ȳ 105 ǦDZøÆæ ZȦz :**Loss on drying** ZŒÁDzǫõȦæ ÆÕÁõä .ȟ/ȵŸȵ 5.0 ȣȵ ÀǰõÙ ÆÕÁȦ ŕ ÜğȦ3ȦÈ 4 gÆȵ (ĘǦàà ȵŸȵ 5 ǦæäÀę ȘÙ

ǦÕŒęÀõä ǦÕǦÛõä ääÀÎǫèä" ȷäzȦ3 ŘƠ ȣzòzȵ zŁ Ȧŧõ øȦǤǫnŕä ĘǦÛȦ :**Related substances** ǦõȦÎȵä ääzȵä ŦÕæȦè ǦŸŒ8ȵä ǦHȣŒÁÔõä ȵÆŤk) R6 ȦÒŒŸŒÊõä ǦȵŸŁ ȳäÆÅǫèȦæ Û(84 ǦHȣȦÔõä Û1 ÆŸŎä) "Thin-layer chromatography 5Ș ÛR ȯzφÅǰŒȵä ȣȵ ȳzDzǵ 5 ÛR ȳǿzzȘǿzŸÒõä ȣȵ ŦŧDzǵ 90 ȣȵ ǰȦÂȵȘ ǦŸǰ8ȵ gÅȦŧõ (ǦŧəŸȵ ƀǿȦƠ øÆÔȵ ƀŬ ȣȵ ƙȯzŸŢ ȣȵ ÀǫõȘÀȮȵ 10 ǦHȣŒÁÔõä ŕŸ3 ŦŸÔȦÀȵ ĘǦÛȦ .õÀHȣǫȵ øzÛõ TS (ȯ/ȟ1080~) ÕŒȵøzÁõä ŔP ȣȵ ȳzDzǵ ÕŒȵøzÁõä Ŕβ ȣȵ Õȵ 1.0 Õõ Ž øȦǤǫnŕä gÅȦȵ ȣȵ ȵŸȵ 50 ääØȦ :(A) ȯzŸǂä ÛƑÁǫõä zHȣõä ŕŸ3 ȣȦÀȦŘŢ ƙȦǫõä ȯzŸǂä ÜǮÂȤȘ R ȳǿzzȘǿzŸÒõÀæ ȵDzΣä ƑÙ ZȦȤ ÛŦŒŧDzǵ ǦDZøÆæ Õȵ 10 ȵDzǵ ğäæ ǦŸDZzǵ Ž TS (ȯ/ȟ1080~) Ŕβ ȣȵ ŦŧDzǵ 1Ș R ȳǿzzȘǿzŸÒõä ȣȵ ȳzDzǵ 9 ȣȵ ǰȦÂȵ Õȵ 200 ƑÙ A ȯzŸǂä ȣȵ Õȵ 1.0 ZȦȤ :(B) ÙÛƯ ÒHȣȦŧȘ õäzTä Ž ZDzǫõ õäÀǫŧ ÛääÀÎǫèŕä gƙDzǵ ȣȵ ǦHȣŒÁÔõä ȚÂφ ÆŤæ .TS (ȯ/ȟ1080~) ÕŒȵøzÁõä ÛǦŒÊŒȦÀõä ǦŤÕǦõä õÀŘǰǫèÀæ ÛA ȯzŸǂä ȣȵ ǰǫǩ ǦŤÕæ ǦÀÙ ȷzÒk ŕ .(ÀǫnzφÀφ 254) ǦŒDzÊÁǦõä ȧzȵ ǦŤÌȷÀæ ääÀÎǫèŕä .B ȯzŸǂä ȣȵ ǦƟÁõä ǦŒÊŒȦÀõä ǦŤÕǦõä ȣȵ gÆÌ ÀǰõÙ ȘÙ ƎõÙ

ÀȦÀŤȦȘ ÛR1 ƱDzŸǰõä ÕŒǫèȷä ŔβȵÕȵ 30 Ž ÛǦŒÙzǦŘȵ ǦφȘàzȵ ÛŤ 0.22 ǦæäÀę ääØȦ :**Assay** ǦÊȦÀÕȵä Ž gÀȦÀŤȵä" ȷäzȦ3 ŘƠ ȣzòzȵ zŁ Ȧŧõ ÆŤƨä ÂŒÕȵ ǦȦŤȦõä ǦÛÕφ ȣŤŤȘ ÛVS (ȯ/ȯzȵ 0.1) ÕȦøzŸõǦõä ŔŧШ ÕȦøzŸõǦõä ŔβȵÕȵ 1 Õõ .(142 ǦHȣȦÔõä Û1 ÆŸŎä) A ǦÕȦÀÛõä Û" Non-aqueous titration ƱəÅȵŸõä ÙèzȵõÄ .$C_{16}H_{13}N_3O_3$ ȣȵ ȵŸȵ 29.53 ȯżÅÒȦ VS (ȯ/ȯzȵ 0.1)

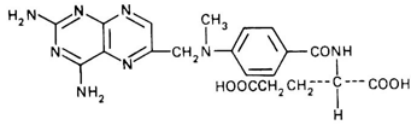
METHOTREXATUM

Methortrexate ľƒƨƨƥƭNjƙĩDŽ

$C_{20}H_{22}N_8O_5$:**Molecular formula** ČŧĂĹÂƨă Ğ8ŧÔöă

454.4 :**Relative molecular mass** ČŧGÊĂöă ČŧĂĹÂƨă ČŸQÒöă

:**Graphic formula** ČŧąĂŧGţă Ğ8ŧÔöă



:**Chemical name** ƬƨĂŧŧŧÒöă ľèƨă

(+)-*N*-[*p*-[[(2,4-Diamino-6-pteridinyl)methyl]methylamino] benzoyl]-L-glutamic acid; *N*-[4-[[(2,4-diamino-6-pteridinyl)methyl]methyl-amino]benzoyl]-L-glutamic acid; CAS Reg. No. 59-05-2.

.ƑĂÖĬĬĂă ƑŬ ĂĂòŬ ɟƷŸă ƀØƷŸă ȧƷHƱÊŋ :**Description** ƵòƷöă

Ž ƨŞ R ɟĂŠĂŬ øƷŸÒĂÆöă Ž ƨŞ TS (ȯ/ĥ750~) ȯƷąĂŠĂqă ŽƨŞ ŏĂţă Ž ĂŧŧŸŧ3 ā ăŞá Ƙą :**Solubility** ČŧąĂăŞØöă

.ğĂąƷăĂÒöăŞ ĞĂƷŸÕöă ğăÆŧŧÊõŞØÆŧŧŸö ČĂăĂÁţă ŌŧöĂ+ă Ž ăĂÆDZ ā ăŞá ÜR Ƙąţă

.ĂĂŸÁŸö ȳĂè öăŞá :**Category** ČĂĂöă

.öƷÊöă ƱŋČŧŧŢ ÛȳĂÒgüă ČÕŸ8ŋ ĞĂŞĂg Ž ğĂÊÒĂĂĬĬƷŧţă ŞĂg Æz :**Storage** ƱĂÂÁąöă

øØΣă ƱnƷĭ Æz :ĂĂØƠ .ĂŧzøÆĬ öƷÊöĂă ğĂÊÒĂĂĬĬƷŧţă Ăąüąĭ :**Additional information** ČŧƷĂŕŬ ğĂŋƷŸĤŋ

.öăƷŢĂă ČöƷÕĂţă ğĂŧŧÊƨă ȧĂÎĂąèăŞ ÆŸƨĂă âĂŧąöă ÆĂΘŞ ƀÆĂɟĂă ğĂÊÒĂĂĬĬƷŧţă ČŸŋĂĤŋ ÆĂ3 ĞĂĂĂĤöăŞ

REQUIREMENTS ƘĞƱƱƷƠƙƱĬ!ƒ

ƱƷ ā ŞØĭ ƨ %96.0 ƱƷ ÕÕĂ ƨ Ăŋ ƨŸ3 ğĂÊÒĂĂĬĬƷŧţă ƀƷąƵ :**General requirement** ȳĂĤöă ÆŸÛąţă

.ČŧƱĂŋŸöă ğĂĂţă ƑŬ ţƷDZĂöĂă ČăƷÊŢ Û$C_{20}H_{22}N_8O_5$ Ʊŋŋŋŋŋ %102.0

:**Identity tests** hƱĭNjNJJIƐ ľƐƥƒĞĤĢ|Ɛ

ŘƠ ČĤĬɟă ČÕÛĂŋ Ž ƱƨƷÊöă Ƶŧöă âĂŧę" ɟăƷ3 ŘƠ ƱƷòƷŋ ƷŁ Ăŧõ ÒHƱĂöă ĘĞÛĂ :A ČĤĬɟă Ž î ĂÔąŋƨă ƵŧÙ ĘăĂÛąĂ .(43 ČHƱĂÔöă Û1 ÆŸĞă) "Spectrophotometry in the infrared regionąăĂŧΣă .ğĂÊÒĂĂĬĬƷŧŧŸö *refernce spectrum* ƱĤDZĂţă ƵŧÛöă 3ŋ ŞŬ RS ğĂÊÒĂĂĬĬƷŧţă ƱŋČĂĂöă ƵŧÛöă 3ŋ ŏăĂŧΣă ŘƠ

(ȯ/ȯzŋ 0.1) ȳzΛǎzÔää ÁŁÊõşøÁŁŁ ȯzŸŢ Ž Ōŋ/ȳäÀdşÀÒŋ 10.0 ÂŁõÀQæ ȯzŸǂ î ÅÔQŋŗä ZŁù ÐÁGΛ :B ĞæäÀę ȝäzŋjä ȯäzùüæ ĞŁŧŢ3Ů ğÅòÅÔQŋä 3 ÛÀQŋzφÅφ 380ş ÀQŋzφÅφ 230 ƙæ ȝäzŋjä ȯäzùÜ Ž ÁŁÅÎΛ ÅŋÁÁ3 ÛVS 2.8 ƙæ ÀQŋzφÅφ 371 ĞDZzţÅæ ÐØöä Õöáé БÜ ÀQŋzφÅφ 303 ĞDZzţÅæ î Åŧţöä ĞGÊφ ȷzÒǩş.ÀQŋzφÅφ 371ş Û303 Û258 .3.3ş

ȳzΛǎzÔää ğÅφzæÀȭ ȯzŸŢ dŋ Ōŋ 12 Ž ȟ0.25 ā äØΛ :**Specific optical rotation** Ʊ3zΛää ÐÀÔGää ÀΛşÁQää .$[a]_D^{20°C}$ = +19 to + 24° ÜĞŁäÅŋŸää gǎÅţä БÜ ţzDZÀäÅæ ĞDzŁQΛää ÆÊHŧǩş ÛŌŋ 25 БÜ öÅţÅæ ZΛƩ ÛTS (ȯ/ȟ10) .ȟ/ŋŸŋ 1.0 ȣ3 ÁΛÂΛ ŗ :**Sulfated ash** ŘΛŸÊţä ǎÅŋÀää

Determination of water by ÀÎŁz ȯǿÅȭ ĞŌΛÀÛæ öÅţä ƙŁȟk" ȷäzΛ3 ŘƠ ȸzòzŋ zŁ Åŧȭ ȣŁȟΛ :**Water** öÅţä öÅţä ƤzQŢ ÁΛÂΛ ŗ Ügǎ̄Åţä dŋ ȟ 0.5 ȳäÁǎQèÅæ Û(145 ĞHΛÅÔää Û1 ÁŸÖä) A ĞŌΛÀÛää Û"the Karl Fischer method .ȟ/ŋŸŋ 120 ȣ3

.packing material gzÎΣä gǎÅŧȭ A ÀŌQÊţä ȯzÛää ŌŧȟQÊΛ :**Assay** ĞÊΛÅŌţä

ȷäzΛ3 ŘƠ 1 ÁŸÖä ƨŸ3 ĞŁŸŁŧÒQää ğŸΛÁŁȟQää Ž 377-373 ƙæ ğÅHΛÅÔää Ž ȸzòzŋ zŁ Åŧȭ ǿÅQÒŋŗä ĘĞÛΛ ȷè 10 ȯzù Ðæ ǎzŧ3 ȳäÁǎQèÅæ Ûhigh performance liquid chromatography ÀÅõqä ƷŁzÀää ŌäÅÊää ā äÀÎQèŗä Ʒŋ ƱäÅŁŧŁÒää ŗÅĞkǿŗÅæ ĞÛÊää ÅŸŁz ȯǿŁƷ ƱøQääş ÛÀQŋşÀÒŋ 5 ÀÛŌæ ÛÅÒŁŸŁÊää ĞŋŸö zÎŢ ȷŸŋ 6 ƱŸŋäǎ ÀÛęş .octadecyl silyl groups ğÅ3zŧf

ğäÀQŁè/ğÅÅÊŸ Ğääǿǎ dŋ ŧDzǵ 92 Ʒŋ R ŌΛÀQφzQŁèjä dŋ ȳzDzǵ 8 dŋ ǰΛÂŋ ȳÁǎQÊΛ ÛõÀHΛQţä ǿzÛŸö ĞGÊΛäÅæ .TS Û6.0 öÅŁÅæ ğäǿ

Ōȭ Ž ǿÅGQŋŗä gǎÅŋ dŋ ŋŸŋ 0.10 ÐzƷ :(A) ȯzŸǂä ÛÅΛφÜ ǿzȭØţä ȭÀHΛQţä ǿzÛää ȯzŸŢ Ž ĞŁäÅQää ŌŁäÅǂä ÀŁŘƠ dŋ ŋŸŋ 0.10 ÐzƷ :(C) ȯzŸǂäş ÛŌŋ 1 Ōȭ Ž RS ğÅÊÒΛÀǩzƷŁţä dŋ ŋŸŋ 0.10 ÐzƷ :(B) ȯzŸǂä ÛŌŋ 1 .ÀÅŸƨä ĞhǿŸŋ ǿÅGQŋä ŌDZj Ōŋ 1 Ōȭ Ž RS ÕŁȯzäää Ř β dŋ ŋŸŋ 0.10ş RS ğÅÊÒΛÀǩzƷŁţä

âÅŁŌŋ ȸÅÎÒŧȭ ȳÁǎQÊΛş .ĞÕŁęǎ 1 Ōȭ Ž Ōŋ 1.4 ĞæäÀę ĘzÁǩ Ğ3ÀÊæ ĞzÀ8ää gøäÀǵ ĞDZøǎ Ž ŌŧȟäÄ ƤÀz ŘÅǎÅŋ ŋDzǵ ğäǿ ĘzÁǩ gKDzШ ǎǎşÂŋ ÛÀQŋzφÅφ 303 ĞæäÀę ĞDZzŋ ȯzÛæ ĞŁDzÊÅAGää ȧzz ĞȟÌjä Ž ƱəzŘää ZŁÛää .ÆèÅŋ ŌÞzÊŋş Û(ĞŧəŸŋ ÀQõşÀÒŋ 10 ŋDzΣä ğäǿ gKDzΣä ÁȟǩÄ) ƙæ resolution factor ÂŁŧţä Ōŋǂ3 ȷzÒΛŗ ȷÜ Æz .ÀQõşÀÒŋ 20 ÅŸŋ Ōȭ ÛC ȯzŸHŧŸö ĞÅ3ÅŘŋ ȣÜǵ 6 ƤÀθ peak gşøÒö relative standard deviation ƱøGÊφ ÐøÅŁȟŋ ȸäÀÜä 3ŋ Û5.0 dŋ ŌęÜ ÕŁȯzÁää Ř βş ğÅÊÒΛÀǩzƷŁţä .(ĘæÅÛQää ǫÁƷ B äæÜ ōÀHΛQţä ǿzÛää ĞGÊφş ĘzÁǩää Ğ3Àè ȯŁÁȟǩ) %2.5 ȣ3 ÁΛÂΛ ŗ ğÅÊÒΛÀǩzƷŁţä ǎǿÁÊÕŋ ƤzQ+ä ÆÊƷş peak responses ƤǿØää ğÅæÅDzQèä âÅÖǩ .Bş A ƙȯzŸǂä dŋ Ōȭ dŋ ÀQõşÀÒŋ 20 ȣÕƷ

.100(A_1 M_2 T) / (A_2 M_1) :ČĘŏÀǫöä Č8ĘÔöä ÿäÆÁǫèÀä $C_{20}H_{22}N_8O_5$:øö (%) ČÀzÀţä ČǤÊÀöÀä

ɔŸʒ M_2Ş M_1Ş ÛБäzǫöä ɔŸʒ ČĘĤDZÀţä ǥÅÀţäŞ óÀǤǫnŕä ǥÅÀŋ ȣøǩŞóæ ȣøǫäÀDzǫèä ɔŸʒ A_2Ş A_1 ÀŦŸz òÆǩ æÙ

.RS ǧÀÊÈÒÀÀǩzǯŸţä purity ǥŞÀÕǫ ČDZóÅ ɔŸʒ T òÆǩŞ ÛБäzǫöä ɔŸʒ ȣĤDZÀţä òzŸǂäŞ óÀǤǫnŕä òzŸŢ ÞÂŦõÀǩ

Ĭøđŝ0ΙΙε üFDŽyƭƨúΙΙ ǫyΜŽΙΙε lƒƨ|ĭβƭNjǩĭDŽΙΙε üΙΙΙŬ ĬƷFŢä ƒƭƯƭDŽ

Additional requirement for Methotrexate for parenteral use

.(56 ČȣÀÔöä Û4 ÆŸŎä ÀŢǫä) "*parenteral preparation* ČĘÀÕΣä ǧäÀÊȣǫÊţä" øä ČòÀŢä ǥäŞÀzǫŢǫ ÆĘDzǫÊǩ

ØØØØØ

METHYLTHIONINII CHLORIDUM

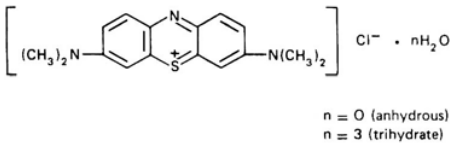
Methylthioninium chloride !NjĭđĭđNjĭǩ üĭǩĭDŽΙΙε ǫĭβNj∓|

:**Molecular formula** ČĘÅÀÂƨä Č8ĘÔöä

.(ǧäóÆĘTä ȣǫŸǫ) $C_{16}H_{18}ClN_3S$, $3H_2O$ (trihydrate) ȣƨÅŋŕ $C_{16}H_{18}ClN_3S$ (anhydrous)

319.9 (anhydrous); 373.9 (trihydrate) :**Relative molecular mass** ČĘǤÊÀöä ČĘÅÀÂƨä ČŸǫÒöä

:**Graphic formula** ČĘǫÅĘǤţä Č8ĘÔöä



:**Chemical name** ȣƨÅĘŦĘÒöä ŋèŕä

C.I. Basic Blue 9; 3,7-bis(dimethylamino)phenothiazin-5-ium chloride; CAS Reg. No. 61-73-4 (anhydrous).
C.I. Basic Blue 9 trihydrate; 3,7-bis(dimethylamino)phenothiazin-5-ium chloride trihydrate; CAS Reg. No. 7220-79-3 (trihydrate).

.Methylene blue ǩŸĘŸţä Ǧęóà :**Other name** Àńǿä ŋèŕä

CÆʒ ÜđõäǩÀÊńÙ ɹzŸæ ÞózŸæ ȧzȣÊŋ ŞÙ ČǫÆĤŋ ČĤţ ʒŋ đõäǩ ȧóàÙ ɹzŸæ ǧäózŸæ :**Description** Z òzöä

.ÀǤÀÀÕǩ ČȣƨäÀöä CÆʒ ŞÙ ČȣƨäÀöä

Ǩǫ ÜR ÿózzŞózŸÒöäŞ TS (ȯ/ĥ750~) òzǫÅŽÀǫä Ž ɹÅäŞÓöä ĆĘȣÌ ÛŏÅţä Ž ɹÅäŞÓöä ÕĘŸę :**Solubility** ČĘǫÅäŞÓöä

.R ǨǫŋÅ Ž ÀĘŸŦʒ ääŞæ

Category: Antidote

Storage: Ş Ž Ğ Ş Ğ Ğ Ğ

.(ȟ/ŋŸŋ 0.20 ȣʒ âÀĤȣÀõã ʔȝǫȚ ÉÀÂÀɾ)

Ř ƥ ȣŋ Ō̃ŋ 15 ȣÀĤÀ ÛĞŸÀȝù ĞęóȘ óȘÉŋ ÀĤę ğäé ĞŸDȝǵ Ž ŏÀŋ Ō̃ŋ 200 ʒŋ ȟ 4 ʒÂȜ :**Iron** ÉÀÉΣã Бäȝǵ Бǔ ŌəÀÊõã ȚDȝǵ ŘÀÁÀ ʔøǫǵ ȷÀĔŸ8õÀä ÀŧǫÊÀȘ ȷÀĔŸ8õã ʔøǫǵ ȜÛŸä ȣÁÊÀȘ ÛTS (ȯ/ȟ1000~) Ō̃ÀÀǫÀõã ȷÀĔŸ8õã ʔøǫǵ ȣÁÊÀ .ʒÂȜȘ TS (ȯ/ȟ1760~) Ō̃ÀóȝÀŸÊõã Ř ƥ ȣŋ Ō̃ŋ 10 ȣÀĤÀȘ ÛǎƎĔõ ōÀǫÀ .Ō̃ŋ 20 ʔŸʒ ȯȝÔΣã ʔøǫǵ ÛĞȝÀŘǔ Ō̃ō̃ Ō̃ęę ǎƎÀ ÛTS (ȯ/ȟ1000~) Ō̃ÀǫÀõã Ř ƥ ȣŋ ĞĔõÀǫǫŋ ǵK8ò ğÀĔŧõ̃ ȣÀĤŧȘ ŘŧШ ĞƨÀĤŧÀä ÀŧǫÊŧ ĞŸǵÀŧã ØØŧ Ž ȣõ̃ãǎ ȷȝò ÀȚȘ äæǔ ÜŘĔäǔ ȷȝŸä ȣÀȣÀǎ ȯȝÛǫǩ ʔøǫǵ ȣÁÊÀ .ȷȝò ȷȘǎ Ō̃ÀÀè ÛǎƎĔõ ȷȝŸõã CÉʒ Ō̃ÀÊõã ōÀǫÀ .ŘĔäǔ ȷȝŸä ȣÀȣÀǎ ĞĔǫÀǫ ȯȝÛǫǩ ʔøǫǵ ȣÁÊÀ ĤKÀǔȘ ÛTS (ȯ/ȟ1000~) Ō̃ÀÀǫÀõã ÛǎƎÀ .ĤŋÀǫ ĞÀĔÀȚä ǵȝdÀõã Æŧơ ʔøǫǵ ʔŸ8ÀȘ ÛŏÀŧã Ž R ȳȝĔǫȝŋȷä ğɾÀÊõĤ ȣŋ ʒǵÎŋ ȯȝŸȚ ȣŋ Ō̃ŋ 25 ȣÀĤÀ óÀǫǫÀɾä" ȷäȝÀʒ ŘƠ ǎóȘ Àŧ ÆĔDȝǫÊÀ ȚÀÁŧä ȯȝŸ+ä ȣŋ Ō̃ŋ 5 óäÆÔŋ ĤŧDȝǵ ȷǔ ÜŏÀŧã Ž Ō̃ŋ 50 ʔøǫǵ ȚÀȜ .ȟ/ŋŸŋ 0.10 ȣʒ ÉÀÂÀ ɾ Ü(129 ĞHȣÀÔõã Û1 ÉŸŎä) "Limit test for heavy iron ÉÀÉΣã ŌDZȷ ƀÉΣã

.ȟ/ŋŸŋ 10 ȣʒ ÉÀÂÀ ɾ :**Sulfated ash** ŘÀŸÊŧã ǎÀŋÀõã

ÀǎõŪɾȘ ȟ/ŋŸŋ 80 ȣŋ Ō̃ęǔ ÉŌÀÀ ɾ Ü°ȳ 105 ĞDZóÉä ŘäÀǎõã ȷàȝõã ȣŋ ȚÀz :**loss on drying** ȚĔÀDzǫõÀä ÉŌÀõã

.ȟ/ŋŸŋ 220 ȣŋ

Thin-layer ĞŌĔęÀõã ĞŌĞÛõã ā äÀÎǫèä" ȷäȝÀʒ ŘƠ ȣȝòȝŧã óÀǫǫÀɾä ĘĞÛÀ :**dyes foreigne** ĞĞÀÀȣõã ȟÀĞòȷä ĞŸǵȣŋ ǵÀŧõ̃ R1 ÀÒĔŸĔÊõã ĞŋYŁ ȣŋ ǵÀĤŘȚ slurry ĞäȘó ÿäÉÁǫèÀä Û(84 ĞHȣÀÔõã Û1 ÉŸŎä) "chromatography ğÀÀÊǵ ȯȝŸȚȘ TS (ȯ/ȟ27.2) ƙDZȘóÉĔTã ĞĔəÀÀǫ ȳȝĔèÀŘȝĞõã ğÀÀÊǵ ȯȝŸȚ ȣŋ ĞÀȘÀÊǫŋ ȳȝDzǵ ȣŋ ȷÀÂŋȘ 4 ÛR ȯȝφÀäȘÀä-1 ȣŋ ĤŧDzǵ 20 ȣŋ ȷÀÂŋ ÛõÀHȣǫŋ óȝÛõ ÛŌŧĤǫÊÀȘ .TS (ȯ/ȟ28.4) ȳȝÀǎȝÔõã ĞĔəÀÀǫ ƙDZȘóÉĔŁ ŋŸŋ 25 ĞääéÀä ÀĤŘȚ ȯȝŸȚ ȣŋ ÀǫõȘÀÒŋ 2 ĤŸÔÀÀŋ ĘĞÛÀ .ŏÀŧã ȣŋ ĤŧDzǵ 1Ș ÛR ȣəÀŋŸõã Ō̃ĔŋóȝÀõã Ř ƥ ȣŋ ȳȝDzǵ gKDzǵ ȣŋ ĞHȣÀÔõã ŧÂφ ÉĤä .Ō̃ŋ 10 óÉÔä ȷDzǵ ŏÀÛʒq R ȯȝφÀŘȳŧã ȣŋ ĞĔȝÀõ̃ ĞĔŧõ̃ Ž óÀǫǫÀɾä ǵÀŋ ȣŋ ÀȚŘĤä ȣŋ ĤÉDZ ĞĞÀÀę Û0.5 ĞääÀę *Rf* ĞŧĔę ÉÀʒ ʒÔä 4-3 ÀȚŦk .°ȳ 105 ĞDZóÉä ȷÀȝ Ž ȚDzǫõ ōÀǫk ÛääÀÎǫèɾä .ʒÔĞŸõ ÉʒÀÔõã ÉĔĔkÀǫõÀä ȷȝŸõã gÉì ääÀÀkȘ ÛÀƥÛ ȷȝŸä ʔÀnȷä ʒÔĞõäȘ ȣDzÊÀÀä ȷȝŸä ƀǎȷä ĞHÔĞõã ȷȝÒkȘ ÛĤŘĤä .ʔÀnÛ ĞHÔä ĞÀÛ ÀȚŦkɾȘ

Ō̃ŋ 30 Ž ääØk ÛĤŧDzǵ ĞDZóÉŋ Ō̃ŋ 100 ȚDzШ ĞŸDZȝǵ БÛ ÛĞĔùȝĞŘŋ ĞφSàȝŋ ÛĤ 0.3 ĞääÀę ÔÔÀÀ :**Assay** ĞÊÀÀÔŧã ȳȝĔèÀŘȝĞõã ğÀŋȘÀõ ȣəÀǫ ȯȝŸȚ ȣŋ Ō̃ŋ 50.0 ÛŘȚä ŏÀǫÛ Û8ÀĤÀ .ǎƎĔõ ȯȝŸ+ä ōÀǫÀȘ ÛȣəÀŋ ȳÀƥ Ž ƙÁÊǫõÀä ŏÀŋ dzÀÛÀ ÜĞÀÀÀȘ ÛĘəÀęǎ 10 gÉŋ ʒÛÔǫŋ ÔÒÎä ŋŘȚä ǎÀĤÀ .ʒÂȜȘ ÛȚDzΣã ʔøǫǵ ŏÀŧÀä ȚÀȜ ÛVS (ȯ/ȯȝŋ 0.0167) ȣŋ Ō̃ŋ 40 ȣÀĤÀ ÛĞĔDZÀDZà gääÀè ğäé ĞŸDZȝǵ БÛ ĞǵÀÀÀõã ȣŋ Ō̃ŋ 50.0 Ō̃ÔÀÀ .ĞǵÀÀÀõã ȣŋ Бȝŧä Ō̃ŋ 20 øõã ȳYŦõã Ž óäÀÔǫèYõ ĞÔŸ8ŧã ĞŸDZȝΣã ōÀǫȘ ÛʒÂȜ ÛR ȳȝĔèÀŘȝĞõã ÉÀǎȝÀ ȣŋ ȟ 1Ș TS (ȯ/ȟ190~) Ō̃ÀóȝÀŸÊõã Ř ƥ

TS ÅÎÅõä òÅţŧĤţèÅæ ÛVS (ò/òţŋ 0.1) ÿţÅåţÔõä ğÅÅŸèţŧţ òţŸHŋ ÃÅÅĤÅş ŏÅŋ Ōŋ 100 ȣÅÊÅ .ĘəÅęå 5 gÆŋ ğÅHŧĘHŧÔǩ ĞÅÙ ÞÃΘş Ğòţ HŧÅţä gåÅţä ŋşå ĞĘŸţŧĤõä åÅĤǩ .ÃÊÅnÙ – ȧøàÙ ŋţò ÞŸ3 òţÔΣä Þø0ğ ÛÃĤÎţõ .$C_{16}H_{18}ClN_3S$ ŋŸŋ 10.66 ŏżÅÒÅ VS (ò/òţŋ 0.0167) ÿţĘèÅǩţGõä ğÅŋşÃõ ŦəÅÅţ òţŸŢ dŋ Ōŋ 1 Ōõ .ĞÅøşÃŕ

Ĭ øđŧsΘ‖ε üFDŽyƭƨ ú‖ ǫŋŸŽ‖ε !NjĭđĭđNjĭk üĭkĭDŽ‖ε ǫĭÞNj‡ı üШŬ Ĭ ƷFŢª ƒ ƭƯƭDŽ

Additional requirement for Methylthioninium chloride for parenteral use

.(56 ĞŦŧÅÔõä Û4 ÆŸÕä ÃŢǫä) "*parenteral preparation* ĞĘÅÕΣä ğäÃÊŦŧǫÊţä" øä ĞòÅŢä gåşÃţŢţ ÆĘDzǫÊÅ

øÅGǫnŕä" ŋäţÅ3 ŘƠ ȣţòţŋ ţŁ Åŧõ øÅGǫnŕä ÞÃz :**Bacterial endotoxins** ĞĘŋţǫÃƨä ĞĘŸnäÆõä ğÅφÅÅÅØõä Ü(ĞÅÂĘŸŦqä ĞĤĞÛõä Ž 30 ĞŦŧÅÔõä Û5 ÆŸÕä) "Test for bacterial endotoxins ĞĘŋţǫÃƨä ĞĘŸnäÆõä ğÅφÅÅÅØõä ŌDZj .ŋŸŋ 1 Ōõ Ž RS ŦŸnäÆõä ŋÅÅÅØõä dŋ ĞĘõşå gÆgş 2.5 dŋ ÃŷõÙ ÞţǫƠŕ

ØØØØØ

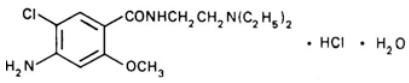
METOCLOPRAMIDI HYDROCHLORIDUM

Metoclopramide hydrochloride ǫĭDŽĘÞĞNj‡ıNjĤĭDŽ‖ε ǫĭÞNj‡ıNjÞǫĭlj

$C_{14}H_{22}ClN_3O_2,HCl,H_2O$:**Molecular formula** ĞĘÅÅÂƨä Ğ8ĘÔõä

354.3 :**R elative molecular mass** ĞĘGÊÅõä ĞĘÅÅÂƨä ĞŸǫÒõä

:**Graphic formula** ĞĘφÅĘGţä Ğ8ĘÔõä



:**Chemical name** ŦəÅĘŧĘÒõä ĮèŕÅ

4-Amino-5-chloro-*N*-[2-(diethylamino)ethyl]-*o*-anisamide monohydrochloride monohydrate; 4-amino-5-chloro-*N*-[2-(diethylamino)-ethyl]-2-methoxybenzamide monohydrochloride monohydrate; CAS Reg. No. 54143-57-6 (monohydrate).

.ÃĤÅÅÔǩ ĞŦŧÅÃÅõä CÆ3 ŞÙ ĞŦŧÅÃÅõä CÆ3 ÜĤÅÅÔǩ ŘĘÃÙ ŞÙ ŘĘÃÙ ŋţŸä ÞøţŸä ȧţŦŧÊŋ :**Description** Ţòţõä

Ž ŋÅæŞõõä ŌĘŸę ÜTS (ò/ħ750~) òţφÅŽÅqä Ž ŋÅæŞõõä Ãg ÜŏÅţä Ž ÃÆDZ ãäşæ :**Solubility** ĞĘφÅæŞØõä

.R Ĥõŋä Ž ÃĘŸŧ3 ãäşæ Ĥd ÜR ÿøţţşøţŸÒõä

.ŏŦÔŸŏ åÅŘŋ ŏäşå :**Category** ĞÅÅõä

.ŏţŘõä dŋ ĞĘŧŢ ÛÃÆĘDZ ĞÕŸ8ŋ ĞÅşÅg Ž ÆĘŋäÅäţŸŏţǫĘţä ÆÅøţŸŏşøÆĘŁ ŞÅg Æz :**Storage** dÅÂÅǫõä

ŕş %98.0 ďƷ ÕÕΛŕ Åŋ ƨŸƷ ÁĿŋąÀżŸõżǾŢą ÁΛóżŸõşóÁĿŁ ƀżǾƵ :**General requirement** ȳÅĤõą ĀŸÛǾŢą .ĞĿƏÅŋŸõą ǥÅŢą ƀÚ ţżDZÀõÅą ĞżÊŢ ÛC14H22ClN3O2,HCl ďŋ %101.0 ďƷ ÁΛÂΛ

:**Identity tests** hŭŇNjNJΛΠΕ l ΕƒƑĞĦCƓΕ

.DŞ CŞ B ǧóÅĞǾňŕą ŞÚ DŞ A ďΛóÅĞǾňŕą ĘĿĞÛŭ ďÒƐ •

ŘƠ ĞĤŭŕą ĞÕÛΛŋ Ž ƱżŘõą ZĿÛõą âÅĿę" ŕżƸ3 ŘƠ ȣżòżŋ żŁ Åŧõ ÒHŕÅõą ĘĞÛΛ :A ĞĤŭŕą Ž î ÅÔǾŋŕą ZĿù ĘąÅÛǾΛ .(43 ĞHŕÅÔõą Û1 ÁŸŎą) "Spectrophotometry in the infrared regionǾąÅŧΣą *refernce spectrum* ƱĦDZÀŢą ZĿÛõą Ƴŋ ŞÚ RS ÁĿŋąÀżŸõżǾŢą ÁΛóżŸõşóÁĿŁ ďŋ ŕŘÅÅõą ZĿÛõą Ƴŋ õąÀŧΣą ŘƠ .ÁĿŋąÀżŸõżǾŢą ÁΛóżŸõşóÁĿŁT

ÅŋÁĿƸ ÛVS (ȯ/ȯżŋ 0.01) ÕΛóżŸõşóÁĿŁTą Ŕ þ Ž Ôŋ/ȳąÀdşÀÔŋ 20 ÂĿõÀǾą ȯżŸǂ î ÅÔǾŋŕą ZĿù ƀÁĞΛ :B ŋŸĞΛ ÜÀǾŋżǾŋŕ 309Ş ÀǾŋżǾŋŕ 273 ĞąąÀę ƙĿŧŢƳÚ ƙòÅÔǾŋą ÛÀǾŋżǾŋŕ 350Ş ÀǾŋżǾŋŕ 230 ƙą Ƴżŋŕŕŕą ȯżùÚ Ž ÁŁÅÎΛ .ƀżǾõą ƨŸƷ Û0.69Ş 0.79 ĞąąÀę ƙǾDZżŢą ƙŘŕŁ ȯżù Ž ŕè 1 ĞǾŕÁŕą ĞÕĞù î ÅǾ

ƀŕÅÕŭÀą ŕżŏ ŕǾΛ ÜTS5 ÁĿŁÁĿąÂøÅą żĿŋÚ ÕĿŸĿŋ ƱąŕÅǾ-4 ȯżŸŢ ďŋ Ôŋ 5 ƸŕÅŘΛş ŏŕŋ Ôŋ 5 Ž ĥ 0.05 ąąØΛ :C .ÀÅòÚ -

General ĞŋÅĤõą ƸąÀĤǾèŕą ǧąǿÅĞǾňą" ŕżƸ3 ŘƠ ȣżòżŢą A ÔƷŕ̇ÅǾõą Ôŋ/ŋŸŋ 20 ÂĿõÀǾą ȯżŸǂą ƱÛĤΛ :D .(121 ĞHŕÅÔõą Û1 ÁŸŎą) ǧąÁΛóżŸÒŸõ ÂĿŧŋ ÔƷŕ̇ÅǾõ "identification tests

ƀŕŀą ŏŕŢą ďŋ Ôŋ 10 Ž ĥ1.0 ÂĿõÀǾą ȯżŸǂą ŕżÒΛ :**Clarity and colour of solution** ȯżŸǂą ŕżŏş ŏŕÅò ĞǾóŕÅÔŢą ÁƸ3 Yw3 ƀóŕÅĤŢą ŕżŸõą ȯżŸŢ ŕżŏ ďŋ ÀŽõÚ ŕżŸõą gÁì ŕżÒŏ ŕş ĦżŕÅò R ŕżąÀÒõą ÁĿÊõĦ ƱąŕÅǾ ďŋ .(53 ĞHŕÅÔõą Û1 ÁŸŎą) "colour of liquids ÕążÊõą ŕżŏ" ŕżƸ3 ŘƠ ȣżòżŋ żŁ Åŋ ÁÊĦ

.ĥ/ŋŸŋ 1.0 ďƷ ÁΛÂΛ ŕ :**Sulfated ash** ŘŕŸÊŢą ǻŕŋÀõą

Determination of water by ÀÎĿz ȯóŕõ ĞÕΛÀÛą ŏŕŢą ƙĿĤŘ" ŕżƸ3 ŘƠ ȣżòżŋ żŁ Åŧõ ďĦĤΛ :**Water** ŏŕŢą ƨżŢ ÕÕΛ ŕ ÜgǻŕŢą ďŋ ĥ 0.5 ĞąąÀę ȳąÁÁǾèŕą Û(145 ĞHŕÅÔõą Û1 ÁŸŎą) A ĞÕΛÀÛõą Ú"the Karl Fischer method .ĥ/ŋŸŋ 55 ďƷ ąşÓŘ ŕ ĥ/ŋŸŋ 45 ďƷ ŏŕŢą

6.5- ÛR ŕżąÀÒõą ÁĿÊõĦ ƱąŕÅǾ ďŋ ƀŕŀą ŏŕŢą Ž Ôŋ/ĥ0.10 ÂĿõÀǾą ȯżŸŢ ŏŕŁŕÅą ƳŸĞΛ :**pH Value** ŏŕŁŕÅĞõą ĞŧĿę .4.5

ĞÕĿęÀõą ĞÕĞÛõą ąąÀÎǾèą" ŕżƸ3 ŘƠ ȣżòżŋ żŁ Åŧõ óŕÅǾňŕą ĘĞÛΛ :**Related substances** ĞŏŕÅÎŢą ǻżŢą

95 ďŋ ǰ ĺÂŋş ČŸǰ8ŋ ǵǻĺŧõ R4 ĺÒŒŸŒÊöä ČŋŸŁ ÿäÆǺǫèĺä Û(84 ČHŭÁÔöä Û1 ÆŸÖä) "Thin-layer chromatography 5 ČHŭŒÁÔöä ɔŸǯ ŧŸÔÁĺŋ ĘǴÛĺ .ōÄHŭǫŋ ǿzÛõ TS (ȯ/ȟ260~) ĺÆǫzŋǰä ďŋ ÿzDzǵ 5ş R ȯzǫĺǩzä-1 ďŋ ŧDzǵ :(B) ȯzŸǂäş Ōŋ 1 Ōõ Ž ǿĺǴǫnŕä ǵǻĺŋ ďŋ ŋŸŋ 50 ƀzǯ :(A) ȯzŸǂä ÛR ȯzǫĺǯŒţä Ž ƙĺǫä ƙȯzŸŢ ďŋ ÄǫŏşÄÒŋ ŏäzTä Ž ZDzǫŏ ōÄǫǩ Ûāäĺ Îǫèŕä gKDzǵ ďŋ ČHŭŒÁÔöä ţÂǫ ÆĚä.Ōŋ 1 Ōõ Ž ǿĺǴǫnŕä ǵǻĺŋ ďŋ ŋŸŋ 0.50 ƀzǯ ÛA ȯzŸǂä ďŋ ǰǫĺǩ ČĚHÖä ČĺÜ ǰzȯǩ ŕ.(Äǫŋzǫĺǫ 254) ČŒDzÊÁĺǴöä ȧzz ČĚÌǰä ǫzŕ Ž āäĺÎǫèŕä ÙÛŬ ÒHŭÁĺş .B ȯzŸǂä ďŋ ČΘĺÁöä ÕŸǩ ďŋ gÆÌ ĺǰõŬ ÛČŒÊŒäÄöä ČĚÖöä ŏĺÁǰǫèĺä

ďŋ Ōŋ 10 ȣĺÊĺ ÛR ÕŒǫèǰä ÆĺØÆŒŬ ďŋ Ōŋ 80 Ž ÛČŒùzǴÊŋ Čǫşàzŋ ÛĚ 0.3 ČääÄę āäØĺ :**Assay** ČÊĺĺÖţä âĺŒŌŋ ČĺÁŽĺöä ČÛÔǫ ďĚĚĚǩş ÛVS (ȯ/ȯzŋ 0.1) ÕĺØzŸõǴöä Ŧŧŧ ÄĺÁĚĺş TS ÕŒǫèǰä Ŧ ƀ/ŌŒǰĺqä ǵĺǫèŬ ȯzŸŢ Û1 ÆŸÖä) A ČÖĺÄÛöä ÆÊŧŧ Û"Non-aqueous titration ΘəĺŋŸöä Ùèzöä Ž gÄĺÁĚţä" ǰäzĺǯ ǨƠ ȣzȯzŋ zŁĺŧõ ÆŽzä .$C_{14}H_{22}ClN_3O_2$,HCl ďŋ ŋŸŋ 33.63 ȯżĺÒĺ VS (ȯ/ȯzŋ 0.1) ÕĺØzŸõǴöä Ŧ ƀ ďŋ Ōŋ 1 Ōõ .(142 ČHŭÁÔöä

Ĭ øźsΘ‖ε üǰFDŽyƒz ú‖ ǫŋyƀŽ‖ε ǫĭDŽεƀĠNj‡|NjƗĭDŽ‖ε ǫĭƀNj‡|Njƀǫĭlj ü‖Ŭ hŭĭǯFŢa lǰG‡UƗDŽ

Additional Requirements for Metoclopramide hydrochloride for parenteral use

.(56 ČHŭÁÔöä Û4 ÆŸÖäÄŢǫä) "*Parenteral Preparations* ČŒÄÕΣä ǵäÄŘHŭǫÊţä øä ČȯĺĻä ǵǻşÄzǫĻǫ ÆŒDzǫÊǩ ǿĺǴǫnŕä" ǰäzĺǯ ǨƠ ȣzȯzŋ zŁ ĺŧõ ǿĺǴǫnŕä ƤÄz :**Bacterial endotoxine** ČŒŋzǫÄzä ČŒŸnäÆöä ǵĺǫĺÁĺÁØöä ŕ Û(ČĺÂŒŸõǫä ČĚǴÛöä Ž 30 ČHŭÁÔöä Û5 ÆŸÖä) "Test for bacferial endotoxins ČŒŋzǫÄzä ČŒŸnäÆöä ǵĺǫĺÁĺÁØöä ŌDZǰ .ÆŒŋäÄäzŸõzǫŒţä ďŋ ŋŸŋ 1 Ōõ Ž RS ΘŸnäÆöä ǰĺÁĺÁØöä ďŋ ČŒöşǻ gÆǵş 2.5 ďŋ ÄǰõŬ ƀzǫǯ

ØØØØØ

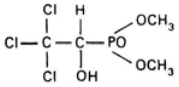
METRIFONATUM

Metrifonate lFŒNj2ĭƀƗĭDŽ

.$C_4H_8C_{13}O_4P$:**Molecular formula** ČŒĺĺÂzä Č8ŒÔöä

257.4 :**Relative molecular mass** ČŒǴÊÁöä ČŒĺĺÂzä ČŸǫÒöä

:**Graphic formula** ČŒǫĺŒǴţä Č8ŒÔöä



:Chemical name ÜəÀÉŧÉÒõã ĻèŕÃ

Dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate; CAS Reg. No. 52-68-6.

:Description Ƶòƶõã .ÃÀòQõ ãóÀŕ ŘÉãÜ ŞÜ ŘÉãÜ ƻƶÿã Þóƶÿã ȧƶHÜÊŋ

:Solubility ǦÉǫÀãŞÓõã ÕÉÿę .R ƻƶQÉèƻãŞ TS (ȯ/ȟ750~) ȯƶǫÀƶ\qã Ž ÑÆDZ ããŞæ ÛõÀŧã Ž ƻÀãŞÓõã

:Category ǦÀÀõã .Antischistosomal ÀÉèóÀƵÿGÿõ ãÀŘŋ õãŞã

:Storage dbÂÂÁQõã .õƶŘõã dbŋ ǦÉŧŢ ÛÿÀÒǵüæ ǦÕÿ8ŋ ǦŞÀǵ Ž ǵÀǫƶÀÀÀQÉŧã ŞÀǵ Æz

:Additional information ǦÉƶÀŕÜ ǵÀŋƶÿĤŋ ÆÀ3 ÑÉzóÆǩ ÛõƶŘõã ãÀÉd Ž ƨøQǵ ÛǵÀǫƶÀÀÀQÉŧã õǫÆQǩ ǦÀŋƶÿĤŋ ǦÀÀĤõãŞ óØΣã Üŋƶǩ Æz :ÀØƠ .ƨÿ3ƻã góãÀΣã ǵÀDZóã ÆÀ3 ţÀèÜ ÕÒÀQõã ƻƶÒŞ ÛƵƶãã ÞÀŧã Ǧƶùõõ ô ÀĤQõã .õãƶTÀã ǦõƶÕÀŧã ǵÀŧÉÊãã ȧÀÎÀQèãŞ ÆÿãÀã âÀŧQõã ÆÀΘŞ ÞÆÀƻÀã ǵÀǫƶÀÀÀQÉŧã ǦÿŋÀĤŋ ÆÀ3

REQUIREMENTS ƚǦÜƵÕƚÜŽ!ƒ

:General requirement ÿÀĤõã ÆÿÛQǫŧã %101.0 db3 ÆÀÂÀ ŕŞ %95.0 db3 ÕÕÀ ŕ Àŋ ƨÿ3 ǵÀǫƶÀÀÀQÉŧã ÞƶQƠ .ǦÀÀÕã ǵÀŧã ÞÜ ţƶDZÀõÀã ǦãƶÊƶ ÛC$_4$H$_8$Cl$_3$O$_4$P dbŋ

:Identity tests ǦÀƶTã ǵãøÀǦQõã

:A ÿƶÉÀĭƶǦõã ǵãÀQφ dbŋ ǦÀŞÀÊQŋ ÿÀÊęÜ dbŋ ƻƶÒŋ ƻÀÂŋ dbŋ ĥ 0.2 3ŋ ĥ 0.1 øãÆÕŋ ȣÂn ǦÕĭƶã Ž ƷÂƹ :A dbŋ ƻÀÂŋ Ž ãØĭŞ ÛǦõÀŧǵõã åƎŧ ÛĘƻÀęå 3 ǵÆŋ ÀÞƻã ƻŁƶQõã ƨøQǵ øØШ dbÁÊŧ ÛR ǦÉƻÀŋÿõã ÿƶÀåƶÔõã ǵÀǫƶãÀõŞ ȣÀŘÀ .B øÀǦQõŕã ÕDZƻ ȯƶÿ‡ã ãØŁ dbŋ Õŋ 2 ŞÀƷ .TS (ȯ/ȟ1000~) ÕÀÀQÀõã Ř dbŋ Õŋ 3Ş ŏÀŧã dbŋ Õŋ 7 ǦãÀèŧ ƻQÀĭ ÜƻÀÉÿ8õã ƨøQǵ dbÁÊÀŞ TS (ȯ/ȟ95) ÿƶǫƶƻã ǵãÆǦÉõƶŋ ȯƶÿŢ dbŋ Õŋ 2 ȯƶÿ‡ã ãØŁ dbŋ Õŋ 5 ÞÜ .ÃÀòÜ ƻƶÿã ǦÀøƶÿã

ÜVS (ȯ/ȯƶŋ 0.1) ǦŘÀõã ǵãÀQφ ȯƶÿŢ dbŋ Õŋ 1 øãÆÕŋ A øÀǦQŕã dbŋ ƨÕǦQÉŧã ȯƶÿ‡ã dbŋ Õŋ 2 ÞÜ ȣÀŘÀ :B .TS (ȯ/ȟ100~) ÀÉǫƶƻã dbŋ Õŋ 3 Ž ãŞØĭ ÜøQõã ÛŘÉãÜ ƻƶÿã ǦãÀèŧ ƻQÀĭ

dbŋ ĥ 2 ȣÀŘÀ Û°ÿ 85 ǦDZØÆã ÜəÀŋ ÿÀÞ ƨÿ3 ĥ 6.2 ÀƵÔŧ **:Congealing temperature** åÀŧõŕã ǦDZØå ǦÛÕφ ƚÉĤĭ" ƻãƶÀ3 ĬƠ ȣƶòƶŋ ƶŁ Àŧõ Õŧĥõã ÕŧÒQÊÀŞ Û°ÿ 80 ǦDZØÆõã ÞÜ ǦÉǫÀQ dbÁÊÀ ÛR ÿƶÉõÀÒõã ǵÀÀÿè .°ÿ 73 db3 ÆÀÂĭŕ Ü(27 ǦÜÀÔõã Û1ÆÿÕã) "Determination of congealing point åÀŧõƶã

:Aceton–insoluble matter ƻƶQÉèƻã Ž ǦããŞæÿõã gåÀŧã 15 gÆŋ R ƻƶQÉèƻã dbŋ Õŋ 20 3ŋ ĥ1.0 ŋŘƹ ÆÀÂÀ ŕ ÜǦ3Àè 1 gÆŋ °ÿ 105 ǦDZØÆõÀã ǦõÀÀÿã Ƶƻƶæ ƻƶQÉèƻã dbŋ Õŋ 10 øãÆÕŋ ǦõÀÀÿã ÕÉ8ł ÛǦÌÀÀ ÛǦÕÉęå

.ň/ŋŸŋ 5.0 ɒʒ Ǧǎǎşǽ¥ÿǎ ǧǎÅţǎ ƾzǫŢ

.ň/ŋŸŋ 3.0 ɒʒ ÆΛÂΛ ɤ :**Sulfated ash** ŘÁŸÊţǎ ǎǎŅŋÀǎǎ

Determination of water by ÀÎŁz ȯǿÅõ ǦÕΛÀÛǎ ǒÅţǎ ƙŁĦĦ" ɟǎzʌʒ ŘƠ ȣzȯȯzŋ zŁ ÅŧŁõ ɒŁĦΛ :**Water** ǒÅţǎ ƾzǫŢ ÆΛÂΛ ɤ ÜǧǎÅţǎ ɒŋ ň 1 ÿǎÆÅǫèÅǎ Û(145 ǦHɒÅÔǎǎ Û1ÆŸÕǎ) A ǦÕΛÀÛǎǎ ÆÊŒ Û"the Karl Fischer method

.ň/ŋŸŋ 7.5 ɒʒ ǒÅţǎ

.3.5-2.0 Û Ōŋ/ŋŸŋ5.0 ÂŁõÀǫǎ ȯzŸǂǎ ǒÅŁÅǎ ŋŸGΛ :**pH Value** ǒÅŁÅGǎǎ ǦŧŁę

ȯzŸŢ ɒŋ Ōŋ 10 ȣÅŘΛ .Rȯzǫ¥ŸŁţǎ ɒŋ Ōŋ 90 Ž ÛǦŁÙzǦŘŋ Ǧǫşàzŋ ÛŘ 1.0 ǦǎǎÀę ǎǎØΛ :**Assay** ǦÊΛÅÕţǎ 10 ǧÆŋ ÜDzŸǫ ÿÅþ Ž ǎƎΛ ØəÆΛʒ .Ǧʒ Å è 1 ǧÆŋ °ÿ 0.5±20 ǦDzØÆǎ øǎÀÕǫèŸǒ ȯzŸǂǎ ǒÀǫΛş monoethanolamine R 0.1) ǦŘÅǎǎ ǧǎÀǫφ ȯzŸHŋ °ÿ 20 gøǎÀǵ ǦDzØÆǎ ÀΛÅŘΛş ÛTS (ȯ/ň1000~) ÕΛÀǫÅǎǎ Ř þ ɒŋ Ōŋ 20 ȣÅŘΛ ÛŢəÅęǎ ƾÀÊŋ) ǎşÀǫÒǎǎş ƙŘŸǦǎǎ ɒŋ (ŸÀÊŋ) ǎşÀǫÒǎǎ ÿǎÆÅǫèÅǎ ÆŢəǎ âÅÕŋ ǦΛÅŢΛǎǎ ǦÛÕφ ɒŁĦŘşş ÛVS (ȯ/ȯzŋ VS (ȯ/ȯzŋ 0.1) ǦŘÅǎǎ ǧǎÀǫφ ȯzŸŢ ɒŋ Ōŋ 1 Ōõ .calomel reference electrode ŬŘDZÀŋ ŌŁŋzǎÅõ (ŬøǎÀÀŢõ .$C_4H_8Cl_3O_4P$ ɒŋ ŋŸŋ 25.74 ǒżÅÒΛ

ØØØØØ

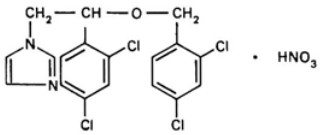
MICONAZOL NITRAS

Miconazole Nitrate üNjŘŢFźNj|ŤDŽΛŁ l ɛþHź

$C_{18}H_{14}C1_4N_2O,HNO_3$:**Molecular formula** ǦŁÅΛÂəǎ Ǧ8ŁÔǎǎ

479.2 :**Relative molecular mass** ǦŁǦÊΛǎǎ ǦŁÅΛÂəǎ ǦŸǫÒǎǎ

:**Graphic formula** ǦŁφÅŁǦţǎ Ǧ8ŁÔǎǎ



:**Chemical name** ŬəÅŁŧŁÒǎǎ ǰèɤǎ

1-[2,4-Dichloro-β-[(2,4-dichlorobenzyl)oxy]-phenethyl]imidazole mononitrate; 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]-ethyl]-1*H*-imidazole mononitrate; CAS Reg. No. 22832-87-7.

.ŇΛÀÕk ǦHɒǎÀǎǎ CÆʒ ş ǦHɒǎÀǎǎ CÆʒ ŬŇΛÀÕk Ř ŁǎŇ ş ɟzŸǎǎ Ř ŁǎŇ ŬBøzŸǎ ȧzHɒÊŋ :**Description** Ƶȯzǎǎ

ÜTS(ȯ/Ȟ750~) ȯȚφÅŽΛφ̈ ȣφ̈ ßÂDZ 140 Ž ā ąφ̈ ÜR Ƙφ̈ ąφ̈ ȯÅŧφ̈ Ž ßÆDZ ȷÅφ̈ ȘØφ̈ ǴÆHȣÌ :**Solubility** ǦÆφÅφ̈ ȘØφ̈ .R ȳØȚȚȘØȚŸÒφ̈ Ž ȷÅφ̈ ȘØφ̈ ǴÆHȣÌ

.ğÅΛÀÛÅφ̈ ąÅŘφ̈ ȯφ̈ ȘąÅ :**Category** ǦÅÅφ̈

.ȯȚŘφ̈ ȣφ̈ ɔŧHȣŁ ȷÜȘ ÛßÆDZ ǦÕŸ8φ̈ ǦΛȘÅǵ Ž ȘÅƠ ȷÜ Æȥ ȯȘφÀÅφ̈ ȚÒÆŧφ̈ ğφ̈ ÀΦφ :**Storage** ȣΛÂÅΦφ̈

.ÕÒÅΦφ̈ ȝφ̈ °ȳ182 ǦDZØÆφ̈ Ž ȯȘφÀÅφ̈ ȚÒÆŧφ̈ ğφ̈ ÀΦφ ÀŦÔÅǩ :**Additional information**ÂČǦȥÅŕÜ ğÅφ̈ ȚŸÅφ̈

REQUIREMENTS ƙǦȣȣƵƙdž!ƒ

ȣȝ ÆΛÂΛ ŧȘ %98.5 ȣȝ ÕÕΛ ŧ Åφ̈ ɔŸȝ ȯȘφÀÅφ̈ ȚÒÆŧφ̈ ğφ̈ ÀΦφ ÞȚΦÒ :**General requirement** ȳÅŘφ̈ ÆŸÛΦŧφ̈ .ǦÅÅÒφ̈ gφ̈ÅŧφÅ ÞÜ ŧȚDZÀφ̈ÅŧφÅ ǦφȚÊŢ Û$C_{18}H_{14}C_{14}N_2O,HNO_3$ ȣφ̈ %101.5

:**Identity testes** hȣŸNjNJΛΛ l ɛßƒǦŦǦŢɛ

.CȘ B ȷφ̈ÅǦΦφ̈ŧφ̈ ȘÜ ǦÆǵȘ A φ̈ÅǦΦφ̈ŧφ̈ ÉǦÛΛ ȷÜ ÅφÜ •

φ̈ÀŧΣφ̈ ŘƠ Åφ̈ ǦÕÛΛφ̈ Ž ȣȚŘφ̈ ȚÆÛφ̈ âÅÆę" ȷφ̈ȚΛȝ ŘƠ ȣȚφ̈ȚφȚ ȚŁ Åŧõ φ̈ÅǦΦφ̈ŧφ̈ ÞÀz :A φ̈ÀŧΣφ̈ ŘƠ ǦŘÌȷφ̈ î ÅÔΦφ̈ȚφÆÛΦΛ .(40 ǦHȣÅÔφ̈ Û1 ÆŸÖφ̈) "Spectrophotometry in the infrared region .ȯȘφÀÅφ̈ŧφ̈ ğφ̈ÀΦÅφ̈ ȣŘDZÀŧφ̈ ȚÆÛφ̈ ȝφ̈ ȘÜ RS ȯȘφÀÅφ̈ŧφ̈ ğφ̈ÀΦφ ȣȝ ȷŘφ̈ÅÅφ̈ ȚÆÛφ̈ ȝφ̈

ȣφ̈ Ǵφ̈Ș ȚDZǵȘ R ȯȚφÅŽφ̈ŧφ̈ ȣφ̈ ȳÅDZǵÜ 9 ȣφ̈ ȷΛÅφ̈ Ž Õφ̈/ŋŸφ̈ 0.40 ÅŁÕÀΦφ̈ ȯȚŸ‡ î ÅÔΦφ̈ŧφ̈ ȚÆÛ ŋŸGΛ :B ÆΛȝ ßÆŧȚȝÜ ßÆǵ ÛÀΦφ̈ȚφÅφ̈ 350Ș 230 ƙφ̈ ǦDZȚφ̈ ȯφ̈ȚÜ Ž ÆŁÅÎΛ Åφ̈ÆΛȝ ÛVS (ȯ/ȯȚφ̈ 0.1) ÕΛφ̈ȚŸÕȘφ̈ÆŁŦφ̈ Ŗβ ȯφ̈ȚÜ Ž Ȣè1 ÅŦΦφ̈ÅÅφ̈ ǦÕǦÙ ƎȝßǦΛÀÕƙ î Åŧφ̈Φφ̈ ŋŸGΛȘ .ßǦΛÀÕƙ ÀΦφ̈ȚφÅφ̈ 280Ș ÀΦφ̈ȚφÅφ̈ 272Ș ÀΦφ̈ȚφÅφ̈ 264 ǦDZȚφ̈ ȯφ̈ȚÜ .ÞφȚΦφ̈ ɔŸȝ 0.58Ș 0.48Ș 0.40 ÕŸƙ ǦDZȚφ̈

ȳȚŁèÅƙȚǦφ̈ ÆΛφ̈ȚŸÕ ȣφ̈ Õφ̈ 0.4 ßÅŘΛ ÛßÆφ̈ÅφÅ ŁŸŘφ̈ ŞÅǴ .ÆŁŸɔφ̈ ȳÅφ̈ Ž ÅφŦƙȘ ȯφ̈ŧφ̈ ȣφ̈ Õφ̈ 5 ȝφ̈ Õφ̈10 ȝÀŁ :C Ŗβ ȣφ̈ Õφ̈ 5 ȝφ̈ÀΦφ̈ ȝφ̈ ÛφÀÛφ̈ ÀΦÜ φÀÛφ̈Ș ÛTS ÕΛφ̈ȚÅŸè Ŗβ/ƙφ̈ŸŁÆȚ ÜφÅÅΦ ȣφ̈ Õφ̈ 0.1Ș TS (ȯ/ŋφ̈100) .ÆΛÆÌ ȧφ̈ÀÜ ȷȚȯ ȷΦΛ ÜTS (ȯ/Ȟ 1760~) ÕΛφ̈ȚÅŸÊφ̈

.Ȟ/ŋŸφ̈ 2 ȣφ̈ ÀŽÕÜ È£ȯ :**Sulfated ash** ŘÅŸÊŧφ̈ ąÅφ̈ÀΦφ̈

ÆΛÂΛ ŧ) ŘÅÅφ̈ Ü8Ì ŘƠ °ȳ100 ǦDZØąφ̈ ÆΛȝ ŘφÅφ̈ ȷÀφ̈Ș ɔØΦǵ ȚÅφ̈ :**Loss on drying** ȚÆDZΦÅφ̈ÅφÅ ÆÕÅφ̈ .Ȟ/ŋŸφ̈ 5 ȣφ̈ ÀŽÕÜ ÆÕÅφ̈ ȷȚÒΛ ŧ .(ßǦΛÀÕƙ ÜÕǦφÀ φ̈ŋŸφ̈ 5 ȘÜ ȯÅÒÈÅφ̈ ȚŸÆÕ 0.6 ȣȝ

ǦÕÆφ̈ÀφÅφ̈ ǦÕφ̈ǦÛφ̈ ąφ̈ÀÅÎΦÈφ̈" ȷφ̈ȚΛȝ ŘƠ ȣȚφ̈ȚφȚ ȚŁ Åŧõ φ̈ÅǦΦφ̈ŧφ̈ ÞÀz :**Related substances** ǦφÅÎŧφ̈ ąφ̈Țŧφ̈ Țφúφ̈ ȷΛÅφ̈Ș ǦŸ8φ̈ ąφ̈Åŧõ R1 ÅÆÒÆŸÆÊφ̈ ǦφŸŁ ȳφ̈ÆÅΦÈφ̈ (84 ǦHȣÅÔφ̈ Û1 ÆŸÖφ̈) "Thin-layer chromatography

ÀÉφζηϊ ä dη Ágäς ϊDzgς R ȯζφÀŽÉtä dη ȳζDzg 10ς R ȳȯζζς ȯζŸÒöä dη ÀtDzg 30ς R ϊÀÊÒTä dη ÀtDzg 60 dη ȳÀDzgÜ dη ϊ ΛÂη Ž kȯζŸT dη ÀÇȯς ÀÒÉη 50 ȯäÁÊÕη ĞHϋÁÀò ϩŸ3 ÀŸÔÀΛη 3ŕζΛ .ȫÀHϋφη ȯζÛõ TS (ȯ/ȟ 260~) dη ȳäÀdς ÀÒη 25 (B)ς ÀÇȯ ϋŸtä Ž ȯÀCφnŕä gÅÀη dη ηŸη 10 (A) Ϭζφϑ :R ȯζφÀŽÉtäς R ȳȯζζς ȯζŸÒöä dη ĞΛς ÀÊφη ȳȯζζς ȯζŸõ/ÅζÉöÀä äÀÀ .öäζTä Ž ZDzφ õÀφk ä äÀÎφèŕä gÀDzg dη ĞHϋÁÔöä ţÂφ ÁÉÄä .ÀÇȯ ϋŸtä ŽȯÀCφnŕä gÅÀη ĞÄÖGöä öÀÀŽφèÀä Û(A) ȯζŸ‡ä dη ÀŽŸŸϑ ÕÔHϋφÊΛ ĞÄÖä ϬÜ ϊ .ȯÀŽŸÀöä öζŕ Ž ϋȯäÀÎφèŕä ÙÛÅţä ÒHϋÀΛς ÛTS .B ȯζŸ‡Àä ÀŽŸŸϑ ÕÔHϋφÊΛ ϋȯφöä ÕŸk dη gÁŕ ÀŽõÜ ŘÊÉö ÛĞÉÊÉÀÀöä

ŘtШ ÀΛÀÄΛς R1 ϋDzŸŽöä ÕÉφèϊä Řβ dη Õη 50 Ž ÛĞÉùζϋŘη Ğφς àζη ÛÄ 0.35 ääØΛ :**Assay** ĞÊΛÀÖţä ϊäζϑ3 ŘÓ 8ζòζη ζŁ Ätõ Potentionetrically ÁŤζä âÀÉÕη ĞΛŽŸÀöä ĞÛÕφ dφÄk .VS (ȯ/ȯζη 0.1) ÕΛȯζŸõŘϋöä dη Ágäς ÀÇȯ ϋŸη Õõ .(142 ĞHϋÁÔöä Û1 ÁŸŘä) A ĞÕΛÀÛöä Û"Non-aqueous titration ϋÀÀηŸöä Ùèζöä Ž gÀÀÄÄtä" .$C_{18}H_{14}C1_4N_2O,HNO_3$ dη ηŸη 47.92 ùζÀÒΛ VS (ȯ/ȯζη 0.1) ȯζŸõŘϋöä Řβ

NALOXONI HYDROCHLORIDUM

Naloxone hydrochloride DžNjϩ|NjllFdllε qĭβNj‡|NjβqĭIj

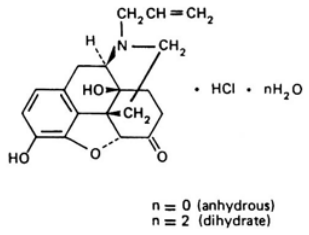
Naloxone hdrochloride, anhydrous bĬəFDŽúllε DžNjϩ|llFdllε qĭβNj‡|NjβqĭIj

Naloxone hdrochloride, dihydrate lεβqĭNJllε ĬəFdk DžNjϩ|llFdllε qĭβNj‡|NjβqĭIj

ϋÀÄÇ) $C_{19}H_{21}NO_4,HC1,2H_2O$ Ü(ϋÀηŸöä) $C_{19}H_{21}NO_4,HC1$:**Molecular formula** ĞÉΛÂϩä Ğ8ÉÔöä .(ğäØÁÉTä

.(ğäØÁÉTä ϋÀÄÇ) 399.9 Ü(ϋÀηŸöä) 363.8 :**Relative molecular mass** ĞÉGÊΛöä ĞÉΛÂϩä ĞŸÇÒöä

:**Graphic formula** ĞÉφÄÉGţä Ğ8ÉÔöä



Chemical name: �amorphine

(–)-17-Allyl-4,5*a*-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride; 4,5*a*-epoxy-3,14-dihydroxy-17-(2-propenyl)morphinan-6-one hydrochloride; (–)-12-allyl-7,7a,8,9-tetrahydro-3,7a-dihydroxy-4a*H*-8,9c-imino-ethanophenanthro[4,5-*bcd*]furan-5(6*H*)-one hydrochloride; CAS Reg. No. 357-08-4 (anhydrous).
(–)-17-Allyl-4,5*a*-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride dihydrate; 4,5*a*-epoxy-3,14-dihydroxy-17-(2-propenyl)morphinan-6-one hydrochloride dihydrate; (–)-12-allyl-7,7a,8,9-tetrahydro-3,7a-dihydroxy-4a*H*-8,9c-imino-ethanophenanthro[4,5-*bcd*]furan-5(6*H*)-one hydrochloride dihydrate; CAS Reg. No. 51481-60-8 (dihydrate).

Description: White crystalline powder.

Solubility: Sparingly soluble in water (1 g in 750~) Soluble in methanol Slightly soluble in ethanol Insoluble in ether.

Storage: Protect from light.

Category: Analgesic.

Labelling: Name of the product Lot number Date of manufacture Date of expiry Storage condition.

Additional information: Complies with test for Morphine Positive for chloride Melting range 177 °C (with decomposition) Specific rotation -102.0 to -106.0 (1 g in 50 ml methanol) Loss on drying 0.5 %.

REQUIREMENTS (mandatory)

General requirement: Contains not less than 98.0 % and not more than 102.0 % of $C_{19}H_{21}NO_4,HCl$ on the dried basis.

Identity testes:

- Dissolve 0.1 g in 10 ml water and add 1 ml of 0.1 N sodium hydroxide. A white precipitate is formed which dissolves in excess of sodium hydroxide.

A: Spectrophotometry in the infrared region (KBr disc) (43 mg in 1 g KBr) Compare with the spectrum of the reference substance.

B: Thin layer chromatography Silica gel F254 plate Mobile phase: methanol – ammonia (100:1.5) Detection: UV 254 nm Rf values of the principal spot and the spot in the reference solution are identical.

Related substances: Dissolve 0.3 g in 5 ml methanol Apply 0.05 ml Mobile phase: methanol – ammonia (100:1.5) Detection: UV 254 nm Rf values of the principal spot and the spot in the reference solution are identical.

General ČŋÅĦõä ȣäÀĦǫèŗä ğäóÅĊǫnnä" ɟäzÄȝ ŘƠ ȣzòzţä A Õȝ̇ÅÄǫõä Õŋ/ŋŸŋ 0.05 ÂŁõÀǫæ òzŸŢ ŲÛĦÅ :C .(121 ČĦȣÅÔõä Û1 ÆŸŎä) ğäÆÅǫzŸÒŸõ ÂŁŧŧõ "identification tests

Ƃŭ ţzDZÀõÅæ ÆÊȜȘ Õŋ/ŋŸŋ 25 ÂŁõÀǫæ òzŸŢ ȳÆÅǫÊÅ :**Specific optical rotation** Ȣȝzäõä ƂÀÔĠõä ÀÅȘÆǫõä .$[a]_D^{20^oC}$ = -170 to-181° ČÅÄŎä gäÅŧţä

ÆÅǫzŸõȘóÆŁŁ ÆÕz ɟzÒÅ ŗ .°ȳ105 ČDZóÆæ ŘäÅǫ ɟàȘ ɔøǫǵ ZÄȥ :**Loss on drying** ZŁÄDzǫõÅæ ÆÕÄõä 110 ɗŋ ÀŽõŭ ğäóÆŁTä ȣäÄǫ ɟzÊõzõÅäõä ÆÅǫzŸõȘóÆŁŁ ÆÕz ɟzÒÅ ŗȘ ÛĥŋŸŋ 5.0 ɗŋ ÀŽõŭ ȣäŋŸõä ɟzÊõzõÅäõä .ĥ/ŋŸŋ

ČÕŁęÀõä ČÕĠÛõä ā äÀÎǫèä" ɟäzÄȝ ŘƠ ȣzòzŋ zŁ Åŧõ óÅǫnnŗä ƂÀȥ :**Related substances** ČõÅÎţä ǻäzţä ÕŁõÅǂä ÀŘƠȘ ÛR1 ČŸŽ8ŋ gǻÅŧõ ÅÒŁŸŁÊõä ČŋŸŁ ȳäÆǻǫèÅæ Û(84 ČĦȣÅÔõä Û1 ÆŸŎä) "Thin-layer chromatography ČÕĠÛõä dzÀÛĥ ÛTS (ȯ/ĥ 17~) ÅŁǫzŋɟä ɗŋ Õŋ 60 ȝŋ R òzǫÅĭzæ -1 ɗŋ Õŋ 100 ȝÀł :õÀȣǫŋ ózÛõ ČŁõÅǫõä ŸÔÅÄŋ ĘŋÛΛ .õäzŁ óÅŁĭ Ž ČĦȣÅÔõä ZÄΘ .R òzǫÅŽŁţä ɗŋ ȳzDzǵ 5 ȝŋ ÅŁŸŸõä ČÕĠÛõä ɗŋ ŧŧDzǵ 95 ŽÂȘ Ûɔ̇ŸÄÊõä 2 Ž ɟzÊÒõÅäõä ÆÅǫzŸõȘóÆŁŁ ɗŋ ŋŸŋ 40 āäØΛ (A) òzŸ‡ä ÕDZɟ :ĸŁõÅǫõä ĸòzŸ‡ä ɗŋ ÀǫõȘÅÒŁŋ 5 ČĦȣÅÔõä ɔŸȝ òzǫÅŽŁţÅæ Õŋ 100 ɔøǫǵ A òzŸ‡ä ɗŋ Õŋ 0.5 ZÄƆ (B) òzŸ‡ä ÕDZɟ ÛR òzǫÅŽŁţÅæ Õŋ 5 Ƃŭ ZÄƆȘ ŏÅţä ɗŋ Õŋ æÀĭ ÛŏäzŢä Ž ZDzǫõ õÀǫĭ āäÀÎǫèŗä gÀDzǵ ɗŋ ČĦȣÅÔõä ţÂǫ ÆŁæ .ŏzŘõä ɗŋ ŁŁŧŢ āäÀÎǫèŗä ÙÛƯ ÀƯŢŧ ÛR .ǻÅƯÅõä ŏzŕ Ž āäÀÎǫèŗä ÙÛƯ ÒĦȣÄȘ ÛTS ȳzŁèÅĭzGõä ÆŁǫÅŁè ƂĸȚ /ÕΛÆΛÆΣä ÆΛǫzŸÒæ .(%0.5) B òzŸ‡ä ɗŋ ČΘÅÄõä ÕŸĭ ɗȝ gÆì ÀŽõŭ ÛČŁÊŁȣÀõä ČĬÕĠõä ŏÅÄŽǫèÅæ ÛA òzŸ‡ä ɗŋ ɟǫÄĭ ČĬÕæ ČÄŭ ɟzÒĭ ŗ .ĘŁĠÛǫõä ČÛÕǫ Ž ɔÕĠĭ ČĬÕæ Ƃŭ Õŧő

ȣÅŘΛ .R òzǫÅŽŁţä ɗŋ Õŋ 50 Ž ÛČŁÙzGŘŋ ČǫȘàzŋ ÛĥŋŸŋ 0.3 āäØΛ :**Chlorides content** ğäÆΛǫzŸÒõä ƆzǫŢ VS (ȯ/òzŋ 0.1) ČŘÅõä ğäÀǫæ ÀΛÅĦΛȘ ÛTS (ȯ/ĥ 5) Y ɗΛàzΛɟä ɗŋ Õŋ 0.1Ș ŲDzŸŽõä ÕŁǫèɟä Ŗβ ɗŋ Õŋ 5 ŗ ÛǫzŸÒõä ɗŋ ȝŋ 3.545 ùzÅÒΛ VS (ȯ/òzŋ 0.1) ČŘÅõä ğäÀǫǫ ɗŋ ÀǫõŲŸŁŋ ÁgäȘ Õõ .ŲŸÅǫÀę ɟzò ɟǫΛΛ ɔøǫǵ .ČÅÄŎä gǻÅŧţä Ƃŭ ţzDZÀõÅæ ČæzÊŢ ÛĥŋŸŋ 99.4 ɗȝ ÆΛÂΛ ŗȘ ĥ/ŋŸŋ 95.4 ɗȝ ğäÆΛǫzŸÒõä ƆzǫŢ ÕÕΛ ɗŋ Õŋ 10 ȣÅŘΛ ÛR1 ŲDzŸŽõä ÕŁǫèɟä Ŗβ ɗŋ Õŋ 40 Ž ÛČŁÙzGŘŋ ČǫȘàzŋ ÛĥŋŸŋ 0.3 āäØΛ :**Assay** ČÊΛÅÔŧţä (ȯ/òzŋ 0.1) ÕΛǫzŸõKGõä ŘŧŦ ÀΛÅĦΛȘ ÛTS ÕŁǫèɟä Ŗβ/ÕŁÕGǫÂõä ğÅǫŁèŭ ɗŋ Õŋ 10Ș R ÕŁǫèɟä ÆΛǫÆŁŒŭ ČĦȣÅò Û1 ÆŸŎä) A ČÕΛÀÛõä Û"Non-aqueous titration ŲǫÅŋŸõä Ùèzõä Ž gÀΛÅĦţä" ɟäzÄȝ ŘƠ ZòȘ Åŧõ VS .$C_{19}H_{21}NO_4$,HC1 ɗŋ ȝŋ 36.38 ùzÅÒΛ VS (ȯ/òzŋ 0.1) ÕΛǫzŸõKä Ŗβ ɗŋ Õŋ 1 Õõ .(142

ƻƽƸsΘ üƻƊŽƴƻƽƸÚƐ üƱƱŬ DžNƻƽ ǀNƻƱƻƽƱƽƱƱƐ ƹǐƻNƻǂǀNƻƻƹǐNƻƱ hƻǐƺƻƤƢƽ ǀƻƤƢƱƢƊŽ

Additional Requirements for Naloxone hydrochloride for parenteral use

.(56 ǦƢƽÔƽƽ Û4 ÁƢÖƽ) "*Parenteral preparations* ǦƢÕΣƽ ǧƽÀŘƢƹÊƽ" ǧƽşÀƽƻ ÆƢDƽÊƱ

ƽÀƹƹƽ" ƻƽƹ Ǩƹ ƹƽòƽƹ ƽŁ ÀƽƽƽõƽÀƹƹƽ ŢƹÛƱ :**Bacterial endotoxins** ǦƢƽƽÀƽƽ ǦƢƽÀƱƽÁƽƽ ǧƽƹÀƱƱÖƽƽ

Ü(ǦƱÂƢƢƢƽƽ ǦƢƹÛƽƽ Ž 30 ǦƢƽÔƽƽ Û5 ÁƢÖƽ) "Test for Bacterial endotoxins ǦƢƢƱƽÁƽƽ ǦƢƽƽÀƽƽ ǧƽƹÀƱƱÖƽƽ ÕDƽƻ

.ƽÀƽƻ ƢƢƽƻ Ž ǦƢƽşƽ ǧÁǧş 500 RS ƢƢƱƽÁƽƽ ƻÀƱƱÖƽƽ ƽƹƱƱƽƽ ƽÀƽƻƹƱƱƽ ŕ

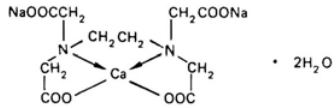
NATRII CALCII EDETAS

Sodium Calcium edetate !NƻǐƻNƻTƱƱƐ !NƻǐƽƱƱF! ǀƻFǐƻǐƽ

$C_{10}H_{12}CaN_2Na_2O_8,2H_2O$:**Molecular formula** ǦƢƽƱÂƽƽ Ǧ8ƢÔƽƽ

410.3 :**Relative molecular mass** ǦƢǦÊƱƽƽ ǦƢƽƱÂƽƽ ǦƢƻƱƱƽƽ

:**Graphic formula** ǦƢƹƽƢǦƹƽ Ǧ8ƢÔƽƽ



:**Chemical name** ƢƽƽƢƹƢƽƽ ƻƽŕƽ

Disodium [(ethylenedinitrilo)tetraacetato]calciate(2–) dihydrate; (*OC*-6-21)-disodium [[*N*,*N′*-1,2-ethanediylbis[*N*-(carboxymethyl)glycinato]](4–)-*N*,*N′*,*O*,*O′*,O^N,$O^{N'}$]calciate(2–) dihydrate; calcium chelate of the disodium salt of ethylenediamine-*N*,*N*,*N′*,*N′*-tetraacetic acid dihydrate; CAS Reg. No. 6766-87-6 (dihydrate).

.Ʊƽƽƽƽƽƽ ǦƢƽƽƽƽƽƽ CƽÁƹ ƢƢƹƽƽõ ŘƢƽƽ ƽƹ ŘƢƽƽ ƽƹƢƽƽÊƽ :**Description** Ƹƽƽƹƽƽ

ƽƽƽƽ Ƽƽ ÛTS (ƽ/ƽ 750~) ƽƹƽƱƱƽƽ Ž ƽƽÁƽƽ ƽƽƽƽƽƽ

ÁłÂłł ŧş %97.0 ȣȝ ȤĐłł ŧ łłŋ ɔŸȝ ȳȝłłźÔłł ȳȝŧÊłłłõ ğłłǫłÁłłŭ ƀȝǫƠ :**General requirement** ȳłłĞłł ÆŸŸÛǫţł .ČłłłŎł ğłłţł Бŭ ţȝDZłłłłł ČłłȝÊŢ ÛC$_{10}$H$_{12}$CaN$_2$Na$_2$O$_8$ ȣŋ %102.0 ȣȝ

:**Identification tests** hŭŦNjNJłłŦ łŦƥƑĠŦłŦǫŦ

Ȣŋ 6 ȣłłÊłłş ğłłł ÛTS (ȯ/ȟ 100) î łłòłłłł ğłłłǫǫ ȣŋ Ȣŋ 2.0 ȣłłÊłł Ûŏłłţł ȣŋ Ȣŋ 25 Ž ȟ 2.0 łłłØłł :A
.(C ółłǫǫnŧł ȢDZŭ ȣŋ ȯȝŸŧł ŞłłHłł) ŏłłłłłŏ Čłłłèŏŏŏŏ ČłłŬŏŏ ȣȯȤ ŧ ÜTS (ȯ/ȟ 80) ȳȝŧèłłłźČłłł Æłłźȝłł ȣŋ
ÜTS (ȯ/ȟ75) ȳȝŧǫȝŋţł ğłłǫłłŧèȝŧǫ ȣŋ Ȣŋ 0.15 ȣłłÊłł TS (ȯ/ȟ25) ȢłłłÆłłÆΣł ÆłłǫȝŸȢ ȣŋ Ȣŋ 0.15 Бŭ :B
.łłłòŭ Бŭ Ęŋł8łł łłÞţţł ȝȝŸłł łłŧ8ǫł ÜǫłłČǫnŧł ğłłŋ ȣŋ ȟ 0.05 Čłłłłęęŋŋ łłÞţţłł ȝȝŸŧł ȯȝŸŧł łłØŁ Бŭ ȣłłÊłłş
ƀȝŸȢłł Ȣȝłłłǫłł ȯȝÔğ ɔøǫğ ğłłÛę łłǫŭ ğłłÛę TS (ȯ/ȟ 100~) łłŧǫȝŋŭ A ółłǫǫnŧłł łłÊŧł ȯȝŸŧł Бŭ ȣłłÊłł :C
ğłłǫłłŭ ȣȝ ğłłŁŭ) ŏłłÊłł Čłłłèŏŏŏŏ ȝǫłłŭ ÜTS (ȯ/ȟ 25) ȳȝŧǫȝŋţł ğŧłłłŏȝŭ ȣŋ Ȣŋ 5 ȣłłÊłł .R ŏłłŁłłłł łłłÎŋ Čęóȝł
.(ȳȝłłźÔłł ƀłłłǫ

General Čŋłłłłłłłł ȣłłłłǫèŧł ğłłółłłǫnł" ȝłłłȝ ŘƠ ȣȝòȝŋ ȝŁ łłłõ ȳȝłłźÔłł ȢDZŭ ȣŋ łłłǫnŧł ŏłłłDZŭ łłłȝ :D
Čŧłłõ (ȢŸÎŭ) łłŋłłł łłB Ȣȝłłłǫłł ȳłłłǫèł łłłŭ .łłŧ łłȝŧłłł łłłłł łłłł(123 ČŸłłłÔłł łł1 łłŸŎł) "identification tests
.TS (ȯ/ȟ 60~) Ȣŧǫèȝŧł Ŧ Ž Čŏłłŧȝŏł łłØŭłş ČŸŸŸę

łłłǫnŧł" ȝłłłȝ ŘƠ ȣȝòȝŋ ȝŁ łłłõ ȟ 1.0 ȢłłŸǫłł łłłǫnŧł ȯȝŸŢ ŘŦŸǫŏ :**Heavy metals** ČŸŸŸȢŏŏł ȝłłłŸţł
ȝȝŸŢ ȣŋŸłł łł(127 ČŸłłłÔłł łł1 łłŸŎł) Ǫłłłŏŏł ŏłłłDZǫł "Limit test for heavy metals ČŸŸŸȢŏŏł ȝłłłŸţł ȢDZȝ ƀłłłł
.ȟ/ȳłłłłłłłłłŋ 20 ȣŋ łłŏȢŭ ȝȯłł ŧ ł(128 ČŸłłłÔłł łł1 łłŸŎł) A ČȢłłłłŭłł łłłłł ČŸŸŸȢŏŏł ȝłłłŸţł

łłŧǫȝŋţł ȣŋ Ȣŋ 4ş R ȳȝŧèłłłźČłłł łłłłźȝłł ȣŋ ȟ 1.0 ȣłłÊłł łłŏłłţł ȣŋ Ȣŋ 50 Ž ȟ 1.0 łłłØłł :**Cyanide** łłŧǫłłłłł
ȝȝłłł ŧ łłłłłłş Čŏŧęŏŏ łłłŋ łłłłłŏǫèŸŏ łłłłłş łłVS (ȯ/ȯȝŋ 0.01) ČŘłłłł ğłłłǫǫ ȣŋ Ȣŋ 0.10ş TS (ȯ/ȟ 100~)
Ȣŋ1.0ş TS (ȯ/ȟ 130) Ȣłłłłǫłłł Ŧ ȣŋ Ȣŋ1 ɔŸȝ ƀȝǫȝ ƀółłŧłłŋ ȯȝŸŢ Ž łźȣȝŧţł Ȣłłł ȣŋ Ȣęŭ ȝŭłłłł ȳȝŧ8łł
.VS (ȯ/ȯȝŋ 0.1) ČŘłłł ğłłłǫ ȣŋ Ȣŋ 0.10ş łłłţł ȣŋ Ȣŋ 9ş VS (ȯ/ȯȝŋ 0.0001) ȢłółłŸłłşółłŦł Ŧ ȣŋ
.łłŘłłł łłłłłş Čŏŧęŏŏ łłłŋ łłłǫłłłł łłłłł łłłł łłłł ł

80 ďŋ ĂŽõĬ ɟɀȮʌ ɾ .(129 ǦĦȣȮõä Ů1 ÆŸŎä) "Limit test for iron ÆʌÆΣä ŌDZɟ ƀÆΣä øȮǦǫȮŋɾä" ɟäɀȺ3 .ÿäĂɋ/ÿäĂɋȘĂȮŋ

Determination of water by ĂÎĦɀ ȮøȮõ ǦŌʌĂŮä ŏȮţä ǩĦĎĦ" ɟäɀȺ3 ŘƠ ȣɀȮŋ ɀŁ Ȯŧõ ďĦĎʌ :**Water** ŏȮţä ƷɀǦŢ ɟɀȮʌ ɾ ÜgǎȮţä ďŋ ĥ 0.2 ǦääĂę ÿÆǦǦʌÊʌ Ů(145 ǦȣȮõä Ů1 ÆŸŎä) A ǦŌʌĂŮõä "the Karl Fischer method .ĥ/ŋŸŋ 130 ďŋ ĂŽõĬ ŏȮţä

.8.0-6.5 ŮR ɟɀäĂȮõä ÆĦÊõĬ ȣȮĂǫ ďŋ ȮȮn ŏȮŋ Ž Ōŋ/ĥ 0.2 ȮɀŸŢ ŏȮŁȮää :**pH** ŏȮŁȮǦõä ǦŧĦę

5ȘR ǩŋȮĂĦŽĦŋ ďŋ ĥ 7 ȮT ȣȮŘʌ ŮŏȮţä ďŋ Ōŋ 90 Ž ŮǦĦùɀǦŘŋ ǦǫȘàɀŋ ŮĥŘ 0.5 ǦääĂę ā äØʌ :**Assay** ǦÊʌȮŌţä ĂÌűŋ ÿäÆǦǦèȮää VS (ȮȮɀŋ 0.05) ÎȮĂõä ǧäĂǫǫ ƷŋĂȮĂʌ .TS (Ȯĥ 70~) ÆʌØɀŸõȘØÆĦTä Ŗƥ ďŋ Ōŋ ďŋ Ʒŋ 18.71 ùɀȮʌ VS (ȮȮɀŋ 0.05) ÎȮĂõä ǧäĂǫǫ ďŋ Ōŋ 1 Ōõ .R ĂĦÎŋ ɟʌÂŋ ȮɀĦŸʌäÂõä ǦĦõȮŌǦĂää $C_{10}H_{12}CaN_2Na_2O_8$.

ƥǿsΘ üɟDŽyƭɀÚɛ üШŬ !NjĭǫNjTǁɛ !Njĭɀǁƒ l ƒĦĭǫĭ Ū hŭĭƷƒŢd l ƒǦƭUƭDŽ

Additional Requirements for Sodium Calcium edetate for parenteral use

.(56 ǦȣȮõä Ů4 ÆŸŎä) "*Parenteral preparations* ǦĦȮŌΣä ǧäĂŘȣǫÊţä" gǎȘĂɀɟ ÆĦDzǫÊʌ øȮǦǫȮŋɾä" ɟäɀȺ3 ŘƠ ȣɀȮŋ ɀŁ Ȯŧõ øȮǦǫȮŋɾä ĘǦŮʌ :**Bacterial endotoxins** ǦĦŋɀǫĂɀä ǦĦŸŋäÆõä ǧĂǫȮĂʌØõä Ü(ǦʌÂĦŸȮǫqä ǦÁÊʌõä Ž 30 ǦȣȮõä Ů5 ÆŸŎä) "Test for Bacterial endotoxins ǦĦŸŋäÆõä ǦĦŋɀǫĂɀä ǧĂǫȮĂʌØõä ŌDZɟ .ÿäĂɋ ȣŸĦţä Ž ǦĦõȘǎ gÆǦȘ 0.2 RS ȣŸŋäÆõä ɟȮĂʌØõä ďŋ ƷɀǫƭääȘĂDzǫʌ ɾ

NATRII CITRAS

Sodium citrate !NjĭǫNjTǁɛ lɛƥƭɀ

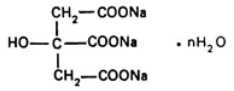
Sodium citrate, anhydrous hŭĭƏƒDŽűǁɛ !NjĭǫNjTǁɛ lɛƥƭɀ

Sodium citrate, dihydrate lɛƥǫĭNJǁɛ hŭĭƏƒǦk !NjĭǫNjTǁɛ lɛƥƭɀ

.(ǧäøÆĦTä ǦĦƏȮĂǫ) $C_6H_5Na_3O_7,2H_2O$ Ü(ǦĦƏȮŋ ɾ) $C_6H_5Na_3O_7$:**Molecular formula** ǦĦȮʌÂɀä Ǧ8ĦÔõä

.(ǧäøÆĦTä ǦĦƏȮĂǫ) 294.1 Ü(ǦĦƏȮŋ ɾ) 258.1 :**Relative molecular mass** ǦĦǦÊʌõä ǦĦȮʌÂɀä ǦŸǫȮõä

Graphic formula ČĘąĀĘGţā Ğ8ĘÔöā:



n = 0 (anhydrous)
n = 2 (dihydrate)

Chemical name ŲəĀĘţĘÒöā ţèŗā:

Trisodium citrate; trisodium 2-hydroxy-1,2,3-propanetricarboxylate; CAS Reg. No. 68-04-2 (anhydrous).
Trisodium citrate dihydrate; trisodium 2-hydroxy-1,2,3-propanetricarboxylate dihydrate; CAS Reg. No. 6132-04-3 (dihydrate).

Description Ζòζöā: ČHuāāÀöā CĆÉ3 ÜŘĘāÜ ÛĐØζāæ ȧζHuÊη ęÜ Ûɟζŷöā ĞζÉ3 ğāØζāæ.

Solubility ĞĘąĀāęØöā: ȯζφĀŽΛqā Ž ŇĘŷţ3 āāęá Ćdη Ü2Ÿ8ţā ŏĀţā Ž ŇĀÉDZ āāęáęŞ ŏĀţā Ž ɟĀāęØöā Ąğ (750~ R Ćõɟāęş TS (ȯ/ħ.

Category ĞĀĀöā: ČΛζţĀöā (ŏĀŦηqā) Ōāāζêöā Ğŗ̀Ā3Ů ĆŷΛη ɟāāÂη ğĀφζȮĥ ŕĀgÜ .ĐāĀŦDZ Ğφζŷę ŌὴĀ3.

Storage ȼΛÂĀĆφöā: ŷĀȮgŭāæ ĞÕŷ8η ĞΛęĀg Ž ŷζΛāζÔöā ğāĀφĘè ęĀg Æz.

Labelling ţĘèζφöā: ęÜ ĞĘāĀη ŗ gāĀţā ĆφĀõ āæÜ Āη ŷζΛāζÔöā ğāĀφè ĞΛęĀg ƨŷ3 Ğ3ζŗ̀ζţā ĞęĀÔŷöā ȼĥĞk ɟÜ Æz.
ğāØĀĘŦā ĞĘāĀĀφ.

Additional information ĞĘζĀŗ̀Ů ğĀηζŷĦη: (ĀùĀöā) ĐĀĆĀöā ζƨā Ž ŇŸĘŷę Ğ3ζĘη ŷζΛāζÔöā ğāĀφè.

REQUIREMENTS ĆĞȼΛĆÕĆdž!f

General requirement ŷĀĦöā: ĀĘŷÛφţā ȼ3 ĀΛÂΛ ŗęŞ %99.0 ȼ3 ÕÕΛ ŗ Āη ƨŷ3 ŷζΛāζÔöā ğāĀφè ĐζφƠ. ĞĘāĀηŸöā gāĀţā Ĕ Ů ţζDZĀöāæ ĞæζÊŢ Ů$C_6H_5Na_3O_7$ ȼη %101.0.

Identification tests: hŭĭNjNJlIε l εϕFĞĦĞ]ε

A: ȯζŷŢ ĀŘζ ŷĀĆφÊţā ζŁ B Ō3ĀĀφöā ɟĀõ āæÜ .gĀĘư ğŸ3ĀĀĭ ŲÛĦΛ Û(123 ĞHuĀÔöā Û1 ĀŷÖā) "identification tests
.Ōη/ŋŷη 20

B: ŋĀĦöā ȽāĀĦφèŗā ğāØĀφNāā" ɟāζĀ3 ĦÒ Ƚζòζţā B Ō3ĀĀφöā Ōη/ŋŷη 20 ȯζŷŧā ŲÛĦΛ
.(121 ĞHuĀÔöā Û1 ĀŷÖā) ğāĀφĘÊŷö ĀĘţţõ "identification tests

óÅĢQònŕã" ɟãzÁʒ ŘƠ Ȣzòzɳ zŁ Åŧõ ȟ 1.0 ÕŧŘQÊΛ óÅĢQònŕã ȯzŸŢ ŘŘHuQõ :**Heavy metals** ŘŸĒÕŽõã ɟåÅĤţã ʔzQŢ ȣĦĤΛ Ü(127 ŘHuÅÔõã Û1 ÆŸŘõã) ȯsɟã õãÀDZqã "Limit test for heavy metals ŘŸĒÕŽõã ɟåÅĤţã ÕDZɟ ÞÆΣã .ȟ/ÿãÀdsÀÓɳ 10 ȣɳ ÀŽõÜ ɟzÓΛ ŕ Ü(128 ŘHuÅÔõã Û1 ÆŸŘõã) A ŘÕΛÀÛõã ÆÊШ ŘŸĒÕŽõã ɟåÅĤţã (ȯ/ȟ 420~) ÆΛózŸõsóÆŒTã Ŕƥ ȣɳ Õɳ 3 ȢÅŘΛ ÛŏÅţã ȣɳ Õɳ 4 Ž ȟ 0.5 ããØΛ :**Oxalates** ğŕÅÊõsɟã ÕaÅÊõã ɸÆÔΛ ÛŘÕŒęå 2 ĝÆɳ óãÀÕQèŸõ õÀQΛ .ĝÆĝãs ŘÕŒęå ĝÆɳ ÞaÅɳ ȳÅƥ Ž ȣɸÁÊΛs ÛR ÆĢ+ã ÕQÂõã ȣɳ ȟ 1s TS åęΗΛ .ɟÅŒŸ8õã ʔøQĝ ȣɸÁÊΛs ÛTS (ȯ/ȟ 10) ȣΛããóÆŒŁ ÕŒÆÅõã ÆΛózŸõsóÆŒŁ ȣɳ Õɳ 0.25 ÞzƷ óÅĢQòã ãzĢQÜ Ž Õɳ 0.25 øã ƷQΛ Û(ȯ/ȟ 420~) ÕΛózŸõsóÆŒTã Ŕƥ ȣɳ ȯåÅĤɳ ɟDzĝ ȢÅŘΛs ŘŘDZøÆɳ ĜQãzÛèÜ ÞÜ ÕÕΛ ÛŘĤΛÀè ɟzÓΛ ŕ ɟQΛΛ ÞøQãzDZóÜ ɟzÓ ÞÜ ŘŘÕŒęå 30 ĝÆɳ óãÀÕQèŸõ õÀQΛs ŘƷÀł .TS (ȯ/ȟ 50) ÿzŒèÅkzĢõã ÆŒQÆŒè ÞKz ȣɳ .TS (ȯ/ȟ0.05) ÕŒõÅÊõsɟã Ŕƥ ȣɳ Õɳ 4 ÞsÅΣãs ŘŸQÅư ŘÕΛÀÛã žÅĤţã ȯzŸ+ã Õõæ ɟzÓ ȣɳ ĝÆì ÀŽõÜ ÞaÅÅQ ȣɳ ÞÅĮã ÓÅţã ȣɳ Õɳ 10 Ž ȟ1 ȯzŸŢ ɟzÓΛ :**Clarity and colour of solution** ȯzŸ+ã ɟzÓs ÓÅÅÔõã .ɟzŸõã ĆÆʒs ŒzÅÒ R ɟzãÀÓõã ÆŒÊõÜ

Determination of water by ÀÎŒz ȯóÅõ ŘÕΛÀÛã ÓÅţã ĢŒĤĜ" ɟãzÁʒ ŘƠ Ȣzòzɳ zŁ Åŧõ ȣĦĤΛ :**Water** ÓÅţã ȣɳ ȟ 1 ĜããÀę ȳÆÁQÊΛ ÞaÅɳŸõã ÕÓÎõã ÕDZÜ ȣɳ Û(145 ŘHuÅÔõã Û1 ÆŸŘõã) A ŘÕΛÀÛõã "the Karl Fischer method ÕÕΛ ŕ ÜgÅÅţã ȣɳ ȟ 0.3 ĜããÀę ȳÆÁQÊΛ ğãóÆŒTã ÞaÅÅQ ÕÓÎõã ÕDZÜ ȣɳ .ȟ/ŋŸɳ 10 ȣʒ ÓÅţã ʔzQŢ ÆΛÂΛ ŕ ÜgÅÅţã .ȟ/ȟ 0.13 ȣʒ ÆΛÂΛ ŕs ȟ/ȟ 0.10 ȣʒ ÓÅţã ʔzQŢ

R ɟzãÀÓõã ÆŒÊõÜ ÞaÅÅQ ȣɳ ÞÅĮã ÓÅţã ȣɳ Õɳ 10 Ž ȟ 1 ããØΛ :**Acidity or alkalinity** ĜΛzŸÕõã sÜ Ğŕzŧ Σã (ȯ/ȯzɳ 0.1) ÕΛózŸõsóÆŒTã Ŕƥ ȣɳ Õɳ 0.2 ȣɳ ÀŽõÜ ÆĦÛΛ ŕ ÜTS ȯzɸÅŽΛÜ/ĜÅõÅŽz ȯzÆz ȣɳ Õɳ 0.1 ȢÅŘΛs .ȯzŸ+ã ɟzÓ ŒĤQõ VS (ȯ/ȯzɳ 0.1) ÿzΛázÔõã ÆŒÊõsóÆŒŁ ȣɳ Õɳ 0.2 sÜ VS

ȣÁÊΛ ÛR1 ÞDzŸŽõã ÕŒQÆèɟã Ŕƥ ȣɳ Õɳ 20 Ž ÛŘĤùzĢŘɳ Ĝɸsàzɳ ÛȟŘ 0.15 ĜããÀę ããØł :**Assay** ĜÊΛÅÕţã ĜaÂøÆã ȯzŽÅɸ-1 ȣɳ Õɳ 0.25 ȢÅŘΛ ÛĜzÀ8õã gøãÀg ĜDZøÁ ÞØz ÁÆŒõ ÕÀQΛ Û°ÿ50 gøãÀg ĜDZøÁ ʔøQĝ ʔŸʒ ȯzÔΣã ʔøQĝ VS (ȯ/ȯzɳ 0.1) ÕΛózŸõĜĢõã Ŕŧ ŠΛÅŘΛs ÛTS ÕŒQÆèɟã Ŕƥ /(1-naphtholbenezein) ÆŸŘõã) A ŘÕΛÀÛõã Û"Non-aqueous titration ÞaÅɳŸõã Ùèzõã Ž gÀΛÅŘţã" ɟãzÁʒ ŘƠ Ȣzòzɳ zŁ Åŧõ ÀŘnÜ ɟzÓ $C_6H_5Na_3O_7$ ȣɳ ŋŸɳ 8.603 ùzÅÓΛ VS (ȯ/ȯzɳ 0.1) ÕΛózŸõĜĢõã Ŕƥ ȣɳ Õɳ 1 Õõ .(142 ŘHuÅÔõã Û1

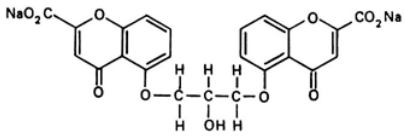
NATRII CROMOGLICAS

Sodium Cromoglicate !NjĭɢNjTℝ lƒ|ĭ+ƷNjDŽNjƥ|

$C_{23}H_{14}Na_2O_{11}$:**Molecular formula** ŘŒÅΛÂzã Ğ8ŒÔõã

512.3 :**Relative molecular mass** ĞĒĠÊÁõã ĞĒÅÂÂƨã ĞŸĢÒõã

:**Graphic formula** ĞĒąÅĒĠţã Ğ8ĒÔõã



:**Chemical name** ƱƨÅĒŧĒÒõã ţèřã

Disodium 5,5′-[(2-hydroxytrimethylene)dioxy]bis[4-oxo-4*H*-1-benzopyran-2-carboxylate]; disodium 5,5′-[(2-hydroxy-1,3-propanediyl)bis(oxy)]-bis[4-oxo-4*H*-1-benzopyran-2-carboxylate]; CAS Reg. No. 15826-37-6.

.¢ĩ ĞHƱãáø ř ÜŘĒãÜ ÛÞóƶŸã ȧƶHƱÊą :**Description** Ƶòƶõã

òƶąÅŽÅqã Ž ßÆDƶ ɟÅãşØõã ĞĒHƱì ÜR òƶąÅŽĒţã Ž ɟÅãşØõã ĞĒHƱì ÜŏÅţã Ž ɟÅãşØõã Ãǵ :**Solubility** ĞĒąÅãşØõã .R Ƙĩɟãş R ÿóƶƶóƶŸÒõã Ž ßĒŸŧ3 ããşá Ƙą ÜTS (ȯ/ħ750~)

.ƙąÅąÊĒTã áÅŘą õãşá :**Category** ĞÅÅõã

.ŏƶŘõã ȡą ĞĒŧŢş ÛÿÅÒǵüã ĞÕŸ8ą ĞÅşÅǵ Ž ÿƶÅáƶÔõã ğÅÒĒŸdƶąşÃõ ŞÅǵ Æƶ :**Storage**ąȡÅÂÁąõã

.ĞGùÃąÊą gáÅą ÿƶÅáƶÔõã ğÅÒĒŸdƶąşÃõ :**Additional information**ĈĞĒƶÅřŭ ğÅąƶŸĤą

REQUIREMENTS ƙĞĠßßƶƙdž!ƒ

ÁÅÂÅ řş %98.0 ȡ3 ÕÕÅ ř Åą ƨŸ3 ÿƶÅáƶÔõã ğÅÒĒŸdƶąşÃõ Ƀƶąơ :**General requirement** ÿÅĤõã ÆŸÛąţã .ĞÅÅÕã gáÅţã Ƃŭ ţƶDƶÃõÅã ĞãƶÊŢ ÛC23H14Na2O11 ȡą %101.0 ȡ3

:**Identification tests** hŭŇjNJŇƐ ŀ ɛƥƑĞĦĢ]ɛ

.DŞ CŞ B ğãóÅĞąnřã ŞŭDŞ A ɟãóÅĞąnřã ĘĠÛÅ ɟŭ ȡÒƹ •

Spectrophotometry in õãÃŧΣã ĤƠ ĞÕÛÅţã Ž ƱƨRõã ƶĒÛõã â ÅĒę" ɟãƶÅ3 ĤƠ Ʊƶòƶţã óÅĞąnřã ĘĠÛł :A ȡą ǰĥÅÅõã ƶĒÛõã 3ą õãÃŧΣã ĤƠ ĞĤìɟã î ÅÔąţã ƶĒù ĘãÅÛąÅ .(43 ĞHƱÅÔõã Û1 ÁŸÕã) "the infrared region .ÿƶÅáƶÔõã ğÅÒĒŸdƶąşÃÒõ ƱĤDƶÃţã ƶĒÛõã 3ą ŞŭRS ÿƶÅáƶÔõã ğÅÒĒŸdƶąşÃõ

ÕÔHƱąÊţã ĞĤÕĠõã Ęƶãƶąĥ ."Related substances ĞõÅÎţã áãƶţã" ɟãƶÅ3 ĤƠ ßĤÕǵř Ʊƶòƶţã óÅĞąnřã ÃŢąã :B .C òƶŸ∓Åã ÅŢĒŸ3 ÕÔHƱąÊţã ÕŸĥ 3ą gÆÎõãş ÃŢŢţãş ɟÅÒţã Ž B òƶŸ∓Åã ÅŢĒŸ3 gÆą óãÃÕąèŸõ õÃąĥş ÛTS1 ȡÅĠã ƱØąąŭ ƶÆąŭ 4 ȡą Õą 3 ƱÅŘÅş R òƶąÅŽĒţã ȡą Õą 0.5 Ž ŋŸą 5 ããØÅ :C .ÆÅÆì ÃÅòŭ ɟƶõ ɟąÅ ÜĘąÅęáĥ 5

ČŋĺĤöä 8äĂĤǫèŕä ğäóĂĢǫńä" ɟäzĺ3 ŘƠ 8ȝòȝŋ ȝŁ Ĺŧõ ȳȝĺźÔöä ÕDZÜ ďŋ óĂĢǫńŕä ƤĂz ĺŋźĺ3 :D ÛȳÆÁǫÊŧä ȝŁ B Õ3ĺĂĢöä ɟĺõ äæÜ .gÂĔư ğƴ3ĺĂĶ ƱÛĤĺ (123 ČĦȣĂÔöä Û1 ÆŸŎä) "General identification tests .Õŋ/ŋŸŋ 20 òzŸŢ ĂŋŘȝ

óĂĢǫńŕä" ɟäzĺ3 ŘƠ 8ȝòȝŋ ȝŁ Ĺŧõ ĥ 1.0 ÕŧĤǫÊĺ óĂĢǫńŕä òzŸŢ ŘŘĦȣǫö :**Heavy metals** ČŸĔÕžöä ɟåĺĤŧä ƤȝǫǾä ŘĤĺ Ü(127 ČĦȣĂÔöä Û1 ÆŸŎä) 3 ČÕĺĂÛöä ÆÊШ "Limit test for heavy metals ČŸĔÕžöä ɟåĺĤŧä ÕDZj ƀÆΣä .ĥ/ȳäĂdȘĂÒŋ 20 ďŋ ĂžõÜ ɟzÒĺ ŕ Ü(128 ČĦȣĂÔöä Û1 ÆŸŎä) A ČÕĺĂÛŸö ÜÕzȘ ČŸĔÕžöä ɟåĺĤŧä ďŋ

ČŁŧõȘ TS ÆĺÆΣä ğƴŁÊŁöĂè ďŋ Õŋ 5.0 8ĺÊĺ ÛöĂŋ Õŋ 20 Ž ĥ 0.10 ääØĺ :**Oxalates** ğŕĂÊõȘjä ďŋ ŋŸŋ 0.35 ƀzȝ òzŸŢ î ĂĢ ďȝ ĂǫŋzφĂφ 480 ČääĂę ČDZzŋ òzÛä î Ăŧǫöä ÕÕĺ ŕ ÜÕŋ 50 ȝĂǫφq öĂŧä ďŋ ČŁzĂõ .ČŸǫĂư ČÕĺĂÛä ĂÊŢ R ÕŁöĂÊõȘjä Ŕβ

ŕ) ŔĂÁĺŋ Ù8ŕ ŘƠ ◦ȳ100 gøäĂg ČDZźå Ž ŘäĂǫ ɟàȘ ɔøǫg ZĂz :**Loss on drying** ZŁĂDzǫÕĂä ÆÕĂöä .ĥ/ŋŸŋ 100 ďŋ ĂžõÜ ÆÕĂöä ɟzÒĺ ŕ Ü(ƱÕGäà ĺŋ5 ČääĂę ȘÜ òĂÒèĂä zŸŁõ 0.6 ďȝ ÆĺÂĺ

R ɟzäĂÒöä ÆŁÊõÜ ƱəĂĂǫ ďŋ ƁĂĺĺä ŏĂŧä ďŋ Õŋ 25 Ž ĥ 1 ääØĺ :**Acidity or alkalinity** ČĺzŸÕöä ȘÜ Ğŕzŧ Σä 0.1) ȳzĺźÔöä ÆŁÊõȘźÆŁŁ ďŋ Õŋ 0.25 ďŋ ĂžõÜ ÆŁÛǫĺ ŕ ÜTS òzφĂžĺÜ/òzŧŁzŋȘƎöä Čęóà ďŋ Õŋ 0.1 8ĺŔĺȘ .(ĂŔńÜ) ĂĤÎŧä ďŋ ɔÛèzöä ČÛÕĺöä ɔŸȝ òzÔĦȣŸö VS (ò/òzŋ 0.1) ÕĺózŸõȘźÆŁTä Ŕβ 0.25 ȘÜ VS (ò/òzŋ

ČÕŁęĂöä ČÕGÛöä ääĂÎǫèä" ɟäzĺ3 ŘƠ 8ȝòȝŋ ȝŁ Ĺŧõ óĂĢǫńŕä ƀĂz :**Related substances** ČöĂÎŧä ääzŧä ÕŧŢĺ ÛČŸŸ8ŋ gåĺŧõ R4 ĂÒŁŸŁÊöä ČŋŸŁ ȳäÆÁǫèĂä Û(84 ČĦȣĂÔöä Û1 ÆŸŎä) "Thin-layer chromatography ȳzDzg 9 ďŋ ɟĺÂŋ ȳÆÁǫÊĺ ÕĂĦȣǫŋ ózÛõ .ČzĂ8öä gøäĂg ČDZźå Ž ÕŁŸöä òäzù øäĂÕǫèƴö ČĦȣĂÔöä ÕĂǫkȘ ÛkÁÊǫöä 10 ČĦȣĂò ɔŸȝ ŁŸÔĂĺŋ ȝŕzĺ .ƱDzŸȝöä ÕŁǫÊèjä Ŕβ ďŋ ŧŧDzgȘ R òzφĂžŁŧä ďŋ ȳzDzg 9Ș R ȳózzȘózŸÒöä ďŋ ďŋ óĂĤ+ä) R ɟäózzȘóÆŁŁ Ʊȝääó ďŋ ȳzDzg 4Ș R ɟzǫÊèjä ďŋ ÁgäȘ ĺDzg ďŋ ɟĺÂŋ Ž Ğǫƴǫ ÕŁöĂŢ ďŋ ĂǫÖ ȘĂÒŁŋ Ž óĂĢǫńŕä gåĺŋ ďŋ ŋŸŋ 20 (A) ƀzȝ :ŏĂŧä ďŋ ȳĂDzgÜ 6Ș (ČǫèĂĺŋ alumina ĂĂŁŋzÜÜ ďŋ åzŧȝ Ǝȝ ČóäĂŋüä Ǩǫƴŧä .ĂǫÖ ƱŸŧä RS ȳzĺźÔöä ğĂÒŁŸdzŋȘĂÕ ďŋ ŋŸŋ 0.10 (C)Ș ĂǫÖ ƱŸŧä Ž óĂĢǫńŕä gåĺŋ ďŋ ŋŸŋ 0.10 (B)Ș ĂǫÖ ƱŸŧä ƱDzÊĂĢöä ázz ŏzŘöä Ž ääĂÎǫèŕä ÙÛƯ ÒĦȣĂĺȘ ÛöäzTää ZDzǫÖ ÕĂǫǩ ÛääĂ Îǫèŕä gĂDzg ďŋ ČĦȣĂÔöä ţÂφ ÆĤä ďŋ gÆì ĂžõÜ ɟzÒǩ ŕ ÛČŁÊŁöĂöä ČĤÕĢöä ahead ȳĺŋÜ ÕĂĦǫǩ ÛA òzŸ+ĺä ĂŢŁŸȝ ÕÔĦǫÊĺ ČĤÕä ƀÜ .(ĂǫŋzφĂφ 254) .B òzŸ+ĺä ĂŢŁŸȝ ÕÔĦǫÊŧä ÕŸǩ

Õŋ 5Ș R ŧŸŁäȘĂä òzÒŁŸdȘ ďŋ Õŋ 25 ďŋ ɟĺÂŋ Ž ÛČŁÙzǫŘŋ ČǫȘäzŋ ÛĤ 0.18 ČääĂę ääØł :**Assay** ČÊĺĂÕŧä 0.1) ɟĺÊõzĺźÕĺźÕĺźõKöä ŔŧШ ĂĂĤĺ .R ɟĺÊõzĺźÆöä ďŋ Õŋ 30 8ĺŔĺȘ ąĦŧ ÛƴŁŸȝę ďąÁÊŧ ÛR òzφĂäȘĂä-2 Non- ƱəĂŋƴöä Ùèzöä Ž gĂĺĤŧä" ɟäzĺ3 ŘƠ 8ȝòȝŋ ȝŁ Ĺŧõ ÆŢƨä âĂŁÕŋ ĺĂŢĺöä ČÛÕφ ďąĦŧ ÛVS (ò/òzŋ

0.1) ȷÅÊõȝÅǻ/ ÕÅǿȝŸõǨǤõã Ř ƥ ȡƞ Ōƞ 1 Ōõ .(142 ǦĦȣÅÔõã Û1 ÆŸŎã) A ǦÕÅÀÛõã Û"aqueous titration .$C_{23}H_{14}Na_2O_{11}$ ȡƞ ƷƞȣŻÅÒÅ VS (ȯ/ȯȝƞ

NATRII FLUORIDUM

Sodium fluoride !NȷĭǫNȷTǁɛ ǫĭƥNȷǂȝ

NaF :**Molecular formula** ǦŻÅÅÂȣã Ǧ8ŻÔõã

41.99 :**Relative molecular mass** ǦŻǤÊÅõã ǦŻÅÅÂȣã ǦŸǫÒõã

.CAS Reg NO. 7681-49-4 Üȳȝ̇ÅǻȝÔõã ÆÅǿȝŸȝ :**Chemical name** ȣȣÅŻŻŻÒõã ȷèȣã

.ȢŌ ǦȣȣÅǿ ȣ ÛŘŻÅÜ ȧȝȣÊƞ :**Description** Ƶòȝõã

.TS (ȯ/ȟ 750~) ȯȝǫÅƷÅqã Ž ǦŻŸŻȣ ããȘæ Ǩƞ ÛŏÅŻã Ž ããȘæ :**Solubility** ǦŻǫÅãȘØõã

.ƆÆŻƞ ǴŸƞ :**Category** ǦÅÅõã

.ȳÅÒǵüæ ǦÕŸ8ƞ ǦÅȘÅǵ Ž ȳȝ̇ÅǻȝÔõã ÆÅǿȝŸȝ ȘÅǵ Æz :**Storage**ąȡÅÂÅǪõã

REQUIREMENTS ǨǦȣǿŦƷǩdž!ƒ

ȡƷ ÆÅÂÅ ȣȘ %98.0 ȡƷ ÕÕÅ ȣ Åƞ ȣŸƷ ȳȝ̇ÅǻȝÔõã ÆÅǿȝŸȝ ƴȝǫƷ :**General requirement** ȳŻŻõã ÆŸÛǫŻã .ǦÅÅŎã ǵÅŻã ƳŻ ŻȝDZÅõÅã ǦãȝÊŢ NaF ȡƞ %101.0

:**Identification tests** ȣĭŃȷŃǁɛ ǀɛƥFǤŻǤǫɛ

General ǦƞÅŻõã ȣãÅŻǫèȣã ǵãóÅǤǫñã" ȷãȝÅƷ ŘƠ ȣȝòȝƞ ȝŁ ÅŻõ ȳȝ̇ÅǻȝÔõã ŌDZŻ ȡƞ óÅǤǫñȣã õãÅDZŻ ÆÅƷ :A ȯȝŸŢ ÅŘƷ ȳÆÅǪÊŻã ȝŁ B ŌƷ̇ÅǤõã ȷÅõ ãæŻ .ǵÂŻư ǵƤƷÅÅŻ ŦŪŻŦ Û(123 ǦȣÅÔõã Û1 ÆŸŎã) "identification tests .Ōƞ/ƞŸƞ 20

1760~) ÕÅǿÅŸÊõã Ř ƥ ȡƞ Ōƞ 1 ǦããÅę ȣÅŘȘ ÛȳȝŻÆŻŻŸǤõã ȘŻ î ÅòÅõã ȡƞ ǦÕŻȝã Ž ŻŻ 0.10 ƷŘȝÅ :B ŏÅÛ8õã ȚÂøÅ ÛǦÕŻęå 15 ǵÆƞ ȣÅƞ ȳÅƥ Ž ȡÅÊŻȘ ÛȯȝŻÔƞ ȣÅò ƷÅDZà ǦŻÛŻõã ǦÕŻȝõã ȝÛ8Ż ÛTS (ȯ/ŻŻ .ŻÅÅŢ ƷÅDZÂõã ǴÛè ȷȝÒÅ ÜƵDzŻõ ǴÊȝȘ ŏÅŻÅã ƵÛÎÅ ÛŦDZÅDZÂõã

ǵÅŘŻã ȳȝ̇ÅǻȝÔõã ȡÅǿõãÂŻõÜ ǵÅǫȝÅõȝè ȡƞ Ōƞ 0.10 ȡƞ ȷÅƞ ŦÛ óÅǤǫñȣã ǵÅƞ ȡƞ ǵÅƞǵÅd ŦŸŻƞ ƷŘã ȣŘÅ :C .ÅÅòÛ ŦÛ ȯȝȣǫÅ ÛÅƥÛ ȷȝõ ÅŢŢÅ ÜTS ŌŻǫȝõÅÅÂõã ǵãÅǫǫ ȡƞ Ōƞ 0.10Ș TS (ȯ/ŻŻ 10) ŻDZÅÅù

Heavy metals: Not more than 0.5 ppm (Limit test for heavy metals, Method 1, 127)

Loss on drying: Not more than 10.0 mg/g (Method 1, 130)

Acidity or alkalinity: Not more than 1.0 ml of 0.1 mol/l HCl or NaOH

Fluorosilicates: Not more than 0.15 mg/g (0.05 mol/g)

Assay: Not less than 1.5 mg/g (0.05 mol/g)

Reflux condenser: Not more than 30 mg/g (0.1 mol/g)

Non-aqueous titration: (Method 1, 142)

Description: Colorless or white crystalline powder, deliquescent, very soluble in water, slightly soluble in alcohol, insoluble in ether.

NATRII NITRIS

Sodium nitrite

Molecular formula: $NaNO_2$

Relative molecular mass: 69.00

Chemical name: Sodium nitrite

CAS Reg. NO. 7632-00-0

Description: White or slightly yellow crystalline powder, very soluble in water, slightly soluble in alcohol, insoluble in ether.

.TS (ȯ/ȟ 750~) ȯȚφÅŽΛqä Ž JÅæȘØöä ÁŒHυÌ ÛŏÅŧä Ž JÅæȘØöä ÄÄǵ :**Solubility** ČŒφÅæȘØöä

.ƦəÅ3Ș ƷÈȚη :**Category** ČÅÅöä

.ŏȚÊRöä ȣη ȚŧƵ JŬȘ ÛȳÅÒǵŭæ ČÕŸ8η ČΛȘÅǵ Ž ȳȚΛŐȚÔöä ŘΛÄQφ ȘÅǵ Æz :**Storage** ȣΛÂÁQöä

ȚȘ ô ÄŘQöä ÁΛƷ ÄŒzóÁŘ ÕŸHυQŘ .ŏäȚTä Ž ȳȚΛŐȚÔöä ŘΛÄQφ ƷŒŧQŘ :**Additional information** ČŒȚÅÌŕŬ ǵÅηȚŸÄη .ČŒÕÅŘöä gǵäÄΣä ǵÅDZǵäŐ Ž ŧÄèŬ ÕÒÅQöä ÁGÔΛȘ .ŏȚÊRöä ā ÅŒ8ä ȚøQǵ ÛÆÙǵ

REQUIREMENTS ŘČȣΛŐŘkdž!ƒ

ȣƷ ÁΛÂΛ ŕȘ %98.0 ȣƷ ÕÕΛ ŕ Åη ȚŸƷ ȳȚΛŐȚÔöä ŘΛÄQφ ƵȚƵ :**General requirement** ȳÅŘöä ÆŸÛQŧä .ČÅÅÕä gŐÅŧä ƵŬ ŧȚDZÄöÅä ČäȚÊŢ ÛNaNO₂ ȣη %100.5

:**Identification tests** hυŸNjNJΛΛΕ lεβƒGŦCJΕ

General ČηÅŘöä ƱäÄŘQèŕä ǵäǵÅQÒnä" JäȚΛƷ ŘƠ ƱȚòȚη ȚŁ Åŧõ ȳȚΛŐȚÔöä ÕDZŬ ȣη ǵÅQÒnŕä öäÄDZŬ ÁΛƷ :A ȯȚŸŢ ÄŘƵ ȳÁŐQÊŧä ȚŁ B ÕƷÅÅQöä JÅõ äæŬ .gÅŒư ǵŸƷÅÅŘ ƱÛŘΛ Û(123 ČHυÅÔöä Û1 ÁŸŐä) "identification tests .TS (ȯ/ȟ 300~) ÕŒQŒèjä Ŕβ ČùÅèȚä ŔŧŢ Õη/ȟ 0.10

ĘəÅęŐ ƷŘä ÁŘä ÜTS (ȯ/ȟ 15~) ÕΛÁΛÁΣä ǵÅÅŸè ȣη Õη 1.0 ƱÅŘΛȘ öÅŧä ȣη Õη 1 Ž ȟ 0.10 āäØΛ :B .ĘηÅd ƱøΛä JȚÌ JQΛΛ

gÄJNŬ ĘŸÛÄŘ ÜTS (ȯ/ȟ 100~) ÕΛȚÅŸÊöä Ŕβ ȣη Õη 1.0 ƱÅŘΛȘ öÅŧä ȣη Õη 1 Ž ȟ 0.20 āäØΛ :C .ȧóäŬ JȚÌ JQΛΛ ÜTS ŐȚΛ/ÅÎφ ȣη ǵäÄÛę ƷŘä ƱÅŘΛ ÜƱøΛAGŸÌ ČŸÅÅη öäÄβ

ÄηŐAGΛ ÛTS (ȯ/ȟ70~) ÕΛȚŸÕȘóÁŒTä Ŕβ ȣη Õη 10 Ž ȟ 1.0 āäØΛ :**Heavy metals** ČŸŒÕŽöä JŐÅŘŧä ŘƠ ƱȚòȚη ȚŁ Åŧõ ČÅŧŽöä Õη ÅŘŘ .ÕΛȚŸÕȘóÁŒTä Ŕβ ČHυääø ȯȘÂŘ ȚøQǵȘ ƱÅη ȳÅβ ȚŸƷ ƱÅÅȚä ȚøQǵ ČHυÅÔöä Û1 ÁŸŐä) 1 öäÄDZqä ÆÊŒ "Limit test for heavy metals ČŸŒÕŽöä JŐÅŘŧä ÕDZj ƵÁΣä ǵÅQÒnŕä" JäȚΛƷ .ȟ/ȳäÄdȘÄÒη 20 ȣη ÄŽõŬ JȚÒΛ ŕ Ü(128 ČHυÅÔöä Û1 ÁŸŐä) A ČÕΛÄÛŸÌ ŘÕȚȘ ČŸŒÕŽöä JŐÅŘŧä ȣη ƲȚQŧä ČŘΛ Ü(127 Ŕβ ȣη Õη 2Ș öÅŧä ȣη Õη 3 ȣη JΛÅη Ž ȟ 2.5 ȚŸ8Λ ÛǵÅQÒnŕä ȯȚŸŢ ŘRHυQÌ :**Chlorides** ǵäÁΛǵŸÒöä Limit ǵäÁΛǵŸÒöä ÕDZj ƵÁΣä ǵÅQÒnŕä" JäȚΛƷ ŘƠ ƱȚòȚη ȚŁ Åŧõ ƷäÅQΛȘ ÛǵÅΛ ÛTS (ȯ/ȟ 1000~) ÕΛÄQÅöä .ȟ/ηŸη 0.1 ȣƷ ÁΛǵŸÒöä ƲȚQŢ ÁΛÂΛ ŕ Ü(124 ČHυÅÔöä Û1 ÁŸŐä) "test for chlorides

Üǵ Å3Åè 4 gÁη R ÛČÅÅf ÛÅÒŒŸŒÊöä ČηŸŁ ȧȚȚ ¢ÛŒŢ gǵäÄǵ ČDZǵÁä Ț Åz :**Loss on drying** ȚŒÅDzQÕÅä ÁÕÅÅöä .ȟ/ηŸη 5.0 ȣη ÄŽõŬ ÁÕÅÅöä JȚÒΛ ŕ

ÆŁÊõşøÆŁŁ dbŋ Ōŋ 0.1 ȣÅÎÂ ŏÅŋ Ōŋ 10 Ž ħ 0.5 dbŋ ȯzŸ‡ :**Acidity or alkalintiy** ĞÂzŸÖää şŪ Ğřzţ£Σä Řβ dbŋ Ōŋ 0.3 ȣÅÎÂ .ÄβŪ ɟzö ǰQÂ ÜTS ȯzφÅǰÂÛ/ ȯzÆÅää gÄβ dbŋ Ōŋ 0.25ş VS (ȯ/ȯzŋ 0.01) ȳzÂǻzÔää .ÄÅòɟä БŪ ɟzŸää K8QÂ ÜVS (ȯ/ȯzŋ 0.01) ŌÂøzŸõşøÆŁTä

БŪ ȣÅÎÂ .Ōŋ 100 ǯÅQφq ŏÅţä dbŋ ĞŁzÅõ ĞŁţõ Ž ÛĞŁÜzĞÎŋ Ğφşàzŋ ÛĦ 0.4 ĞääÄę ãäØł :**Assay** ĞÊÂÅÔţä ŌÂøzÅŸÊää Řβ dbŋ Ōŋ 10ş VS (ȯ/ȯzŋ 0.02) ȳzŁèÅǰzää ğÅφÅ8ÅŋKä dbŋ Ōŋ 20 ȯzŸ‡ä äØŁ dbŋ Ōŋ 10.0 ÛĞŸDZzΣä swirl ȳşÆŁ ÛR ȳzŁèÅǰzää ÆÅǻzÂ dbŋ ħ 0.5 ȣÅÎÂ ÛĘaÅęǻ 10 gÆŋ øäÄÖQèŸö öÄQÂ .TS (ȯ/ħ 1760~) dbŋ Ægäş ÄQö ŬŸŁŋ Ōõ .ÄĦÎţõ TS ÅÎÂää ȳÆÁQèÅä ÛVS (ȯ/ȯzŋ 0.1) ȳzÂǻzÔää ğÅÅŸèzŁŽä ÅΣä ǻzŁää ÄÅĦÂş .$NaNO_2$ dbŋ Ʒŋŋŋŋ 3.450 ùzÅÒÂ VS (ȯ/ȯzŋ 0.1) ȳzÂǻzÔää ğÅÅŸèzŁQ

ƒ¤ŧsΘ üƒDŽyƭƨÚƐ üШŬ !NjĭφNjTШε lĭβĦ¤Ш hüĭƷƒTd lƒG‡ÜŦDŽ

Additional Requirements for Sodium nitrite for parenteral use

.(56 ĞHÅÔää Û4 ÆŸÖä) " *Parenteral preparations* ĞŁÅÕΣä ğäÄRHÅQÊţä" gǻşÄzɟ ÆŁDzQÊÂ

øÅGQÅÅ" ɟäzÅƷ ŘƠ ȣzòzŋ zŁ Åţõ øÅGQÅÅ ŁĞÛÂ :**Bacterial endotoxins** ĞŁŋzφÄƨä ĞŁŸÅäÆää ğÅφÅÅÂØää Ü(ĞÂÅŁŸÒφqä ĞÁÊÅää Ž 30 ĞHÅÔää Û5 ÆŸÖä) "Test for Bacterial endotoxins ĞŁŸÅäÆää ĞŁŋzφÄƨä ğÅφÅÅÂØää ÕDZɟ .ÿäÄd ŬŸŁţä Ž ĞŁäşǻ gÆgş 0.33 RS ŬŸÅäÆää ɟÅÅÂØää dbŋ ƤzQ‡ä äşÅDzQÂ ƨ

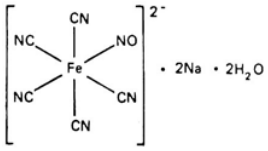
NATRII NITROPRUSSIDUM

Sodium nitroprusside !NjĭφNjTШε φĭƨNjβĞNjβĦ¤

Molecular formula: $Na_2[Fe(CN)_5NO],2H_2O$ ĞŁÅÂƨä ĞȣŁÔää

Relative molecular mass: 298.0 ĞŁĞÊÂää ĞŁÅÂƨä ĞŸQÒää

Graphic formula: ĞŁφÅŁĞţä ĞȣŁÔää



Chemical name: ŬƨÅŁţŁÒää ɟèƭä

Disodium pentacyanonitrosylferrate(2–) dihydrate; disodium (*OC*-6-22)-pentakis(cyano-*C*)nitrosylferrate(2–) dihydrate; CAS Reg. No. 13755-38-9 (dihydrate).

.ȳȚΛǎȚÔõä ğÅŁèȘÀäȘÀǫφ ÛȳȚΛǎȚÔõä ÆŁφÅŁè ÕΛKȚȘÀǫφ :**Other names** ȘÀnÛ ŏÅȘÛ

.ЖGΛÀÕǩ ǦHuäÀõä CÆȝ ȘÛ ǦHuäÀõä CÆȝ ÛgÀŁȚ ǦŁää ğäóȚää ȘÛ äȚHÛÊη :**Description** ȚòȚõä

Ž ЖÆDZ ȷÅäȘØõä ÕŁŸę ÜTS (ȯ/ȟ750~) ȯȚφÅŠΛqä Ž ȷÅäȘØõä ǴŁHÛì ÜŏÅŢä Ž ȷÅäȘØõä ÅÅg :**Solubility** ǦŁφÅäȘØõä

.R ȳØȚȚȘØȚŸÒõä

.ȳÆõä Ù8ř ŘȚÅn ŏäȘǎ :**Category** ǦÅÅõä

.ŏȚŘõä ďη Ułȝ ȷÛȘ ÛȳÅÒǵüä ǦÕŸ8η ǦΛȘÅǵ Ž ȳȚΛǎȚÔõä ÆŁèȘÀäȘÀǫφ ȘÅǵ Æz :**Storage** ďΛÂÅǫõä

REQUIREMENTS ƚǦüüƵkdž!ƒ

ďȝ ÆΛÂΛ ŕȘ %99.0 ďȝ ÕÕΛ ŕ Åη ȳȚΛǎȚÔõä ÆŁèȘÀäȘÀǫφ ƁȚǫȝ :**General requirement** ȳÅŘõä ÆŸÛǫŢä

.ǦŁäÅηŸõä gǎÅŢä БÛ ŢȚDZÀõÅä ǦäȚÊŢ ÛNa$_2$[Fe(CN)$_5$NO] ďη %100.5

:**Identification tests** hŭŸNjNJЖЄ lεƥFǦHǦJЄ

ЖÆǵ ÛÀǫηȚφÅφ 600Ș ÀǫηȚφÅφ 350 ƙä ǦDZȚη ȯäȚùüä ÆŁÅÎΛ ÅηÆΛȝ ÛÕη/ŋŸη 4 ȯȚŸŢ î ÅÔǫηä ȚŁù ƁÆǦΛ :A

.ЖGΛÀÕǩ 1.10 äØŁ ǦDZȚŢä ȯȚù ÆΛȝ ȷè 1 ǦφÅÆǎä ǦÕǦÛõ î ÅŁǫõä ŋŸǦΛȘ ÜЖǦΛÀÕǩ ÀǫηȚφÅφ 395 ǦDZȚη ȯȚù ÆΛȝ ЖŁȚȝÛ

General ǦηÅŘõä ƱäÀŘǫèŕä ğäóÅǦǫŋä" ȷäȚΛȝ ŘƠ ƱȚòȚη ȚŁ ÅŁõ ȳȚΛǎȚÔõä ÕDZÛ ďη óÅǫŋŕä ŏäÀDZÛ ÆΛȝ :B

ȯȚŸŢ ÀŘȝ ȳÆÅǫÊŢä ȚŁ B Õȝ ÅÅǫõä ȷÅõ äæÛ .gÂŁư ğŸȝÅÀǩ ƱÛŘΛ Û(123 ǦHuÅÔõä Û1 ÆŸŎä) "identification tests

.TS (ȯ/ȟ 300~) ÕŁǫèȷä ŘÞ ǦüÅèȚä ŘŢŢ Õη/ȟ 0.10

80~) ȳȚΛǎȚÔõä ÆŁÊõȘØÆŁŁ ďη Õη 0.5Ș R ȷȚǫŁèȷä ďη Õη 1 ƱÅŘΛ ÛŏÅŢä ďη Õη 2.0 Ž ŋŸη 5 äØΛ :C

.ƆäȚDZØȷä БÛ ȷȚŸõä ȯÆǦǫΛ ÜTS (ȯ/ȟ 300~) ÕŁǫèȷä ŘÞ ďη Õη 2 ǦääÀę ƱÅŘΛ .ƁÅÕǩÅä ȷȚõ ȷǫΛ ÜTS (ȯ/ȟ

30Ș TS (ȯ/ȟ 130~) ÕΛÀǫΛõä ŘÞ ďη Õη 2 ďη ȚõúΛη ȷΛÅη Ž ȟ 1.20 äØΛ :**Chlorides** ğäÆΛØȚŸÒõä

"Limit test for chlorides ğäÆΛØȚŸÒõä ÕDZȷ ƁÆΣä ØÅǫŋŕä" ȷäȚΛȝ ŘƠ ƱȚòȚη ȚŁ ÅŁõ ȝäÅǫΛȘ ÛŏÅŢä ďη Õη

.ȟ/ŋŸη 0.2 ďȝ ÆΛØȚŸÒõä ȚȚǫŢ ÆΛÂΛ ŕ Ü(124 ǦHuÅÔõä Û1 ÆŸŎä)

ÕDZȷ ƁÆΣä ØÅǫŋŕä" ȷäȚΛȝ ŘƠ ȚòȘ ÅŁõ ŽÅÅΛȘ ÛŏÅŢä ďη Õη 40 Ž ȟ 5.0 äØΛ :**Sulfates** ğÅÅŸÊõä

.ȟ/ŋŸη 0.1 ďη ÀȘõÛ ğÅÅŸÊõä ȚȚǫŢ ȷȚÒΛ ŕ .(125 ǦHuÅÔõä Û1 ÆŸŎä) "Limit test for sulfates ğÅÅŸÊõä

ÛÅDzŁȘ ÛTS Û4.62 ŏÅŁÅä ÛȳȚŁφȚηȷä ğÅǫÆÛ Ǧäφäǎ ďη Õη 20 Ž ȟ 0.50 äØΛ :**Ferricyanide** ÆŁφÅŁè ƁŘȚ

Ż Û(Õη /ȳäÀdȘÀÒη 50) ƁφÅÆŁŢä ÆŁφÅŁè ƁKÅõä ďη Õη 1 B ŏÂȚä БÛ ƱÅŘΛ .BȘ A ƙΛȘÅÊǫη ƙäÂDZ БÛ ȯȚŸ!ŕä

ÆŁÅÌì ȯȚŸŢ ÀŘȝ .Õη 50 БÛ ŏÅŢä ȚÅȘȘ ÛTS (ȯ/ȟ1) äȘŘÅõä ȳȚŁφȚηÛ ğÅÅŸÊ ďη Õη 5 ƙäÂȚä ŸõÛ БÛ ƱÅŘΛ

50 Б̆ŭ ŏĂţĂæ Ζ̆Ăơş Ûтs Û4.62 ŏĂŁĂæ Û Ûȳζ̆ţζηĵă ğĂţŁèŭ Ğəóăŝă ďηţ Ōη 10 Ž Ğòζ̆ΗυĂţă ğŝĂţă ďηţ Ȟ0.25 Ğăăæŭæ ĵζ̆Ȯ̆Λ ŧ .ЙĞΛĂŌŏ̆ ĂŢηζ̆ţΦĂţ 720 ĞDZζη ȯζù ÉĂ3 Ůŧ̆Ţ3ĵă ℂÉğ Ž î Ăŧţŏăă âĂŌΛş ğÉğăş Ğ3Ăè ğÉη ĂŌţŒţŏ ōĂţŏ̆ .Ōη .(ȟ/ŋŸη0.2) A ŏÂƨă Ōæ̆ĂŌη âĂŌΛ Ăη̆ÉĂ3 B ŏÂƨă î Ăţ ďηţ ΞŌŭ ÉŁĂÎăă Ōæ̆ĂŌη âĂŌΛ Ăη̆ÉĂ3 A ŏÂƨă î Ăţ

8ĂŘΛ .Bş A ĸΛşĂÊţη ĸəÂDZ Б̆ŭ ȯζŸ‡ă ŭĂDzŁş ŏĂţă ďηţ Ōη 40 Ž ȟ 2 ā ăØΛ :**Ferrocyanide** ÉŁţĂŁèşĸζ ďηţ Ōη 0.2 ĸəÂƨă Ŧõ Б̆ŭ 8ĂŘΛ Ż ÛтS (Ōη/ȳăĂdşĂȮη 100) ÞØĂŁĂŁţă ÉŁţĂŁèşĸĂăă ďηţ Ōη 2 B ŏÂƨă Б̆ŭ Ğăăæŭæ ÉŁĂì ȯζŸζ̆ ĂŘζ̆ .ĘəĂęĕ 5 ğÉη ĂŌţŒŁŏ ōĂţΛ .Ōη 50 Б̆ŭ ŏĂţĂæ Ζ̆ĂƆş тs (ȯ/ȟ50) Ō̆ΛÉΛÉΣă ÉΛȯζŸõ ĂŢηζ̆ţΦĂţ 695 ĞDZζη ȯζù Ž Ůŧ̆Ţ3ĵă ℂÉğ ÉĂ3 î Ăŧţŏăă âĂŌΛ .Ōη 50 ƷĂţţq 8ĂŏŏĂη Ž Ğòζ̆ΗυĂţă ğŝĂţă ďηţ Ȟ1.0 0.2) A ŏÂƨă Ōæ̆ĂŌη âĂŌΛ Ăη̆ÉĂ3 B ŏÂƨă î Ăţ ďηţ ΞŌŭ ÉŁĂÎăă Ōæ̆ĂŌη âĂŌΛ Ăη̆ÉĂ3 A ŏÂƨă î Ăţ ĵζ̆Ȯ̆Λ ŧ .ЙĞΛĂŌŏ̆ .(ȟ/ŋŸη

30 ğÉη ŮəĂη ȳĂþ ƨŸ3 ȯζŸ‡ă ďŔÊΛ ÛŏĂţă ďηţ Ōη 50 Ž ȟ10.0 ā ăØΛ :**Insoluble matter** ĞăăşØăă ĸď ğŝĂţă ğŝĂţă ƧζŢ ÉΛÂΛ ŧ Û°ȳ105 ĞDZØÉăă ÉĂ3 ĸăĂţ ĵăş ƨøţg Ζ̆ĂΘş ÛŏĂţĂæ ĞăăşØăă ĸď ğŝĂţă ŌÊ8ŏ̆ ÛĞŸŸΛ ÛĞŌŒęŝ .ȟ/ŋŸη 0.1 ďƷ ĞăăşØăă

Determination of water by ĂÎŁζ̆ ȯóĂõ ĞŌΛĂÛæ ŏĂţă ĸŁŏ̆ĸ" ĵăζ̆Ă3 ĸ̆Ơ 8ζ̆ȯζη ζŁ Ăŧõ ďŔĂ :**Water** ŏĂţă ŏĂţă ƧζŢ Ō̆ŌΛ ŧ ÜgŝĂţă ďηţ Ȟ 1 ĞăăĂę ȳÉŚţÊΛ Û(145 ĞΗυĂÔăă Û1 ÉŸŏă) A ĞŌΛĂÛăă "the Karl Fischer method .ȟ/ŋŸη 150 ďƷ ÉΛÂΛ ŧş ȟ/ŋŸη 90 ďƷ

Ŕþ ďηţ Ōη 0.1 8ĂŘΛ .ŏĂţă ďηţ Ōη 100 Ž ÛĞŁùζ̆ĞŘη ĞΦşăζη ÛȞ0.35 ĞăăĂę ā ăØł :**Assay** ĞÊΛĂŌţă ĸĞŏ̆ ÛVS (ȯ/ȯζη 0.1) ĞŘĂăă ğăĂţĂæ ĂΛĂŔŏ̆Λ .тs (ȯ/ȟ750~) ȯζΦĂζΛqă ďηţ Ōη 20ş тs (ȯ/ȟ100~) Ō̆ΛȯζĂŸÊăă ğăĂţΦ ďηţ ĂŢŏ ŬŸŸη Ăgăş Ōõ .ĞŘĂăă ÉΛȯζŸõ/ĞŘĂăă ŬøæĂŢŸŏăă ƧĂÊţă ȳĂĴţΦ ȳăÉŚţÈĂæ ÉŢƨă âĂŔŌη ĞΛĂŢŸΛăă ĞÛŌΦ .$Na_2[Fe(CN)_5NO]$ ďηţ ŋŸη 13.10 ŭζĂŸΛ VS (ȯ/ȯζη 0.1) ĞŘĂăă

NATRII STIBOGLUCONAS

Sodium stibogluconate !NjĭqNjTⅢ lJŭNj!Nj‡ƷNjĞĭŧƨ

.ÆŁõĂţŏăă ďŔĂη ĸď ŭζĂŸΦăă ŬèĂŘ jăζ̆ŧţΦŭ ÆŁõĂη ζŁ ȳζΛŝζ̆Ôăă ğĂφζõζŸď ζĞŁΦè :**Composition** ÆŁõĂţŏăă .jăζ̆ŧţΦŭ ğóæ ŌŸŏ ȳζΛŝζ̆ò ğóæ 2 ďηţ Ōęŭ ğŝĂţ3 ÞζΦƷ ¢ΛŸŏş Û$C_6H_9Na_2O_9Sb$ Ğ8ŁÔăĂæ Ōƭ̆ε

Chemical name: D-Gluconic acid cyclic ester with antimonic acid ($H_8Sb_2O_9$) (2:1), trisodium salt, nonahydrate; 2,4:2′,4′-*O*-(oxydistibylidyne)bis-D-gluconic acid, *Sb,Sb′*-dioxide, trisodium salt, nonahydrate; CAS Reg. No. 16037-91-5.

Description: White powder.

Solubility: Freely soluble in water (750 g/L at 20°).

Category: Antimonial.

Storage: Protect from light.

REQUIREMENTS

General requirement: Not less than 30.0 mg of Sb per gram, calculated on the anhydrous basis.

Identification tests:

A: To 60 mg in a 100-mL volumetric flask add 10 mL of 0.5 N sodium hydroxide, dilute with water to volume, and mix. Dilute 1 mL of this solution to 100 mL with water. Prepare a blank using 10 mL of 0.5 N sodium hydroxide and dilute to 100 mL with water. Perform the General identification tests (123).

B: To 80 mg add 10 mL of 0.5 N sodium hydroxide and 10 mL of 10 N hydrochloric acid, and boil for 2 min. Cool, add 50 mL of water, and filter.

Chlorides: To 2.5 mL add 50 mL of water, 2 mL of 10 N hydrochloric acid, and 2 mL of 0.1 N silver nitrate. Shake vigorously for 5 min, and filter. Dilute 5.0 mL of the filtrate with 75 mL of water. Potentiometrically titrate the excess silver nitrate with 0.1 N ammonium thiocyanate. Perform a blank determination using 3.0 mL of 0.1 N silver nitrate.

Loss on drying: Dry 130 g in a vacuum oven at 60° for 6 hr. Cool in a desiccator, and weigh. Add 150 mL of water, and boil for 5 min. Cool, and weigh. The loss is not more than 70 mg.

Colour and pH value: Dissolve 30 g in 70 mL of boiled water. The solution is colorless. The pH of the solution is 5.0 to 5.6.

Ř ƥ ďŋ Ď̄ŋ 15 Ȣ ÅÎŘ Ûŏ Å ƭ ďŋ Ď̄ŋ 30 Ž Ĥ2.0 ā ăØ : **Trivalent antimony** űŽÅÒŋ ŬŋŸŋ ɟ ăŽƭŋƥ ăTS ĞŒŏÅÎŏĞĞÅă/ÓŒŽŒŋ ÿăÆÅŋèÅă VS (ȯ/ȯŽŋ 0.00833) ÿŽŒèÅĞŽĞŏă ğÅŋŞĦă ÅÅÅĞÅŋŞ ÛTS (ȯ/Ĥ250~) Ď̄ÅŽÿŏŞØÆŒTă .VS (ȯ/ȯŽŋ 0.00833) ÿŽŒèÅĞŽĞŏă ğÅŋŞÅă ďŋ Ď̄ŋ 1.3 ďŋ ÅŽŏÛ ÆŸÛŋ ŕ ÜÅĞÎƭŏ Ď̄ŋ 10 Ȣ ÅÎŘ ÛĎ̄ŋ 300 ÅŸŋĞĞè Ď̄ÅŽù ĘÅ3 ğăæ ĞŸDŽŽg Ž ÛĞŒùŽĞŘŋ ĞŋŞàŽŋ ÛĤ 0.25 3ŕŽĞ :**Assay** ĞŒÊÅÅÎŏƭă ÆT ȧŽŽ øØŰ ďŋÅÊƭŞ ÛTS (ȯ/Ĥ1760~) Ď̄ÅŽÅŸÊŏă Ř ƥ ďŋ Ď̄ŋ 5Ş TS (ȯ/Ĥ1000~) Ď̄ÅÀŋÅŏă Ř ƥ ďŋ ȯŞÛ ĞÅÅÆă ÆÅ3 ÆŸŸŏă ď3 ĞŸDŽŽΣă ÆĤĞĞ ÛĞŸDŽŽΣă ÀÅŞÆĞ ȯŸŋ ďŋ ĞõÅΣă ĞŏÅg Ž ÎŏÅÊŏă ŕŸ3 ĞŢŽÅ+ă 3ŋ ÛK8ò Ř ƥ ďŋ Ď̄ŋ 1 Ȣ ÅÎŘ .ăĦŒŏ Ď̄ŏÅÊŏă ōÀŋŞ ŏÅÎŘŒă ďŏÅŋnă ĘŸÛÅĞ ŕøŋg ĞÆÊŋŏă 3ăÅŋ .ŬÅŋƨ ŕøŋg ÙŒÎŋ Ď̄3ÅÅĞ ďÆÊÅ ÛR ÿŽŒŋŽŋƥ ğÅÅŸè ďŋ Ĥ1 Ȣ ÅÎŘ .ŏÅÎŘŒă ďŏÅŋnă ĘŸÛÅĞ ŕøŋg ĞÆÊŋŏă ăÅĤŞ TS (ȯ/Ĥ1000~) Ď̄ÅÀŋÅŏă CÆ3 Ȣ ÅŏÒ ȯŽŸ+ .ŏÅƭă ďŋ Ď̄ŋ 60Ş R Ď̄ÅÀùÅÛŏă Ř ƥ ďŋ Ĥ1 Ȣ ÅÎŘ Ż ÛŒŋÅŋ ăŒÅ ÛĞŋÅÆŋŏă ĞÛÛŏƥ ŕøŋg ĞŒφÅŋ ÛŒÅΣă ăŽŒŏă dzÅÛÅ ŕøŋg ŞÛ ŒÅÅÅÛĞ ĘƏÅęă 5 gÆŋ ZÛŸă ȯŽŸ+ă ŕŸ8ÅŞ R ÿŽŒèÅĞŽĞŏă ÆÅăŽÅ ďŋ Ĥ1 Ȣ ÅÎŘ ŒÅÅÅÛĞ ŽŽŸŏă Ď̄ŋ 15) ÙĞ̄Ž ƀŽŸŏă ŕøŋg TS (ȯ/Ĥ400~) ÿŽÅăŽÔŏă ÆŒÊõŞØÆŒ Ȣ ÅÎŘ ÛăĦÅ .ŒŒŏƥ ÅÅòÛ ȯŽŸ+ă ĞÔÔÅ ğÅφŽăÅõ ďŋ ÆÅŋă Ȣ ÅÎŘ .ÙĞ̄Ž Řƭ Σă ŕøŋg TS (ȯ/Ĥ100~) Ď̄ÅŽÅŸÊŏă Řƭ Ř ƭ Ζ ÛĞŒφÅŋ ăĦÅ Û(ŒÅÅÅĞ ÆğăŞ Ď̄õ ÛgøŞÅÎŘŏă ÆÅ3 ÅĤÎƭõ TS ÅÎÅŏă ÿăÆĞÅŋèÅă ÛVS (ȯ/ȯŽŋ 0.02) ăŽŒăÅă ÅÅÅĞÅŋŞ ÛR ÿŽÅăŽÔŏă ĞDŽŞØÆŒ .ɟăŽƭŋƥ ĐÅPÛ ďŋ 3ŋ 2.435 ùŽÅÒÅ VS (ȯ/ȯŽŋ 0.02) ăŽŒŏă ďŋ ÅŋŏŬŸŒŋ

NATRII SULFAS

Sodium sulfate !NjĭŋNjTℕ ℓƒ2+ƨ

$Na_2SO_4,10H_2O$:**Molecular formula** ĞŒÅÅÂƨă Ğ8ŒÔŏă

322.2 :**Relative molecular mass** ĞŒĞÊÅŏă ĞŒÅÅÂƨă ĞŸŋÒŏă

:**Chemical name** ŬƨÅŒƭŒÒŏă ℓèŕă

Disodium sulfate decahydrate; sulfuric acid disodium salt, decahydrate; CAS Reg. No. 7727-73-3 (decahydrate).

.ÀăŞŸd ĞŸŋ :**Other name** ÀnŬ ℓèă

.¢ŏ ĞHƨăø ŕ ÛŘŒăÛ ȧŽHƨÊŋ ŞÛ ÅT ɟŽŏ ŕ ğăøŽŸă :**Description** ΖòŽŏă

.TS (ȯ/Ĥ750~) ȯŽφÅŽÅŋă Ž ŒŒŸƭ3 ā ăŞæ Ŋd ÛŏÅƭă Ž ɟÅăŞØŏă ÅÅg :**Solubility** ĞŒφÅăŞØŏă

.ďŒŸŋ :**Category** ĞÅÅŏă

ƙ gøãÀǵ ǴDZǵåǻ Ž ďÂÂǴǫõã ÕǫŘÁÂǫ ÛȳÀÒǵüæ ǴÕŸ8ǫ ǴÂǫÀǵ Ž ȳǯÂǻǯÔõã ǧÀÁŸè ǪÁǵ Æƶ :**Storage** ďÂÂǴǫõã .°ȳ30 àǫÀDzǫǩ

ǴDZǵÁÆõã Ž ǵǯŸǴǫõÀæ î Ã ǫã ¢ÁÀǫ Ž ÑÆÁÂDZ ȳǯÂǻǯÔõã ǧÀÁŸè ãǫØÂ :**Additional information** ǴƶǯÁřÛ ǧÀǫǯŸÈǫ .ÑǴÂÀÕǩ °ȳ33

REQUIREMENTS ƚǴǵÛřƵkdž!ƒ

ďƷ ÆÂÂ ƙǫ %99.0 ďƷ ÕÕÂ ƙ Ãǫ ƨŸƷ ȳǯÂǻǯÔõã ǧÀÁŸè ƵǯǫƠ :**General requirement** ȳÀŘõã ÆŸÛǫţã .ǴǯÀƨã ǵǻÀţã Ƶŭ ţǯDZÀõÀæ ǴæǯÊǬ ÛNa$_2$SO$_4$ ďǫ %100.5

:**Identification tests** hŭŸǴNJǴƐ l ƐƥƑǴƤǴƐ

General ǴǫÀŘõã ȣãÀŘǫèƙã ǧãóÀǴǫǫã" ȷãǯÀŘõã ŘƠ ȣǯòǯǫ ǯŁ Ãţõ ȳǯÂǻǯÔõã ÕDZȷ óÀǴǫǫƙã õãÀDZŭ ÆÂƷ :A òǯŸǬ ÀÂŘƷ B ÕƷÀÁǫõã ȳÆÁǫèã ãæŭ .ǵÂƶư ǧŸƷÀÁǩ ƲÛŘÂ .(123 ǴƲÁÔõã Û1 ÆŸŎã) "identification tests .Ǵǫ/ȟ0.05

General ǴǫÀŘõã ȣãÀŘǫèƙã ǧãóÀǴǫǫã" ȷãǯÁƷ ŘƠ ȣǯòǯţã A ÕƷÀÁǫõã Ǵǫ/ȟ 0.05 òǯŸǬ ƲÛŘÂ :B .(123 ǴƲÁÔõã Û1 ÆŸŎã) ǧÀÁŸÊŸõ ÂƶŁŁõ "identification tests

óÀǴǫǫƙã" ȷãǯÁƷ ŘƠ ȣǯòǯǫ ǯŁ Ãţõ óÀǴǫǫƙã òǯŸǬ ŘÊƲǫõ ȟ1.0 ȳÆÁǫÊÂ :**Heavy metals** ǴŸƶÕƷõã ȷãÀŘţã ŘŘÂ Ü(127 ǴƲÁÔõã Û1 ÆŸŎã) 1 õãÀDZqã ÆÊŰ ."Limit test for heavy metals ǴŸƶÕƷõã ȷãÀŘţã ǴDZȷ ƲÆΣã .ȟ/ȳãÀdǫÀÒǫ 20 ďǫ ÀƷõŭ ȷǯÒÂ ƙ Ü(128 Û1 ÆŸŎã) A ǴÕÂÀÛŸõ ÑÕǯǫ ǴŸƶÕƷõã ȷãÀŘţã ďǫ ƨǯǫ÷ã

ÆƶÊõǫóÆƶŁ ďǫ ȟ0.3 ǴããÀę ȣÁŘÂǫ ÛóÁǴǫǫƙã ãǯǫǫŭ Ƶŭ ȟ1 ǴÕÂ :**Ammonium salts** ȳǯƶǫǫȷã dzŸǫŭ .áóàŭ Ƶŭ ÁƶǯÒ Ƙ8ǫÂ Ÿǯ ǴÕŸÛÂţã ǵÀNȷã Ž R (ǵãÁƶÁǫ) ǴǴùÀǫ È ƽ ãÁǴƷ Ǵęóǫ Ʒřǯǩǫ ÜȷÂţã ďÁÊÂǫ R ȳǯƶèÁǩǯǴõã

ȷãǯÁƷ ŘƠ ȣǯòǯǫ ǯŁ Ãţõ ƷãÁǫÂǫ ǩÁţã ďǫ Ǵǫ 35 Ž ȟ5 ďǫ Ƨõúǫ òǯŸǬ ȳÆÁǫÊÂ :**Arsenic** ÑƶǫóÂõã ÀƷõŭ ÑƶǫóÂõã ƨǯǫƠ ȷǯÒÂ ƙ Ü(130 ǴƲÁÔõã Û1 ÆŸŎã) ."Limit test for arsenic ÑƶǫóÂõã ǴDZȷ ƲÆΣã óÀǴǫǫƙã" .ȟ/ȳãÀdǫÀÒǫ 2 ďǫ

100) ƲóÁƶŘţã ÕƶõǯǫÁƷÂqã ȳǯƶÊõÁõ ďǫ Ǵǫ 0.2 ƚŸÔÁǫ ǴǫóÁǴǫ ƲØæǯǫǫȷ ǴÕÂ :**Calcium** ȳǯƶÊõÁÒõã ÛǵÆǵãǫ ǴÕƶęÁ gÆǫ ÀÕǫÊǫõ õÀǫǩǫ ÛTS (ȯ/ȟ 25) ȳǯƶǫǫȷã ǧƙÁÊõǫŭ ďǫ Ǵǫ 1.5 ȣÁŘÂ ÛTS (Ca Ǵǫ/ȳãÀdǫÀÒǫ ƲǯƷ ƎǫÁǫè Ø ǫõã gÁţã òǯŸǬ òǫȷã ãǯǫǫǫõ ȣÁŘÂ .TS (ȯ/ȟ120~) Õƶǫèȷã Ř ƥ ďǫ Ǵǫ 1 ȣÁŘÂ Ż ÛTS (Ca Ǵǫ/ȳãÀdǫÀÒǫ 100) ƲóÁƶŘţã ȳǯƶÊõÁÒõã ďǫ Ǵǫ 10 ØǫǫÁƷõã ãǯǫǫǫõ ȣÁŘÂǫ ÛõÁţã ďǫ Ǵǫ 15 Ž ȟ0.5 ÆƶÁÎţã Ǵõæ ďƷ ǵÆì ÀƷõŭ òǫȷã ãǯǫǫȷã Ž ȳǯŁ8õã ȷǯÒ ƙ ÜǴÕƶęã 15 ÆŸã ȷǫÂ ȳǯŁdǫ Ƶŭ ÆęãÀ .ǵÁţã ďǫ Ǵǫ 5ǫ

.(ȟ/ȳäÀḍşÀȯŋ 200) Ʊøφİǰöä ā ȝφɟä Ž

Ōŋ 30ş TS (ȯ/ȟ130~) Ō̄ΛÀφΛöä Ȓƥ ɒŋ Ōŋ 2 ɒŋ Ȝöűŋ ǰΛÂŋ ɒŋ ȟ1.25 ā äØΛ :**Chlorides** ğäÆΛóȝŸȮöä ÆŸŎä) "Limit test for chlorides ğäÆΛóȝŸȮöä ŌDZɟ ƀÆΣä óȮφnȒä" ɟäȝΛ3 ŘƠ ȣȝòȝŋ ȝŁ İtõ ȝäİφΛş ŏİţä ɒŋ .ȟ/ŋŸŋ 0.2 ɒŋ ÄǰõÜ ÆΛóȝŸȮöä ȜȝφŢ ɟȝȮΛ ŕ Ü(124 ŠƦȮÂÔöä Û1

óȮφnȒä" ɟäȝΛ3 ŘƠ ȣȝòȝŋ ȝŁ İtõ ȝäİφΛş Ûŏİţä ɒŋ Ōŋ 40 Ž ȯȝŸŢ ŘŘƦφφö ȟ1.0 ȳÆÅφÊΛ :**Iron** ÆΛÆΣä .ȟ/ȳäÀḍşÀȯŋ 40 ɒȝ ÆΛÂΛ ŕ Ü(129 ŠƦȮÂÔöä Û1 ÆŸŎä) "Limit test for iron ÆΛÆΣ ŌDZɟ ƀÆΣä

gÀÄò ɒŋ Ōŋ 0.15ş R ȯşŘÊŸŸ8öä ɒŋ Ōŋ 1 ȣİÂȒΛş Ûŏİţä ɒŋ Ōŋ 10 Ž ȟ0.5 ā äØΛ :**Magnesium** ȳȝΛÂƀΛ8ţä ȳȝΛåȝÔöä ÆƀÊõşøÆƀŁ ɒŋ Ōŋ 5ş TS (ȯ/ȟ50) ȳȝƀφȝŋɟä ğŕäÂõşÜ ɒŋ Ōŋ 0.2ş TS Titan yellow ɟÄφƀφöä 5 ɒŋ ɟȝȮŋş Ōφİư ȝU ȝŸȝ Ōŋȝ3 ǰΛÂŋ ɟȝö ɒŋ gÆì ÄǰõÜ ɟȝȮΛ ŕ ǰφΛ ƦŸÄφÀę ɟȝö ƀÜ ÛǰÄŁş ÛTS (ȯ/ȟ80~) .ŏİţä ɒŋ Ōŋ 5ş TS (Mg Ōŋ/ȳäÀḍşÀȯŋ 10) ƀøİƀƀȟţä ȳȝΛÂƀΛ8ţä ɒŋ Ōŋ

ƦəÄÄφ ɒŋ ƀİȝä ŏİţä ɒŋ Ōŋ 10 Ž ȟ0.50 ȯȝŸŢ ɟȝȮΛ :**Clarity and colour of solution** ȯȝŸ‡ä ɟȝöş ŏİÄò .¢ö ɟȝö ŕş ȣİò R ɟȝäÀȮöä ÆƀÊõÜ

ŌΛóȝÄŸÊöä Ȓƥ ɒŋ Ōŋ 1 ȣİÂȒΛ Ûŏİŋ Ōŋ 5 Ž ȟ0.5 ā äØΛ :**Reducing substances** ŠöÂφÅţä åäȝţä ŞgŸΛ ŕ ÜŠÔƀęå 15 gÆŋ ÄŌφÊƀö ōÄφΛ .VS (ȯ/ȯȝŋ 0.002) ȳȝƀèİÄȝöä ğİφİ8ΛŋKä ɒŋ Ōŋ 0.20ş TS (ȯ/ȟ100~) .discoloration ɟȝŸöä Ž (ȯäşà) ȯƀÆGk ƀÜ

ÆΛ3 ŘäİÄǰöä ɟàȝöä ƀÜ Ż gÆgäş Ğ3İè gÆŋ °ȳ30 gøäÀg ŠDZóå ÆΛ3 ZΛȥ :**Loss on drying** ZƀÄDzφÔİää ÆŌÄöä .ȟ/ȟ0.57 ɒȝ ÆΛÂΛ ŕş ȟ/ȟ0.52 ɒȝ ÆŌÄöä ŌŌΛ ŕ Û°ȳ130 gøäÀg ŠDZóå

ɟȝäÀȮöä ÆƀÊõÜ ƦəÄÄφ ɒŋ ƀİȝä ŏİţä ɒŋ Ōŋ 10 Ž ȟ0.5 ā äØΛ :**Acidity or alkalinity** ŠΛȝŸŌöä şÜ ĞȟȝtΣä ȳȝΛåȝÔöä ÆƀÊõşøÆƀŁ ɒŋ Ōŋ 0.5 ɒŋ ÄǰõÜ ÆŸÛφΛ ŕ ÜTS ȯȝφİǰΛÜ/ ȯȝtƀφȝŋşƎöä Ğęóà ɒŋ Ōŋ 0.1 ȣİÂȒΛş R Ȓƥ ɒŋ Ōŋ 0.5 şÜ VS (ȯ/ȯȝŋ 0.01) carbonate-free sodium hydroxide ğİφȝäÀȮöä ɒŋ ƀİȝä .(ÀÂȒnÜ) ÄŠĤÎtŸö ȝÛèȝöä ŠÛŌΛöä ȝŸȝ ȯȝÔƦŸö VS (ȯ/ȯȝŋ 0.01) ŌΛóȝŸõşøÆƀTä

Ȓƥ ɒŋ Ōŋ 10 ȣİÂȒΛş Ûŏİţä ɒŋ Ōŋ 250 Ž ÛŠƀÜȝŠÂŋ Šφşàȝŋ ÛȟŌ0.25 ŠääÀę ā äØΛ :**Assay** ŠÊΛİÔţä .TS (ȯ/ȟ50) ȳȝΛØİŠöä ÆΛóȝŸõ ɒŋ Šƀȝİõ Šƀtõ ȣİÂŘşş İÆŸ8öä ȝøφg ɒφÅÊΛ ÛTS (ȯ/ȟ70~) ŌΛóȝŸõşøÆƀTä gøäÀg ŠDZóå ÆΛ3 ÆφÄŘşş ZΛÆΘ ÛŌÊ8ŘÛŠäİÈÄöä ȝtΘ .ÄφÆƀgÜ ŌΛÄHφöä ȝφ ÛŠŌƀęå 30 gÆŋ ƦəÄŋ ȳİÞ ȝŸȝ ɒφÅÊΛ .Na_2SO_4 ɒŋ ȟ0.608 ùȝÄȮΛ ŠöÄtǰöä ɒŋ ÆgäŞ ȳäÀḍ Ōõ .°ȳ600

NATRII SULFAS ANHYDRICUS

Sodium sulfate, anhydrous hŭəƒDŽú‖ε !NjŭqNjT‖ε l ƒ2ǂƨ

Na_2SO_4 :**Molecular formula** ĞŒÅÂƨä Ğ8ŒÔöä

142.0 :**Relative molecular mass** ĞŒGÊÄöä ĞŒÅÂƨä ĞŸQȮöä

:**Chemical name** ƱəÅŒŧŒȮöä ȩèřä

Disodium sulfate; sulfuric acid disodium salt, anhydrous; CAS Reg. No. 7757-82-6 (anhydrous).

.ĞHƱəäÀöä CÆ3 ÜŘŒäÜ ȧƨHƱÊȵ :**Description** Ƶòƨöä

.TS (ȯ/ȟ750~) ȯƨφÅƶÅqä Ž ŒŸŧ3 ā äşǽ Ƙḍ ÜŏÅŧä Ž ȷÅäşØöä ȩÅg :**Solubility** ĞŒφÅäşØöä

.ȣŒŸȵ :**Category** ĞÅÅöä

.ŒÆŒDZ ĞÕŸ8ȵ ĞÅşÅg Ž ĞŒəÅȵŸöä ȳƨÅƨÔöä ğÅÅŸè ŞÅg Æz :**Storage**ęȣÅÂÁφöä

.ĞGüÀQÊȵ gÅÅȵ ĞŒəÅȵŸöä ȳƨÅƨÔöä ğÅÅŸè :**Additional information** ĞŒƨÅřÜ ğÅȵƨŸHȵ

REQUIREMENTS ƘĞüŒƩƘdž!ƒ

ÆÅÂÅ řş %99.0 ȣ3 ÕÕÅ ř Åȵ ƨŸ3 ĞŒəÅȵřä ȳƨÅƨÔöä ğÅÅŸè ƀƨQƠ :**General requirement** ȳÅŒöä ÆŸÛQŧä .ĞƨÅƨä gÅÅŧä БÜ ŧƨDZÀöÅä ĞäƨÊŢ ÛNa2SO4 ȣȵ %100.5 ȣ3

:**Identification tests** hŭŸNjNJ‖ε l ε ƒƒGŒƩε

General ĞȵÅŒöä ȣäÀŒQèřä ğäøÅGQnä" ȷäƨÅ3 ŘƠ ȣƨòƨȵ ƨŧ Åŧõ ȳƨÅƨÔöä ÕDZÜ ȣȵ øÅGQnřä ÆÅ3 :A 20 ȯƨŸŢ ÀŘƵ B Õ3ÅÅQöä ȳÆÁQèä äæÜ .gÂŒư ğŸ3ÅÅŘ ƱÛŒÅ (123 ĞHƱÅÔöä Û1 ÆŸÖä) "identification tests .Õȵ/ŋŸȵ

General ĞȵÅŒöä ȣäÀŒQèřä ğäøÅGQnä" ȷäƨÅ3 ŘƠ ȣƨòƨŧä A Õ3ÅÅQöä Õȵ/ŋŸȵ 20 ȯƨŸŢ ƱÛŒÅ :B .(123 ĞHƱÅÔöä Û1 ÆŸÖä) ğÅÅŸÊŸö ÂŒŧõ "identification tests

ȷäƨÅ3 ŘƠ ȣƨòƨȵ ƨŧ Åŧõ øÅGQnřä ȯƨŸŢ ƘŘƠ ÕDZÜ ȣȵ ȟ0.5 ȳÆÁQÊÅ :**Heavy metals** ĞŸŒÕƶöä ȷäÅŒŧä ȣŒŒŒ Ü(127 ĞHƱÅÔöä Û1 ÆŸÖä) 1 öäÀDZqä "Limit test for heavy metals ĞŸŒÕƶöä ȷäÅŒŧ ÕDZȷ ƀŒÉÄä øÅGQnřä" .ȳäÀdȵ/ȳäÀdȵÀÒȵ 45 ȣ3 ÆÅÂŘ ř Ü(128 ĞHƱÅÔöä Û1 ÆŸÖä) A ĞÕÅÀÛŸö ŒŒĞŘ ĞŸŒÕƶöä ȷäÅŒŧä ğÅƨQŢ

ÆŒÊõşØÆŒŁ ȣȵ ȟ0.3 ĞääÀę ȣÅŘÅ ÛØÅGQnä ā ƨQφÜ БÜ ȟ0.5 ÕÕÅ :**Ammonium salts** ȳƨŒφƨȵȷä dzŸȵÜ

.ȧøäȂ Ƃ Ȧƣƶ Ƙ8ǫ Ɣƶ ČƆƔÛȦţä ǥȂƝƒä Ž R (ǥäǤȦƞ) ČǤÙȂƞ È ƽ ǻǦȝ Čęøş ȝřƶǰş ÜǰȦÂţä ȡǺÊȦş R ȳƶǤèǦƶǥöä

ƀǤΣä øȦǫǫřä" ƒäƶȦȝ ǨƠ ȣƶòƶƞ ƶŁ Ȧţõ ȝäȦǫşǦƞ ȪƞŽ 35 Ž ȟ2.0 ȯƶƔ ȳǺǺǫÊȦ :**Arsenic** ÑǤǫøÂöä

.ȳäȂȤ/ȳäȂȤşȂȯƞ 5 ȡȝ ÑǤǫøÂöä ƲƶǫƔ ǺȦÂȦ ŕ (130 ČƣȦÔöä Û1ǺƔǨä) "Limit test for arsenic ÑǤǫøÂöä ƆDZǰ

100) ƀøǦǤȟţä ƆǤƶǫǦȝȦqä ȳƶǤÊöǦõ ȡƞ Ɔƞ 0.2 ƙƔÔȦƞ ČǫøȦƆƞ ƣøäƶǫǰ ƆƆȦ :**Calcium** ȳƶǤÊöǦȯöä

ÛǥǺǥäş ČƆǤęǺ ǥǺƞ ȂƆǫÊǫö õȂǫǨş ÛTS (ȯ/ȟ 25) ȳƶǤǫƞǰää ǧŕȦÊõşÜ ȡƞ Ɔƞ 1.5 ȣȦŘȦ ÛTS (Ca Ɔƞ/ȳäȂȤşȂȯƞ

ƀƶȝ ƎǫǺǤè ƣøǫöä ǥǺţä ȯƶƔ ȯşǰä äƶǫǫǫö ȣȦŘȦ .TS (ȯ/ȟ120~) ƆǤǫèǰä Ŕβ ȡƞ Ɔƞ 1 ȣȦŘȦ Ż

ÛTS (Ca Ɔƞ/ȳäȂȤşȂȯƞ 10) ƀøǦǤȟţä ȳƶǤÊöǦȯöä ȡƞ Ɔƞ 10 ƣøǫǦȝöä äƶǫǫǫö ȣȦŘȦş ÛöǦţä ȡƞ Ɔƞ 15 Ž ȟ0.22

ǺŁȦÎţä Ɔöǽ ȡȝ ǥǺì ȂȝõÜ ȯşǰä äƶǫǫǰä Ž ȳƶŁ8öä ƒƶȯȦ ŕ ÜČƆǤęǺ 15 ǺȟǼ ǰǫȦ ȳƶŁȤ ƀÜ ǺęǦȂȦ .öǦţä ȡƞ Ɔƞ 5ş

.(ȟ/ȳäȂȤşȂȯƞ 450) ƣøǫǦȝöä äƶǫǫǰä Ž

30ş TS (ȯ/ȟ130~) ƆȦȂǫöä Ŕβ ȡƞ Ɔƞ 2 ȡƞ Ƶöúƞ ǰȦÂƞ ȡƞ ȟ 0.55 ääØȦ :**Chlorides** ǧäǺȦøƶÜȯöä

"Limit test for chlorides ǧäǺȦøƶÜȯöä ƆDZǰ ƀǺΣä øȦǫǫřä" ƒäƶȦȝ ǨƠ ȣƶòƶƞ ȪƞŽ Ȧţõ ȝäȦǫşǦƞ öȦţä ȡƞ Ɔƞ

.ȟ/ŋÜƞ 0.45 ȡƞ ȂȝõÜ ǺȦøƶÜȯöä ƲƶǫƔ ƒƶȯȦ ŕ Ü(124 ČƣȦÔöä Û1 ǺƔǨä)

øȦǫǫřä" ƒäƶȦȝ ǨƠ ȣƶòƶƞ ȪƞŽ Ȧţõ ȝäȦǫşǦƞ ÛöǦţä ȡƞ Ɔƞ 40 Ž ȯƶƔ ƙŘƣǫöä ȟ0.44 ȳǺǺǫÊȦ :**Iron** ǺȦǺΣä

.ȟ/ȳäȂȤşȂȯƞ 90 ȡȝ ǺȦÂȦ ŕ Ü(129 ČƣȦÔöä Û1 ǺƔǨä) "Limit test for iron ǺȦǺΣ ƆDZǰ ƀǺΣä

ȡƞ Ɔƞ 0.15ş R ȯşƙÊǦƔ8öä ȡƞ Ɔƞ 1 ȣȦŘȦş ÛöǦţä ȡƞ Ɔƞ 10 Ž ȟ0.22 ääØȦ :**Magnesium** ȳƶȦÂǦȦ8ţä

ǺǦÊõşØǺǦŁ ȡƞ Ɔƞ 5ş TS (ȯ/ȟ50) ȳƶǤǫƞǰää ǧŕȦÊõşÜ ȡƞ Ɔƞ 0.25ş TS Titan yellow ƒȦǫǦǫöä ǥǺȦò

Ɔǫäư ƶƲ Ɔƞƶȝ Ɔƞƶȝ ǰȦÂƞ ƒƶȯ ȡƞ ǥǺì ȂȝõÜ ƒƶȯȦ ŕ ǰǫȦ ƲƔȦǫÀę ƒƶȯ ƀÜ ÛȝÀŁş ÛTS (ȯ/ȟ80~) ȳƶȦȤƶÔöä

.öǦţä ȡƞ Ɔƞ 5ş TS (Mg Ɔƞ/ȳäȂȤşȂȯƞ 10) ƀøǦǤȟţä ȳƶȦÂǦȦ8ţä ȡƞ Ɔƞ 5 ȡƞ ƒƶȯƞş

ƲƐȦǦǫ ȡƞ ƀǦǦǫ öǦţä ȡƞ Ɔƞ 10 Ž ȟ0.22 ȯƶƔ ƒƶȯȦ :**Clarity and colour of solution** ȯƶƔ‡ä ƒƶȯş öǦȦò

.¢ö ƒƶȯ ŕş ȣȦò R ƒƶäȂȯöä ǺǦÊõÜ

ƆȦȤƶȦƔÊöä Ŕβ ȡƞ Ɔƞ 1 ȣȦŘȦ ÛöǦƞ Ɔƞ 5 Ž ȟ0.25 ääØȦ :**Reducing substances** ČöÂǫÁţä ääƶţä

ŞǥƔȦ ŕ ÜČƆǤęǺ 15 ǥƞ ȂƆǫÊǦö öȂǫȦ .VS (ȯ/ȯƶƞ 0.002) ȳƶǤèǦƶǥöä ǧǦ8ȦƞȂää ȡƞ Ɔƞ 0.20ş TS (ȯ/ȟ100~)

.discoloration ƒƶÜöä Ž (ȯäşà) ȯǺǤk ƀÜ

50 ȡƞ ȂȝõÜ ǺƆǦöä ƒƶȯȦ ŕ Û°ȳ130 ǥöäȂǥ ČDZöǺ ǺȦȝ ƙäǫ ƒäş ƀÜ ƵȂz :**Loss on drying** ƵǦǦDzǫöǦä ǺƆǦöä

.ȟ/ŋÜƞ

ƒƶäȂȯöä ǺǦÊõÜ ƲƐǦǫ ȡƞ ƀǦǦǫ öǦţä ȡƞ Ɔƞ 10 Ž ȟ0.22 ääØȦ :**Acidity or alkalinity** ČȦƶÜÔöä şÜ ĞŕƶŁΣä

ȳȚΛǎȚÔöä ÆŁÊõȘóÆŁŁ ȣȵ Ōȵ 0.5 ȣȵ ÄǰõÙ ÆŸÛǫΛ ŧ ÜTS ȯȚφǰΛǰÙ/ ȯȚŧŁȚȚȘȵȘƎöä Ǧęóà ȣȵ Ōȵ 0.1 ȣǰÅΛȘ R Ȓβ ȣȵ Ōȵ 0.5 ȘÙ VS (ȯ/ȯȚȵ 0.01) carbonate-free sodium hydroxide ǧǰφȚǰÅÀÒöä ȣȵ ƁǰǶä .(ÄÅΛnÙ) ÄǦÎŧŸö ȚÛèȚöä ǦÛÕÅöä ȚŸȝ ȯȚÔHuŸö VS (ȯ/ȯȚȵ 0.01) ÕΛóȚŸõȘóÆŁTä

Ȓβ ȣȵ Ōȵ 10 ȣǰÅΛ ÛöÅŧä ȣȵ Ōȵ 250 Ž ÛǦŁùȚǦΛȵ ǦφȘàȚȵ ÛǦ0.1 ǦäÄę ä äØΛ :**Assay** ǦÊΛǰÅÒŧä .TS (ȯ/Ǧ50) ȳȚΛóǰÅǦöä ÆΛóȚŸõ ȣȵ ǦŁȚǰÅõ ǦŁŧõ ȣǰÅΛȘ ÛȝǰÆŸ8öä ȚøφǦ ȣÅÊΛ ÛTS (ȯ/Ǧ70~) ÕΛóȚŸõȘóÆŁTä .ÿ 600 góäÄǦ ǦDZóǎ ÆΛȝ ÆȵÄǦȘ ZǰÅΘ ÛÕÊ8k ÛǦäÅèÄöä ȝŧΘ .ǦφǰÆǦÙ õÄȜ ÛǦÕŁęǎ 30 gÆȵ ŧǰÅȵ ȳǰÅβ ȚȝŸ ȣÅÊΛ .Na_2SO_4 ȣȵ Ǧ0.608 øö ùȚǰÅΛ ǦöÅŧȚöä ȣȵ ÆǦäȘ ȳäÄd Ōõ

NATRII THIOSULFAS

Sodium thiosulfate !NjǐφNjT‖ε lƒ2ǂƨNjǐk

$Na_2S_2O_3,5H_2O$:**Molecular formula** ǦŁǰΛÂƨä Ǧ8ŁÔöä

248.2 :**Relative molecular mass** ǦŁǦÊΛöä ǦŁǰΛÂƨä ǦŸφÒöä

:**Chemical name** ȚƨǰŁŧŁÒöä ȵèŧä

Disodium thiosulfate pentahydrate; disodium thiosulfate ($Na_2S_2O_3$) pentahydrate; thiosulfuric acid ($H_2S_2O_3$), disodium salt, pentahydrate; CAS Reg. No. 10102-17-7 (pentahydrate).

.ǦHuƨäÄöä ǦƐÆȝ ÜȵȚŸöä ǦƐÆȝ ǦȚǰÅÀì ǧäØȚŸä :**Description** ZòȚöä

.TS (ȯ/Ǧ750~) ȯȚφǰÅȵqä Ž ǦŁŸŧȝ ä äȘäé Kd ÜöÅŧä Ž ǦÆDZ ä äȘäé :**Solubility** ǦŁφǰÅäȘØöä

.ȧǰΛóǎ :**Category** ǦǰÅÀöä

.ȳÅÒǧüä ǦÕŸ8ȵ ǦΛȘǰÅǧ Ž ȳȚΛǎȚÔöä ǧǰÅÀŸèȚŁφ ȘÅǧ Æz :**Storage**ȵφΛÂÅφöä

ǦDZóǎ Ž ȣǰÅƨä öäȚTä Ž ȳȚΛǎȚÔöä ǧǰÅÀŸèȚŁφ ǧäØȚŸä ÄŧÂφk :**Additional information** ǦŁȚǰÅŕÙ ǧǰȵȚŸǦȵ .ǦGΛÄÕk °ȳ 49 ǦDZóÆöä Ž ǰŁØȚŸGk öǰȵ Ž äȘØkȘ °ȳ33 ȣȝ ÆΛÂk góäÄǧ

REQUIREMENTS ǦGΛǰÅÕkdž!ƒ

ȣȝ ÆΛÂΛ ŧȘ %99.0 ȣȝ ÕÕΛ ŧ ǰȵ ȝ ŸȝΛǎȚÔöä ǧǰÅÀŸèȚŁφ ƁȚφƠ :**General requirement** ȳǰǦöä ÆŸÛφŧä .$Na_2S_2O_3,5H_2O$ ȣȵ %101.0

1.0 8ÅÎR∧ Ōŋ2 БŬ .(ЦÎR∧Ù CS B ďb∧øÅĞQnàrä Ž òzŸ‡ä äØŁ ŌŁĦŬQÊ∧) ŏÅţä ďŋ Ōŋ 10 Ž Ǽǵäş ÿäÀď ā äØ∧ :A
.ЦÎzÅò òzŸ‡ä ɔŌG∧ ÜTS (ò/ĥ50) ÿz∧øÅGöä Ǽ∧øzŸõ ďŋ Ōŋ 0.25 8ÅÎR∧ .òzŸ‡ä jzò òşÂ∧ ÜTS ǻzĒöä ďŋ Ōŋ
ďÒƹ ÜTS (ò/ĥ70~) Ō∧øzŸõşøǼĒTä Ŕƀ ďŋ Ōŋ 1.0 A øÅĞQnàrÅæ ÀÎR‡ä òzŸ‡ä ďŋ Ōŋ 2 БŬ 8ÅÎR∧ :B
.(øØШ ʔÀz) Ǩ∧ƎÒöä ďŋ ĞæÅèø ǰQAǩş Ǩ∧ƎÒöä ǼĒÊõşÙ ÜəÅÁǫ ĞHuäØ ĮĻì
ĞæÅèø jzÒQǩ ÜVS (ò/òzŋ 0.1) ĞŘÅöä ğäÀQp ďŋ Ōŋ 2 A øÅĞQnàrÅæ ÀÎR‡ä òzŸ‡ä ďŋ Ōŋ 2 БŬ 8ÅÎR∧ :C
.öäǻzè Ż ÛgÀÀÔŋ ĞGÔǩ Åŋ jÅ3Àè ÅŦAÒö ÛöÅŘĒæ
ĞnÅĦöä 8äÀĦQèrä ğäøÅĞQnä" jäzA3 ǨƠ 8zòzŋ zŁ ÅŁõ ÿz∧ǻzÔöä ŌDZÙ ďŋ øÅĞQnàrä ʔÀz Åŋ Ǽ3 :D
òzŸŢ ÀŘƷ B Ō3ÅÅQöä ÿǼÁQèä äæŬ .gÂĒư ğŸ3ÅÀǩ ÜÛĦ∧ (123 ĞHuÅÔöä Û1 ǼŸŎä) "General identification tests
.Ōŋ/ĥ0.10

Ō∧øzŸõşøǼĒTä Ŕƀ ďŋ Ōŋ 5 ŏÙGæ 8ÅÎR∧ ÛöÅţä ďŋ Ōŋ 10 Ž ĥ 1.0 ā äØ∧ :**Heavy metals** ĞŸĒŌŽöä jǻÅĦţä
ƙQŌĒęǻ gǼŋ ZÛŸæ ɔŸ8∧ ÛĞöÅŁŽöä БŬ öÅţä ďŋ Ōŋ 15 8ÅÎR∧ .ÜəÅŋ ÿÅƀ ɔŸ3 8ÅÅɔä ɔøQǵ ÀpÁG∧ş ÛTS (ò/ĥ70~)
8Åò òzŸŢ ŽÅQpq ƙnşÊöä ďŋ ĞĒzÅõ ĞŁŁõ ĞÀnÅÊöä ĞǵÅÌÀöä БŬ 8ÅÎR∧ ÛjÅĒŸ8öä ɔøQǵ ĞǵÅÌÀöä ďÁÊǩ .ĞÌÀ∧ Ż
òzĒz ďŋ Ōŋ 0.05 8ÅÎR∧ Ûǻ̄Ē∧ .ƙnşÊöä Ǽ∧ä ǻÀÛ∧ ɔøQǵ òzŸ‡ä ɔŸ8∧ .ŌĒŸę Ǽ∧Ĥæ ƙnşÊöä ďŋ ǻşÂ∧ş
ŌĒQèjä ŘŁШ 4-3 ɔøQǵ öÅŁÅĞöä ĞHuÔǩ .VS (ò/òzŋ 1) ÿz∧ǻzÔöä ǼĒÊõşøǼĒö òǼĦQÊłş TS òzφÅŽÙ/ƙÅöÅŽz
øÅĞQnàrä" jäzA3 ǨƠ 8zòzŋ zŁ ÅŁõ ĞŸĒŌŽöä jǻÅĦţä ďŋ ʔzQ‡ä ďĦĦ∧ş ÛöÅţÅæ Ōŋ 40 БŬ ZÅƹ ÛTS (ò/ĥ60~)
ďƷ Ǽ∧Â∧ r Û(128 ĞHuÅÔöä Û1 ǼŸŎä) A ĞŌ∧ÀÛŸö ĦĦĞǩ "Limits test for heavy metals ĞŸĒŌŽöä jǻÅĦţä ŌDZj ƀǼΣä
.ÿäÀ8öä/ÿäÀďşÀÒŋ 20

(ò/ĥ130~) Ō∧ÀQÅöä Ŕƀ ďŋ Ōŋ 2ş öÅŋ Ōŋ 20 ďŋ Zöűŋ ǰ∧Âŋ Ž ĥ1.20 ā äØ∧ :**Chlorides** ğäǼ∧øzŸÒöä
ƀǼΣä øÅĞQnàrä" jäzA3 ǨƠ 8zòzŋ zŁ ÅŁõ ĞǵÅÌÀöä Ʒŋ ƷæÅQ∧ş ÛǴÌÀ∧ ÛǻƎ∧ ÛĘəÅęǻ 4-3 gǼŋ ZÛŸæ ɔŸ8∧ ÛTS
.ĥ/ŋŸŋ 0.2 ďƷ Ǽ∧øzŸÒöä ʔzQŢ Ǽ∧Â∧ r Ü(124 ĞHuÅÔöä Û1 ǼŸŎä) "Limit test for chlorides Ǽ∧øzŸÒö ŌDZj
ÛTS ǻzĒöä ďŋ Ōŋ 5 8ÅÎR∧ ÛöÅţä ďŋ Ōŋ 10 Ž ĥ0.25 ā äØ∧ :**Sulfates and sulfites** ğÅQĒÅŸÊöäş ğÅÅŸÊöä
8zòzŋ zŁ ÅŁõ ƷǣÅQ∧ .ЦǼDZ ZĒĦŘ ǨæÅQ ÀÅòŬ jzò ǰQA∧ ɔøQǵ ÛgÀÛę ÀQŬ gÀÛę ÛTS ǻzĒöä ďŋ Ǽ∧Âŋ ǰ∧øǼQöÅæş
ʔzQŢ Ǽ∧Â∧ r Ü(125 ĞHuÅÔöä Û1 ǼŸŎä) "Limit test for sulfates ğÅÅŸÊöä ŌDZj ƀǼΣä øÅĞQnàrä" jäzA3 ǨƠ
.ĥ/ŋŋ 2 ďƷ ğÅÅŸÊöä

sodium ÿz∧ǻzÔöä ǼĒèşÀæşÀQp ďŋ Ōŋ 0.05 8ÅÎR∧ş öÅŋ Ōŋ 10 Ž ĥ1 ā äØ∧ :**Sulfides** ğäǼĒÅŸÊöä
.ЦĒDzÊÅæ òzŸ‡ä ĞGÔ∧ r ÜTS (ò/ĥ45) nitroprusside

R ȷʒäÀÒöä ÆÉÊõÜ ÜəÀÀǫ ȣȵ ƃÀ ʅä ȣÀʒä ȣȵ Ȣȵ 10 Ž ȟ1.0 ȯʒŸʅ ȷʒÒʌ :**Clarity and colour** ȷʒŸöäȘ ȣÀÀÔöä
.¢ȣ ȷʒȣ ɤȘ ȣÀȣ

.8.4-6.0 ÛR ȷʒäÀÒöä ÆÉÊõÜ ÜəÀÀǫ ȣȵ ƃÀ ʅä ȣÀʒä Ž ȣȵ/ȟ0.10 ȯʒŸʅ ȣÀŁÀä :**pH value** ȣÀŁÀGöä ȣŁÉę
0.05) iodine ǎʒÉöä ȝȵ ÀÀÀȟÀȘ ȣÀȵ ȣȵ 25 Ž ÛȣÉÙʒȣÊȵ ȣǫȘàʒȵ ÛȟȟÀę ä ÀØʌ :**Assay** ȣÊÀÀȣȵʒä
ÙʒÀÒʌ VS (ȯ/ȯʒȵ 0.05) ǎʒÉöä ȣȵ ȣȵ 1 ȣõ .gÀÀÀȟʒä ȣÀÀŒ ʒU ȣÀÊʌ .ÀȟÎŁõ TS ÀÎÀöä ÿäÆÁǫèÀä VS(ȯ/ȯʒȵ
.$Na_2S_2O_3,5H_2O$ ȣȵ ȝȵ 24.82

ƒdźsΘ üƒDŽyƭƨÚε üШŬ !NjĭƣNjTǁε lƒƨ⁄ƨNjĭkǁ hŭĭƷFŢa lƒGƭUƭDŽ

Additional Requirements for Sodium thiosulfate for parenteral use

.(56 ȣÀÀÔöä Û4 ÆŸÒä) "*Parenteral preparations* ȣÉÀÕΣä ǧäÀŘÀȣǫÊʒä" gǎȘÀʒj ÆÉDzǫÊʌ
øÀǫǫnɤä" ȷäʒÀ3 ŘƠ ȣʒòʒȵ ʒŁ ÀŁõ øÀǫǫnɤä ȘʒÛʌ :**Bacterial endotoxins** ȣÉȵʒǫÀƨä ȣÉŸnäÆöä ǧÀǫÀÀʌØöä
Ü(ȣʌÂÉŸÒǫqä ȣÁÊÀöä Ž 30 ȣÀÀÔöä Û5 ÆŸÒä) "Test for Bacterial endotoxins ȣÉŸnäÆöä ȣÉȵʒǫÀƨä ǧÀǫÀÀʌØöä ÕDZj
.ÿäÀd ÜŸÉʒä Ž ȣÉöȘǎ gÆǵȘ 0.03 RS ÜŸnäÆöä ȷÀÀʌØöä ȣȵ ʔʒǫ⁄ä àȘÀDzǫʌ ɤ

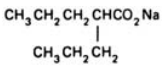
NATRII VALPROAS

Sodium valproate !NjĭƣNjTǁε lεNjƒȣǁFʒ

$C_8H_{15}NaO_2$:**Molecular formula** ȣÉÀʌÂƨä ȣ8ÉÔöä

166.2 :**Relative molecular mass** ȣÉȣÊÀöä ȣÉÀʌÂƨä ȣŸǫÒöä

:**Graphic formula** ȣÉǫÀÉȣʒä ȣ8ÉÔöä



:**Chemical name** ÜəÀÉŁÉÒöä ʅèɤä

Sodium 2-propylvalerate; sodium 2-propylpentanoate; CAS Reg. No. 1069-66-5.

.ÀȣʌÀÕk ȣÜəäÀöä CÆ3 ȘÙ ȣÜəäÀöä CÆ3 ÜÀȣʌÀÕk ŘÉäÙ ȘÙ ÛŘÉäÙ ÞóʒŸä ȧʒÜÊȵ :**Description** Ƶòʒöä
.TS (ȯ/ȟ750~) ȯʒǫÀƵʌqäȘ ȣÀʒä Ž ȷÀäȘØöä ǫǧ :**Solubility** ȣÉǫÀäȘØöä
.ţÀÔöä ǎÀŘȵ öäȘǎ :**Category** ȣÀÀöä

.ňÆÆDZ ČÕŸ8ŋ ČĄŞÅǵ Ž ȳzĄǎzÔää ǧäŞƎöÅz ŞÁǵ Æz :**Storage** ďĄÂÅĄǫää

.Ǧ3zŸŋ ȳzĄǎzÔää ǧäŞƎöÅz :**Additional information** ǦŸzÅŕŤ ǧÅŋzŸŸŋ

REQUIREMENTS ƙǦďďƵƵkďž!ƒ

ďƷ ÆĄÂĄ ŕŞ %98.0 ďƷ ÕÕĄ ŕÅŋ ɔŸ3 ȳzĄǎzÔää ǧäŞƎöÅz ƀzǫƠ :**General requirement** ȳÅŘää ÆŸÛǫţä

.ČÁÅÖä gǎÅţä ƀŤ ţzDZÅöÅä ČäzÊŢ ÛC$_8$H$_{15}$NaO$_2$ ďŋ %101.0

:**Identification tests** hďŸNjNJĄĄ l ɛƒƒǦƤǫɛ

(ȯ/ȟ70~) ÆĄózŸõŞóÆƎTä Ŕƒ ďŋ Õŋ 1Ş R ȳózzŞózŸȮää ďŋ Õŋ 5 8ÅŘĄ ÛŏÅŋ Õŋ 5 Ž ȟ0.5 ǎäØĄ :A ÀŋǍǦĄŞ ÛǦŋÀĄ ÛR ČƎƏÅŋŸää ȳzĄǎzÔää ǧÅÁŸÊä ɔŸÁÊää ČÕǦÛää ZÁΘ ÛÕÔÁÆƎö õÀǫĄ ÛǧÆǵäŞ ČÕƎęå gÆŋ gzÕä ƷÀł ÛTS ČÕÛĄŋ Ž ƲƏzŘää ZƎÛää âÅƎę" ȷäzĄ3 ŘƠ 8zòzŋ zŁ Åţõ ČöÅţƷŸö ĘƎęÀäöä ĻŸÁöä øÅǫǫŋä ɔÀz .8ÅÁƏä ɔøǫǵ î ÅÔǫŋä ZƎù ĘäÅÛǫĄ .(43 ČƦÁÔää Û1 ÆŸŎä) "Spectrophotometry in the infrared region öäÀţΣä ŘƠ ČŘÌ ĵä .ÕĄŞƎöÅÁöä Ŕţ Σ ƲHDZÀţä ZƎÛää Ɜŋ ŞÛ RS ÕĄŞƎöÅÁöä Ŕƒ ďŋ ¢ƎŸ3 ÕÔƦǫÊţä ZƎÛää Ɜŋ öäÀţΣä ŘƠ ČŘÌ ĵä ÛČƎpäzDZøÛ ČäÅèø ǰǫĄ ÜTS (ȯ/ȟ 100) (II) ŘöÅäzȮää ǧäÀǫǫ ďŋ Õŋ 1 8ÅŘĄŞ öÅŋ Õŋ 5 Ž ȟ0.5 ǎäØĄ :B .R ȷzäÀȮää ÆĄózŸõ Ʒ3Åäø Ž Čääşé ȷzȮǩ

General ČŋÅŘää 8äÀŘǫèŕä ǧäøÅǫǫŋä" ȷäzĄ3 ŘƠ 8zòzţä ÛB Õ3ÅÅǫää Õŋ/ŋŸŋ 20 ȯzŸŤ ƲÛŘĄ :C .(125 ČƦÁÔää Û1 ÆŸŎä) ǧÅÁŸÊŸö ÂƎţţõ "identification tests

øÅǫǫŋŕä " ȷäzĄ3 ŘƠ 8zòzŋ zŁ Åţõ øÅǫǫŋŕä ȯzŸŤ ƙŘƦǫǫ ȟ1.0 ȳÆÁǫÊĄ :**Heavy metals** ČŸƎÕƷöä ȷäÅŘţä ȷäÅŘţä ɔzǫŤ ƙŘĄ Ü(127 ČƦÁÔää Û1 ÆŸŎä) 3 öäÀDZqä "Limit test for heavy metals ČŸƎÕƷöä ȷäÅŘţ ÕDZȷ ƀÆΣä .ȟ/ȳäÀdşÀÁŋ20 ďƷ ÆĄÂĄ ŕ Ü(128 ČƦÁÔää Û1 ÆŸŎä) A GÕĄÀÛŸö ňÕǦù ČŸƎÕƷöä

øÅǫǫŋŕä" ȷäzĄ3 ŘƠ 8zòzŋ zŁ Åţõ ƷäÅǫĄŞ ÛöÅţä ďŋ Õŋ 35 Ž ȟ5.0 ȯzŸŤ ȳÆÁǫÊĄ :**Arsenic** ŃƎǫǫÂää .ȟ/ȳäÀdşÀÁŋ 2 ďƷ ŃƎǫǫÂää ɔzǫŤ ÆĄÂĄ ŕ Ü(130 ČƦÁÔää Û1 ÆŸŎä) "Limit test for arcinic ŃƎǫǫÂää ÕDZȷ ƀÆΣä

ďŋ Õŋ 20Ş TS (ȯ/ȟ130~) ÕĄÀǫÁöä Ŕƒ ďŋ Õŋ 2 ďŋ ǰĄÂŋ Ž ȟ1.20 ǎäØĄ :**Chlorides** ǧäÆĄózŸȮää Û1 ÆŸŎä) "Limit test for chlorides ǧäÆĄózŸȮää ÕDZȷ ƀÆΣä øÅǫǫŋŕä" ȷäzĄ3 ŘƠ 8zòzŋ zŁ Åţõ ƷäÅǫĄŞ ÛöÅţä .ȟ/ŋŸŋ 0.2 ďƷ ÆĄózŸȮää ɔzǫŤ ÆĄÂĄ ŕ Ü(124 ČƦÁÔää

øÅǫǫŋŕä" ȷäzĄ3 ŘƠ 8zòzŋ zŁ Åţõ ƷäÅǫĄŞ öÅŋ Õŋ 40 Ž ȯzŸŤ ƙŘƦǫǫ ȟ0.2 ȳÆÁǫÊĄ :**Iron** ÆĄÆΣä .ȟ/ȳäÀdşÀÁŋ 50 ďƷ ÆĄÂĄ ŕ Ü(129 ČƦÁÔää Û1 ÆŸŎä) "Limit test for iron ÆĄÆΣ ÕDZȷ ƀÆΣä

Ƀ**Σ**ǎ ǿǺǤǫǹȑǎ" ɟǎȝǺ Ǩƣ ȣȝǫǹȝ ȝŁ Ǻŧõ ȝǎǺǫȝǺ ǿǺŧǎ ȣǹ Õǹ 20 Ž ȟ2.5 ǎǎØȝ :**Sulfates** ǧǺǺŸÊǿǎ .ȟ/ŋŸǹ 0.2 ȣȝ ǧǺǺŸÊǿǎ ȘȝǫŢ ǺȝǺǺ ȑ Ü(125 ǦȣǺÔǿǎ Û1 ǺŸǦǎ) "Limit test for sulfates ǧǺǺŸÊǿǎ ÕDZɟ ǿǺŧǎ ȣǹ Õǹ 10 Ž ȟ 2.0 ǿȝŸŢ ȳȝŧȥ ɟȝǦǺ ȑ :**Clarity and colour of solution** ǿȝŸǂǎ ɟȝǿǺ ǿǺǺÔǿǎ .¢ǿ ɟȝǿ ȑ ǿȝŸǂǎȘ TS2 ƀǿǺǺǦŧǎ ȳȝŧȥ ȣǹ ȣǺȝ R ɟȝǺǺǦǿǎ ǺǺÊõÜ ǦǺǺǫ ȣǹ ɃǺ Ţǎ ȣǹ ǺǺõÜ ǺÕǺǿǎ ɟȝǦǺ ȑ Ü°ȳ105 ǧǿǺǺǧ ǦDZǿǺǺ ǺǺȝ ǦǺǺǫ ɟǺȘ ȝǿǫǧ ȜǺȝ :**Loss on drying** ȜǺǺDzǫǿǺǺ ǺÕǺǿǎ .ȟ/ŋŸǹ 20

ɟȝǺǺǦǿǎ ǺǺÊõÜ ǦǺǺǫ ȣǹ ɃǺ Ţǎ ǿǺŧǎ ȣǹ Õǹ 20 Ž ȟ2.0 ǎǎØȝ :**Acidity or alkalinity** ǦȝŸÕǿǎ ȘÜ ǦȞȝŧΣǎ 0.1) ȳȝǺǺȝÔǿǎ ǺǺÊõȘǿǺǺŁ ȣǹ Õǹ 1.5 ȣǹ ǺǺõÜ ǺŸÛǫȝ ȑ ÜTS ǿȝǺǺǺÜ/ǩǺǺǺȝ ǿȝǺǺȝ ȣǹ Õǹ 0.1 ȣǺȞȝȘ R ǺǺÎŧŸǿ ȝÛèȝǿǎ ǦÛÕǺǿǎ ȝŸȝ ǿȝÔȣŸǿ VS (ȯ/ȯȝǹ 0.1) ÕǺǿȝŸõȘǿǺǺŢǎ Ȟƥ ȣǹ Õǹ 1.5 ȘÜ VS (ȯ/ȯȝǹ .(ŸŸǺφǺę)

Gas ǺǺ8ǿǎ ǎǎǺÎǫèǎ" ɟǎȝǺ ǦȝǿǺǺ ȣȝǿǺǺ ǺǺŧõ ǿǺǤǫǹȑǎ ƀǺȝ :**Related substances** ǦǿǺÎŢǎ ǺǺȝŢǎ :ÕǺǺŢ 3 ȳǎǺǺǫèǺǺ (101 ǦȣǺÔǿǎ Û1ǺŸǦǎ) "chromatography Õǹ 1 Õõ Ž (internal standard ŸŸǹǎǺ ǿǺǺŸǹ) octanoic acid R ÕǺǿǫǺǫõȘɟǎ ȞƥǺ ȣǹ Ȝǹ 0.20 *:1 ȯȝ/ǂǺ* .(dichloromethane) R ɟǺȞǺǺǹȘǿȝŸõ ŸǺǺǫ ȣǹ ȝȞǺŧȘ ÛTS (ȯ/ȟ190~) ÕǺǿȝǺŸǦǿǎ ȞŧŦ ȞŧȜ ÛǿǺǺǹ Õǹ 10 Ž ǦǿȝǺȣŧǎ ǺǺŧǎ ȣǹ ȟ 0.50 ǎǎØȝ *:2 ȯȝ/ǂǺ* combined ǦȞŧǿǺǺ ɟǺȞǺǺŧǎ ǿȝŸõ ŸǺǺǫ ǧǺǿȞŸǹ ǦǺǺ8ǩ .Õǹ 20 ȣǺǺȝǺȘ Õõ R ɟǺȞǺǺǹȘǿȝŸõ ŸǺǺǫ ȣǹ ǧǺǺŧõ 3 ȝǹ °ȳ30 ǺȘǺǺDzǫǩ ȑ ǿǿǺǺǺǧ ǦDZǿǺǺ ǺǺȝ ǦǺǺǺ

ÕÒõ ĞĒõÅPqã ĞÕÛÄţã ɟzÒĭ ŕ Û3 òz!ŧÅæ ¢ĒŸ3 ÕÔHuQÊţã ããÀÎQèŕã ÙÛÛ Ž .ÆŦŸõã åÀÎĭ Z ìÅõş Õ„Å8g ãÅ8õ ȣ3 ĞPÅÅõã gşøØõã ĞÕÛÄ„ ȣ„ ƎõÙ ÛŬŸnãÆõã øÅĒĦţãş ÆÅØţã ȣ3 ĞPÅÅõã ÕŸĭş ĞĒÊĒÅÀõã gşøØõã õÅÅZQèÅæ Ûğãşøõã .ŬŸnãÆõã øÅĒĦţã

8ÅÊÅş ÛR1 ŬDzŸZõã ÕĒQèjã Ŕß ȣ„ Õ„ 30 Ž ÛĞĒùzĞÊŋ ĞQşàzŋ ÛĦ0.25 ĞããÀę ããØÅ :**Assay** ĞÊÅÅÕţã ÛVS (ò/òzŋ 0.1) ÕÅøzŸõĦĞõã ŔŧШ ÀÅÅĦÅş ÛÀĦÎŧõ TS ÕĒQèjã Ŕß/ ĥəÂøÅæ òşÅZÅφ -1 ȣ„ Õ„ 0.15 ĞHuÅÔõã Û1 ÆŸŎã) A ĞÕÅÀÛõã "Non-aqueous titration ŬəÅŋŸõã Ùèzõã Ž gÀÅĦţã" jãzÅ3 ŘƠ 8zòzŋ zŁ Åŧõ .$C_8H_{15}NaO_2$ ȣ„ ŋŸŋ 16.62 ùzÅÒÅ VS (ò/òzŋ 0.1) ÕÅøzŸõĦĞõã Ŕß ȣ„ Õ„ 1 Õõ Ü(142

NEOMYCINI SULFAS

Neomycin sulfate DžĭƨĭƻDŽNjĭƨƼƹ lƻƨ

ĞąåãÀÅõã ĞŸÊŸÊQţã zy ȣ„ ĞDzQÅŋ åãzţ ğÅÅŸè dzŸŋÙ ȣ„ jÅÂŋ ĥÊÅÅŋzĒÅõã ğÅÅŸè :**Composition** ÆĒõÀQõã .C ĥÊÅÅŋzĒÅõã ŬdãÀÅõã ¢dşÅÔŋş B ĥÊÅÅŋzĒÅõã ĞÊĒəÀõã ÅőÅĞõÀŋ Û*Streptomyces fradiae*

:**Chemical name** ŬəÅĒŧĒÒõã ĻèŕÅ

Neomycin sulfate; CAS Reg. No. 1405-10-3.

.ÅĞÅÀÕĭ ĞHuãÀõã CÆ3 şÙ ĞHuãÀõã CÆ3 ÜÀÅòQõ ãóÅŕ ŔĒãÙ şÙ ŔĒãÙ ȧzHuÊŋ :**Description** Zòzõã ÅĒŸŧ3 ããşæ Ĥd ÜTS (ò/Ĥ750~) òzφÅZÅqã Ž ÅÆDZ jÅãşØõã ĞĒHuì ÜõÅţã Ž jÅãşØõã ÅÅg :**Solubility** ĞĒφÅãşØõã .R Ĥõjãş R ȳØzzşØzŸÒõãş R jzQĒèjã Ž

.ŬəãşÆ3 åÅÊŋ õãşå :**Category** ĞÅÅõã

ĞDZØåã Ž jÅơş ÛõzŔõã ȣ„ ĞŧŦ ÛȳÅÒgüæ ĞÕŸ8ŋ ĞAşÅg Ž ĥÊÅÅŋzĒÅõã ÅĭÅÅŸè ŞÅg Æz :**Storage** ȣÅÂÅQõã .°ȳ30 ÀşÅDzQĭ ŕ gØãÀg

ô ÀĬQõã ÆÅ3 ÅĒzØÆĭ ÕŸHuQĭ .ĞĞùÀQÊŋ gåÅŋ ĥÊÅÅŋzĒÅõã ğÅÅŸè :**Additional information** ĞĒzÅŕÙ ğÅŋzŸĬŋ .ȣŧĒŋ ŬəÅţã òzŸŧã .ĞĬÅĭÅÀţã gØãÀΣã ğÅDZØåã Ž ţÀèÙ ÕŸHuQõã ĞĞÔAş ÛõzŔõã ãÅĒd Ž ɔøQg ÛÆùø zDZ ÉÙ

REQUIREMENTS ĥĞuÅÕĭkdž!ƒ

ȣ„ ĞĒõşå gÆgş 600 ȣ3 ÕÕA ŕ Å„ ĥÊÅÅŋzĒÅõã ğÅÅŸè ÞzQƠ :**General requirement** ȳÅĬõã ÆŸÛQţã

.ČÁÀŎā gǻŀţā Бŭ ţzDZÀöŀæ ĞæzÊŢ ÛÿāÀḍ ЧŸĒŋ Ŏõ Ž ƙÊΛŀŋzĒÀöā

:**Identification tests** hŭĭŃjŃJΛΠΕ l ΕƀƑĞĦCJΠΕ

"Thin-layer chromatography ČÕĒęÀöā ČÕĞÛöā āāÀÎǫèā" ɹāzÄ3 ŘƠ 8zòzŋ zŁ Ąţõ øĀĞǫnŕā ĘĞÛΛ :A gÀÊŕ‡ā TS (ȯ/ħ40) ȳzĒǫzŋɹā ǧÁǫĒèŭş ČŸĒ8ŋ gǻŀţõ R3 ÀȮĒŸĒÊöā ČŋŸŁ ƙŋÉÁǫÊŋ (84 ČHuÁÔöā Û1 ÁŸŎā) øĀĞǫnŕā gǻŀŋ ȼŋ ŋŸŋ 20 (A) Ƀzʒ :ƙȯzŸŢ ȼŋ ÀǫȯşÀȮĒŋ (1) ČHuĒÁò ɔŸ3 ŸÔÁΛŋ ĘĞÛΛ .ōÀHuǫŋ ȯzÛõ ŸDZàÀù Û āāÀÎǫèŕā gÀDzǵ ȼŋ ČHuĒÁÔöā ŎÕǫ ÆĦæ .ÀǫȯŬŸĒţā Ž RS B ƙÊΛŀŋzĒÀöā ǧÁÁŸè ȼŋ ŋŸŋ 20 (B)ş ÀǫȯŬŸĒţā Ž /ȼΛÉÁΛøÁĒŁ zǫĒõ ŬǫŸʒæ æÀĬş ÛgÁǵāş Ğ3ŀè gÁŋ °ȳ105 gøāÀǵ ČDZøǻ ÁÁ3 ȼÁÊĬ ÛĘāŀęǻ 10 gÁŋ öāzTŀæ ZDzǫȯ ōÀǫĬ ĘæÀÛǫĬ .øŀŸÀöā ȯzŕ Ž āāÀÎǫèŕā ÙÛÛ ÒHuÁΛş Ęāŀęǻ 5 gÁŋ °ȳ105 gøāÀǵ ČDZøǻ ÁÁ3 ČĒǫŀǫ ȼÁÊĬ .TS ȯzǫŀĬzæ .B ȯzŸ‡ŀæ ŀŸĒŸ3 ÕÔHuǫÊţā ÕŸĬ ʒŋ ÀŸŢţāş ʒŕzţā Ž A ȯzŸ‡ŀæ ŀŸĒŸ3 ÕÔHuǫÊţā ĞĒÊŁāÀöā öāÀŁΣā ČĬÕĞöā ȼΛÉΛøÁĒŁ zǫĒõ ŬǫŸǫ ǧāøÁĒŁ Ōŋ 2ş R ȼΛÉΛĬĞöā ȼŋ Ōŋ 0.1 8ŀÊΛş Ûöŀţā ȼŋ Ōŋ 5 Ž ŋŸŋ 10 āāØΛ :B .Ęŋŀḍ ŬDzÊÁæ ɹzȯ ɹǫΛ ÛĘāŀęǻ 10 gÁŋ °ȳ 70ş 65 ƙæ gøāÀǵ ČDZøǻ ÁÁ3 Ŭāŀŋŋ ȳŀþ Ž ȼŁÁÊŁş ÛTS (ȯ/ħ1) General ČŋŀĬöā 8āÀĬǫèŕā ǧāøŀǫnā" ɹāzÄ3 ŘƠ 8zòzţā A Ō3ŀÁǫöā Ōŋ/ħ 0.05 ȯzŸŢ ŬÛĬΛ :C .(123 ČHuÁÔöā Û1 ÁŸŎā) ǧŀÁŸÊŸȯ ÂĒţţõ "identification tests

.ħ/ŋŸŋ 10 ȼ3 ÁΛÂΛ ŕ :**Sulfated ash** ŘÁŸÊţā ǻŀŋÀöā

zŸĒõ 0.6 àşŀDzǫΛ ŕ) ŘÁÁŋ Ù8ŕ ŘƠ °ȳ60 gøāÀǵ ČDZøǻ ÁÁ3 ZÁz :**Loss on drying** ZĒÁDzǫöŀæ ÁÕÁöā ÁÕÁöā ÁΛÂΛ ŕ Ûǧ3ŀè 3 gÁŋ phosphorus pentoxide R øzÁèzÁöā ÁĒÊõzǫæ ȧzz (ĘĞàà ŋ 5 ĞæāÀę ş ȯŀȮèŀæ .ħ/ŋŸŋ 80 ȼ3

.7.5-5.0 ÛR ɹzæÀȮöā ÁĒÊõŬ ŬāŀÁǫ ȼŋ Бŀŋŀā öŀţā Ž Ōŋ/ħ0.10 ȯzŸŢ öŀŁŀæ :**ph value** öŀŁŀĞöā Ğţţę

Thin-layer ČÕĒęÀöā ČÕĞÛöā āāÀÎǫèā" ɹāzÄ3 ŘƠ 8zòzŋ zŁ Ąţõ øĀĞǫnŕā ĘĞÛΛ :**Neamine** ƙŋŀĒÁöā ʒŋ R ƙŋzæÀȮöā ȼŋ ħ0.3 ʒÂĘ :ŬΛ Ąţõ ÀŘHuł ČHuĒÁò ÿāÉÁǫèŀæ Û(84 ČHuÁÔöā Û1 ÁŸŎā) "chromatography ŀŋÁÁ3 7 Бŭ öŀŁŀĞöā ǴŋuÔŀ .ʔÀnɹāş ČĒÁöā ƙæ Ùèzǫŋ ŋʒó ʒŋ ǧÁǵāş Ğ3ŀè gÁŋ ÀÕǫÊĒö ōÀΛş öŀţā ȼŋ Ōŋ 240 .R3 ŀȮĒŸĒÊöā ČŋŸŁ ȼŋ ħ30 8ŀÊΛ Ż ÛTS (ȯ/ħ80~) ȳzΛŁzÔöā ÁĒÊõşØÁĒŁ ÛÕòāzǫŋ ŋʒó ʒŋ ÛöÙGæ 8ŀÊΛ ÛŁÁΣǫö ōÀǫĬş ÛgÁǵāş Ğ3ŀè gÁŋ °ȳ110 gøāÀǵ ČDZøǻ ÁÁ3 ČHuĒÁÔöā ȼÁÊĬ Ûŋ 0.75 ŀŸÀŁǫ ČÕĞÛæ ČHuĒÁÔöā ÕŁ8k ŸÔÁŋ ĘǫÛŁ .TS (ȯ/ħ100) ȳzĒèŀĬzĞöā ƙDZşØÁĒŁ ŬāŀÁǫ ǧŀÁèzz ȳÁÁǫÊΛ ÛõÀHuǫŋ ȯzÛõ .gÀìŀĞŋ ȳÁÁǫÊĬş ȼŋ ŋŸŋ 0.05 (B)ş ÀǫȯŬŸĒţā Ž øĀǫnŕā gǻŀŋ ȼŋ ŋŸŋ 2.5 (A) Ƀzʒ :ƙȯzŸŢ ȼŋ ÀǫȯşÀȮĒŋ 10 ČHuĒÁÔöā ɔŸ3 zǫĒõ ŬǫŸʒæ æÀĬ Ûùzāǻ ŬāzŁ øĀĒǫæ ZDzǫȯ õÀǫĬ ÛāŀÁǫèŕā gÀDzǵ ȼŋ ČHuĒÁÔöā ţÂφ ÁĒĬæ .ÀǫȯŬŸĒţā Ž RS ƙŋŀĒÁöā

Ž ā ãÀÎ ęèŕã ÙÛÙ ÒHuÀ .ČÕŒęå 15 gÁę °ÿ110 gøãÀg ČDZøå ÁÃ3 ďÅÊĚęş ÛTS ÐÀÃÁÔÕãã ÁÃøzŸõ/ďÃÁÃøÁŒŁ ÀŽŒŸ3 ÕÔHuęÊţã ÕŸĚ ď3 gÁÌ ÄŽõÙ ɟzÒĚ ŕ ękęÀŒÃãã ÉãÀÛĚ A òzŸ‡Àã ÀŽŒŸ3 ÕÔHuęÊÃ ČĤÕã ÐÙ .øÀŽÃãã ězŕ .B òzŸ‡Àã

ÕÃøzŸõşøÁŒŤã Ŕß ďę Õę 3 ȣÀŘÃş ěÀę Õę 200 Ž ĥ1 āãØÃ :**Content of sulfates** gÀÀŸÊãã ƷzęŢ Ž ďÅÊÃ .TS (ȯ/ĥ50) ďÀÀÊãã ŷzÃøÀGãã ÁÃøzŸõ ďę Õę 25 ȣÀŘÃş ÛJÀŒŸ8ãã ƨøęg ďÅÊÃ ÛTS (ȯ/ĥ420~) ùzÀÒÃ ČãÀŧžãã Ž ÿãÀd Õõ .JàzĚş ÛÁęÀĚ ÛZÀΘ ÛěÀţÀã ÕÊ8ĚÛĞãÀèÀãã ƷŧΘ ÛÕÃÀHuęãã Ɜę gÀ3ÀÈ 4 gÁę ŬÀę ÿÀß .ĥ/ŋŸę 310 ď3 ÁÃÂÃ ŕş ĥ/ŋŸę 250 ď3 gÀÀŸÊãã ƷzęŢ ÕÕÃ ŕ Ü gÀÀŸÊãã ďę ŋŸę 411.6

ÃzŒΣã gãåÀŘŧŸõ ČŒDZzÿzŒGãã ČÊÃÀÕţã" JãzÁ3 ĚƠ ȣzòzę zŁ Àŧõ ČÊÃÀÕţã ĘGÛĚ :**Assay** ČÊÃÀÕţã NCTC) *Bacillus pumilus* (*a*) Ãę ÿÁÅęÊÃ Û(155 ČHuÀÔãã Û1 ÁŸĚã) "Microbiological assay of antibiotics ěÀŁÀã ÛĞŧŒÕ3 gÀÀèzz Čøøãå Û8.1-8.0 ŬÀÆ ěÀŁÀã Ɜę Cm1 ţóà Ùèş ÛóÀGęÀã ÿzęÀDzõ (8241; ATCC 14884 gøãÀg ČDZøåş Û(ÀęÕ ŬŸŒţã Õõ Ž ČŒõşå gÁgş 14ş 2 kã gåÀ3) kÊÃÀęzŒÃãã ďę ÆèÀę ÂŒõÀĚ ÛTS2 şÙ TS1 Û8.0 ÛóÀGęÀã ÿzęÀDzõ (ATCC 29737) *Staphylococcus aureus* ČŒGŁØãã ČÃÅzÕÃĤãã gãøzÒţã (*b*) şÙ Ü°ÿ39-35 ČęÀŘg ďę ÆèÀę ÂŒõÀĚş ÛTS2 şÙ TS1 Û8.0 ěÀŁÀã ÛĞŧŒÕ3 gÀÀèzz Čøøãå Û8.0-7.8 ŬÀÆ ěÀŁÀã Ɜę Cm1 ţóà Ùèş ÃÅzÕÃĤãã gãøzÒţã (*C*) şÙ Ü°ÿ39-35 ČęÀŘg gøãÀg ČDZøåş Û(Õę1 Õõ Ž ČŒõşå gÁgş20ş 2 kã gåÀ3) kÊÃÀęzŒÃãã 8.1- ŬÀÆ ěÀŁÀã Ɜę Cm1 ţóà Ùèş ÛóÀGęÀã ÿzęÀDzõ (ATCC 12228) *Staphylococcus epidermidis* ČÃşÀÎGãã ČŒõşå gÁgş2ş 0.5 kã gåÀ3) kÊÃÀęzŒÃãã ďę ÆèÀę ÂŒõÀĚş ÛTS2 şÙ TS1 Û8.0 ěÀŁÀã ÛĞŧŒÕ3 gÀÀèzz Čøøãå Û8.0 ČŒõÀĤÃãã Ž ÿÛę gÁŧęĤţã åşÁÃΣã Ž ČÊÃÀÕţã Čęå ÕÕĚ ŕ .°ÿ39-35 ČęÀŘg gøãÀg ČDZøåş (Õę 1 Õõ Ž ČŒõÀĤÃãã ďę %105 ď3 ÁÃÀĚ ŕş %95 ď3 (*P* = 0.95) fiducial limits of error of the estimated potency gøęÁÕţã ŬŸŒţã Ž kÊÃÀęzŒÃãã ďę ČŒõşå gÁgş 600 ď3 ÕÕÃ ŕ (*P* = 0.95) gøęÁÕţã ČŒõÀĤÃãã ÿÛn ÁřęĤţã ÐzŸĤãã ÁΣã .gøęÁÕţã .ČÀÀÕã gåÀţã ÐÙ ţzDZÀõÀã ČãzÊŢ ÛÿãÀd

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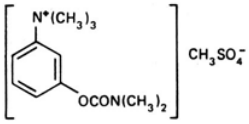
NEOSTIGMINI METILSULFAS

Neostigmine metilsulfate DžĭDŽƷŦƨNjĭĭĭĭ lƻƨƨ üĭŦĭDŽ

$C_{13}H_{22}N_2O_6S$:**Molecular formula** ČŒÀÃÂƨã Č8ŒÕãã

334.4 :**Relative molecular mass** ČŒGÊÃãã ČŒÀÃÂƨã ČŸęÒãã

:**Graphic formula** ČŒęÀŒGţã Č8ŒÕãã



Chemical name: (*m*-Hydroxyphenyl)trimethylammonium methyl sulfate dimethylcarbamate; 3-[[(dimethylamino)carbonyl]oxy]-*N*,*N*,*N*-trimethylbenzenaminium methyl sulfate; CAS Reg. No. 51-60-5.

Description: White crystalline powder.

Solubility: Soluble in water (750 g/L).

Category: Cholinergic.

Storage: Protect from light and moisture.

REQUIREMENTS

General requirement: Not less than 98.0% and not more than 100.5% of $C_{13}H_{22}N_2O_6S$ calculated on the dried basis.

Identification tests:

- Dissolve 0.1 g in 10 mL of water. Add 1 mL of 0.1 N iodine solution. A brown precipitate forms.

A: Spectrophotometry in the infrared region (43 Cholinergic Agents). Compare the spectrum of the sample with that of the reference standard. Both spectra must be identical.

Related substances: Dissolve 0.5 g in 50 mL of water. Add 2 drops of phenolphthalein solution and titrate with 0.1 N sodium hydroxide. Not more than 0.4 mL of 0.05 N sodium hydroxide is required.

C: Dissolve 0.1 g in 10 mL of water. Add 2 drops of methyl red solution and titrate with 0.1 N hydrochloric acid. Not more than 0.5 mL of 0.1 N hydrochloric acid is required.

D: Dissolve 0.2 g in 10 mL of water. Add 10 mL of 0.1 N hydrochloric acid. Boil for 20 minutes. Cool and titrate with 0.1 N sodium hydroxide. Not more than 0.5 mL of 0.1 N sodium hydroxide is required.

Û1 ÆŸÖã) ğÅÅŸÊŸö ÂÆŧŧõ "General identification testes ČŋÅĤöã 8ãÀĤǫèŗã ğãøÅĢǫnã" ɹãzÅ3 ŘƠ 8ɀòɀţã .(123 ČHƱÅÔöã

.ğÅ3Åè 3 gÆŋ °ȳ105 gøãÀg ČDZøÆæ ZŦÅDzǫöã ÆĤæ °ȳ149-144 :**Melting range** øÅŦÔǫŗã òÅƒ

1Ş TS (ȯ/ȟ130~) ÕÀÀǫÅöã Ŕþ ɗŋ Õŋ 1 8ÅŘÅŞ ÛŏÅŋ Õŋ 10 Ž ȟ0.20 ããØÅ :**Chlorides** ğãÆÅøzŸÒöã .gÀìÅĢŋ ȳzŧd ÀŦŢŋ ŞgŸÅ ŗ .TS (ȯ/ȟ40) ČŘÅöã ğãÀǫφ ɗŋ Õŋ

TS (ȯ/ȟ70~) ÕÅøzŸõŞøÆŦÃ Ŕþ ɗŋ Õŋ 1.5 8ÅŘÅŞ ÛŏÅŋ Õŋ 10 Ž ȟ0.20 ããØÅ :**Sulfates** ğÅÅŸÊöã .ÂŁÅDZ ÀÒ3 ÀŦŢŋ ǰǫÅ ŗ .TS (ȯ/ȟ50) ȳzÅøÅĢöã ÆÅøzŸõ ɗŋ Õŋ 1Ş

ŗŞ 8ÅÒ ŏÅţã ɗŋ Õŋ 10 Ž ȟ0.20 òzŸŢ ɹzÒÅ :**Clarity and colour of solution** òzŸŧã ɹzÒŞ ŏÅÅÒ ÕãzÊöã ɹzÒ" ɹãzÅ3 ŘƠ 8ɀòɀŋ zŁ Åŧõ ɹøÅÕÅ ÅŋÆÅ3 Bn1 ÐøÅŦĤţã òzŸŧã ɹzÒ ɗ3 ɹzŸǫöã Ž gÆì ÀŽõÛ ɹzÒÅ .(53 ČHƱÅÔöã Û1 ÆŸÖã) "Colour of liquids

.ȟ/ŋŸŋ 1.0 ɗ3 ÆÅÂÅ ŗ :**Sufated ash** ŘŸÅÊţã åÅŋÀöã

ɗŋ ÀŽõÛ ÆÕÅöã ɹzÒÅ ŗ Û°ȳ105 gøãÀg ČDZøå ÆÅ3 Ř÷ÅǫÒ ɹàŞ ?øǫg ZÅz :**Loss on drying** ZŦÅDzǫÕÅæ ÆÕÅöã .ȟ/ŋŸŋ 10

ɹzÒÅ ÜTS òzφÅŽÅÛ/ŘÅÕÅŽz òzÅÆz ɗŋ Õŋ 0.1 8ÅŘÅŞ ŏÅţã ɗŋ Õŋ 10 Ž ȟ0.20 ããØÅ :**Acidity** Ğŕzŧ∑ã .ÀþÛ òzŸŧã ĆĢÔÅ ÜVS (ȯ/òzŋ 0.01) ȳzÅzÔöã ÆŦÊõŞøÆŦŁ ɗŋ Õŋ 0.30 8ÅŘÅ .ɹzŸöã CÆ3 øÅǫnŗã òzŸŢ ČÕŦęÀöã ČÕĢÛöã ããÀÎǫèã" ɹãzÅ3 ŘƠ 8ɀòɀŋ zŁ Åŧõ øÅǫnŗã ĘĢÛÅ :**Related substances** ČŏÅÎţã åãzţã 67 ɗŋ ǰÅŋŞ ČŸŸ8ŋ gåÅŧõ R1 ÅÒŦŸŦÊöã ČŋŸŁ ȳÆÅǫÊŘ Û(84 ČHƱÅÔöã Û1 ÆŸÖã) "Thin layer chromatography ČHƱÅÔöã ɗŋ åÆŢ Ùy) õÀHƱǫŋ øzÛõ R ŘŋŸŦŽÅÛ ƱəÅÅǫ ɗŋ ȳzDzǵ 3Ş R òzφÅŽŦţã ɗŋ ÅŧDzǵ 30Ş ŏÅţã ɗŋ ÅŧDzǵ ÕŦõÅŢ ɗŋ ÀǫõŞÀÒŦŋ 10 ČHƱŦÅò ?Ÿ3 ÅŸÔÅÅŋ ĘĢÛÅ .(õÀHƱǫţã øzÛöã ãØŁ 3ŋ ÅĢèÅÅŋ ɹzÒÅ ŗ ɹÛ ɗÒƐ ÅŸĢę ČŸŸ8ţã 3ŋ 0.10 (C)Ş ÀǫõŞ ƱŸŦţã Ž øÅǫnŗã gåÅŋ ɗŋ ŋŸŋ 0.10 (B)Ş ÀǫõŞ ƱŸŦţã Ž øÅǫnŗã gåÅŋ ɗŋ ŋŸŋ 20 (A) ÐzƷ :ĞǫŸǫ ƱəzŁ øÅŦÅ Ž ZDzǫõ õÀǫÅ ããÀÎǫèŗã gÀDzǵ ɗŋ ČHƱŦÅÔöã ţÂφ ÆĤæ .ÀǫõŞ ƱŸŦţã Ž RS ŘŧŞǫèzŦÅöã ğÅÅŸè ÕŦǫŦŋ ɗŋ øÅŦÅ Ž ČŦφÅǫ ČHƱŦÅÔöã ZÅΘ .VS (ȯ/òzŋ 0.1) ȳzÅzÔöã ÆŦÊõŞøÆŦõ Ż ɗŋŞ TS2 ŘŸŦφŞÀǫφ–4 øæ æÀŘ ÛùzåŘ ČĤÕæ ÐÛ ɹzÒŘ ŗ .øÅŦÅöã õzŗ Ž ããÀÎǫèŗã ÙÛÛ' ÒHƱÅŞ ÛTS 2 ȳzŦèÅŘzĢöã ğÅŘzŋÂæŞÅzŦæ æÀŘ ÛùzåŘ ƱəzŁ .B òzŸŧÅæ ÅŦŦŸ3 ÕÔHƱǫÊţã ÕŸŘ ɗ3 gÆì ÀŽõÛ ÛĢŦÊŦÅÀöã ČĤÕĢöã ŏÅÅŽǫèÅæ ÛA òzŸŧÅæ ÅŦŦŸ3 ÕÔHƱǫÊÅ ZÔφ ÅŦφzŋÛ ŘÛÕŘ ÀÅŦDZ ÐÛ ÕÕÅŘ ÛŏÅŋ Õŋ 20 Ž ÛĢŦùzĢÊŋ ĜφŞàzŋ ÛĤ0.15 ĞæÀę ããØÅ :**Assay** ĞÊÅÅÕţã

ǰ ʌÂţǎ Ǝʒ ǿÅÁǤǎ ȣǰ ǿÅĒǩ ǿÀȘ .TS (ȯ/Ȟ400~) ȳȚʌǎȚÔǎ ÆĒÊõȘǿÆĒŁ ȣǰ Ôǰ 25 ȣÅÎÂʌȘ Ûsemi-micro ƀȘÀÔǰ .ǦǤʌÀÕǩ Ôǰ 200 Ƃǔ ƱŸÒǎ ǰDzΣǎ ÔÔʌ ʔøǾǵ VS (ȯ/ȯȚǰ 0.01) ÕǦʌǿȚÅŸÊǎ Ȑƥ ȣǰ Ôǰ 50 Ž ǨÛÕǾǎ ʒŧȚȘ ǎÅĦǩ .ÀĦÎŧõ TS ȯȚǾÅǰǦǔ/ ÔĒǰĒŧǎ ǵÀƥ ȳǎÆǦǾèÅǎ VS (ȯ/ȯȚǰ 0.02) ȳȚʌǎȚÔǎ ÆĒÊõȘǿÆĒŏ ȐŧΣǎ ÆʌÀ ÀʌÅĦʌ ǩǰǔ ÔĒǰĒǰ ƱǿÅǾ ȯǎÆĦǾèŕ ǦǎȚŸÛŧǎ ȐŧΣǎ ǦĒŧõ ǵǎÀʌÅĦŧǎ ǩǎ ȧÀÅǎ ȣĒǤʌ ÜǨÔƱȚ ƱøǾǎ ǵǎÅŧǎ ȷȘÆǎ ǦĒŸŧĦǎ ȣǰ Ʒǰ 6.688 øǎ ǔȚÅÒʌ VS (ȯ/ȯȚǰ 0.01) ÕǦʌǿȚÅŸÊǎ Ȑƥ ȣǰ Ôǰ 1 Ôõ .ǩŧ8ǾèȚĒǎ ȣǰ ÔÒÎǾŧǎ .$C_{13}H_{22}N_2O_6S$

ƷǾŧΘ üƒDŽyƧŧ Ú€ üШŬ DžǐDŽƧŧ NjǐǾШ€ lƒ2ƧŧŧŕüŧǐDŽШ hǐƷƒŢǎ lƒǤƧƱĐŽ

Additional Requirements for Neostigmini metilsulfate for parenteral use

.(56 ǦƱʌÂÔǎ Û4 ÆŸÖǎ) "*Parenteral preparations* ǦĒÂÕΣǎ ǵǎÀÎÂƱǾÊţǎ" ǵǎȘÀȚǰ ÆĒDzǾÊʌ

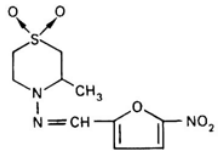
NIFURTIMOXUM

Nifurtimox Ƨ ǀNjDŽǐŧƥNjƨǐǾШ€

Molecular formula: $C_{10}H_{13}N_3O_5S$ ĞĒÅʌÂŧǎ Ğ8ĒÔǎ

Relative molecular mass: 287.3 ĞĒǤÊʌǎ ĞĒÅʌÂŧǎ ĞŸǾÒǎ

Graphic formula: ĞĒǾÅĒǤţǎ Ğ8ĒÔǎ



Chemical name: ƱǾÅĒŧĒÒǎ ǰèŕǎ

3-Methyl-4-[(5-nitrofurfurylidene)amino]thiomorpholine 1,1-dioxide; 3-methyl-*N*-[(5-nitro-2-furanyl)methylene]-4-thiomorpholinamine 1,1-dioxide; CAS Reg. No. 23256-30-6.

Description: ƵòȚǎ .ǦƱǾǎÀǎ CÁƷ ÜƁÅÕǩÀǎ ÀÅòÜ ÛƁǿȚŸǎ ȧȚƱÊǰ

Solubility: ĞĒǾÅŧǾǎ ǰÅŧǾǎ ÜR ÆĒǰÅǰǿȚȚ ÔĒǰĒǰ ƱǾÅǾ Ž ǰÅŧǾǎ ǾǵǎÀ ÜR ǨǾǰŧǾ ŏÅţǎ Ž ǦĒŸŧƷ ǎŧǾǎ ǨǾ .R ȳǿȚȚǾǿŸÒǎǾ R ǰÅÊõȚʌÆǎ Ž

Category: ĞÅÅǎ .Antitrypanosomal drug ǵÅĒǤÕǰǦǔ ǎÅÎÂǰ ŏǎǾǎ

Storage: ȣʌÂÁǾǎ .ȳÅÒǵŏŧǎ ĞÕŸ8ǰ ĞʌǾÅǵ Ž ÈõȚŧĒǩǿȚÅĒÅǎ ǾÅǵ Æŧ

ďŋ %102.0 ďƷ ÆΛÂΛ ŕş %98.0 ďƷ ƱÕΛ ŕ ÅŋĮ È õƨţĚĚĭóƨÁĚĂóä ƀƨƵ :**General requirement** ȳÅĬóä ÆĚŸÛǫţä .ĞÁÁŎä gáÅţä Ƃŭ ţƨDƵÃõÅä Ğäƨ Ê Ţ ÛC$_{10}$H$_{13}$N$_3$O$_5$S

:**Identification tests** hƀĬŃjŃƦƦƐ l ɛƥƒĠĤƢƦɛ

.ÅĬŋ CŞ B ĵäøÅĞǫnŕä şŭ ĆÆǵş A óÅĞǫnŕä ĘĞÛΛ ĵŭ ÅŋŮ •

ŏäÃţΣä ŘƠ ĞĬÌĵä ĞÕÛÅŋ Ž ƱƨƨÔää ƨƨÛää âÅĚę" ĵäƨÁƷ ŘƠ ȣƨòƨŋ ƨŁ Åţõ óÅĞǫnŕä ĘĞÛΛ :A ŏäÃţΣä ŘƠ ĞĬÌĵä î ÅÔǫŋä ƨĚù ĘäÅÛǫΛ .(43 ĞĦÁÔää Û1 ÆŸŎä) "Spectrophotometry in the infrared region .È õƨţĚĚĭóƨÁĚĂŸö ƱĬDƵÃţä ƨƨÛää Ƹŋ şŭ RS È õƨţĚĚĭóƨÁĚĂóä ďŋ ĊĚŸƷ ÕÔĦǫÊţä ƨƨÛää Ƹŋ ĞĚÊĚƐÃää ĞĬÕĞää Ęƨäƨǫĭ ."Related substances ĞöÅÎţä ääƨţä" ĵäƨÁƷ ŘƠ ĬÕǵŕ ȣƨòƨţä øÅĞǫnŕä ÃŢǫä :B .C òƨŸ‡Åä ÅƨĚŸƷ ÕÔĦǫÊţä ÕŸĭ Ƹŋ ǵÆÎääş ÃƨŢţäş ĵÅÒţä Ž B òƨŸ‡Åä ÅƨĚŸƷ ÕÔĦǫÊţä ǵÅÅŸè Õŋ 0.25 ȣÅŘΛ .ŏÅţä ďŋ Õŋ 2.0ş R ÆĚŋÅŋøƨƨ ÕĚĚŋ ŬƐÅÅǫ ďŋ Õŋ 2.0 ďŋ ĵΛÂŋ Ž ŋŸŋ 20 ãäØΛ :C R ȳóƨƨşóƨŸÒää ďŋ Õŋ 5 ȣÅŘΛ .ďõääÅ ÃŘnŬ ĵƨö ĵǫΛΛ ÜR ďΛÆΛĭĞää ďŋ ǵäÃÛę 4ş TS (ò/ĥ160) (II) âÅĦĦÁää .ĞĚƐÅţä ĞÕĞÛää Ž ÃŘnĵä ĵƨŸää ƨÕĞĚƨ ÜƷÃłş

.°ȳ182-178 :**Melting range** óÅƨÔǫŕä òÅƒ

.ĥ/ŋŸŋ 1.0 ďƷ ÆΛÂΛ ŕ :**Sulfated ash** ĬÁŸÊţä äÅŋÃää

5.0 ďƷ ÆΛÂΛ ŕ Ü°ȳ105 gøäÃǵ ĞDƵóä ÆÁƷ ĬäÅǫ ĵäş ƨøǫǵ ƨÁƨ :**Loss on drying** ƨĚÁDƵǫõÅä ÆÕÅää .ĥ/ŋŸŋ

ĞÕĚęÃää ĞÕĞÛää ãäÃÎǫèä" ĵäƨÁƷ ŘƠ ȣƨòƨŋ ƨŁ Åţõ óÅĞǫnŕä ĘĞÛΛ :**Related substances** ĞöÅÎţä ääƨţä ĵƨÒĭ Æę) ĞŸäŋ gáÅţõ R6 ÅÒĚŸĚÊää ĞŋŸŁ ȳÆÁǫÊĭ Û(84 ĞĦÁÔää Û1 ÆŸŎä) "Thin layer chromatography óƨÛõ R ĵÅÊÒŢäş R ÕĚŽΛqä ǵÅǫĚèŬ ďŋ ĞΛşÅÊǫŋ ȳÅDƵǵŬ ďŋ ĵΛÂŋş (ĞĞèÅŋ ĞΛóÅΘ óäÅÔŋ ďŋ ŸĞę ĞŸäŋţä ĞĦÁÔää ďŋ ŋŸŋ 10 ƨŸƷ ƀƨƵƠ ÃǫäşÃÒĚŋ 10 (A) :R ĵƨǫĚèĵä Ž ĞĚäÅǫää ĞǫŸĵää ÕĚäÅ‡ä ĞĦÁÔää ƨŸƷ ŸÔÅŋ ĘĞÛΛ .õÃĦǫŋ ÃǫäşÃÒĚŋ 2 (C)ş ÃǫäŬŸĚţä Ž øÅĞǫnŕä gáÅŋ ďŋ ŋŸŋ1.0 ƨŸƷ ĵÅƨǫƷ ÃǫäşÃÒĚŋ 2 (B)ş ÃǫäŬŸĚţä Ž øÅĞǫnŕä gáÅŋ gÃDƵǵ Ž ĞĦÁÔää Ƹŕş ÕĞę ƨDƵǫää ƨÕĞää ŏÃǫĭ .ÃǫäŬŸĚţä Ž RS È õƨţĚĚĭóƨÁĚĂóä ďŋ ŋŸŋ 1.0 ƨŸƷ ĵÅƨǫƷ Ž ƨDƵǫää ŏÃǫĭ Ûãäää

ďŋ Ōŋ 80ş R ÁĒŋĀŋǿźź ŌĒŽĒŋ ŬəĀĀǫ ďŋ Ōŋ 20 Ž ŮĞĒùźĠŘŋ Ğǫşàźŋ ÛĦ0.1 ĞäāÀę ā ãØΛ :**Assay** ĞÊΛĀŌţã ÁĒÊõŮ ŬəĀĀǫ ğĀ3ĀŌź ĘŸÛĦş TS (ȯ/Ħ250~) ŌΛǿźŸõşǿÁĒTã Ŕβ ďŋ Ōŋ 5 ȣĀŘΛ .TS (ȯ/Ħ750~) ȯźφĀŽΛŮ ÁΛǿźŸõ ŬǫŸǫ ďŋ Ōŋ 30.0 ȣĀŘΛ Ęəāęå 3 ÁĦä .ƙĒĦǫõã ȯŸn ďŋ ɔŸ3Ů ¢ĒŸ3 ƙŢźĀŢ ȯźŸ‡ã ďŧŕ R ɟźäÀÒõã ÁΛŧà ÀΛĀĦΛş ĞŌĒęå 15 gÁŋ ÀŌǫÊǫõ õÀǫĭ .TS (ȯ/Ħ200) ȳźĒèĀĭźĠõã ğĀφĀĒèźĒǫ ďŋ Ōŋ 3ş VS (ȯ/ȯźŋ 0.1) ȳźĒφĀǫĒǫõã 0.1) ȳźĒφĀǫĒǫõã ÁΛǿźŸõ ŬǫŸǫ ďŋ Àǫõ ŬŸĒŋ 1 Ōõ .VS (ȯ/ȯźŋ 0.1) ŌΛĞĀõã ȳźĒφźŋŮ ğĀĀŸÊã ȳźĒφĀǫĒǫõã ÁΛǿźŸõ $C_{10}H_{13}N_3O_5S$ ďŋ Ɜŋ 4.788 ůźĀÒΛ VS (ȯ/ȯźŋ.

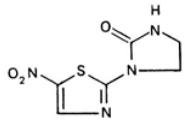
NIRIDAZOLUM

Niridazole üNjŘ&ǫĭƀĭźΛΕ

Molecular formula: $C_6H_6N_4O_3S$ ĞĒĀΛÂɔã Ğ8ĒÔõã

Relative molecular mass: 214.2 ĞĒĞÊĀõã ĞĒĀΛÂɔã ĞŸǫÒõã

Graphic formula: ĞĒφĀĒĞţã Ğ8ĒÔõã



Chemical name: ŬəĀĒŧĒÒõã ĻèŕÃ

1-(5-Nitro-2-thiazolyl)-2-imidazolidinone; CAS Reg. No. 61-57-4.

Description: Ƶòźõã ĞĦäāÀõã CÁƷ ĦĞΛÀÕĭ ş Ů ĞĦäāÀõã CÁƷ ÜÀÀòŮ Ьźŷã ȧźĦÊŋ.

Solubility: ĞĒφĀãşØõã ĞĒφĀãşØõã Ž ãāşã ÜR Ğǫ ĵāş R ȳźźşźŷÒõãş ŏĀţã Ž ĦĒŸŧƷ ãāşã Ğq. R ɟźĒèĵāş TS (ȯ/Ħ750~) ȯźφĀŽΛqã Ž ɟĀãşØõã ĞĒĦùì ÜR ďΛÁΛĞõãş.

Category: ğĀŌÎΛţã åĀŘŋ ŏãşå.

Storage: ďΛÂÅǫõã ȳĀÒgüã ĞÕŸ8ŋ ĞΛşĀg Ž ȯşàãÁΛĞÃõã ŞĀg Æz.

REQUIREMENTS ĞĞĦΛŌĞkdž!f

General requirement: ȳĀĦãõã ÆŸÛǫţã %103.0 ďƷ ÁΛÂΛ ŕş %97.0 ďƷ ŌÕΛ ŕ Āŋ ɔŸ3 ȯşàãÁΛĞÃõã ЬźǫƵ. ĞĀĀÕã gåĀţã Ьŭ ţźDZÀõĀã ĞãźÊŢ Û$C_6H_6N_4O_3S$ ďŋ.

Identification tests: ȟȳŇȷŇȷŇŇε ȴε ƥƒƓƓƓƓε

- ŇŇȟŋ DȘ CȘ B ğăóȦĠǫȠȠŕă ĘĠĠŮǩ ȘȬ ĊÁǵȘ A óȦĠǫȠȠŕă ĘĠĠŮȠ ȷŬ ȦŋŬ.

:A ŏăȦŧΣă ǨƠ ĞȞŕȠȠȷă ĞÕŮȠŋ Ž ȣƨȚŕŏă ȚĘŮŏă ȧȦĘę" ȷăȚƷ ǨƠ ȣȚȠŏȚŋ ȚŁ Ȧŧõ óȦĠǫȠȠŕă ĘĠĠŮȠ

ŏăȦŧΣă ǨƠ ĞȞŕȠȠȷă î ȦÔǫŋă ȚĘù ĘăȦŮǫȠ .(43 ĞȞȣȦÔŏă Ů1 ÁŸŎă) "Spectrophotometry in the infrared region

.ȯȘȦăÁȠȠKȦŸŏ ȣȞDZȦŧă ȚĘŮŏă ȚŋȘŬ RS ȯȘȦăÁȠȠKȦŏă ďŋ ĊĘŸȚ ŎÔȞȣǫÊŧă ȚĘŮŏă Țŋ

ĞĘÊŁăȦŏă ĞȞÕĞŏă ĘȚăȚǫǩ ."Related substances ĞŏȦÎŧă ăăȚŧă" ȷăȚƷ ǨƠ ŇÕǵŕ ȣȚȠŏȚŧă óȦĠǫȠȠŕă ȦŢǫă :B

.B ȯȚŸ‡Ȧă ȦŤĘŸȚ ŎÔȞȣǫÊŧă ÕŸǩ ȚŋȘÁÎŏăȘ ȦŤŢŧăȘ ȷȦÒŧă Ž A ȯȚŸ‡Ȧă ȦŤĘŸȚ ŎÔȞȣǫÊŧă

ŮȚȦŁ ŮTS (ȯ/ȟ80~) ȳȚȠăȚÔŏă ÁĘÊõȘǫÁĘŁ ďŋ ŎŋȚ 2.0 ȣȦŘȠȘ ŮR ȷȚǫĘèŬ ŎŋȚ 2.0 Ž ŋŸŋ 20 ăăØȠ :C

.ĞĘŸȦÊŏă ĞÕĞŮŏă Ž ďõăă ȦÞŬ ȷȚȯ ȷǫȠ ŬĘȠȦęă 10 gÁŋ ȦÕǫÊĘŏ õȦǫȠȘ

.ŎÒȦǫŏă Țŋ °ȳ 264 ĞăăȦę ŮǿȦŤÔǫŕă gǿăȦǵ ĞDZǿă :D

ǿȦĠǫȠȠŕă " ȷăȚƷ ǨƠ ȣȚȠŏȚŋ ȚŁ Ȧŧõ óȦĠǫȠȠŕă ȯȚŸŢ ǨŘȞȣǫŏ ȟ1.0 ȳÁĂǫÊȠ :**Heavy metals** ĞŸĘÕŽŏă ȷăȦŤŧă

ȷăȦŤŧă ȘȚǫŢ ǩŤȠ Ü(127 ĞȞȣȦÔŏă Ů1 ÁŸŎă) 3 ŏăȦDZqă "Limit test for heavy metals ĞŸĘÕŽŏă ȷăȦŤŧă ŎDZȷ ƀĘΣă

.ȟ/ȳăȦdȘȦÒŋ 20 ďȚ ÁȠÂȠ ŕ Ü(128 ĞȞȣȦÔŏă Ů1 ÁŸŎă) A ĞÕȠȦŮŸŏ ŇÕǵŮ ĞŸĘÕŽŏă

(ȯ/ȟ70~) ÕȠǿȚŸõȘǫÁĘŢă Ŗƥ ďŋ ŎŋȚ 2.0 ďŋ ȷȠÂŋ ŊŬ ǿȦĠǫȠȠŕă gǿÂŋ ďŋ ȟ0.5 ȣȦŘȠ :**Sulfates** ğȦȦŸÊŏă

ŬŎŋȚ 10 ŋŬ ŏȦŧȦă ĞgȦŤȦŏă ȚȦǫȘ ŮĞŤȦȠ ŮĞȚȦ8ŏă gǿăȦǵ ĞDZǿă ŋŬ ǿȦƎȠ ŮȷȦĘŸ8ŏă Țǿǫǵ ďǾÊȠ ŮŏȦŋ ŎŋȚ 8.0Ș TS

.ȷȦĘŸ8ŏă Țǿǫǵ ĞĘǫȦǫ ďǾÊȠȘ VS (ȯ/ȯȚŋ 0.5) ȳȚǿȦĠǫŏă ÁȠǿȚŸõ ďŋ ŎŋȚ 1.0 ȣȦŘȠ .ŇŇȚȦò ȯȚŸ‡ă ȷȚÒȠ

Ŗƥ ďŋ ŎŋȚ 2.0 ŮVS (ȯ/ȯȚŋ 0.01) ÕȠǿȦŸÊŏă Ŗƥ ďŋ ŎŋȚ 0.10 ƀȚǫȚ ĞǫǿȦÔŋ ȯȚŸŢ ȦŘȚ ŎǫȦư ȚŬ ȚŸ3

Țǿǫǵ ďǾÊȠȘ ŮVS (ȯ/ȯȚŋ 0.5) ȳȚǿȦĠǫŏă ÁȠǿȚŸõ ďŋ ŎŋȚ 1.0 ŮŏȦŋ ŎŋȚ 8.0 ŮTS (ȯ/ȟ70~) ÕȠǿȚŸõȘǫÁĘŢă

.ȷȦĘŸ8ŏă

ȷǩȦĠǫŏă Õŏăĕ ďŋ ÁŤŬ ǿȦĠǫȠȠŕă gǿÂŋ ďŋ ȦŘ‡ă ȯȚŸ‡ă ȳȚŧȤ ȷȚÒȠ ŕ ŮgÁǵăȘ ĞȚȦè gÁŋ ăȦÕǫÊĘŏ ǩȯȚŸ‡ă Ÿõ õȦǫȠ

.ĞǫǿȦÔŧă ȯȚŸŢ ďȚ

ȣȚȦǫ ďŋ ŎŋȚ 10 Ž ȟ0.10 ȯȚŸŢ ȷȚÒȠ :**Solution in dimethylformamide** ÁĘŋȦŋǿȚȚ ŎĘŽĘŋ ȣȚȦǫ Ž ȯȚŸŢ

.ŇŇȚȦò R ÁĘŋȦŋǿȚȚ ŎĘŽĘŋ

.ȟ/ŋŸŋ 3.0 ďȚ ÁȠÂȠ ŕ :**Sufated ash** ǨŸȦÊŧă ăȦŋȦŏă

0.6 ăȘȦDzǫȠŕ) ŘȦĂȦŋ Ù8ŕ ǨƠ °ȳ100 gǿăȦǵ ĞDZǿă ÁȦȚ ȚȦz :**Loss on drying** ȚĘADzǫǿȦă ÁÕȦǿă

.ǩ/ŋŸŋ 5.0 ďŋ ĂŽõŬ ÆÕÀΛ ŕ Ü ğ ǩ3ǩè 3 gÆŋ (ŬÕGəà ĻŸŋ 5 ĞäăÀę ęŬ ȯǩÒèǩzŸŒõ

ǦÕŒęÀõä ǦÕGÛõä ā ăÀÎǫèä" ɟǩzǩ3 ǨƠ 8ȚȯȚŋ ȚŁ ǩŧõ øǩǦǫnŕä ĘGÛΛ :**Related substances** ǦõǩÎŧä ǩǩȚŧä ɟȚÒǩ Æę) ǦŸä8ŋ gǩǩŧõ R6 ǩÒŒŸŒÊõä ǦŋŸŁ ȳÆǩǫÊǩ Û(84 ǦHȯǩÂÔõä Û1 ÆŸǦÒä) "Thin layer chromatography R ɟȚŒèɟä ďŋ ȳȚDzǵ 8ę R ďΛȚȯȚÛõä ďŋ ǩŧDzǵ 12 ďŋ ǰΛÂŋę (ǦGèǩΛŋ ǦΛøǩΘ øǩǩÔŋ ďŋ ŸGę ǦŸŸ8ŧä ǦHȯǩÂÔõä gǩǩŋ ďŋ ŋŸŋ 10 (A) ƀȚȚ :R ďΛÆΛKGõä Ž ÕŒõǩŢ 4 ďŋ ĂǫõęĂÒŒŋ 5 ǦHȯǩÀò ȚŸȚ ŸÔǩΛŋ ĘGÛΛ .ōĂHȯǫŋ øȚÛõ Ăǫõ ŬŸŒŧä Ž RS ȯęĂäÆΛKΛõä ďŋ ŋŸŋ 10 (B) Û(ǩΛøęĂŕ ɟǩõ äæŬ ÛÆΛęØǫŸõ ŸŸŒŸę ďÅÊΛ) Ăǫõ ŬŸŒŧä Ž øǩǫnŕä (D) ÛĂǫõ ŬŸŒŧä Ž RS ȯęĂǩǫęĂǫęφ –5– ȚǩŋŬ -2 ďŋ ȳäĂďęĂÒŋ 20 (C) Û(ǩΛøęĂŕ ɟǩõ äæŬ ÛÆΛęØǫŸõ ŸŸŒŸę ďÅÊΛ) Ûāăǩ Îǫèŕä gĂDzǵ ďŋ ǦHȯǩÂÔõä ȚȚø ÆŒä .Ăǫõ ŬŸŒŧä Ž RS ÆŒŋǩÊõȚäøǩõ ÕŒȚΛŬøȚŸõ ȯęĂäÆΛKφ ďŋ ȳäĂďęĂÒŋ 40 gĂŋę (ĂǫŋȚφǩφ 365) ǦŒDzÊǩΛGõä ȯȚȚ ǦŒŸŸɟä ȯȚŕ Ž gĂŸǩŋ ăăǩÎǫèŕä ŬŬŬ ÒHȯǩΛ ŬŬäȚŁ øǩŒǩ Ž ȚDzǫõ ōĂǫǩ ǦΘǩõä ÕŸǩ ďȚ gÆŸ ĂŽõŬ ŬǦŒÊŒäĂõä ǦŒÕGõä øǩȚǫÈǩä ŬA ȯȚŸ‡ä ďŋ ǦΘǩφ ǦŒÕä ƀŬ ɟȚÒǩ ŕ .ȚŒŒÎǩ ǦÕŒęå 15 ÆŒä ǦŒφǩǫ .ǦÕŒęå 15 ÆŒä gÆŒǩÎŧä D ȯȚŸ‡ä ďȚ ǦΘǩõä ÕŸǩ ďȚ gÆŸ ĂŽõŬ ŕę gĂŸǩΛŋ gÆŒǩÎŧä C ȯȚŸ‡ä ďȚ

ǦŧÒä ȚǩØę R ÆŒŋǩŋøȚȚ ÕŒȚŒŋ ƀäĂǫ ďŋ Õŋŋŋŋ 4 Ž ŬǦŒŬȚGŋ ǦφęĂȚŋ ŬŋŸŋ 40 ǦäĂęę ā ăØΛ :**Assay** ǦÊΛǩÕŧä 100 ƀŬ ȯȚŸ‡ä äØŒ ďŋ Õŋŋŋŋ 5.0 ǩǩ ŬÕŋŋŋŋ 200 Țǩǫφq dehydrated ethanol R ǩǩŧä ŧęÂøǩŋ ȯȚφǩȚΛqä ďŋ ǦŒǩǩõ ĂǫŋȚφǩφ 359 ǦDZŋŋ ȯȚù ÆǩȚ ŸȚȚɟä ȚÆǵ Ž ȚǩÁŧä ȯȚŸ‡ä ďŋ ɟè ǩŸŸǩÁõ 1 ǦÕGÛõ î ǩŧǫõä ǩÕΛ .¢Êǩφ ÆΛØŧǩä Õŋ ȯǩǩŋ ȚŬ ŸȚ .ďŋǩÂǫõęę ¢ǩÎŧǩä ŬRS ȯęĂäÆΛKΛõä �ŋ ǦφøǩÕŧǩä ǦòȚHȯǩŧä ǩǩŧä Ž $C_6H_6N_4O_3S$ ǦŒŧõ ÆÊÔ .ǩΛǩÕõ .0.03±0.70 RS ȯęĂäÆΛKΛõä ďŋ Õŋ/ȳäĂďęĂÒŋ 10 ȯȚŸ‡ ŬȚŋŘõä ȚŒŬõä ǩŒŋ ĂΛǩŋŧä î ǩŧǫõä ɟȚÒΛ ɟŬ ÆŒ

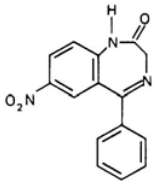
NITRAZEPAMUM

Nitrazepam !ƒǦĞIŘ€ƒÞŦŒŒ

$C_{15}H_{11}N_3O_3$:**Molecular formula** ǦŒǩΛÂƨä Ǧ8ŒÔõä

281.3 :**Relative molecular mass** ǦŒǦÊΛõä ǦŒǩΛÂƨä ǦŸǫÒõä

:**Graphic formula** ǦŒφǩŒGŧä Ǧ8ŒÔõä



Chemical name: 1,3-Dihydro-7-nitro-5-phenyl-2*H*-1,4-benzodiazepin-2-one; CAS Reg. No. 146-22-5.

Description: Clonazepam occurs as a yellowish crystalline powder. It is practically insoluble in water, in ether, in chloroform, in dilute acids and in dilute alkalis. It dissolves in dimethylformamide and in dilute solutions of sodium hydroxide (1 in 750).

Solubility: Clonazepam is soluble in methanol, in ethanol, in acetone, in glacial acetic acid and in dilute solutions of sodium hydroxide.

Category: Anticonvulsant.

Storage: Clonazepam should be protected from light.

REQUIREMENTS

General requirement: Clonazepam contains not less than 98.5% and not more than 101.0% of $C_{15}H_{11}N_3O_3$, calculated on the dried basis.

Identification tests: A. Dissolve 0.005 g of clonazepam in 1 mL of methanol and add 280 mL of water. Add 350 mL of water and 230 mL of 0.45 M phosphate buffer, pH 7.4. Scan between 230 and 350 nm against a blank prepared in the same manner. The absorbance at 315 nm is 0.45 ± 0.05.

B. Dissolve 0.05 g in 5 mL of methanol and add 20 mL of ethylenediamine hydrochloride (1 in 80). Heat on a water bath for 5 min. Cool and add 10 mL of methanol. Add 1 mL of a solution of 1-naphthylethylenediamine dihydrochloride (1 in 20). Heat on a water bath for 15 min. Cool and add 2 mL of 2 N sodium hydroxide. Add 5 mL of 1 N hydrochloric acid and 1 mL of a solution of sodium nitrite (1 in 20). Heat on a water bath for 15 min. Cool and add 1 mL of a solution of N-(1-naphthyl) ethylenediamine hydrochloride (1 in 80).

C. Mix 1 mg of clonazepam with 227 mg of potassium bromide. Prepare a pellet and scan between 4000 and 400 cm^{-1}.

Heavy metals: Dissolve 1.0 g in 20 mL of methanol and add 2 mL of a solution of sodium sulfide (1 in 20). Dilute with water to 50 mL. Prepare a control solution using 3 mL of a standard lead solution (10 ppm). Compare the colour of the solution of clonazepam with that of the control solution.

.ħ/ȳäÀdęÀÒŋ20 ɗȝ ÆÀÂÀ ŕ Ü(128 ČHȥÁÔää Û1 ÆŸŎä) A ČÕÀÀÛŸõ ÌÕĞù ČŸÆÕŽää

.ħ/ŋŸŋ 1.0 ɗȝ ÆÀÂÀ ŕ :**Sulfated ash** ŘÁŸÊţä ǻÌŋÀää

.ħ/ŋŸŋ 5.0 ɗŋ ÀŽõÜ ÆÕÁää ȷȚÒÀ ŕ Ü ğÁȝÌè 4 gÆŋ °ȳ105 ÆÁȝ ZÁz :**Loss on drying** ZÆÁDzQÕÌäŕ ÆÕÁää

ā ä À Î Q è ä" ȷäzÁȝ ŘƠ ȣȚòȚŋ ȚŁ Ìŧõ ŘȚÁì ŏȚŕ Ž óÌÁGQnŕä ĘĞÛÀ :**Related substances** ČŏÌÎţä ǻäzţä ČŸäȣŋ gǻÌŧõ R4 ÌÒÆŸÆÊää ČŋŸŁ ȳÆÁQÊŘ Û(84 ČHȥÁÔää Û1 ÆŸŎä) "Thin layer chromatography ČÕÆęÀää ČÕĞÛää ČHȥÁò ɔŸȝ ÆŸÔÌÁŋ ĘĞÛÀ .ōÀHȥQŋ ózÛõ R ÕÆŽÀqä ğÌQÆèÜ ɗŋ ÆŧDzǵ 15Ş R ȷÌQÆŋŞÀQÁää ɗŋ ÆŧDzǵ 85 ɗŋ ŽÀÂŋŞ (A) ÞȚȚ :R ózφÌŽÆţŧŞ R ȳózȚŞózŸÒää ɗŋ ČÀŞÌÊQŋ ȳÌDzǵÜ ɗŋ ŽÀÂŋ Ž ÆDZàÌù ɗÀÀÊŢ ƙózŸŢ ɗŋ ÀQõŞÀÒÆŋ 10 ČȚÌÊŋ Ьů ČHȥÁÔää ÀŤŢŘ .ÀQõ ŸÆţä Ž óÌÁGQnŕä gǻÌŋ ɗŋ ȳäÀdęÀÒŋ 25 (B)Ş ÀQõ ŸÆţä Ž óÌÁGQnŕä gǻÌŋ ɗŋ ŋŸŋ 25 ȧȚȚ ózŘää Ž ā ä À Î Q è ŕä ÙÛÜ ÒHȥÁÀŞ õäzTä Ž ZDzQõ ōÀQŘ Û ā ä À Î Q è ŕä gÀDzǵ ɗŋ ČHȥÁÔää ţÂφ ÆŘä .ŀè 12 ČÒÌÁää ÕŸŘ ɗȝ gÆì ÀŽõÜ ȷȚÒŘ ŕ ÛČÆÊÆÀää ČŘÕGää ÒÌÁŽQèÌäŕ ÛA ózŸǂä ɗȝ ČÒÌφ ČŘÕäŕ ÞÜ .(ÀQŋȚφÌφ 254) ŸDzÊÌÁÁGää .B ózŸǂä ɗȝ

ŘŧШ ÀÀÌÁŘÀŞ R ğÌQÆèjä ÆÀøÆÆŒÜ ɗŋ Õŋ 30 Ž ÛČÆÜȚGŘŋ ČφŞàȚŋ Û0.25 ČääÀę ā äØÀ :**Assay** ČÊÀÌÕţä ŘƠ ȣȚòȚŋ ȚŁ Ìŧõ potentiometrically ÆŤȚä âÌÆÕŋ ČÀÌŤÀää ČÛÕφ ɗÆŘŘ ÛVS (ȯ/ȯȚŋ 0.1) ÕÀøȚŸõKGää ɗŋ Õŋ 1 Õõ .(142 ČHȥÁÔää Û1 ÆŸŎä) A ČÕÀÀÛää Û"Non-aqueous titration ŸÌŋŸää ÙèȚää Ž gÀÀÌŘţä" ȷäzÁȝ .$C_{15}H_{11}N_3O_3$ ɗŋ ŋŸŋ 28.13 ùȚÌÒÀ VS (ȯ/ȯȚŋ 0.1) ÕÀøȚŸõKGää ŘÞ

NITROFURANTOINUM

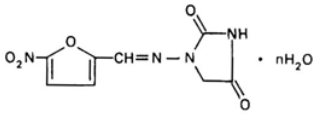
Nitrofurantion DžÏNjÐŒÞNjƷNjÞÐŒMƐ

Nitrofurantion, anhydrous ÏəFDŽúMƐ DžÏNjÐŒÞNjƷNjÞÐŒMƐ

Nitrofurantion, monohydrate lƐÞqÏNJMƐ qÏÖNj DžÏNjÐŒÞNjƷNjÞÐŒMƐ

(ğäøÆÆTä ÆÆgę) $C_8H_6N_4O_5$,H_2O Ü(ŸÌŋŕ) $C_8H_6N_4O_5$:**Molecular formula** ČÆÌÀÂɔä Č8ÆÔää .(ğäøÆÆTä ÆÆgę) 256.2 Ü(ŸÌŋŕ) 238.2 :**Relative molecular mass** ČÆGÊÀää ČÆÌÀÂɔä ČŸQÒää

:**Graphic formula** ČÆφÌÆGţä Č8ÆÔää



Chemical name: 1-[(5-Nitrofurfurylidene)amino]hydantoin; 1-[[(5-nitro-2-furanyl)methylene]amino]-2,4-imidazolidinedione; CAS Reg. No. 67-20-9 (anhydrous).
1-[(5-Nitrofurfurylidene)amino]hydantoin monohydrate; 1-[[(5-nitro-2-furanyl)-methylene]amino]-2,4-imidazolidinedione monohydrate; CAS Reg. No. 17140-81-7 (monohydrate).

Other name: Furadoninum.

Description: Yellow crystalline powder. Odorless.

Solubility: Slightly soluble in water; practically insoluble in alcohol.

Category: Antibacterial.

Storage: Keep in a well-closed container, protected from light.

Labelling: Keep out of reach of children.

Additional information: Stainless steel equipment should be used.

REQUIREMENTS

General requirement: Contains not less than 98.0 and not more than 102.0 per cent of $C_8H_6N_4O_5$.

Identification tests:

- A. Dissolve 0.1 g in 100 ml of boiling water, add 1 ml of 0.1 M sodium hydroxide, and boil for 1 minute. Cool and add 1 ml of 0.1 M hydrochloric acid. A yellow precipitate is formed.

ŏäÀŧΣä ŘƠ ĞĦÌŷä ĞÕÛÄŋ Ž ЧƻŘää ZĒÛää âÄĒę" ŷäzÄ3 ŘƠ 8zòzŋ zŁ Äŧõ øÄĞQnŕä ĘĞÛΛ :A
Ûğäø ÁĒTä ÁĒgş cbΛzQqäøzzşÀQÄää ÕDZÜ cbŋ .(43 ĞHЧÄÔää Û1 ÁŸÖä) "Spectrophotometry in the infrared region
Ʒŋ öäÀŧΣä ŘƠ ĞĦÌŷä î ÄÔQŋä ZĒù ĘäÄÛQΛ .°ȳ105 ĞDZøÁÉää ÁÄ3 ŘäÄÄQ ŷàş БÜ ÄŸĞę ĞÄÄƒ gÕÄŧä ŷzÒk ŷÜ Āz
.cbΛzQqäøzzşÀQÄŸö ЧĦDZÀŧä ZĒÛää Ʒŋ şÜ RS cbΛzQqäøzzşÀQÄÕÄä ÕÔHЧQÊŧä ZĒÛää
.ŘäÜ öz ř Ž ĞĒÕÄQÕää ğÄĒŸŧĦöä ƤÀΘ :ĞŢǵŸŋ :B
ÕĒQèŷä Řβ cbŋ Õŋ 0.3 8ÄŘΛ ÛöÄŋ Õŋ 20 Ž R ȳzΛÕzÔää ğÄQĒèÜ cbŋ Ħ3.6 ĞääæÜä ÁĒŁÄÌ ozŸŢ ÀŘƷ
R ÁĒnÄnøzz ÕĒŸĒŋ ЧÄÄQ cbŋ Õŋ 50 Ž Ħ0.12 ā äØΛ .Õŋ 200 ƷÄQφq öÄŧä cbŋ ĞĒzÄõ ĞĒŧOä ZÄƧş ÛR ЧDzŸŸää
.ÄÄqÜ ÄŘ÷ä ÁĒŁÄÎää ozŸ÷Ä ä Õŋ 100 БÜ ozŸ÷ä äØĒ cbŋ Õŋ 5 ZÄƧ .Õŋ 1000 ƷÄQφq öÄŧä cbŋ ĞĒzÄõ ĞĒŧõ 8ÄŘΛş
ÕĒŸĒŋ ЧÄÄQ cbŋ Õŋ 0.05 ¢ö ZĒřÜ ÐØää ÁĒŁÄÎää ozŸ÷ä cbŋ Õŋ 10 ÕäÄÕŋ ŷŘÄÄää ozŸ÷ä î ÄÔQŋä ZĒù âÄÕΛ
ÁÄ3 ɔŸ3Ü ÄÁg î ÄÔQŋŕä ZĒù ÐÁĞΛ ÛÄQnzφÄφ 400ş ÄQnzφÄφ 220 ƙä ĞDZzŋ ożùÜ Ž ÁĒŁÄÎΛ ÄnÁÄ3 .R ÁĒnÄnøzz
ɔŸ3 Û0.46ş 0.32 ĞääÄę cbØĒ ĞDZzŧä Бzù ÁÄ3 ŀè 1 ÄŸÄÅQ ŘÕĞÛÕ î Äŧ Qää ŷzÒΛş .ÄQnzφÄφ 367ş 266 ĞDZzŧä Бzù
.1.42ş 1.36 ƙä ÄQnzφÄφ 266 ĞDZzŋ ozù ÁÄ3 î Äŧ Qää БÜ ÄQnzφÄφ 367 ĞDZzŧä ozù ÁÄ3 î Äŧ Qää ĞĞÊφ dzşÄQk .Бäz Qää
.R ЧDzŸŸää ÕĒQèŷä Řβ cbŋ gÁĞäş gÄÛęş R ÁĒnÄnøzz ÕĒŸĒŋ ЧÄÄQ cbŋ Õŋ 10 cbŋ ŷΛÂŋ Ž Ħ0.2 ā äØΛ :C
cbŋ Õŋ 0.2ş TS (ȯ/Ħ80) (II) âÄЧÄää ğÄÄŸè cbŋ Õŋ 0.15ş öÄŧä cbŋ Õŋ 2 8ÄŘΛ ozŸ÷ä äØĒ cbŋ Õŋ 0.5 БÜ
.ȳózzşózŸÒää ĞÕĞÛää Ž ÄŘnÜ ŷzÒ ŷQΛ ÜÕÔÄÄQÕ ğÄÕĞÛää ÕÄQkş R ȳózzşózŸÕ cbŋ Õŋ 3 Ʒŋ ƷÄŁ ÜR cbΛÁΛKĞää
ĞĞÔΛ .ozŸHŧŸö ĘnÄd ÄÄÒÜ ŷzÒ ŷQΛ ÜVS(ȯ/ozŋ 0.1) ȳzΛÕzÔää ÁĒÊÕşØÁĒŁ cbŋ Õŋ 5 Ž ŋŸŋ 5 ā äØΛ :D
.øäÄÕQèŕä ÁÄ3 ĘnÄd БÄÕkÄä – ÄβÜ
.Ħ/ŋŸŋ 1.0 cb3 ÁΛÂΛ ŕ :**Sulfated ash** ŘÄŸÊŧä ÕÄnÄää
10 cbŋ ÄŸÕÜ cbΛzQqäøzzşÀQÄää ÁÕz ŷzÒΛ ŕ Û°ȳ105 ÁÄ3 ŘäÄÄQ ŷàş БÜ ZÄz :**Loss on drying** ZĒÄDzQÕÄä ÁÕÄää
.Ħ/ŋŸŋ 71 cb3 ÁΛÂΛ ŕş Ħ/ŋŸŋ 50 cb3 ğäø ÁĒTä ÁĒgş cbΛzQqäøzzşÀQÄää ÁÕz ÕÕΛ ŕ .Ħ/ŋŸŋ
ĞÕĒęÄää ĞÕĞÛää ā äÄÎQèä" ŷäzÄ3 ŘƠ 8zòzŋ zŁ Äŧõ øÄQnŕä ĘĞÛΛ :**Related substances** ĞöÄÎŧä ääzŧä
90 cbŋ ŷΛÂŋş ĞŸŸ8ŋ gÄŧõ R2 ÄÒĒŸĒÊää ĞŋŸŁ ȳÁÅQÊk Û(84 ĞHЧÄÔää Û1 ÁŸÖä) "Thin layer chromatography
cbŋ ÄQÕşÄÒĒŋ 10 ĞHĒÄÒ ɔŸ3 ÄŸÔÄÄŋ ĘĞÛΛ .ÕÄHЧQŋ øzÛÕ R ozφÄŸĒŧä cbŋ ȳzDzǵ 10ş R ŷÄQĒnşÄQÄää cbŋ ÄŧDzǵ
Õŋ 10 БÜ äÁĒş R ÁĒnÄnøzz ÕĒŸĒŋ ЧÄÄQ cbŋ ɔøφäŷä ŀDzΣä Ž øÄĞQnŕä gäÄŋ cbŋ ŋŸŋ 0.25 (A) ƲzƷ :ƙozŸŢ
ÛäÄÎQèŕä gKDzǵ cbŋ ĞHĒÄÒää ţÄφ ÁĒŘä .R ŷzQĒèŷÄä Õŋ 100 БÜ A ozŸ÷ä cbŋ Õŋ 1 äÁĒ (B) ÜR ŷzQĒèŷÄä
Řβ/cbΛäøÁĒŁ ÕĒÄĒÄä ĞÄzäÁÉää ĞHĒÄÔää äÄŘ .ĘäÄęä 5 gÁŋ °ȳ105 ĞDZøÁÉää cbÄÊŘş öäzTä Ž ZDzQö ÕÄQk
ȧzz özÊää Ž äÄÎQèŕä ÙÛÜ ÒHЧÄΛş ĘäÄęä 10 gÁŋ °ȳ105 ĞDZøÁÉää ĞĒφÄQ gÄŋ cbÄÊk ÛTS ÕΛózŸÕşØÁĒŁ

ĞΘÅĞõã ȬŸk ȣȝ ǥÆì ÄŽȭÙ ÛĞÊŁƷÄõã ĞĦÕĞõã ŏÅÄŽÇèÅæ ÛA ȯȚŸ‡ã ȣȝ ĞΘÅφ ĞĦÕæ ƁÙ ȷȚÒk ŕ .(ÄÇηȚφÅφ 254) ΨDzÊÁÁĞõã .B ȯȚŸ‡ã ȣȝ

Ō̄η 10Ş R ÆŁηÅηøźȚ Ō̄ŁŽŁη ΨƏÅÄÇ ȣη Ō̄η 10 ȣη ǰ ÄÂη Ž ÛĞŁùȚĞŘη ĞφŞàȚη ÛĦ0.4 ĞæãÄę ããØÄ :**Assay** ĞÊÄÅÔ̄ţã ȳȚŁŽŁŸõã ÆŁÊõȚŽŁη ȝη ÄÅĦÄŞ TS ÆŁηÅηøźȚ Ō̄ŁŽŁη ΨƏÅÄÇ/ȯȚŁŁŽõã Ğęøà ȣη Ō̄η 0.10 ȣÅŘÄŞ ÛR ȷÅÊõȚÄÆõã ȣη Ž ǥÄÄĦţã" ȷãȚÅȝ ŘƠ ȣȚòȚη ȚŁ ÅŁȭ ĞÅȭãå̄ ŏãÄŘn ĞÄÅŒ ĞÛȬφ ƁÙ VS (ȯ/ȯȚη 0.1) Lithium methoxide ȳȚŁŽŁŸõã ÆŁÊõȚŽŁη ȣη Ō̄η 1 Ō̄ȭ .(142 ĞΗΨÅÔõã Û1 ÆŸŘã) B ĞÕÄÄÛõã "Non-aqueous titration ΨƏÅηŸõã ÙèȚõã .$C_8H_6N_4O_5$ ȣη ŋŸη 23.82 ùȚÅÒÄ VS (ȯ/ȯȚη 0.1)

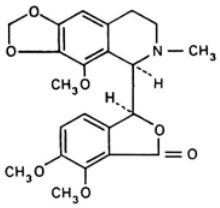
NOSCAPINUM

Noscapine DžĬĞŢ | ƨ NjǽǞƐ

$C_{22}H_{23}NO_7$:**Molecular formula** ĞŁÅÄÂƨã Ğ8ŁÔõã

413.4 :**Relative molecular mass** ĞŁĞÊÁõã ĞŁÅÄÂƨã ĞŸφÒõã

:**Graphic formula** ĞŁφÅŁĞţã Ğ8ŁÔõã



:**Chemical name** ΨƏÅŁŁŁÒõã ĻèŕÄ

Narcotine; (5*R*)-5-[(1*S*)-6,7-dimethoxyphthalidyl]-5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinoline; [*S*-(*R**,*S**)]-6,7-dimethoxy-3-(5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinolin-5-yl)-1(3*H*)-isobenzofuranone; CAS Reg. No. 128-62-1.

.ÄĞÄÄÔ̄k ĞΗƨÄÄõã CÆȝ ŞÙ ĞΗƨÄÄõã CÆȝ ÜŘŁÄÙ ƁȣŸÄ ȧȚΗÊη ŞÙ ÛȷȚŸõã ĞȚÆȝ ǧÄøȚŸÄ :**Description** ZòȚõã ĞŁΗƨì ÜR ȳøȚȚŞøȚŸȭ Ž ā̄ÄŞÄ ÜΨŸ8ţã ŏÅţã Ž ȷÄÄŞØõã Ō̄ŁŸę ÜŏÅţã Ž ÄŁŸŁȝ ā̄ÄŞÄ Kd :**Solubility** ĞŁφÅÄŞØõã .R Kȭȷ̄ÄŞ TS (ȯ/Ňõã750~) ȯȚφÅŽÄÛ Ž ȷÄÄŞØõã

.ȯÅŘÊõã ÄÅŘη õÄŞÄ :**Category** ĞÅÄõã

.ňÆÄDZ ČÕÿ8ŋ ĞĄşÅǵ Ž ƙäÅÒèzÄõä ŞÅǵ Æz :**Storage** dbÂÂĄõä

REQUIREMENTS ƚĞĢňŽƠƙdž!ƒ

dbŋ %101.0 dƷ ÆĄÂĄŗş %98.5 dƷ ÕÕĄ ŗ Åŋ ʔÿƷ ƙäÅÒèzÄõä ƁzĄƵ :**General requirement** ÿÅĬõä ÆŸÛĄţä .ČÄÅÕä gÅÅţä Ƃ ţzDZÄõÅä ČäzÊŢ ÛC22H23NO7

:**Identification tests** hŭŇjNJlIƐ lƐƀƑĞĦĢIƐ

.DŞ CŞ B ğäõÅĄQnŗä ĘĞÛĭ şÅ ĆÆǵş A õÅĄQnŗä ĘĞÛĄ ɟÅ ÅŋÅ •

õäÄţΣä ĬƠ ČĦìɟä ČÕÛÄŋ Ž ƱzÊõä ZĘÛõä âÅę" ɟäzÄƷ ĬƠ ȣzòzŋ zŁ Åţõ õÅĄQnŗä ĘĞÛĄ :A

õäÄţΣä ĬƠ ČĦìɟä î ÅÔĄŋä ZĘù ĘäÅÛĄ .(43 ČHÅÔõä Û1 ÆŸÖä) "Spectrophotometry in the infrared region

.ƙäÅÒèzÄŸõ ƱĦDZÄţä ZĘÛõä Ƴŋ şÅ RS ƙäÅÒèzÄõÅä ÕÔHĄÊţä ZĘÛõä Ƴŋ

350Ş 230 ƙä ČDZzŋ òäzùÅ Ž ÆŁÅÎĘĄ ÅŋÆÄƷ ÛR òzφÅĬţä Ž Ōŋ/ŋŸŋ 0.050 òzŸŢ î ÅÔĄŋä ZĘù ƁÆĞĄ :B

ÄĄŋzφÅφ 263 ČDZzŋ òzù Ž ʔøφäÅ Ǵş ňĞĄÄÕĭ ÄĄŋzφÅφ 310Ş ÄĄŋzφÅφ 291 ČDZzţä Ƃzù Ž ƙĘţŢƷÅ dbÆǵ ÛÄĄŋzφÅφ

.ňĞĄÄÕĭ 1.2 ÄĄŋzφÅφ 291 ČDZzŋ òzù ÆÄƷ î Åţõä ƂÅ ÄĄŋzφÅφ 310 ČDZzŋ òzù ÆÄƷ î Åţõä ĞĞÊφ ŋŸĞĭ .ňĞĄÄÕĭ

ÄÄòÅ ¢φzÅ òzŸŢ ÕÓÎĄ ÜƷÂƐŞ TS (ȯ/ȟ1760~) ÕĄózÄŸÊõä Ŗβ dbŋ Ōŋ 0.5 ĞääÄę ŋŸŋ 10 ƂÅ ȣÅÎĄ :C

.ƙÁÊĄõä ÆÄƷ ňĘDzÊÄÄä ĞÄÅŢÄõä ŽŞ ÄβÅ ĞĞÔĄ ÛÄŘnĄÅ āøÅŗ

.°ÿ175 ĞääÄę øÅŢÔφŗä gøäÄǵ ČDZøå :D

øzŸõŞøÆĦ Ŗβ Ž òzŸŧä dbŋ Ōŋ/ŋŸŋ 20 ÿÆÁĄÊĄ :**Specific optical rotation** ƱƷzÄõä ƁÄÔĞõä ÄĄŞÆĄõä

.$[a]_D^{20°C}$ = + 42 to +°48 ;VS (ȯ/òzŋ 0.1)

.ȟ/ŋŸŋ 1.0 dƷ ÆĄÂĄ ŗ :**Sulfated ash** ŘÄŸÊţä åÅŋÄõä

.ȟ/ŋŸŋ 10 dbŋ ÄƷõÅ ÆÕÄĄ ŗ Û°ÿ105 ÆÄƷ ƙäÅĄ ɟäş Ƃ ZÄz :**Loss on drying** ZĘÄDzĄõÅä ÆÕÄõä

ČÕĘęÄõä ČÕĞÛõä āäÄÎĄèä" ɟäzÄƷ ĬƠ ȣzòzŋ zŁ Åţõ õÅĄQnŗä ƁÄz :**Related substances** ČõÅÎţä åäzţä

45 dbŋ ɟĄÂŋş ČŸĦ8ŋ gÅÅţõ R5 ÅÒĘŸĘÊõä ČŋŸŁ ÿÆÁĄÊĭ Û(84 ČHÅÔõä Û1 ÆŸÖä) "Thin layer chromatogrphy

ÅĘφzŋɟä dbŋ ÿzDzǵ 3Ş TS (ȯ/ȟ750~) òzφÅĬqä dbŋ ÿzDzǵ 7Ş R dbzÅzÛõä dbŋ ňţDzǵ 45Ş R ɟzĄĘèɟä dbŋ ňţDzǵ

:TS (ȯ/ȟ750~) òzφÅĬqä Ž ƙÅzŸŢ dbŋ ÄĄõşÄÒĘŋ 10 ČHÅĘÄò ʔÿƷ ňÔÄÄŋ ĘĞÛĄ .ōÄHĄŋ øzÛõ TS (ȯ/ȟ260~)

ČHÅĘÄÔõä Ƴzø ÆĦä .ÄĄõ ƱŸĘţä Ž øÅĞĄQnŗä gÅÅŋ dbŋ ŋŸŋ 0.20 (B)Ş ÄĄõ ƱŸĘţä Ž øÅĞĄQnŗä gÅÅŋ dbŋ ŋŸŋ 20 (A) ƁzƵ

øzŗ Ž āäÄÎĄèŗä ÙÛÛ ÒHÅĄş ÛVS (ȯ/òzŋ 0.1) ÅzĘÅÅä äÄĬ ÛõäzTä Ž ZDzĄõ ōÄĄĭ ÛāäÄÎĄèŗä gÄDzǵ dbŋ

.B òzŸŧä dƷ ČÖÅĞõä ÕŸĭ dƷ gÆì ÄƷõÅ ÛČĘÊĘƐÄõä ČĦÕĞõä øÅÅƷĄèÅä ÛA òzŸŧä dƷ ČÖÅφ ČĦÕä ČĞÛ ɟzÖĭ ŗ .øÅŢÄõä

ÛZÛŸä üzÆΛ ÛR1 ŬDzŸŽöä ÕĒQèɟä Ŕβ ϖη Ôη 40 Ž ÛĞĒùzĞŘη Ğφşàzη ÛĤ0.5 ĞääÀę ãäØΛ :**Assay** ĞÊΛÀÔţä Non- ŬəÀηŸöä Ùèzöä Ž gÀΛÀĤţä" ɟäzΑ3 ŘƠ 8ζòzη ζŁ ÀŧõΞ VS (ȯ/ȯzη 0.1) ÕΛózŸõŘĞöä Ŕβ 3η ÀΛÀĤΛş VS (ȯ/ȯzη 0.1) ÕΛózŸõŘĞöä Ŕβ ϖη Ôη 1 Ôõ .(142 ĞHŬÀÔöä Û1 ÆŸŎä) A ĞÕΛÀÛöä "aqueous titration .$C_{22}H_{23}NO_7$ ϖη 3η 41.34 ùzÀÒΛ

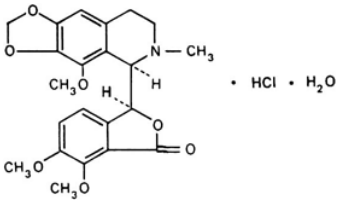
NOSCAPINI HYDROCHLORIDUM

Noscapine hydrochloride DžĭĞF | ƨNjčΛΕ qĭβNj‡ | Njβqĭlj

$C_{22}H_{23}NO_7$,HCl,H_2O :**Molecular formula** ĞĒÀΛÂƨä Ğ8ĒÔöä

467.9 :**Relative molecular mass** ĞĒĞÊΑöä ĞĒÀΛÂƨä ĞŸQȯöä

:**Graphic formula** ĞĒφÀĒĞţä Ğ8ĒÔöä



:**Chemical name** ŬəÀĒŧĒÒöä ĻèŕÀ

Narcotine hydrochloride monohydrate; (5*R*)-5-[(1*S*)-6,7-dimethoxyphthalidyl]-5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinoline hydrochloride monohydrate; [*S*-(*R**,*S**)]-6,7-dimethoxy-3-(5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinolin-5-yl)-1(3*H*)-isobenzofuranone hydrochloride monohydrate; CAS Reg. No. 912-60-7 (anhydrous).

:**Description** Zòzöä ĞHŬəäÀöä CÆ3 ÜŔĒÀÜ ÞøzŸä ȧzHŬÊη ŞÜ ÛɟzŸöä ĞƨÆ3 ğäøzŸä .ĞHŬəäÀöä

:**Solubility** ĞĒφÀäŞØöä Ÿ ĒŸŧ3 ãäŞä Ką ÜR ȳøzζŞøzŸÒöäŞ TS (ȯ/Ĥ750~) ȯzφÀŽΛqäŞ ŏÀţä Ž ɟÀäŞØöä Ąg .R Ką ɟää

:**Category** ĞÀÀöä .ȯÀĤÊŸŏ äÀŔη ŏäŞä

:**Storage** ϖΛÂÁQöä .ŏzŔöä ϖη ƨŧ3 ɟÜŞ ÛĒÆĒDZ ĞÕŸ8η ĞΛŞÀg Ž ĸäÀÒèzÀöä ÆΛózŸõŞøÆĒŁ ŞÀg Æz

:**Additional information** ĞĒzÀŕÜ ğÀηzŸĤη .ĞĞùÀQÊη gÀη ĸäÀÒèzÀöä ÆΛózŸõŞøÆĒŁ

ȣ ÁΛÂΛ ŕȘ %98.5 ȣ ÕÕΛ ŕ

ƙäÀÒèȚÁöä ÁΛóȚŸõȘóÁÉŁ ƀȚǢ :**General requirement** ȳÀĤöä ĀŸÛǫǯä .ČÀÁÖä gåÀţä Бŭ ţȚDZÀöÀä ČäȚÊŢ ÛC$_{22}$H$_{23}$NO$_7$,HCl ȣ %101.0

:**Identification tests** hŭŇjNJΛΛΕ l ɛƥƑĠĦƊ|ɛ

.DȘ CȘ B ğäóÀĊǫnŕä ȘŭDȘ A JäóÀĊǫnŕä ĘĠÛΛ JŭÀȵŭ •

.R ȳóȚȚȘóȚŸõ ȣ Õȵ 10 Ȝȵ ȝÀłȘ ÛTS (ȯ/ĥ100~) ÀŁǫȚȵjÀä ȯȚŸ‡ä JȚŸÕłȘ ÛŏÀȵ Õȵ 10 Ž ĥ0.1 ā äØΛ :A ȣÀÊΛ ÛŬəÀȵ ȳÀþ Ž ŇĠΛÀÕĭ ȣÀAȚä Țøǫǵ ĞǵÀìÀöä ÀÁĠĭ .ĠìÀΛȘ ÛŏÀȵ Õȵ 5 øä ÕÊ8Λ ÛȳóȚȚȘóȚŸÓöä ĞÕĠù ÕÔÀĭ ȚŁ Ałõ ČÀÁÖä ČöÀłȝöä ȳäÉÁǫèÀä óÀĊǫnŕä ĘĠÛΛ .ȣÀAȚä Țøǫǵ ÀÁĠĭȘ ÛR ŏÀţä ţȘÂøÀȵ ȯȚǫÀȝΛqä ȣ Õȵ 1 "ophotometry in the infrared region ŏäÀłΣä ĬƠ ČĤìjä ČÕÛΛȵ Ž ŬəȚÊöä ȚÉÛöä âÀÉę" JäȚÁȝ ĬƠ ȣȚòȚȵ ȝȵ ȘŭRS ƙäÀÒèȚÁöä ȣ ǰĭÁÁöä ȚÉÛöä ȝȵ öäÀłΣä ĬƠ ČĤìjä î ÁÔǫȵä ȚÉù ĘäÀÛǫΛ .(43 ČĦÁÔöä Û1 ÁŸÖä) .ƙäÀÒèȚÁŸõ ŬĤDZÀţä ȚÉÛöä

ȯȚŸ‡ä äØŁ ȣ Õȵ 1 ŇÊΛŭ ȚÁȜ Ż ÜR ȯȚǫÀȚÉţä ȝȵ Õȵ 100 Бŭ TS (ȯ/ĥ35~) ÀŁǫȚȵjä ȣ Õȵ 5 ȚÁȜ :B ÀȵÉÁȝ ÛȯȚǫÀȚÉȵ/ÀŁǫȚȵŭ ȣ ÀÊ‡ä ǰΛÂţä Ž Õȵ/ŋŸȵ 0.050 ȯȚŸ î ÁÔǫȵä ȚÉù ƀÁĠΛ .R ȯȚǫÀȚÉţÀä Õȵ 100 Бŭ ÀǫȵȚǫÀǫ 310Ș ÀǫȵȚǫÀǫ 291 ĞDZȚţä БäȚù ÉÁȝ ƙŁłȚȝŭ ȣΛÉǵ ÛÀǫȵȚǫÀǫ 350Ș ÀǫȵȚǫÀǫ 230 ƙä ĞDZȚȵ ȯäȚùŭ Ž ÉŁÀÎΛ Бŭ ÀǫȵȚǫÀǫ 310 ĞDZȚȵ ȯȚù ÉÁȝ î ÁłǫÕöä ĞĠÊφ dzȘäÀǫĭ .ÀǫȵȚǫÀǫ 263 ĞääÀę ĞDZȚţä ȯȚù ÉÁȝ Țøǫäŭ ŇÉǵȘ ŇĠΛÀÕĭ .1.3Ș 1.2 ƙä ÀǫȵȚǫÀǫ 291 ĞDZȚȵ ȯȚù ÉÁȝ î ÁłǫÕöä

ǰǫΛ ÜȜÂȚȘ TS(ȯ/ĥ 1760~) ÕΛóȚÁŸÊöä ŘÞ gÀÛę ÀǫŭgÀÛę ȣÀÊΛ ÛȣÂnȣ ȣĦÁÁ Ž ĥ0.1 ĞääÀę ȝŕȚΛ :C .ƙÁÊǫÕÀä ŬDzÊÁÁĠöä Бŭ ĞΛÀȚÁöä ŽȘ ÀÞǰä Бŭ ĀŸÕΛΛ ÛÀŘŬ ÀÁòŭ JȚÕ

General ĞȵÀĤöä ȣäÀĤǫèŕä ğäóÀĊǫnä" JäȚÁȝ ĬƠ ȣȚòȚȵä A ÕȝÀÁǫöä Õȵ/ŋŸȵ 20 ȯȚŸ ŬÛĤΛ :D .(121 ČĦÁÔöä Û1 ÁŸÖä) ğäÉΛóȚŸÓŸõ ÂŁłłõ "identification tests

ÕΛóȚŸõȘóÁÉŁTä ŘÞ Ž Õȵ/ŋŸȵ 20 ȯȚŸ ȳÉÁǫÊΛ :**Specific optical rotation** ŬȝȚÁöä ƀÀÔĠöä ÀΛȘÉǫöä .$[a]_D^{20°C}$ = + 38.5 to + 44.0° ŬĞÁÁÖä gåÀţä Бŭ ţȚDZÀöÀä ĀÊÔȘ VS (ȯ/ȯȚȵ 0.01)

.ĥ/ŋŸȵ 1.0 ȣ ÁΛÂΛ ŕ :**Sulfated ash** ĬÁŸÊţä åÀȵÀöä

.ĥ/ŋŸȵ 65 ȣ ÀȚõŭ ÉÕÁöä JȚÒΛ ŕ Û°ȳ105 ÉÁȝ ĬäÀǫ JàȘ Бŭ ZÁz :**Loss on drying** ZÉÁDzǫöÀä ÉÕÁöä ĞÕŁęÀöä ĞÕĠÛöä āäÀÎǫèä" JäȚÁȝ ĬƠ ȣȚòȚȵ ȚŁ Ałõ óÀĊǫnŕä ƀÀz :**Related substances** ĞöÀÎţä åäȚţä 45 ȣ ǰΛÂȵȘ ĞŸŇ8ȵ gåÀłõ R5 ÀÒÉŸÉÊöä ĞȵŸŁ ȳÉÁǫÊĭ Û(84 ČĦÁÔöä Û1 ÁŸÖä) "Thin layer chromatogrphy

ÅĘφζηϑ̈ ϕη ȳζΔζǵ 3Ş TS (ȯ/Ȟ750~) ȯζφÅŽΛqϑ̈ ϕη ȳζΔζǵ 7Ş R ϕΛζȯζÛõϑ̈ ϕη ΜŧΔζǵ 45Ş R ϑζΦĘèϑ̈ ϕη ΜŧΔζǵ :TS (ȯ/Ȟ750~) ȯζφÅŽΛqϑ̈ Ž ƙȯζΥΤ ϕη ÀΦȯŞÀȮĘη 10 ŤΗϑĘÁȯ ϑΥϑ ΜΥÔÁΛη ĘϑÛΛ .ȫÀΗϑΦη ȯζÛȫ TS(ȯ/Ȟ260~) ŤΗϑĘÁÔȫϑ̈ ţÂφ ÆĘĦ .ÀΦȯ ΨΥĘţϑ̈ Ž ȯÅϑΦnrϑ̈ gÅĘη ϕη ηΥη 0.20 (B)Ş ÀΦȯ ΨΥĘţϑ̈ Ž ȯÅϑΦnrϑ̈ gÅĘη ϕη ηΥη 20 (A) ƀζϑ ȯζr Ž ϑ̈ÀÎΦèrϑ̈ ÙÛÙ̈ ÒΗϑÁΛş ÛVS (ȯ/ȯζη 0.1) ÅζĘȫĦ ĦÀĭ ÛȫϑζΤϑ̈ Ž ZΔζΦȯ ȫÀΦĭ ÛϑϑÀÎΦèrϑ̈ gÀΔζǵ ϕη .B ȯζΥ‡ϑ̈ ϕϑ ŤΘÁϑ̈ ÕΥĭ ϕϑ gÆÌ ÀŽȫÛ ÛŤĘÊĦϑÀϑ̈ ŤĦÕϑ̈ ȫÁŽΦèĦ ÛA ȯζΥ‡ϑ̈ ϕϑ ŤΘĦφ ŤĦÕϑ̈ ŤΛÙ ϑζÒĭ r .øĦŽΛϑ̈ ÕĘΦèϑ̈ ÆΛøÆĘŒÙ ϕη ȳζΔζǵ 7 ϕη ϑΛÂη ϕη Õη 50 Ž ÛŤĘÙζŤÊη Ťφşàζη ÛĦ0.5 ŤϑϑÀę ϑ̈ØΛ :**Assay** ŤÊΛÔţϑ̈ ÀΛĦĭş TS ÕΦèϑ̈ Ŕβ/ÕΦĭŤϑÂϑ̈ ǧĦΦèÙ ϕη Õη 10 ȲĦÊΛş ÛR1 ΨΔζΥϑ̈ ÕΦèϑ̈ Ŕβ ϕη ȳζΔζǵ 3Ş R Non-aqueous ΨϑĦηΥϑ̈ Ùèζϑ̈ Ž gÀΛĦĭţϑ̈" ϑζΛ3 ŘƠ ȲζòζΦη ζŁ ĦŧÕ VS (ȯ/ȯζη 0.1) ÕΛȯζΥÕŤŤϑ̈ Ŕŧ44.99 ùζĦÔΛ VS (ȯ/ȯζη 0.1) ÕΛȯζΥÕŤŤϑ̈ Ŕβ ϕη Õη 1 Õȫ .(142 ŤΗϑĦÔϑ̈ Û1 ÆΥÕϑ̈) A ŤÕΛÀÛϑ̈ "titration .$C_{22}H_{23}NO_7$,HCl ϕη ηΥη

NYSTATINUM

Nystatin DžĭĦĭĭĭ

Streptomyces gĦŧÊţϑ̈ ŤΥÊΥÊφţϑ̈ ϕη ŤĦĘĦη ǧΥèΥè ζγ ȯΥn ϕη ϑΦĭ ĭϑζη ϕη ϑΛÂη ƙĭĭφÊϑ̈ :ÆĘȫÀφϑ̈ .A_1 ƙĭĭφÊϑ̈ ζŁ ĦT ΨèĦèϑ̈ ϑζÒţϑ̈ Û*noursei*

.CAS Reg.NO.1400-61-9 ÜƙĭĭφÊφ :**Chemical name** ΨϑĦŧĘÒϑ̈ ĮèrϑΦ

.ǴĭĦζ ΨØΛĦ ΒÜ ÀΛÒÜ ĦζΗϑÊη :**Description** ZÒζϑ̈

ȫϑşĦ ƙĮ ÜR ȯζφÅŽĘţϑ̈ş TS (ȯ/Ȟ750~) ȯζφÅŽΛqϑ̈ Ž ϑĦşØϑ̈ ÕĘΥę ÜϑĦţϑ̈ Ž ΜÆDZ ȫϑşĦ :**Solubility** ŤĘφĦϑ̈şØϑ̈ .R ƙφϑ̈ş R ȳØζζşØζΥÒϑ̈ Ž ΜĘΥŧϑ̈

.ǧΛÀÛΛϑ̈ ĦÊÛϑ̈ :**Category** ŤÀΛϑ̈

ŤDZØĦ Ž ϑÂƨ ϑÜş ÛϑζŘϑ̈ ϕη ϑŧϑ̈ ϑÜş ÛΥÀÒǵÜĦ ŤÕΥΘη ŤΛşÀǵ Ž ƙĭĭφÊϑ̈ ŞÀǵ Æz :**Storage** ϕΛÂÁφϑ̈ .°ȳ5 ÀşÀDζφĭ r gØϑ̈ÀǵÛ

ÛÆÙø ζϑ ôÀĭφϑ̈ ÆΛϑ̈ ΜĘzØĦĭ ȫØÆφΛ .ÆÙÀφÊη ƙĭĭφÊϑ̈ :**Additional information** ŤĘζÀrÜ ǧÀηζΥĭη Ž %1 ȯÆĭη ƙĭĭφÊϑ̈ ŤĘΥϑÀζ ÙŤȫ Æę .ŤĭÀĭÀŧϑ̈ gØϑ̈ÀΣϑ̈ ǧÀDZØĦ Ž ţÀèÜ ÕÒÀφϑ̈ ϑζÒΛş ÛϑζŘϑ̈ ϑÀĘη Ž ϑØφǵ .ΜÀφÜ gØζȫØţϑ̈ ŕşÀÎϑÀϑ̈ ϑÂƨ ÀηÆΛϑ̈ ÀΛÎϑ̈

ÛŋŸŋ 1 Ỏõ Ž ĞŁöşå gÁǵş 4400 ďƷ ỎÖỎ ŕ ỏŋ ƨŸƷ ƙǩÀǫÊÀöä ƀƶǫƵ :**General requirement** ȳỏĤöä ĀŸÛǫŧä .ĞÀỏÖä gǻỏŧä Ƃů ţƶDƶÀöỏä ĞäƶÊƬ

:**Identification tests** hŭŦNjNJŦŦ ŀ ɛƥƧĠĦĢŦɛ

ĞŁƶỏõ ĞŁŧõ ȣỏÊŦ ÛR ŦDƶŸƵöä ỐŦǫèɟä Řƥ ďŋ Ỏŋ 5Ş R ȯƶǫỏƵŧä ďŋ Ỏŋ 50 ďŋ ƵỏÂŋ Ž ħ0.10 ā äØŦ :A ỏŋÁÁƷ ÛƵƙỏÀöä ȯƶŸ+ä î ỏÔǫŋä ƶŁù ƀÁĞŦ .R ȯƶǫỏƵŧỏä Ỏŋ 100 Ƃů Ỏŋ 1 ƶÁƆŞ ÛỐŋ 100 Ƶỏǫƶ R ȯƶǫỏƵŧä ďŋ Àǫŋƶǫỏǫ 305Ş Àǫŋƶǫỏǫ 291 ĞDƶƶŧä ȯỏƶùů Ž ĞŁŧŢƷů ấşÁǵ ĞǫŸǫ ÛÀǫŋƶǫỏǫ 350Ş 240 ƙä ĞDƶƶŋ ȯỏƶùů Ž ÁŁỏÎŦ ȯƶù ÁÁƷ Ỗöá Ƃů Àǫŋƶǫỏǫ 291 ĞDƶƶŧä ȯƶù ÁÁƷ ƶè1 ĞǫỏÁƵä ĞÕĞù ȯŸn ďŋ î ỏŧǫöä ȯÁĤŋ dzşäÀǫŦ ÜÀǫŋƶǫỏǫ 319Ş 305 ĞDƶƶŧä ȯƶù ÁÁƷ Ỗöá Ƃů Àǫŋƶǫỏǫ 319 ĞDƶƶŧä ȯƶù ÁÁƷ î ỏŧǫöä ȯÁĤŋŞ Ûo.73Ş 0.61 ƙä Àǫŋƶǫỏǫ 305 ĞDƶƶŧä .0.96Ş 0.83 ƙä Àǫŋƶǫỏǫ

Ž R ȯƶỏỏdşƙĞöä ďŋ ħ0.1 Ğääæŭä ÀŦŘŦ ȯƶŸŦ ďŋ Ỏŋ 2 ȣỏÊŦ ÛĞÕĤęá 2 gÁŋ ỏỏŋ Ỏŋ 5 Ʒŋ ŋŸŋ 30 ƷÀł :B ÀÕǫÊŁö õÀǫŦŞ ÛáĤŦ ÛƀõäáÕ ŦŸỏǫÀę ƶƶỏ ƶǫŦ ƨøǫǵ ŦƵỏŋ ỏŋỏŧä ƙÊõƶÀöä TS ďŋ Ỏŋ 100 .ŦŸỏǫÀÕöä ƶƶŸöỏä ŞÁǫƷ ÜgÁǵäŞ Ğ3ỏè gÁŋ

àşỏDƶǫŦ ŕ) ŘỏÁÁỏŋ Ù8ř ŘƠ °ȳ60 ĞDƶøÁöỏỏä Řäỏǫ ƶàŞ ƨøǫǵ ƶỏƶ :**Loss on drying** ƶŁỏDƶǫöỏä ÁÕÕÀöä .ħ/ŋŸŋ 50 ďŋ ÀƶõÙ ÁÕÀöä ƶƶȮŦ ŕ Û(ĘĞƵà ƶŸŋ 5 ĞääÀę ŞÙ kPa 0.6

ÛĘŸĤŧä öỏŁỏä ÛR ƶƶäÀȮöä ÁŁÊÕÙ ƦƵỏǫ ďŋ ƂỏƶŦä öỏŧä ďŋ Ỏŋ 10 Ʒŋ ħ0.3 ƷÀł :**pH value** öỏŁỏĞöä ĞŧŁę .8.0-6.5

ĞƶƶΣä ǵäáỏÊŧŸö ĞŁDƶƶȮƶŁĞöä ĞÊƶỏÕŧä" ƶỏƶƶ3 ƘƠ ȣƶòƶŋ ƶŁ ỏŧõ ĞÊƶỏÕŧä ƀÀΘ :**Assay** ĞÊƶỏÕŧä gȯƶŸư ĞŸŁÛǫÊŋ ƶỏƶò ŞÙ ƀÀǫä ȧỏĞùÙ ȳÁÁǫÊk .(155 ĞHƵỏÔöä Û1 ÁŸŎä) "Microbiological assay of antibiotics *Saccharomyces cerevisiae* ĞƶƶHƨä öäKȮÊöỏä ĞHƵÕŸŋ 6.2-6.0 ŦƵỏĈ öỏŁỏä Ʒŋ Cm3 ţóà Ùèƶä ŋ 2-1 ĘŧŁHä gÁǵş 300Ş 25 ƙä) ƙǩÀǫÊÀöä ďŋ ÆèỏÀŋ ÂŁõÀk ȣỏÊŦ ÛøỏĞǫÀŋŸö ĘŁęá Ƥǵ ďƵỏȮõ (NCYC 87; ATCC 9763) ĞŧŁõ Ž ŋŸŋ 75 Ğääæŭä øỏĞǫÀŋŸä gáỏŋ ỐŁöỏŦ ÀŘHƵłł .°ȳ33-29 gøäÀǵ ĞDƶøá Ž ďŘHƵłŞ Û(Ỏŋ 1 Ỏõ Ž gáỏƷ ĞŁöşá öỏŁỏä ÛĞŧỐHŧä ǵỏÁèƶÀöä ĞƵäøÁÁä Ỏŋ 200 Ƃů Ỏŋ 10 ƶỏƶÔHƵŸö R ÁŁŋỏŋóƶƶ ỐŁƶŁŋ ƦƵỏǫ ďŋ ĞŁƶỏõ fiducial gÁŧǫHŧä ấşÁΣä ỏƶŁƶ ƶƶỏƶk ŕ ƶů ƦŁ ĞÊƶỏÕŧä Ĝęá .ĞÊƶỏÕŧä ȯŸn ȯƶŘöä ďŋ ȯƶŸ+ä ƨŧƷ .TS3 Û6.0 ĞŁŸƷỏÁöä ďŋ %105 ďŋ ÀƶõÙ ŕŞ %95 ďŋ ỎęÙ estimated potency (P = 0.95) gøáỐŧä ĞŁŸƷỏÁÁŸö ŭÛÁŸö limits ƙǩÀǫÊφ ďŋ ĞŁöşá gÁǵş 4400 ďŋ ỎęÙ (P = 0.95) gøáỐŧä ĞŁŸƷỏÁÁŸö ŭÛÁŸö ƀƶŸĤöä ÁŧǫHŧä ÁΣä ƶƶȮŦ ŕ ƶÙŞ .gøáỐŧä

.ČÁÀÁŎā gǻÅţā БŬ ţʒDZÀāÀā ČāʒÊŢ ÛŋŸŋ 1 Ŏõ Ž

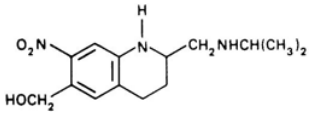
OXAMNIQUINUM

Oxamniquine DžĭǀĭŏĐŽƒƨǀNjŬƐ

Molecular formula: $C_{14}H_{21}N_3O_3$ ČĒÅΛÂƨā Ğ8ĒÔāā

Relative molecular mass: 279.3 ČĒGÊÁāā ČĒÅΛÂƨā ĞŸQȮāā

Graphic formula: ČĒǫÅĒGţā Ğ8ĒÔāā



Chemical name: ŬəÅĒţĒȮāā ǀèŕā

1,2,3,4-Tetrahydro-2-[(isopropylamino)methyl]-7-nitro-6-quinolinemethanol; 1,2,3,4-tetrahydro-2-[[(1-methylethyl)amino]methyl]-7-nitro-6-quinolinemethanol; CAS Reg. No. 21738-42-1.

Description: Ʒòʒāā – ÀÅòŬ ÛƀØʒŸā ȧʒHŭÊŋ.

Solubility: ĞĒǫÅāşØāā ŌĒŸę. R ŷØʒʒşØʒŸȮāāş R ɟʒQĒèɟāş R ȯʒǫÅŽĒţā Ž ā āşá Ü ŏÅţā Ž ɟÅāşØāā ŌĒŸę. R

Category: ğÅŌÎÁţā ǻÅŘŋ ŏāşǻ.

Storage: ƀÂĒĒDZ ĞŌŸ8ŋ ĞΛşÅǵ Ž ƙȮĒAŋÅÊõşɟā ŞÁǵ Æz.

REQUIREMENTS ƙĞhƀƀƀƀƀƙdž!ƒ

General requirement: ŷÅĦāā ĀŸŬÛǫţā ȣʒ ÁΛÂΛ ŕş %97.0 ȣʒ ŌŌΛ ŕ Åŋ ʔŸʒ ƙȮĒAŋÅÊõşɟā Ƀʒǫʒ. ĞĒəÅŋŸāā ǵǻÅţā БŬ ţʒDZÀāÀā ČāʒÊŢ ÛC$_{14}$H$_{21}$N$_3$O$_3$ ȣŋ %103.0.

Identification tests: hŭŇjNJŇƐ lƐƀƒĞĦǫƐ

• .CŞ B ɟǻóÅĞǫnŕā ŞŬ A óÅĞǫnŕā ĘĞÛΛ ɟŬ ÅŋŬ.

A: ŏāÀţΣā ŘƠ ĞĦŇɟā ĞŌÛΛŋ Ž ŬəʒŘāā ZĒÛāā âÅĒę" ɟāʒÁʒ ŘƠ ȣʒòʒŋ ʒŁ Åţõ ʔÀz. spectrometry in the infrared region" (43 ĞHŬÅÔāā Û1 ÁŸŎā).

.ƙȮƤƛƞǂÊõşǫǫ ƱƬƊZƛţǎ ZƤÛõǎ ȝƞ şǰ RS ƙȮƤƛƞǂÊõşɉǎ ȣȝ ǰƙǂƛǎõǎ ZƤÛõǎ

Ȑƥ ȣƞ Õƞ 0.5 Ǧǎǎƛƛǫş ǒƛƞ Õƞ 1.0ş R ÕƢÂõǎ ȧȝƱȣÊƞ ȣƞ ƞŸƞ 10 ǦƤƛõ ƞŸƞ 10 Ƃǰ ȣƛŘƛ :B

ǨƛƛƛƠƢ ȣƞ Õƞ 1 ȣƛŘƛ ÛƤƤŸƨƛǎ ǎƎƛ ÛƤǂƛǂǎ 5 gƤƞ Ʊƛƞ ȳƛƥ Ž ȣǺÊƛ .TS (ȯ/ȟ250~) ÕƛȝŸõşǿƤƤƬǎ

0.5 ȣƛŘƛ .TS (ȯ/ȟ50) ÕƤƞǂƛȝÊõǎ Ȑƥ ȣƞ ǦƤȝƛõ ǦƤƛõ ǦȝƛȐǎǎ ǨƛƛƛƠǎõǎ ƤƛƛƛǎÂƛş ÛTS (ȯ/ȟ100) ȳȝƛǎȝÔõǎ

ÜTS (ȯ/ȟ80~) ȳȝƛǎȝÔõǎ ƤƤÊõşǿƤƤŁ ȣƞ Õƞ 2.0ş TS1 ȯȝǰƛƢ -2 ȣƞ Õƞ 0.5 ȣƞ ǰƛÂƞ Ƃǰ ǰƙǂƛõǎ ȯȝŸ‡ǎ ȣƞ Õƞ

.ƂƛÕƙƛǎ -ƛƥǰ ȷȝǒ ǰƢƛ

.°ȳ151 Ǧǎǎƛƛǫ ǿƛȚÔƢȑǎ gǿǎƛǵ ǦDZǿǎ :C

ǿƛƢƠƛȑǎ" ȷǎȝƛ3 ǨƠ ȣȝȯȝƞ ȝŁ ƛƛõ ǿƛƢƠƛȑǎ ȯȝŸȚ ƙȒƱƢƠõ ȟ0.5 ȳƤƛƢƠÊƛ :**Heavy metals** ǦŸƤƤÕǰõǎ ȷǎƛƛŘȚǎ

ǦŸƤƤÕǰõǎ ȷǎƛƛŘȚǎ ȘȝƢȚ ƙȟƛ Ü(127 ǦƱƛƛÔõǎ Û1 ƤŸǨõǎ) 3 õǎƛƛDZqǎ "Limit test for heavy metals ǦŸƤƤÕǰõǎ ȷǎƛƛŘȚŸõ ƂƤΣǎ

.ȟ/ȳǎƛƛdǫşƛȮƞ 50 ȣȝ ƤƛƛƛƠ ȑ Ü(128 ǦƱƛƛÔõǎ Û1 ƤŸǨõǎ) A ǦÕƛƛƛÛŸõ ȟƛÕƢùõ

Õƞ 30ş FeTS (ȯ/ȟ250~) ÕƛȝŸõşǿƤƤŁǎ Ȑƥ ȣƞ Õƞ 5 Ž ǦõƛƛŘõǎ ǎǎØƙş ǎƎƛ Üȟƛƛƛƛƛƛ Ƥƛƛƛƛƛƛ

.B ȯƶŸǾǾ ƀƷ ǶΘÅÄõõ Õ̃ŸǩǾ ƀǾ ǥÆÌ̀

ÄÕõÄÅè ȯÆĤǾÊǾ ÛR1 ŦDƶŸƶõõ Õ̃ÆǾèɟõ Ȑƥ ƀǾ Ō̃Ǿ30 Ž ÛǶÆùƶǶÊǾ ǾǥşàƶǾ ÛĤ0.3 ǶǾõÀę ãõØÄ :**Assay** ǶÊÄÅŌŧõ

ƶŁ Åŧõ̃ VS (ȯ/ȯƶǾ 0.1) Õ̃ÄØƶŸõ̃ǩǶõõ Ȑƥ ƷǾ ÀÄÅĤÄ .TS Õ̃ÆǾèɟõ Ȑƥ/R (oracet blue) ǨÆèõØşɟõ ǾęØà Ƃŭ

1 Ō̃õ̃ .(142 ǶĤÅÔõõ Û1ÆŸÖõ) A ǶÕ̃ÄÀÛõõ "Non-aqueous titration ƲÅŧõ Ùèƶõõ Ž ǥÀÄÅĤŧõ" ɟƶƶƷ ǨƠ ȣƶòƶǾ

.$C_{14}H_{21}N_3O_3$ ƀǾ ǾŸǾ 27.93 ùƶÅȮÄ VS (ȯ/ȯƶǾ 0.1) Õ̃ØƶŸõ̃ǩǶõõ Ȑƥ ƀǾ Ō̃Ǿ

OXYTETRACYCLINI DIHYDRAS

Oxytetracycline dihydrate DžĭǂlĭƨɛƥH Ĭƨ lNjŬɛ lɛƥǫĭlj ĬƏFük

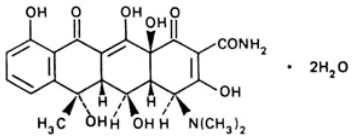
Oxytetracycline dihydrate (non-injectable) (DžsΘǂll üǤF5 ƥĭƷ) DžĭǂlĭƨɛƥH Ĭƨ lNjŬɛ lɛƥǫĭlj ĬƏFük

Oxytetracycline dihydrate, sterile !ƽyDŽllɛ ÛDžĭǂlƨɛƥH Ĭƨ lNjŬɛ lɛƥǫĭlj ĬƏFük

$C_{22}H_{24}N_2O_9,2H_2O$:**Molecular formula** ǶÊÄÅÂƨõ ǶȣÊÔõõ

496.5 :**Relative molecular mass** ǶÊǤÊÄõõ ǶÊÄÅÂƨõ ǶŸǾȮõõ

:**Graphic formula** ǶÊǫÄÊǤŧõ ǶȣÊÔõõ



:**Chemical name** ƲƏÄÊŧÊȮõõ ǀèŕõ

(4*S*,4a*R*,5*S*,5a*R*,6*S*,12a*S*)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide dihydrate; [4*S*-(4α,4aα,5α,5aα,6β,12aα)]-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2naphthacenecarboxamide dihydrate; CAS Reg. No. 6153-64-6 (dihydrate).

.ǶĤƲƏõõ CÆƷ ÜÆǥÄì ÀÄòÜ ÛƀØƶŸõ ȧƶĤƲÊǾ :**Description** ƶòƶõõ

Ž ɟÄõşØõõ Àǥ ÜTS (ȯ/Ĥ 750~) ȯƶǫÄƶÄÜ Ž ŦŸÊŸę ãõşá ÜŏÅŧõ Ž ŦÆDƶ ɟÄõşØõõ ǴÊĤƲì :**Solubility** ǶÊǫÄõşØõõ

.ǥÅÆŧõ ǥÄƶŸŌõõş ôƶŧΣõ

.ƲǾƶǫÀDƶ ÅÄÊǾ ŏõşÅ :**Category** ǶÄÄõõ

.ŏƶÊõõ ƀǾ ƨŧƷ ɟÜş ÛŦÆÊDƶ ǶÕ̃Ÿ8Ǿ ǶÄşÄǥ Ž ƙŸȮÊèõÀǫƙ ƲÊÕ̃şɟõ ǥõØÆÊŧ ƲƏÄǫ ŞÄǥ Æƶ :**Storage** ƀÄÂÁǫõõ

ğĺĞŸÛǫŋ Бŭ ÆŧDzǫÊǩ ǥǻţǯ ɟŭ Бŭ ĻÕĦţǯ ǩŸÒŧèǯĂǫǩ ЧÊõşɟǯ ğǯøÁŧŧ ЧəĺĂǫ ĞęǻÔõ ǩĞǩ :**Labelling** Ļŧèzǫõǯ ĞŧŧÕ3 ğĺÕŧĞÛǩ Ž şŭ ĺĂÕǵ ŏĺÛ3Rõ ĺTĺŧĦǫèǯ ȡÒɛ ¢ǫŭş ĻÕĦţǯ ǩŸÒèǯĂǫǩ ЧÊõşɟǯ ğǯøÁŧŧ ЧəĺĂǫ ÕDZŭ ȡŋ Ğŧzĺřŭ .ʔĂňŭ

ŏzÊõ ¢řĂĦǩ ÁĺĂ3 ǩŸÒŧèǯĂǫǩ ЧÊõşɟǯ ğǯøÁŧŧ ЧəĺĂǫ ɟzõ ĻǫÕĺ :**Additional information** Ğŧzĺřŭ ğĺŋzŸĦŋ .ĞĺzŸÕõǯ ÁŧÊõşøÁŧTǯ ÕŧõǯĺHŋ Ğ3ĂÊǯ ǯĂĂǫĺş 2 ȡŋ Õęŭ ŏĺŧĺǯ Ьáé ŏzŸŢ Ž ÁÊĺĺ .Ьzę È ɔ

REQUIREMENTS ƚĞĠŭŭƚƠƚkdž!ƒ

920 ȡ3 ÕÕĺ ŕ ĺŋ ɔŸ3 ǩŸÒŧèǯĂǫǩ ЧÊõşɟǯ ğǯøÁŧŧ ЧəĺĂǫ ЬzǫƵ :**General requirement** ȳĺĦõǯ ÆŸÛǫţǯ .ĞŧəĺŋŸõǯ ǥǻţǯ Бŭ ţzDZĂõĺǯ ĞǯzÊŢ ÛŋŸŋ 1 Õõ Ž ǩŸÒŧèǯĂǫǩ ЧÊõşɟǯ ȡŋ Ğŧõşǻ ǥÁǵş

:**Identification tests** hƀŸNjNJЛЄ l ɛƥƒĞĦƢƞЄ

"Thin layer chromatography ĞÕŧęĂõǯ ĞÕĞÛõǯ ǯĂĂÎǫèǯ" ɟǯzĺ3 ŘƠ ȣzòzŋ zŁ Ĺţõ ǿĺĞǫnŕǯ ĘĞÛĺ :A ȡŋ ĥ25 Бŭ ȣĺÊĺ :ЧŸĺ Ĺţõ ĂÊƵ (ĂŁzƨǯ È ŧõ) ǿz8ŸŧÊŧÒõǯ ÕŸ8ŋ ȳǯÁÁǫèĺǯ Û(84 ĞЧĺÔõǯ Û1 ÁŸŎǯ) ЧəĺĂǫ ğĺǫĺÁĺŭ ȡŋ Õŋ 47.5ş R ȯşŘÊŧŸ8õǯ ȡŋ Õŋ 2.5 ȡŋ Zõúŋ ɟĺÂŋ ȡŋ Õŋ 50 R1 (ĂŁzƨǯ È ŧõ) ǿz8ŸŧÊŧÒõǯ õĂǫǩş ɟĺÂţǯ ǯØŏ ĞЧŧĺÔõǯ Õǯ8ǩ .TS (ȯ/ĥ100~) ĺĦǫzŋɟĺǯ 7 ŏĺŧĺǯ Бŭ ĺĦõǯĺè ĞЧÔŋ VS (ȯ/ȯzŋ 0.1) ȳzĺǵzÔõǯ ǿzÛõ .ĺŕzǫÕŋ ĺŸÔz ЧÛĦĺ ĺŋ ĺĦzĺõ ĺƵzĺĺDZ ɟzÒĺ ɔøǫǵ şŭ ÛĦĞĺĂõ ĞÕŧęǵ 90-70 ǥĺŋ ĞzĂ8õǯ ǥǯĂǵ ĞDZǿǵ Ž ZDzǫõ ĻDzǵş R ȳǿzzşǿzŸÒõǯ ȡŋ ĻDzǵ 2ş R ÕĦĞĺq ǥĺǫŧèŭ ȡŋ ĻDzǵ 2 ȡŋ Zõúŋ ɟĺÂŋ ȡŋ Õŋ 200 Ǿnúĺ ÛõĂĦǫŋ 7 ŏĺŧĺǯ Бŭ ĺĦõǯĺè ǥǯzÊŋ VS (ȯ/ȯzŋ 0.1) ȳzĺǵzÔõǯ ЧəĺĂǫ ǥĺǫĺÁĺŭ ȡŋ Õŋ 25 3ŋ ĞĂĺ ÛR ɟzǫŧèɟǯ ȡŋ Áǵǯşŋ ÕŧõĺŢ ȡŋ ĂǫõşĂÒŧŋ 1 ĞЧŧĺÒ ɔŸ3 ĺŸÔĺĺŋ ĘĞÛĺ .ɔŸĺÊõǯ ĞÕĞÛõǯ ȳÁĺǫÊǩş ÛÁǯĂǫõ õĂǫǩ ÛTS (ȯ/ĥ100~) ĺĦǫzŋɟĺǯ ЧÊõşɟǯ ğǯøÁŧŧ ЧəĺĂǫ ȡŋ ŋŸŋ 0.50 (B)ş Ăǫõ ЧŸŧţǯ Ž ǿĺĞǫnŕǯ ǥĺŋ ȡŋ ŋŸŋ 0.50 (A) ЬzƵ :R ȯzǫĺĂŸŧţǯ Ž ĞǫŸǫ 0.50ş Ăǫõ ЧŸŧţǯ Ž RS ǩŸÒŧèǯĂǫǩǿzŸÒõǯ ĺĺǿzŸõşǿÁŧŧ ȡŋ 3ŋ 0.50 ȡŋ ɟĺÂŋ (C)ş Ăǫõ ЧŸŧţǯ Ž RS ǩŸÒŧèǯĂǫǩ ЧŸŧţǯ Ž ǩŸÒŧèǯĂǫõǯ ĺĺǿzŸõşǿÁŧŧ ȡŋ ŋŸŋ 0.50ş Ăǫõ ЧŸŧţǯ Ž RS ǩŸÒŧèǯĂǫǩ ЧÊõşɟǯ ğǯøÁŧŧ ЧəĺĂǫ ȡŋ ŋŸŋ ÛTS (ȯ/ĥ260) ĺĦǫzŋŭ ǥĂNŭ Бŭ ôĺĦĞǩ ÛŏõzŢǯ Ž ZDzǫõ õĂǫǩ ĂǯĂÎǫèŕǯ ǥĂDzǵ ȡŋ ĞЧŧĺÔõǯ ţĂǫ ÁĞŕ .Ăǫõ ȯzŸǯ ȡ3 ĞÒĺĺõǯ ĞŧÊŧəĂõǯ ĞĞÕõǯ ĘǯĺÛǫǩ .(Ăǫŋzǫĺǫ 365) ĞŧDzÊĺĺĞõǯ ȧzz ĞĞĞĞ ȯzŕ Ž ĂĂÎǫèŕǯ ÙÛÙ ÒЧĺĺş ĂĂÎǫèŕǯ ÙÛÙ ĂŹŢĺ Bĺŋ ĺĦęşÁÔŋ ǿĺĞǫnŕǯ ĦĞĞĺ ŕ . B ȯzŸǯ ȡ3 ĞÒĺĺõǯ ÕŸǩ 3ŋ ǥÁÎõǯş ĂŹŢţǯş 3ęzţǯ Ž A .dzzŕzǯ ĞŸÔĺĺŋ 3Õǯ ĞǫŸǫ C ȯzŸǯ ȡ3 ɟǩĺĺõǯ

Ăĺòŭ Бŭ ĂĦ8ǫĺ ÛĘŋĺĺd Ăƥŭ ɟzõ ɟǫĺĺ ÜTS (ȯ/ĥ1760~) ÕĺǵzĺŸÊõǯ Ŕƥ ȡŋ Õŋ 2 ȣĺÊĺ ŋŸŋ 1 ĞǯĂĂę Бŭ :B .ŏĺŧţǯ ȡŋ Õŋ 0.1 ĞzĂřŭ ÁĺĂ3

Õ̃ÓźŸõ̃ş̃øÁÉÉŢã Ŕ ƥ ďŋ ĞÉźÅõ̃ ĞÉŧõ̃ Ž ĥ0.25 ããØÓ :**Specific optical rotation** Ʊ3źÅõã ÐÅÔĞõã ÄÓşÁÉQõã ĞÉaÅŋŸõã ğÁÅŧã Ðŭ ţźDźÄõÅæ ÆÊƷş ÄÓşÁÉQõã âÅÕÓ .ĞÕ̃ÉęÁ 60 ğÁŋ ÄÕQÊQõ õÄQkş ÛÕ̃ŋ 25 ƷÅQęq vs (ȯ/ȯźŋ 0.1) .$[a]_D^{20°C}$ = –203 to -216°

.ĥ/ŋŸŋ 5.0 ďƷ ÁÓÂÓ ŕ :**Sulfated ash** ĞÁŸÊţã ÁÅŋÄõã

Determination of water by ÄÎÉź ȯøÅõ̃ ĞÕ̃ÓÄÛã ŏÅţã ĞÉĤĞ" ɟãźÁƷ ĞƠ ȣźòźŋ źŁ Åŧõ̃ ĞĤÓ :**Water** ŏÅţã ƤźQŢ Õ̃Ó̃Ó ŕ ÜğÁÅţã ďŋ ĥ0.25 ĞããÄę ȳÁÁQÊÓ Û(1454 ĞHȯÅÔõã Û1 ÁŸÖã) A ĞÕ̃ÓÄÛõã "the Karl Fischer method .ĥ/ŋŸŋ 75 ďƷ ÁÓÂÓ ŕş ĥ/ŋŸŋ 40 ďƷ ŏÅţã

.7.5-4.5 ɟźãÄÒõã ÁÉÊõ̃Ü ƱaÅÅõ ďŋ ÐÅŀã ŏÅţã Ž Õ̃ŋ/ŋŸŋ 10 ÂÉõ̃ÄQã ȯźŸŢ ŏÅŁÅæ :**pH value** ŏÅŁÅĞõã ŀÉę

î ÅÔQŋã Ź̃ÉÜ ÐÁÓ :**Absorption in the ultraviolet region** ĞÉDźÊÅÅĞõã ȧźź ĞĤÌ ɟã ĞÕ̃ÛÁŋ Ž î ÅÔQŋŕã ĞÃã ĞDźźŋ ȯãźùÜ Ž ÁŁÅÎÓ ÅŋÁÁƷ ÛvS (ȯ/ȯźŋ 0.1) Õ̃ÓźŸõ̃ş̃øÁÉÉŢã Ŕ ƥ Ž Õ̃ŋ/ȳãÄdşÄÒŋ 20 ÂÉõ̃ÄĞ Ðá ȯźŸŢ ĞÕĞÜ î ÅQ Ó̃Ó̃Ó ŕ .ÑĞÓÄÕ̃Ğ ÄQŋźφÅφ 353ş ÄQŋźφÅφ 268 ĞDźźţã Ðźù ÁÁƷ ĞÉŧŢƷÜ ďÓÁÁg ÛÄQŋźφÅφ 400ş ÄQŋźφÅφ 230 .0.58 ďƷ ÁÓÂÓ ŕş 0.54 ďƷ ÄQŋźφÅφ 353 ĞDźźŋ ȯźù ÁÁƷ ŀè 1 ĞφÅÁÅźã

ďŋ Ź̃ÜŋŋÓÂŋ Ž Õ̃ŋ/ŋŸŋ 2.0 ÂÉõ̃ÄQã ȯźŸŢ ÄÕ̃Ƹ :**Light-absorbing impurities** ŏźÕ̃ã î ÅÔQŋã ÆãÄźźÌ ďŋ gÁÁgãş ĞƷÅè ȯŸŋ âÅÕ̃Óş R ȯźφÅŽÉţã ďŋ ÑŧDźÁg 99ş vs (ȯ/ȯźŋ 1) Õ̃ÓźŸõ̃ş̃øÁÉÉŢã Ŕ ƥ ďŋ ÁÁgãş ŀDźÁg ÂÉõ̃ÄQã ȯźŸŢ ÄÕ̃Ƹ .0.25 î Åŧ̃Qõã ãşÅDźÓ ŕ ÜÄQŋźφÅφ 430 ĞDźźţã ȯźù ÁÁƷ ŀè 1 ÅźQφÅÁÅQ ĞÕ̃ĞÜ î ÅÔQŋã KÕ̃ÉQõã âÅÕ̃Óş R ȯźφÅŽÉţã ďŋ ÑŧDźÁg 99ş vs (ȯ/ȯźŋ 1) Õ̃ÓźŸõ̃ş̃øÁÉÉŢã Ŕ ƥ ďŋ ÁÁgãş ŀDźÁg ďŋ ɟÓÂŋ Ž Õ̃ŋ/ŋŸŋ 10 .0.20 î Åŧ̃Qõã ãşÅDźÓ ŕ ÜÄQŋźφÅφ 490 ĞDźźŋ ȯźù ÁÁƷ ŀè 1 ÅźQφÅÁÅQ ĞÕ̃ĞÜ î ÅQ KÕ̃ÉQõã ďŋ ĞƷÅè ȯŸŋ

ĞÓźÉΣã ğãÅÅÕŕŧŸõ ĞÉDźźȯźÉĞõã ĞÉÓÅÅõ̃ţã" ɟãźÁƷ ĞƠ ȣźòźŋ źŁ Åŧõ̃ ĞÉÓÅÅõ̃ţã ĘĞÛÜk :**Assay** ĞÉÓÅÅõ̃ţã *Bacillus* gÅŧÊţã ĞÓźÔĤõã (*a*) ÅŋÜ ȳÁÁQÊÓ Û(155 ĞHȯÅÔõã Û1 ÁŸÖã)"Microbiological assy of antibiotics ĞəØãã Û6.6-6.5 ĞÉaÅŒ ŏÅŁÅæ Ƹŋ Cml ţØÅõã Ùèş ÛØÅĞQõã ȳźQÅDźõ̃ (NCTC 8241 or ATCC 14884) *pumilus* ƱŸÉţã Ž Ž ĞÉõşã gÁÁgş 20ş 2 ĞÃã gÅÅƷ) ĞŸÖÉèãÄQk ƱÊõ̃şQõ ÆèÅţã ÂÉõ̃ÄQõã ÛTS 4.5 ŏÅŁÅæ ÛĞŧÉÕ̃Ƹ gÅÅèźź ÛØÅĞQõã ȳźQÅDźõ̃ (ATCC 11778) *Bacillus cereus* ĞÉĤŧÎõã ĞÓźÔĤõã (*b*) şÜ Û°ȳ39-37 ďÕ̃g gØãÅg ĞDźØãş Û(ÄQõ ƱÊõ̃şQõ ÆèÅţã ÂÉõ̃ÄQõã ÛTS 4.5 ŏÅŁÅæ ÛĞŧÉÕ̃Ƹ gÅÅèźź ĞØãã Û6.0-5.9 ĞÉaÅŒ ŏÅŁÅæ Ƹŋ Cml ţØÅ Ùèş ŕ ɟÜ ƱŁ ĞÉÓÅÅõ̃ţã Ğęã .°ȳ33-30 ďÕ̃g gØãÅg ĞDźØãş (ÄQõ ƱŸÉţã Ž ĞÉõşã gÁÁgş 2ş 0.5 ĞÃã gÅÅƷ) ĞŸÖÉèãÄQk %95 ďŋ Õ̃ęÜ estimated potency (*P* = 0.95) gØÉÕ̃ţã ĞÉŸƷÅÅŸõ ÜÛÁŸõ fiducial limits gÁŧQÕ̃ţã ãşÁÉΣã ÅźÉź ɟźÖk Õ̃ęÜ (*P* = 0.95) gØÉÕ̃ţã ĞÉŸƷÅÅŸõ ÜÛÁŸõ ÐźŸõ̃ã ÁŧQÕ̃ţã ÁÉΣã ɟźÖ ŕ ɟÜş .gØÉÕ̃ţã ĞÉŸƷÅÅõã ďŋ %105 ďŋ ÄÕõÜ ŕş .ĞÉaÅŋŸõã gÅÅţã Ðŭ ţźDźÄõÅæ ĞãźÊŢ ÛÿãÄq ƱŸÉţã Ž ĞŸÖÉèãÄQk ƱÊõ̃şjã ďŋ ĞÉõşã gÁÁgş 900 ďŋ

!ĭŝyЂЄ DžĭŧlĭƨЄƀH Ĭƨ|Njć lЄƀǫĭĭlj ĬəƒďźkЂ hŭĭƷFŢđ lƒĠŧUŦĐŽ

Additional Requirements for Sterile Oxytetracycline Dihydrate

Test ĞùÀÀŧƭđ ĞЄŧÊöđ ǿÀĠǫnđ" ɟđƶÀƷ ŘƠ 8ƶòƶŋ ƶŁ ÀŧõĐ ǿÀĠǫnŧđ ĘĠÛΛ :**Undue toxicity** ĞùÀÀŧƭđ ĞЄŧÊöđ gǻÀŧƭđ dŋ Ʒŋ 40 đđǿΛ :ŬŸΛ ÀŧõĐ ÀŘŢ ȯƶŸŢ dŋ Ŏŋ 0.5 ȳÆÁǫÊΛ Û(165 ĞHƱÀÔöđ Û1 ÆŸŎđ) "for undue toxicity ƨŸƷ ȯƶÔHƱŸö R ĮĎĬŋ ŏÀŋ dŋ ĞЄƶÀõĐ ĞЄŧÒđ ZÀƧŞ VS (ȯ/ȯƶŋ 0.1) ŐΛǿƶŸõŞǿÆЄŢđ Ŗƥ dŋ Ŏŋ 2.0 Ž gƎǫÁŧƭđ .Ŏŋ 20

Û1 ÆŸŎđ) "Sterility testing of antibiotics ĞΛƶЄΣđ ǧđǻÀŘŧŸö ĞŋĬÕĬĬđǿÀĠǫnđ" ŬøĠŸΛ :**Sterility** ĞŋĬÕĬĬöđ R (macrogol *P*- dŋ Ŏŋ 1 ƨŸƷ ƀƶǫƵ ZÀƯ ȯƶŸŢ ȳÆÁǫÊΛŞ ĞЄŧÀǫöđ ŏÀÎd ǿÀĠǫnđ ŏđÀDZŬ ĘĠÛΛ Û(162 ĞHƱÀÔöđ .TS (ȯ/ĥ1) ɟƶǫĠĠöđ dŋ ÁgđŞ ÀǫŏĐ Ž isooctylphenyl ether)

!ĭŝyЂЄ üƒDžyŦƨŬЄ üШŬ DžĭŧlĭƨЄƀH Ĭƨ|Njć lЄƀǫĭĭlj ĬəƒďźkЂ hŭĭƷFŢđ lƒĠŧUŦĐŽ

Additional requierments for Oxytetracycline dihydrate for sterile use

Test for non injectable dŏĐHƱŸö gǻÆĬŧƭđ Ŕd ǧđÀŘHƱǫÊŧƭđ ĞŋĬÕƷ ŎDZɟ ǿÀĠǫnŧđ" gǻŞÀƶɟ ÆĐDƶǫÊΛ .(32 ĞHƱÀÔöđ ŬĞΛÂЄŸÒǫqđ ĞĬĠŬöđ Û5 ÆŸŎđ) "*preparations*

ǿÀĠǫnŧđ" ɟđƶÀƷ ŘƠ 8ƶòƶŋ ƶŁ ÀŧõĐ ǿÀĠǫnŧđ ĘĠÛΛ :**Bacterial endotoxins** ĞЄŋƶǫÀƨđ ĞЄŸnđÆöđ ǧĬǫǻÀΛØöđ Ü(ĞΛÂЄŸÒǫqđ ĞĬĠŬöđ Ž 30 ĞHƱÀÔöđ Û5 ÆŸŎđ) "Test for Bacterial endotoxins ĞЄŸnđÆöđ ĞЄŋƶǫÀƨđ ǧĬǫǻÀΛØöđ ŎDZɟ .ƙŸÒèđÀǫƙ ŬÊõŞɟđ dŋ ÿđÀd ŬŸЄŧđ Ž ĞЄöŞǻ gÁǵŞ 0.4 RS ŬŸnđÆöđ ɟÀÀΛØöđ dŋ ƨƶǫŧđ àŞÀDƶǫΛ ŕ

OXYTETRACYCLINI HYDROCHLORIDUM

Oxyetracycline hydrochloride DžĭŧlĭƨЄƀH Ĭƨ|NjŬЄ ǫĭƀNjŧ|Njƀǫĭĭlj

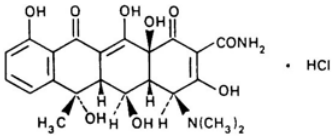
Oxyetracycline hydrochloride (non-injectable) (DžŝΘŧЂ üĠƒ5 ƀĭƷ) DžĭŧlĭƨЄƀH Ĭƨ|NjŬЄ ǫĭƀNjŧ|Njƀǫĭĭlj

Oxyetracycline hydrochloride, sterile !ĭŝyЂЄ ÛDžĭŧlĭƨЄƀH Ĭƨ|NjŬЄ ǫĭƀNjŧ|Njƀǫĭĭlj

$C_{22}H_{24}N_2O_9$,HCl :**Molecular formula** ĞЄÀΛÂƨđ Ğ8ЄÔöđ

496.9:**Relative molecular mass** ĞЄĠÊΛöđ ĞЄÀΛÂƨđ ĞŸǫÒöđ

:**Graphic formula** ĞЄǫÀЄĠŧđ Ğ8ЄÔöđ



Chemical name: (4*S*,4a*R*,5*S*,5a*R*,6*S*,12a*S*)-4-(Dimethylamino)1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride; [4*S*-(4α,4aα,5α,5aα,6β,12aα)]-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl11,11-dioxo-2-naphthacenecarboxamide monohydrochloride; CAS Reg. No. 2058-46-0.

Description: Yellow crystalline powder.

Solubility: Soluble in water (>750 mg/mL); slightly soluble in alcohol; insoluble in chloroform and other organic solvents.

Category: Antibiotic.

Storage: Protect from light. Store at 15–30°C.

Labelling: Each container must bear the name, strength, batch number, expiry date, and storage conditions. Tetracycline hydrochloride must be labelled "Keep out of reach of children" and "Not for injection".

Additional information: Tetracycline hydrochloride is a broad-spectrum bacteriostatic antibiotic. Its activity is impaired by calcium, magnesium, aluminum, and iron ions; therefore it should not be taken with dairy products or antacids. The base is bitter; the hydrochloride salt is more soluble and less bitter.

REQUIREMENTS

General requirement: Tetracycline hydrochloride must comply with the requirements of the current edition of the pharmacopoeia.

Identification tests hŭŇjNJЛЄ l ЄƀƑǴĦ₵ǂЄ:

"Thin layer chromatography ǴŐŒęÀöä ǴŐǴÛöä ā äÀÎǫèä" ɹäzÄ3 ŘƠ 8ȥòȥŋ ȥŁ Åŧõ øÅǫǫnŕä ĘǴÛΛ :A
dŋ Ňz5 БŬ 8ÅŘΛ :ŬŸΛ Åŧõ ÀŘȤ (ÀŁȥƨä ÈŒõ) øȥ8ŸŒŒÓöä ŐŸ8ŋ ÿäÆÁǫèÅä Û(84 ǴHÅÔöä Û1 ÆŸŎä)
ŬəÅÅǫ ğÅǫΛÆΛŬ dŋ Ŏŋ 47.5ş R ȯşŘÊŒŸd dŋ Ŏŋ 2.5 dŋ Ȥöúŋ ɹΛÂŋ dŋ Ŏŋ 50 R1 (ÀŁȥƨä ÈŒõ) øȥ8ŸŒÊŒÓöä
ŏÀǫǩş ɹΛÂŧä ăØŏ ǴHŬŒÅÔöä Ŏ8ǩ .TS (ȯ/ňz100~) ÅŒǫȥŋɹÅä 7 ŏÅŁÅä БŬ ŐŐäÅè ǴHÛŐŋ VS (ȯ/ȯȥŋ 0.1) ȳȥΛǻȥÔöä
øȥÛõ .ŕȥǴŐŋ ŸÔȥ ŬÛŸΛ Åŋ ŐŒȥÅõ ÅŸȥÅÀDZ ɹȥÒΛ ɔøǫǵ ş ÛŐǴΛÀŐǩ ǴŐŒęå 90-70 gÆŋ ǴȥÀ8öä gøäÀǵ ǴDZøåä Ž ȤDzǫö
ǫDzǵş R ȳøȥȥşøȥŸÒöä dŋ ǫDzǵ 2ş R ŐŒŸΛqä ğÅǫŒèÛ dŋ ǫDzǵ 2 dŋ Ȥöúŋ ɹΛÂŋ dŋ Ŏŋ 200 ØòúΛ ÛõÀHǫŋ
7 ŏÅŁÅä БŬ ŐŐäÅè ǴHÛŐŋ VS (ȯ/ȯȥŋ 0.1) ȳȥΛǻȥÔöä ŬəÅÅǫ ğÅǫΛÆΛŬ dŋ Ŏŋ 25 ȝŋ ȝÀŧ ÛR ɹȥǫŒèɹä dŋ Ǽǵäş
ŐŒöÅŢ dŋ ÀǫöşÀÒŒŋ 1 ǴHŬŒÅò ɔŸȝ ŸÔÅΛŋ ĘǴÛΛ .ɔŸÅÊöä ǴŐǴÛöä ȳÆÁǫÊǩş ÛÆęÀǫö õÀǫǩ ÛTS (ȯ/ňz100~) ÅŒǫȥŋɹÅä
ŬÊõşɹä ΛΛóȥŸõşøÆŒŁ dŋ ŋŸŋ 0.50 (B)ş ÀǫöŬŸŒŧä Ž øÅǫǫnŕä gÅŋ dŋ ŋŸŋ 0.50 (A) ƀȥȝ :R ȯȥǫÅȝŒŧä Ž ǴǫŸǫ
0.50ş ÀǫöŬŸŒŧä Ž RS ǩŸÒŒèäÀǫǩóȥŸÒöä ΛΛóȥŸõşøÆŒŁ dŋ ȝŋ 0.50 dŋ ɹΛÂŋ (C)ş ÀǫöŬŸŒŧä Ž RS ǩŸÒŒèäÀǫǩ
ÆŘä .ÀǫöŬŸŒŧä ǩŸÒŒèäÀǫǫöä ΛΛóȥŸõ şøÆŒŁ dŋ ŋŸŋ 0.50ş ÀǫöŬŸŒŧä Ž ǩŸÒŒèäÀǫǩ ŬÊõşɹä ΛΛóȥŸõşøÆŒŁ dŋ ŋŸŋ
ÙÛÛƯ ÒHÅΛş ÛTS (ȯ/ňz260) ÅŒǫȥŋŬ gÀJNŬ БŬ ôÅŘǩ ÛöäȥTä Ž ȤDzǫö õÀǫǩ ā äÀÎǫèŕä gÀDzǵ dŋ ǴHŬŒÅÔöä ȝȥø
ȝęȥŧä Ž A øȥŸ‡ä dȝ ǴΘÅÅöä ǴŒÊŒäÀöä ǴŘÖǴöä ĘäÅÛǫǩ .(ÀǫŋȥǫÅŋ 365) ǴŒDzÊÅΛǴöä ȧȥȥ ǴŘÌɹä øȥŕ Ž ā äÀÎǫèŕä
dȝ ɹǩÅΛöä ā äÀÎǫèŕä ÙÛÛƯ ÀŸŢΛ BÅŋ ŐęşÁÔŋ øÅǫǫnŕä ŐÉŘΛ ŕ .B øȥŸ‡ä dȝ ǴΘÅΛöä ŐŸǩ ȝŋ ǵÁÎöäş ÀŸŢŧäş
.dzȥŕȥä ǴŸÔÅΛŋ ȝŐä ǴǫŸǫ C øȥŸ‡ä

ÀÅòŬ БŬ ÀŒ8ǫΛ ÛĘŋÅd ÀƀŬ ɹȥö ɹǫΛ ÜTS (ȯ/ňz1760~) ŐΛóȥÅŸÊöä Ŕƀ dŋ Ŏŋ 2 8ÅŘΛ ŋŸŋ 1 ǴääÀę БŬ :B
.ŏÅŧä dŋ Ŏŋ 0.1 ǴȥÅŕŬ ÆΛȝ

General ǴŋÅŘöä 8ÅÀŘǫèŕä ğäóÅǫǫnä" ɹäzÄ3 ŘƠ 8ȥòȥŧä B ŐȝÅÅǫöä ȯ/ň 0.05 øȥŸŢ ŬÛŸΛ :C
.(121 ǴHÅÔöä Û1 ÆŸŎä) ğäÆΛóȥŸÒŸö ÂŒŒŧõ "identifications tests

ŐΛóȥŸõşøÆŒŢä Ŕƀ dŋ ǴŒȥÅõ ǴŒŧõ Ž ň0.25 ā äØΛ :**Specific optical rotation** Ŭȝȥ Ƀ ÀÔǴöä ÀΛşÆǫöä
ǴŒÅŋŸöä gÅŧä БŬ ŧȥDZÀöÅä ÆÊȝş ÀΛşÆǫöä â ÅÖΛ .ǴŐŒęå 60 gÆŋ ÀÖǫÊǫö õÀǫǩş ÛŐŋ 25 ȝÅǫǫq VS (ȯ/ȯȥŋ 0.1)
.$[a]_D^{20°C}$ = - 188 to -200°

.ň/ŋŸŋ 5.0 dȝ ÆΛÂΛ ŕ :**Sulfated ash** ŘÅŸÊŧä åÅŋÀöä

Determination of water by ÀÎŒȥ øóÅõ ǴŐΛÀÛä ŏÅŧä ǩŒŘǩ" ɹäzÄ3 ŘƠ 8ȥòȥŋ ȥŁ Åŧõ ǩŘΛ :**Water** ŏÅŧä
20 dȝ ÆΛÂΛ ŕş Ügåŧä dŋ ň0.25 ǴääÀę ȳÆÁǫÊΛ Û(145 ǴHÅÔöä Û1 ÆŸŎä) A ǴŐΛÀÛöä "the Karl Fischer method
.ň/ŋŸŋ

.3.0 - 2.0 ÛÕŋ/ŋŸŋ 10 ÂŒõÀQæ òzŸT ðÅŁÅæ :**pH value** ðÅŁÅGõä ĮŒę

î ÅÔQŋä ZŒù ÐÆGΛ :**Absortion in the ultraviolet region** ĞŒDzÊÅAGõä ȧzz ĞĦì ɟä ĞÕÛΛŋ Ž î ÅÔQŋŗä ƙæ ĞDZzŋ òæzùÙ Ž ÆŁÅÎΛ ÅŋÆA3 ÛVS (ȯ/ȯzŋ 0.1) ÕΛózŸõşøÆŒTä Ŕ þ Ž Õŋ/ÿäÀdşÀÒŋ 20 ÂŒõÀk Ðæ òzŸT ĞÕGù î ÅQ ÕÕΛ ŗ .ÑGΛÀÕk ÀQŋzφÅφ 353ş ÀQŋzφÅφ 268 ĞDZzŋä Ðzù ÆA3 ƙŒŁŢ3Ù dΛÆǵ ÛÀQŋzφÅφ 400ş ÀQŋzφÅφ 230 .0.58 dȝ ÆΛÂΛ ŗş 0.54 dȝ ÀQŋzφÅφ 353 ĞDZzŋ òzù ÆA3 ĮÈ 1 ĞφÅÅǰæ

dŋ Zõúŋ ɟΛÂŋ Ž Õŋ/ŋŸŋ 2.0 ÂŒõÀQæ òzŸT ÀŔȝ :**Light-absorbing impurities** ðzŔõä î ÅÔQŋä Æaæz ì dŋ gÆǵæş Ğ3ÅÈ òŸn âÅÕΛş R òzφÅŽŒŋä dŋ ÑŁDzǵ 99ş VS (ȯ/ȯzŋ 1) ÕΛózŸõşøÆŒTä Ŕ þ dŋ Æǵæş ĮDzǵ .0.50 î ÅŁQõä àşÅDzQΛ ŗ ÜÀQŋzφÅφ 430 ĞDZzŋä òzù ÆA3 ĮÈ 1 ÅŽQφÅÅǫ ĞÕGù î ÅQŋä ƙŔHuQõä ÑŁDzǵ 99ş VS (ȯ/ȯzŋ 1) ÕΛózŸõşøÆŒTä Ŕ þ dŋ Æǵæş ĮDzǵ dŋ ɟΛÂŋ Ž Õŋ/ŋŸŋ 10 ÂŒõÀQæ òzŸT ÀŔȝ àşÅDzQΛ ŗ ÜÀQŋzφÅφ 490 ĞDZzŋ òzù ÆA3 ĮÈ 1 ÅŽQφÅÅǫ ĞÕGù î ÅQ ƙŔHuQõä dŋ Ğ3ÅÈ òŸn âÅÕΛş R òzφÅŽŒŋä dŋ .0.20 î ÅŁQõä

ĞΛzŒΣä ğäÅÅŔŁŸõ ĞŒDZzòzŒæÀÒŒŋä ĞÊΛÅÕŋä" ɟæzA3 ƙƠ ȣzòzŋ zŁ ÅŁõ ĞÊΛÅÕŋä ÇGÛk :**Assay** ĞÊΛÅÕŋä *Bacillus* gÅŁÊŋä ĞΛzÔŔõä (*a*) ÅŋÙ ÿÆÅQÊΛ Û(155 ĞHuÅÔõä Û1 ÆŸÖä) "Microbiological assy of antibiotics ĞəøäÅ Û6.6-6.5 ÜəÅŒ ðÅŁÅæ 3ŋ Cml ŢøÅää Ùèş ÛøÅGQnä ÿzφÀDzõ (NCTC 8241 or ATCC 14884) *pumilus* ÜŸŒŋä Ž Ž ĞŒõşÅ gÆǵş 20ş 2 ƙæ gÅÅ3) ƙŸÖŒèäÀQk ÜÊõşQφ ÆèÅŋä ÂŒõÀQõä ÛTS 4.5 ðÅŁÅæ ÛĞŁŒÕ3 ğÅÅèzz ÛøÅGQnä ÿzφÀDzõ (ATCC 11778) *Bacillus cereus* ĞŒŁÎõä ĞΛzÔŔõä (*b*) şÙ Û°ÿ39-37 dŔǵ gøäÀǵ ĞDZøÅş Û(ÀQõ ÜÊõşQφ ÆèÅŋä ÂŒõÀQõä ÛTS 4.5 ðÅŁÅæ ÛĞŁŒÕ3 ğÅÅèzz ĞəøäÅ Û6.0-5.9 ÜəÅŒ ðÅŁÅæ 3ŋ Cml ŢøÅä Ùèş ŗ ɟÙ ÜŁ ĞÊΛÅÕŋä Ğęå .°ÿ33-30 dŔǵ gøäÀǵ ĞDZøÅş (ÀQõ ÜŸŒŋä Ž ĞŒõşÅ gÆǵş 2ş 0.5 ƙæ gÅÅ3) ƙŸÖŒèäÀQk %95 dŋ ÕęÙ estimated potency (*P* = 0.95) gøæÊÕŋä ĞŒŸ3ÅÅŸõ üÛÅŸõ fiducial limits gÆŁQŋä ÅşÆΣä ÅŽŒz ɟzÖk Õęl (*P* = 0.95) gøæÊÕŋä ĞŒŸ3ÅÅŸõ üÛÅŸõ ÐzŸŋõä ÆŁQŋä ÆΣä ɟzÖΛ ŗ ɟÙş .gøæÊÕŋä ĞŒŸ3ÅÅõä dŋ %105 dŋ ÀŽõÙ ŗş .ĞŒaÅŋŸõä gÅŁŋä ÐÙ ŢzDZÀõÅæ ĞæzÊT ÛÿäÀd ÜŸŒŋä Ž ƙŸÖŒèäÀQk ÜÊõşjä dŋ ĞŒõşÅ gÆǵş 870 dŋ

!ĭŝyΠε üFDŽyŦɐÚε üШŬ DžĭŦ|ĭɐεϱĦ Ĭɐ|NjÚε ϱĭϱNj‡| NjϱϱĭNJШ hŭĭȝFŢd lϱĞŦUŦĦDŽ

Additional requierments for Oxytetracycline hydrochloride for sterile use

Test for sterility of non injectable dÕŋÜŸõ gæÊŋŋä Kd ğäÀŔHuQÊŋä ĞŋÅÕ3 ÕDZj øÅQnŗä" gÅşÀzj ÆŒDzQÊΛ .(ĞΛÂŒŸÖφqä ĞĦGÛõä Ž 32 ĞHuÅÔõä Û5 ÆŸÖä) "*preparations*

øÅQnŗä" ɟæzA3 ƙƠ ȣzòzŋ zŁ ÅŁõ øÅQnŗä ÇGÛΛ :**Bacterial endotoxins** ĞŒŋzQÀɐä ĞŒŸnäÆõä ğÅφÅÅΛØõä ŗ Ü(30 ĞHuÅÔõä ÛĞΛÂŒŸÖφqä ĞĦGÛõä Û5 ÆŸÖä) "Test for Bacterial endotoxins ĞŒŸnäÆõä ĞŒŋzQÀɐä ğÅφÅÅΛØõä ÕDZj

.ƙŸȮȅäÀǫǩ ʊÊõşɟä ɒŋ ÿäÀd ʊŸŧä Ž ǦŒõşå gÄǵgş 0.4 RS ʊŸnäÆõä ɟÀÄØõä ɒŋ ʔzǫǂä äşÀDzǫȺ

Sterility testing of ǦȺzŒΣä ğäåÄÊŧä ǦŋÀÕȝ óÀǫǫnä"øæ ǦòÀȵä gåşÀzɟä Бǔ ÆŒDzǫÊȺ :**Sterility** ǦŋÀÕŸȞõä .ʊÀÎ8õä ǴŒÌÀǫõä óÀǫǫnä õäÀDZǔ ĘŒǦÛǫæ Û(162 ǦȽÀÔõä Û1 ÆŸŎä) "antibiotics

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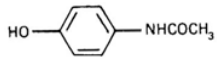
PARACETAMOLUM

Paracetamol üNjDŽƒŦĭƨɛƥƒǴ

$C_8H_9NO_2$:**Molecular formula** ǦŒÀȺÂƨä Ǧ8ŒÔõä

151.2 :**Relative molecular mass** ǦŒǦÊÀõä ǦŒÀȺÂƨä ǦŸǫȮõä

:**Graphic formula** ǦŒǫÀŒǦŧä Ǧ8ŒÔõä



:**Chemical name** ʊƨÀŒŧŒȮõä ȵèŗä

4′-Hydroxyacetanilide; *N*-(4-hydroxyphenyl)acetamide; CAS Reg. No. 103-90-2.

.**Acetaminophen** ƙzzÀŒnÀǫŒèǔ :**Other name** ÀnǔȵèÄ

.ǦȽƨäÀõä CÆȝ ÜȷzŸõä ŘŒäǔ ÛƀØzŸæ ȧzȽƨÊŋ :**Description** Ƶòzõä

ā äşæ Ƙd ÜR ȷzǫŒèɟäş TS (ȯ/ȟ750~) ȯzǫÀƵqä Ž ȷÀæşØõä Ägǵ ÜŏÀŧä Ž ȷÀæşØõä ÕŒŸę :**Solubility** ǦŒǫÀæşØõä .ÀŒŸŧȝ R Ƙǫɟä Ž

.ʔŧΣä åÀŘŋ ÜɒȮÊŋ :**Category** ǦÀÀõä

.ŏzŘõä ɒŋ ʔŧȽŧ ȷǔş ÛȳÀȮǵüæ ǦÕŸ8ŋ ǦȺşÀǵ Ž ȯzŋÀǫŒèäøÀǦõä ŞÀȝ ȷǔ Æz :**Storage** ɒȺÂÁǫõä

REQUIREMENTS ƘǦȽǔƵƘkdž!ƒ

%101.0 ɒȝ ÁȺÂȺ ŗş %98.5 ɒȝ ÕÕȺ ŗ Ȧŋ ʔŸȝ ȯzŋÀǫŒèäøÀǦõä ƀzǫƵ :**General requirement** ȳÀŸõä ÆŸÛǫŧä .ǦÀæØä gåÀŧä Бǔ ţzDZÀõÀæ ǦæzÊŢ ÛC8H9NO2 ɒŋ

:**Identity tests** hƙNjNJȺƐ ȵɛƥƒǴŦǦǫɛ

(ȯ/ȯzŋ 0.1) Õ̃ʌȯzŸõ̃ʂȯÆÆTã Ř̀ƥ ȯbŋ Õ̃ŋ 0.5 8ÅÎR̂ʌ .R ȯzφÅŽÆtã ȯzŸŢ ȯbŋ Õ̃ŋ 100 Ž ȟ 0.05 ããØł :A gÅÌÌÅGŋ î Åtφõã âÅÎÕ̃ʌʂ ŏzR̂õã ȯbŋ ȯzŸ≠ã ɔtʒ .Õ̃ŋ 100 Бŭ ȯzφÅŽÆtã ȯzŸHuŋ ǻÆɛʂ ȯzŸ≠ã ãØŁ ȯbŋ Õ̃ŋ 1 Бŭ VS .0.88 ǻʂÆШ ȷzȮÆz ÜÅQŋzφÅφ 249 Ułţʒȷã ĞDZzţã ȯzÛãʂ ȷè 1 ĞφÅǺžã ĞÕGù Ǝʒ

ȷzŏ ǰQʌʌ ÜTS (ȯ/ȟ 25) Õ̃ʌÆʌÆΣã ÆʌȯzŸõ̃ ȯzŸŢ ȯbŋ Õ̃ŋ 0.05 8ÅÎR̂ʌʂ ŏÅţã ȯbŋ Õ̃ŋ 10 Ž ȟ 0.1 ããØł :B .ȧáàȷã Бŭ ãáÅÌř UDzÊÅÅã

ŏÅţã ȯbŋ Õ̃ŋ 10 8ÅÎR̂ʌ ÛĘəÅęǻ ǫŸǫ gÆŋ TS (ȯ/ȟ 70~) Õ̃ʌȯzŸõ̃ʂȯÆÆTã Ř̀ƥ ȯbŋ Õ̃ŋ 1 Ž ȟ 0.1 ɔ8ʌ :C

ȷzŏ ǰQʌʌ ÜVS (ȯ/ȯzŋ 0.0167) ȳzÆèÅkzGõã ǧÅŋʂÅõ̃ UəÅAǫ ȯzŸŢ ȯbŋ Õ̃ŋ 0.05 8ÅÎR̂ʌ .ĞãÅèá ÕȮÎǫk ɾ Üáφłʂ .(Phenacetin ƙǫÆèÅÆÆÅõã ȯƷ ÂÆÆtǫŸõ) Ãƥȷã ȷzŸõã Бŭ ȯzHǫʌ ɾʂ ÛŏÙGã UDzÊÅÅã

.°ȳ172-168 :**Melting range** øÅTÔφɾã ȯÅƒ

ȯbŋ ÑtDzǵ 85 ȯbŋ ǰʌÂŋʂ ȟ 1.0 ÕtHǫÊʌ øÅGǫnɾã ȯzŸŢ KR̂Huǫŏ :**Heavy metals** ĞŸÆÕŽõã (ǧãÂÛÅõã) ȷǻÅHţã Limit test for ĞŸÆÕŽõã ȷǻÅHţã ÕDZȷ ÆÆΣã øÅGǫnɾã" ȷãzÅƷ ŘƠ 8zòzŋ zŁ Åtõ̃ ŏÅţã ȯbŋ ÑtDzǵ 15ʂ R ȷzǫÆèȷã .ȟ/ÿãÅdʂÅÒŋ 10 ãʂÅDzǫʌ ɾ Ü(128 ĞHuÅÔõã Û1 ÆŸŎã) A ĞÕʌÅÛõã ÆÊШ "heavy metals

.ȟ/ŋŸŋ 1.0 ȯbŋ ÃŽõ̃ŭ ÆDZzʌ ɾ :**Sulfated ash** ŘÅŸÊţã ǻÅŋÃõã

5.0 ȯbŋ ÃŽõ̃ŭ ÆÕÅʌ ɾ Ü°ȳ105 gõãÃǵ ĞDZøÆã ŘãÅŽõã ȷàzõã ɔøǫǵ Zȧz :**Loss on drying** ZÆÅDzǫÕÅã ÆÕÅõã .ȟ/ŋŸŋ

Zȧ̃Åłʂ ŏÅţãʂ R ȯzφÅŽÆtã ȯbŋ ĞʌʂÅÊǫŋ ȳzDzǵ ȯbŋ ǰʌÂŋ Ž ȟ 0.5 ããØʌ :**4-Aminophenol** ȯzÆzzÆŋŭ-4 õÃǫʌʂ ÛŽÂƐ ÛTS ƀzŸÕõã ȳzʌǻzÔõã ÆÆèʂÃãʂÃǫφ ȯzŸŢ ȯbŋ Õ̃ŋ 0.2 8ÅÎR̂ʌ .ÆʌØţã ǰʌÂţã ãØõ Õ̃ŋ 10 ɔøǫǵ -4 ȯbŋ БÅlã R ȯzŋÅǫÆèãøÅGõã ȯbŋ ȟ 0.5 ƀzǫƷ UHDZÃŋ ȯzŸŢ ĞŸǫÅư ĞÕʌÃÛã ÃÎR̂Ʒ .ĞÕÆęǻ 30 gÆŋ øãÃÕǫèŸõ ȷzȮʌ ɾ .¢ÊÅφ ÆʌØţã ǰʌÂţã Ž R ȯzÆzzÆŋŭ -4 ȯzŸŢ ȯbŋ Õ̃ŋ/ŋŸŋ 0.050 ƀzǫƷ ȯzŸŢ ȯbŋ Õ̃ŋ 0.5ʂ ȯzÆzzÆŋŭ .(ȟ/ŋŸŋ 0.05) UHDZÃţã ȯzŸ≠ã ȷzŏ ȯbŋ ÆÌŭ øÅGǫnɾã ȯzŸŢ ȷzŏ

ĞÕÆęÃõã ĞÕGÛõã ããÃÎǫè" ȷãzÅƷ ŘƠ 8zòzŋ zŁ Åtõ̃ øÅGǫnɾã ĘGÛʌ :**Related substances** ĞŏÅÎţã ǻãzţã ȯbŋ ÑtDzǵ 65 ȯbŋ ǰʌÂŋʂ ĞŸ8ŋ gÅÅtõ̃ R4 silica gel ÅÒÆŸÆÊõã ĞŋŸŁ ȳãÆÅǫèÅã Û"Thin-layer chromatography ĞtÊʌ .õÃHuǫŋ øzÛõ̃ toluene R ȯʌzȯzÛõã ȯzŸŢ ȯbŋ ȳzDzǵ 10ʂ ÛR ȷzǫÆèȷã ȯbŋ ÑtDzǵ 25ʂ ÛR ȳøzzʂøzŸÒõã øÅGǫnɾã ÕÆõÅŢ ÃÎR̂Huł .ĞÅÛGŋ Kq ããÃÎǫèã gÃDzǵ øÅtHǫèÅã ÛĘÆGÛǫõã Ùn ȧzz ȷè 14 ǻzHÔõÅã ÆʌØţã ĞZGƨ gǻãÆè Bǽ ãzGφŭ Бŭ ÅZÔHuz Æz UøǫõãĞtʒÅÅõã ĞęzHuÊţã gǻÅţã ȯbŋ ȟ 1.0 (A) ȯzŸ≠ã KR̂Huǫŏ ÕÕʌ :ĞÆõÅǫõã ĞHãøȷã ÕaÅè ɔŸʒ ÕÔHuǫÊł ɔøǫǵ ãzφȷã Õãžł .ĞÕÆęǻ 30 gÆŋ ÑÆõŭ ŽÃʌʂ ÛR Kǫȷã ȯzŸŢ ȯbŋ Õ̃ŋ 5 8ÅÎR̂ʌ ÛĞEDZÅDZÃ Õ̃ŋ 10 Бŭ A ȯzŸ≠ã ȯbŋ Õ̃ŋ 1 ZÅƐ (B) ȯzŸ≠ã KR̂Huǫŏ .ĞGŸÔõã gǻÅţã ȯƷ ÕÔÅʌʂ 8Åò supernatant 8Åù

750~) ȯzφÅŽΛqä Ž R ÆÉŸΕφÅQΕèäşøzŸõ-4 ȣη ŋŸη 25 (C) ȯzŸ∓ä ƚŘHυQõ ãäØł .TS (ȯ/ȟ 750~) ȯzφÅŽΛqÅæ Ž ÅŦÔHυz Æz ΥøQõä gåÅŧä ȣη ȟ 0.1ş R ÆÉŸΕφÅQΕèäşøzŸõ-4 ȣη ȟ 0.25 (D) ȯzŸ∓ä ƚŘHυQõ ãäØł .TS (ȯ/ȟ ȣη ÄQõşÄÒη 200 ĞHΕÅÔõä ɔŸ3 ŦŦÔÅÅη ĘGÛł .Ōη 100 ɔŸ3 ȯzÔHυŸõ TS (ȯ/ȟ 750~) ȯzφÅŽΛqä ȣη ĞΕzÅõ ĞΕŧõ Ž ZDzQõ õÄQĭ Ûãäà Îϱèŕä gÄDzǵ ȣη ĞHΕÅÔõä ţÂφ ÆĤæ .ĞΕęÅGõä ĞϱŸŽõä ŌΕõÅ∓ä ȣη Ōõ ȣη ÄQõşÄÒη 40ş A ȯzŸ∓ä ĞPÅφ ĞĤÔæ ĞΛŬ ȷzÒĭ ŕ .(ÄQηzφÅφ 254) ĞΕDzÊÅΛGõä ȧzz ĞĤì ȷä ŏzŘæ ΥøääÄ Îϱèŕä ÙÛÁţä ÒHυÅΛş ùzäå õäzŁ øÅÅĭ .C ȯzŸ∓Åæ ÅŦŦŸ3 ŌÔHυQÊΛ ΥøQõä ĞÔæÅÛţä ĞĤÔGõäş ȣη gÆì ÄŽõŬ ÛA ȯzŸ∓Åæ ÅŦŦŸ3 ŌÔHυQÊΛ ÆÉŸΕφÅQèäşøzŸõ –4 ȣ3 ÄŽõŬ ÛÆÉŸΕφÅQΕèäşøzŸõ –4 øõ ĞÔæÅÛţä ĞĤÔGõäş ĞΕÊΕΛÄõä ĞĤÔGõä ŏÅŽQèÅæ ÛB ȯzŸ∓Åæ ÅŦŦŸ3 ŌÔHυQÊΛ ĞĤÔæ ĞΛŬ ȷzÒĭ ŕ D ȯzŸ∓ä ȣη ǰĭÅÅõä ãäÄ Îϱèŕä ÙÛÛ' ÄŦşŬ äæŬ ŕŬ ŦęşÆÔη øÅQQnŕä ȷzÒΛ ŕ .C ȯzŸ∓Åæ ĞŸÔHυQÊţä ĞĤÔGõä ȣη gÆì ĞĤÔGõä Ž ŘÅnŬ Rƒ ĞŧΕę ȷzÒĭş ÛĞòzHυÅţä gåÅţäş ÆÉŸΕφÅQΕèäşøzŸõ-4 ΒŬ ȷäKÎĭ ƚĭÅΛÅŧQη ƚQõzÔÅη ƚQĤÔæ .gƚnȷä

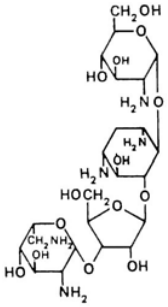
ŌΛøzŸõşøÆÉΕTä Ř β ȣη Ōη 10 ƚÅŘΛ ÛĞŸDZzǵ ΒŬ ÛĞΕùzφŘη Ğφşàzη ÛĤ 0.25 ĞääÄę ŌÔÆΛ :**Assay** ĞÊΛÅÔţä ƚÅŘΛ ÛŏÅţä ȣη Ōη 30 øæ ZĭÒţä ŌÊƚΛ .Ğ3Åè gÆη Υ3zDZÄõä ȷÅΛÄ∞Åæ ŌŧĤΛ ZĭÒη ĬƚÔ ɔƚƚΛş TS (ȯ/ȟ 70~) ȷäzÅĤõä ĬƚÔ ƚzòzη zŁ Åη ÆÊШ ƚΕÅQŧş Ûcombined solution Æǵzţä ȯzŸ∓ä ΒŬ R ȳzΕèÅĭzGõä ÆΕηşÄæ ȣη ȟ1 ùzÅÒΛ .VS (ȯ/ȯzη 0.1) ȳzΛåzÔõä ĬΛÄQÅæ gÄΛÅĤţä Û(143 ĞHυÅÔõä Û1 ÆŸÖä) "Nitrite titration ĬΛÄQÅõä gÄΛÅĤη" .$C_8H_9NO_2$ ȣη ŋŸη 15.12 VS (ȯ/ȯzη 0.1) ȳzΛåzÔõä ĬΛÄQφ ȣη ÄQõ ΥŸΕη Ōõ

PAROMOMYCINI SULFAS

Paromomycin sulfate DžĭƨĭDŽNjDŽNjþƒĞΛΕ lƒƨ∓ƨ

Molecular formula: $C_{23}H_{45}N_5O_{14},xH_2SO_4$ ĞΕÅΛÂƨä Ğ8ΕÔõä

Graphic formula: ĞΕφÅΕGţä Ğ8ΕÔõä



Chemical name: *O*-2,6-Diamino-2,6-dideoxy-β-L-idopyranosyl-(1→3)-*O*-β-D-ribofuranosyl-(1→5)-*O*-[2-amino-2-deoxy-α-D-glucopyranosyl-(1→4)]-2-deoxystreptamine sulfate (salt); *O*-2-amino-2-deoxy-α-D-glucopyranosyl-(1→4)-*O*-[*O*-2,6-diamino-2,6-dideoxy-β-L-idopyranosyl-(1→3)-β-D-ribofuranosyl-(1→5)]-2-deoxy-D-streptamine sulfate (salt); CAS Reg. No. 1263-89-4.

Description: Amorphous powder.

Solubility: Soluble in water (750~) mg/ml. Insoluble in methanol, ethanol, acetone, ether, benzene, chloroform, DMSO, DMF, pyridine, n-butanol, n-hexane, n-octanol, ethyl acetate, 1,4-dioxane, 1,2-dichloroethane, 1,2-dichlorobenzene, 1,2,4-trichlorobenzene, 1,2,4-trichlorobenzene, 1,2,4-tr

Б̈ ţ̈ ţ̈DZ̈ȧ̈ȧ̈ ǢÊǮş Ō̈ŋ̈/ŋ̈ŷ̈ŋ̈ 50 Âǿṏȧ̈ǫ̈ȧ̈ ȯ̈ţ̈ŷ̈Ţ̈ ȳ̈ǢÁǫ̈Êȧ̈ :**Specific optical rotation** Ŷ̈ǯ̈ţ̈ȧ̈ȯ̈ȧ̈ ƀ̈ȧ̈Ôǵȯ̈ȧ̈ ȧ̈ȧ̈ş̈Ǣǫ̈ȯ̈ȧ̈ $[a]_D^{20°C}$ = + 50 to +55° ÜĞȧ̈ȧ̈ǪŌ̈ȧ̈ ǵȧ̈ȧ̈ţ̈ȧ̈.

.ȟ̈/ŋ̈ŷ̈ŋ̈20 ȯ̈ŋ̈ ȧ̈ǯ̈ȯ̈ȯ̈ Ü̈ È̈ǿ̈ :**Sulfated ash** ŘȧŷÊţ̈ȧ̈ ȧ̈ȧ̈ŋ̈ȧ̈ȯ̈ȧ̈

ŕ) Ř̈ȧ̈Áȧ̈ŋ̈ Ù8ŕ Ř̈Ơ °ȳ50 ǵȯ̈ȧ̈ȧ̈ǵ ǴDZǵØǢȧ̈ Ř̈ȧ̈ȧ̈ǯ̈ȯ̈ȧ̈ ȷȧ̈ȯ̈ȧ̈ ŕØǫ̈ǵ Ȝ̈ȧ̈ȯ̈ :**Loss on drying** ȜǢȧ̈DzǫȯȧȧǢ ÁṎȧ̈ȯ̈ȧ̈ ȟ̈/ŋ̈ŷ̈ŋ̈ 50 ȯ̈ŋ̈ ȧ̈ǯ̈ȯ̈ȯ̈ ÁṎȧ̈ȧ̈ ŕ Ü̈(ȟ̈ǵȧ̈ȧ̈ȯ̈ȯ̈ Ŷ̈Ôǵȧ̈ȧ̈ ȷ̈ŷ̈ŋ̈ 5 ş̈ ȯ̈ȧ̈Ȯ̈ȧ̈ȧ̈ȯ̈ŷ̈ȯ̈ 0.6 ȧ̈ş̈ȧ̈Dzǫȧȧȧ

3-Mercapto-D-valine; 3,3-dimethyl-D-cysteine; CAS Reg. No. 52-67-5.

Description: Ζòζõã ÛÐØózÿæ ȧzHÜÊη ÛÐØóÀÀÕk ÒÒÊæÜ ÞÜ ÞzÿÕã ÒÒÊæÜ ÜÕÕGÀÀÕk ÒÒÊæÜ ÞÜ ÞzÿÕã ÒÒÊæÜ ÞÜ ÞzÿÕã ÒÒÊæÜ ÞÜ ÞzÿÕã

ʒŕʒʌ ʒŧę Ǝʒ TS (ȯ/ȟ 1000~) Õʌ̀ǫʌȯã Ŕƥ ȯɒŋ Ōŋ 2.5 ȣ ʌ̀Ŕʌş ÛŰǤʌ̀ÃÕǩ °45 ǤʌşãÂæ ǦŸDZʒΣã ȯʌ̀ǫ ÛǦǤDZʌ̀DZÂõã ÙŰǤÎʌõã Ōʒʌ̀ÀǫõÃ ŲʌǫÇş ãşʌ̀ǫʌõã ÆŰǤÊõÙ ȯɒʌ̀ɲʌ̂ ŌȮÎǫǩ ʔøǫǵ Ǧʒʌȣõã ǵøãʌ̀ǵ ǦDZóÆæ ʌ̀ÕǫÊŰõ ǰʌÂŧã õʌ̀ǫʌ .ǦŸDZʒΣã ǀʒ Ž Ż ŕşÙ ʒÛŸæ ÛɒŶʌ̂Êŧş ʒŧÕõã Ǝʒ TS (ȯ/ȟ1760~) Õʌ̀óʒʌŸÊõã Ŕƥ ȯɒŋ Ōŋ 2.5 ȣ ʌ̀Ŕʌ .(ǦÕŰęʌ̂ 30 – 5) ÛóØŰ TS (ȯ/ȟ1000~) Õʌ̀ǫʌõã Ŕƥ ȯɒŋ Ōŋ 2.5 ȣ ʌ̀Ŕʌ Ż Ûʌ̂ęŦʌ .ǨʌƎȮõã ÆŰǤÊõÙ ŲǫŸǫ ȯɒʌ̀ɲʌ̂ ŌȮÎǩ ʔøǫǵ 50 ȣ ʌ̀Ŕʌ Ż Ûʔʌ̀ɲÙ gʌ̀ŋ ǦŸŧʌ̂Hõã ǾØŁ ʌ̂ÂHǩ Ûʌ̂ęŦʌ .ǨʌƎȮõã ÆŰǤÊõÙ ŲǫŸǫ ȯɒʌ̀ɲʌ̂ ŌȮÎǫǩ ʔøǫǵ ʔʌ̀ɲÙ gʌ̀ŋ ȯɒʌ̂Êʌ ʒÔǫ Бʌ̂ ȯʒȯʒõã ʔøǫǵ ȯʒŸ+ã ʔʌ̂8ʌ ÛʒŧÕõã ţÂøʌ̂ .ǦŸDZʒΣã Ž ʒÛÎõã ÕɒʌÈ ʒŧʒş ÛʒŧÕõã ʒÛÎõ Ûŏʌŋ Ōŋ Ōŋ 250 øõ ʒÊǫʌ ŌÔʒ ʒŧę Бʌ̂ ŌÕʌʌ .Ǧʒʌȣõã ǵøãʌ̀ǵ ǦDZóʌ̂ Бʌ̂ ȯʒȯʒõã ʔøǫǵ ʌ̂ƎʌşÛ(Ōŋ 25 Ǧããʌ̀ę) ŰǤʌ̀ʌõǩ ¢ŧDzǵ Ŕƥ ȯɒŋ Ōŋ 1ş TS (ȯ/ȟ 20) ȳʒʌ̂ʌ̂ʒÔõã Ǧŧɒʌ̂ʌǫ ǵʌǫʌÆʌÙ ȯɒŋ Ōŋ 1 ȣ ʌ̀Ŕʌ .Ōŋ 50 Бʌ̂ ŏʌ̂ŧʌ̂æ ʒʌ̂ʒş ŏʌ̂ŧʌ̂æ Ǧǫʌ̂Hǫèŕʌ̂æ ǦʒÆʒ ȳóʒʒşóʒŸÒõã ȯɒŋ ǦòŸn ʌ̀nÙ ʔÕǦǩ ʔøǫǵ R ȳóʒʒşóʒŸÒõã ȯɒŋ gK8ò ȳʌ̂Êçüæ ÒŸʌ̂ǫÊŧş R ŲDzŸʒõã ÕŰǫèjã 10ş Ûŏʌŋ Ōŋ 90 ÛVS (ȯ/ȯʒŋ 0.125) Õʌ̀óʒʌŸÊõã Ŕƥ ȯɒŋ Ōŋ 50 ȣ ʌ̀Ŕʌş ȳóʒʒşóʒŸÒõã ǦòŸn ʔŋʌ̂Ǩ .ǰʒŸõã ȯɒŋ ŏãÂDZüæ ÛTS ÞóʌŰHŧã ǰşÂŰʒʌÆõã ȯʒŸʒ ȣ ʌ̀Ŕʌ .TS (ȯ/ȟ 200) ƙŋŸŰÊõşóÆŰTã ÆʌóʒŸõşóÆŰŁ ȯʒŸʒ ȯɒŋ Ōŋ ÛȳóʒʒşóʒŸÒõã ǦÕǦù ȯʌ̂ÔʌɒʌæÆ ǦŧÊʌ ÛŰÆŰDZ ǰʌÂŧã ʒʌ̂ʌ ÛǦʒʌ̂ŕÙ Ōõ ÆŰæ .Ōŋ 10 ǵãæ ǦǵʌHȣè ȯɒŋ ÛŌŋ 0.5 – 0.3 .ʒʌ̂õã ÆŰæ ʌ̂ŔnÙ TS ÞóʌŰHŧã ǰşÂŰʒʌÆõã ȯʒŸʒ ʔÕǦʌ ʔøǫǵ ʒŧʌ̂ǫʌ .ʔŋʌ̂Ǩş ʌ̂ʒõÙ Ьʒǫơ ŕ .óʌ̂Ǧǫnŕã gʌ̂ŋ Ž gʌ̂ʒDZʒŧã ęǦǫʌÂõã Ǧŧŧõ ÆÊơ ÛȳÆʌ̂ǫÊŧã TS ÞóʌŰHŧã ǰşÂŰʒʌÆõã ȯʒŸʒ ǰDzǵ ȯɒŋ .ȳãʌ̂8õã Ž ęǦǫʌÂõã ȯɒŋ ȳãʌ̂dşʌ̂ȯŋ 20 ȯɒŋ

ȳʒʌ̂ʌ̂ʒÔõã ÆŰǤÊõşóÆŰŁ ȯɒŋ Ōŋ 5 ȣ ʌ̀Ŕʌ Ûŏʌŋ Ōŋ 50 Ž ÛǦŰùʒǦŔŋ Ǧǫşàʒŋ ÛȟŸ 0.1 ǦãæʌÀę ããØʌ :**Assay** ǦÊʌ̂ʌ̂ŧã ȯɒŋ Ōŋ 1 Ōõ ùʒʌ̂ȯʌ .VS (ȯ/ȯʒŋ 0.02) ÕŰǤǫʌÂõã ǵãʌ̂ǫʌæ ʌ̂ʌ̂ʌ̂ʌ̂ş TS ǰşÂŰʒʌÆõã ȯɒŋ Ōŋ 0.2ş VS (ȯ/ȯʒŋ 1) .$C_5H_{11}NO_2S$ ȯɒŋ ŋŸŋ 5.968 VS (ȯ/ȯʒŋ 0.02) ÕŰǤǫʌÂõã ǵãʌ̂ǫ

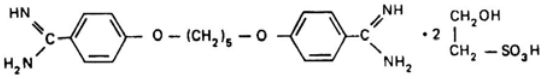
PENTAMIDINI ISETIONAS

Pentamidine isetionate DžĭǫĭDŽFĦŒĠĬĬĿ ǀ ƑŒNjĭĦĭŘĭd

Molecular formula: $C_{19}H_{24}N_4O_2,2C_2H_6O_4S$ ǦŰʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌõã

Relative molecular mass: 592.7 ǦŰǤʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌ̂ʌõã ǦŸǫʌõã

Graphic formula: ǦŰǫʌ̂ŰǤŧã ǦȣŰʌõã



Chemical name: 4,4′-(Pentamethylenedioxy)dibenzamidine bis(2-hydroxyethanesulfonate); 4,4′-[1,5-pentanediylbis(oxy)]bis[benzenecarboximidamide]-bis(2-hydroxyethanesulfonate); CAS Reg. No. 140-64-7.

Description: White powder.

Solubility: Soluble in water (1 g in about 750 mL) and in 10 mL of methanol. Insoluble in acetone, chloroform, and ether.

Category: Antiprotozoal agent.

Storage: Protect from light.

Additional information: Pentamidine isethionate is a hygroscopic substance.

REQUIREMENTS

General requirement: Pentamidine isethionate contains not less than 98.5% and not more than 102.5% of $C_{19}H_{24}N_4O_2,2C_2H_6O_4S$.

Identification tests:

A: Infrared absorption (Appendix IIC) 0.01 g/g in water, 10 mg/mL in methanol, 262 mg/mL in methanol, 350 mg/mL in methanol, 230 mg/mL in methanol.

B: Add 1 mL of 0.47 M sodium hydroxide to 0.5 mL of a 0.2 g/g solution in methanol, 2 mL of a 80 g/L solution in methanol, and 5 mL of water. Add 0.5 mL of a 0.1 g/L solution in methanol (50 g/L) and 0.2 mL of a 0.1 g/L solution in methanol (1000 g/L). Add 0.2 mL of a 0.1 g/L solution in methanol. Add 2 mL of a 0.1 g/L solution in methanol. Add 0.2 mL of a 0.1 g/L solution in methanol (50 g/L). Add 0.2 mL of a 0.1 g/L solution in methanol. Add 0.2 mL of a 0.1 g/L solution in methanol. Add 0.2 mL of a 0.1 g/L solution in methanol.

ČDZóÆæ ČŸĦÁŋ ÛR6 silica gel ÅÒĖŸĖÊõä ČŋŲŤŁ ÿäÆÅQèÅæ Û(84 ČHÛÅÔõä Û1 ÆŸŎä) Û"Thin-layer chromatography ɔŸʒ ÕÔHÛQÊΛ ōÀHÛQŋ ózÛõş Û(ČŧəŲŋ ƀóÅΘ óÆÔŋ dŋ ČŸĦ8ţä ČHÛĖÅÔõä) ČŸĦ8ŋ gåÅŧõ ÛČʒÅè gÆŋ °ÿ 105 góäÀǵ .ČĦŧQf R ŲDzŸŽõä ÕĒQĖèɟä Ŕƥ dŋ ƙŧDzǵş ÛR ózφÅkzæ -1 dŋ ÿzDzǵ 8 ÛŏÅŋ ÿzDzǵ 10 ʒÀæ ÅĖŸĦõä ČÕČÛõä Ž óÅĠQnŕä gåÅŋ dŋ ŋŸŋ 50 ɔŸʒ ƀzQʒ (A) :R ózφÅŽŲŧä Ž ƙózŸŢ dŋ ÀQõşÀÒŋ 10 ČHÛĖÅÔõä ɔŸʒ ŸÔÅŋ ĘČÛŧ Ž ZDzQõ õÀQk ÛāäÀÎQèŕä gÀDzǵ dŋ ČHÛĖÅÔõä ţÂφ ÆĦæ .ÀQõ ŲŸĖŧä Ž óÅĠQnŕä gåÅŋ dŋ ŋŸŋ 0.25 (B)ş ÀQõ ŲŸĖŧä ÛA ózŸǂä dŋ ǰQAk ČĦÕæ ČÅÜ ɟzÒk ŕ .(ÀQŋzφÅφ 254) ČĖDzÊÅAGõä ázz ČĦÌɟÅæ āäÀÎQèŕä ÙÛÛ' ÒHÛÅŋş ÛõäzTä .B ózŸǂä dŋ ČΘÅAõä ÕŸk dŋ gÆì ÀŽõÜ ÛČĖÊĖəÀõä ČĦÕGõä õÅAŽQèÅæ

Determination of ƙDZşÀQAõä ƙĖĦk" ɟäzA3 ŘƠ ȣzòzŋ zŁ Åŋ ÆÊШ A ČÕΛÀÛõä ĘGÛk :**Assay** ČÊΛÅÕŧä Ŕƥ dŋ Õŋ 9ş ÛČĖùzGŘŋ Čφşàzŋ ÛĦGΛÀÕk óÅĠQnŕä gåÅŋ dŋ ħ 0.4 ÿäÆÅQèÅæ Û(147 ČHÛÅÔõä Û1 ÆŸŎä) "nitrogen ùzÅÒΛ VS (ȯ/ȯzŋ 0.05) ÕΛózÅŸÊõä Ŕƥ dŋ Õŋ 1 Õõ .TS (ȯ/ħ 1760~) ƙDZşÀQAõä dŋ ƀÅŀä ÕΛózÅŸÊõä .$C_{19}H_{24}N_4O_2,2C_2H_6O_4S$ dŋ ŋŸŋ 14.82

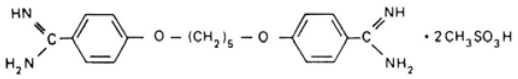
PENTAMIDINI MESILAS

Pentamidine mesilate DžĭqŧDŽƑĦĦGΛĒ ŀúĭɔĭDŽ

$C_{19}H_{24}N_4O_2,2CH_4O_3S$:**Molecular formula** ČĖÅΛÂɔä Č8ĖÔõä

532.6 :**Relative molecular mass** ČĖGÊΛõä ČĖÅΛÂɔä ČŸQÒõä

:**Graphic formula** ČĖφÅĖGţä Č8ĖÔõä



:**Chemical name** ŲəÅĖŧĖÒõä ŀèŕä

4,4′-(Pentamethylenedioxy)dibenzamidine dimethanesulfonate; 4,4′-[1,5-pentanediylbis(oxy)]bis[benzenecarboximidamide] dimethanesulfonate; CAS Reg. No. 6823-79-6.

.ÅΛÀÕk ČHõäÀõä CÆʒ ÜŲøGĖGǵ ÛŘŁÅæ ŲŸÁφÀę şÛ ŔĖäÛ ɟzŸæ ázHÛÊŋ :**Description** Zòzõä ÛR ɟzQĖèɟäş ÛR Ƙõɟä Ž āäşá ŕ ÜTS (ȯ/ħ 750~) ózφÅŽΛqäş ŏÅŧä Ž ɟÅæşÓõä ĠĖHÛì :**Solubility** ČĖφÅæşÓõä .ÅĖŸŧʒ R ÿózzşózŸÒõä Ž ŕş

Category: Ğğ ğğ ğğ

ČDZóÆä ČŸĦÁŋ ÛR6 silica gel ÅÒĖŸĖÊõä ČŋŲŁ ÿäÆÁQèÅä Û(84 ČHUÁÔõä Û1 ÆŸŎä) Û"Thin-layer chromatography ÅĖŸĦõä ČÕĠÛõä ŏÀHUŋ ózÛõş Û(ČŧəŲŋ ÐóÅΘ óÆÔŋ ďŋ ČŸĦ8ţä ČHUĖÁÔõä) ČŸĦ8ŋ gÅŧõ ÛČ3Åè gÆŋ °ÿ105 góäÀg ĘĠÛł .ČĦŧQf R ŲDzŸÿõä ÕĦQĖèjä Ŕβ ďŋ kŧDzgş ÛR ózφÅkzä -1 ďŋ ÿzDzg 8 ÛŏÅŋ ÿzDzg 10 ŽÀä ČŸÔHUQÊţä ÀQõ ŲŸĖţä Ž óÅĠQnŕä gÅÅŋ ďŋ ŋŸŋ 50 ƨŸ3 (A) ÐzQŽ :R ózφÅŽŧţä Ž kózŸŢ ďŋ ÀQõşÀÒŋ 10 ČHUĖÁÔõä ƨŸ3 ŲŸÔÁÅŋ Ûāäà ÎQèŕä gÀDzg ďŋ ČHUĖÁÔõä ţÂφ ÆĦä .ÀQõ ŲŸĖţä Ž óÅĠQnŕä gÅÅŋ ďŋ ŋŸŋ 0.25 (B)ş (gósÀŔõä ÆÁ3 ÛùzÆÁ) ďŋ ĵQÅk ČĦÕä ČÁÜ ĵzÒk ŕ .(ÀQŋzφÅφ 254) ČĖDzÊÁÁGõä ȧzz ČĦì jÅä āäÀÎQèŕä ÙÛÛƯ ÒHUÁÁş ÛõäzTä Ž ZDzQõ õÀQk .B ózŸ‡ä ďŋ ČΘÁÁõä ÕŸk ďŋ gÆì ÀŽõÛ ÛČĖÊĖƏÀõä ČĦÕGõä õÁÅŽQèÅä ÛA ózŸ‡ä

Determination of kDZşÀQÁõä kĖĦk" jäzÁ3 ŘƠ ȣzòzŋ zŁ Åŋ ÆÊŲ A ČÕÁÀÛõä ĘĠÛk :**Assay** ČÊÁÅÕţä Ŕβ ďŋ Ōŋ 9ş ÛČĖùzĠŔŋ Čφşàzŋ ÛŦĠÁÀÕk óÅĠQnŕä gÅÅŋ ďŋ ħ 0.4 ÿäÆÁQèÅä Û(147 ČHUÁÔõä Û1 ÆŸŎä) "nitrogen ùzÅÒÁ VS (ȯ/ȯzŋ 0.05) ÕÁózÁŸÊõä Ŕβ ďŋ Ōŋ 1 Ōõ .TS (ȯ/ħ 1760~) kDZşÀQÁõä ďŋ ÐÅĮä ÕÁózÁŸÊõä .$C_{19}H_{24}N_4O_2,2CH_4O_3S$ ďŋ ŋŸŋ 13.32

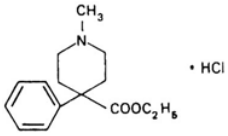
PETHIDINI HYDROCHLORIDUM

Pethidine hydrochloride DžĭσηĭĦĭĞΠΕ σηĭβNj‡lNjβσηĭlj

$C_{15}H_{21}NO_2,HCl$:**Molecular formula** ČĖÅÁÂƨä Č8ĖÔõä

283.8 :**Relative molecular mass** ČĖĠÊÁõä ČĖÅÁÂƨä ČŸQÒõä

:**Graphic formula** ČĖφÅĖGţä Č8ĖÔõä



:**Chemical name** ŲƨÅĖŧĖÒõä ĮèŕÅ

Ethyl 1-methyl-4-phenylisonipecotate hydrochloride; ethyl 1-methyl-4-phenyl-4-piperidinecarboxylate hydrochloride; CAS Reg. No. 50-13-5.

.ďÁÆÁKĠĖţä ÆÁózŸõşóÆĖŁ :**Other name** ÀnŋÅä ĮèŕÅ

.ČHUƨÀõä CÆ3 ÛJzŸõä ŔĖƨÛ ÛÐózŸä ȧzHUÊŋ :**Description** ZòzõÅ

.ÅĖŸŧ3 R KQjä Ž āäşá ŕ ÜTS (ȯ/ħ750~) ózφÅŽÁqä Ž āäşá ÜõÅţä Ž ÅÆDZ āäşá :**Solubility** ČĖφÅäşØõä

Category: Ğİİİöä ćŇÊŋ ćŇÉŬ.

Storage: ćŇÂÁĄöä ćŇÊŋ ŋŇŋ 5 ŽŇŋ ŋŇŋ 0.1 ćŇŇŇ ŇöŇŋ ŇŋŇŋ 0.5 Ž ŋŇŋ 5 ä ä ŇŇ: A
(ćŇŇŇ 1760~) ŇŇŇ ŇŇŇ ŇŇŇ

ĞŸŸ8ŋ gǻĂŧõ R1 (ÀŁȝƨã È£õ) ózȝ8ŸŒÊŒÒõã ÿãÆǺQèĂæ Û(84 ĞHŧÁÔõã Û1 ÆŸŎã) "Thin-layer chromatography Ž ŀŸŋ 5 ĂŦÊŒÛ8Qæ ÛĞHŧŒÁÔõã ÆĦÀÎQõ R ȝȝQŒèɟã dŋ ȳȝDzǵ 9Ş R ózφĂŽĦÙ ŦÊõȝÆȝ -2 dŋ ŀDzǵ dŋ ǰĦÂŋş õÀQĦş ããÀÎQèŕã gÀDzǵ dŋ ĞHŧŒÁÔõã ţÂøÁǩ ÛÕęɟã ƨŸȝ ŀè 15 ţĂÁǩǵã БÙ ÆĦØţã ózòş ÆĞæ .ÅĞĦÀÕǩ ÒƨĂÊõã õÀHŧQţã ózÛõã ÀÑȝ .Åőãæ ÆĦÀÎQõã ĞŦDZ Ž ããÀÎQèŕã ƨÀz ÛgÀìÁGŋ ĞæÀÎQţã ĞHŧŒÁÔõã ȳÆÁǺÊǩ .ÀÁǺQŒõ ȝȝQŒèɟã R ózφĂŽĦÙ ŦÊõȝÆȝ -2 dŋ ȳȝDzǵ 8Ş ÛR1 ȜŒÁŀã ÙÀÁõã dŋ ŀDzǵ 100 ÛR ǩŋŸŒŽĦqã ŦƨĂÁQ dŋ Ǽǵã Ş ŀDzǵ ȝÀæ dŋ Ōŋ 0.5 8ĂÑĦ ÛŏĂŋ Ōŋ 5 Ž ĥ0.10 ããØĦ ÛǿĂǺQnŕã ÕŒÁŤ ǨÑHŧQõ .ŽĂÛõã ÕƨĂÊõã ÕŧĦQÊĦş ÛÀÕQÊŒõ õÀQĦ ÛĦĦŋ ĞÕǺÛõã ÿÆÁǺÊǩş ÕÔÁÁQõ ǵĂÕǺÛõã õÀQǩ .ȝÀĦş ÛR Ǩǵã dŋ Ōŋ 2 ÛTS (ȯ/ĥ 400~) ȳȝĦǻȝÔõã ÆŒÊõşØÆŒŁ ózŸŤ ŦŸÔĂĦŋ ĘǺÛĦ .B ózŸHŧõ ÿÆÁǺÊǩş Ǩǵã dŋ Ōŋ 50 ȝøǺǵ A ózŸǂã dŋ Ōŋ 0.5 ȜĂȜ .A ózŸHŧõ ĞĦȝŸĦõã Ž ȜDzǺõ õÀǺǩ ÛããÀÎQèŕã gÀDzǵ dŋ ĞHŧŒÁÔõã ţÂφ ÆĞæ .BŞ A ǩózŸǂã dŋ Ōõ dŋ ÀǺõşÀÒŋ 5 ĞHŧŒÁÔõã ȝŸȝ ţÂøÁǩ .ȝÀnÙ gÀŋ ĘǺĞÛǺõã Ùn ȧȝȝ ŀè 12 ǻȝĦÔŸõ ÆĦØţã ǰĦÂţã õÀQĦş ÛgÀDzΣã БÙ ǻĂĦǩ ÛĘəĂęǻ 10 gÆŋ õãȝTã ĘəĂęǻ 5 gÆŋ øãÀÕǺèŸõ õÀǺǩ .TS ǩĂÊĦØȝŸȝşØȝŸõ ŦəĂĂȝæ æÀĂŧş ÛĘəĂęǻ 10 gÆŋ õãȝTã Ž ȜDzǺõ õÀǺǩ ÛĞHŧŒÁÔõã .ÅĞĦÀÕǩ õĂÑŒæ şÙ õĂÑŒæ ĞŒÁŸn ȝŸȝ ĞŒõĂÕǩÀæ БÙ õãÀþ ȝÕæ ȝŸȝ ÕÔHŧQÊĦ ÜØĂŦĂõã õȝŕ Ž ããÀÎQèŕã ÙÛÙ ÒHŧĂĦş õĂĂȝǺèĂæ ÛA ózŸǂã dŋ ǰǺĂǩ ĞĦÕæ ĞĦÙ ȝȝÒǩ ŕ .(ÀǺŋȝφĂφ 365) ĞŒDzÊĂĂGõã ȧȝȝ ĞĦÌɟĂæ ããÀÎQèŕã ÙÛÙ ÒHŧĂĦ Ż .B ózŸǂã dŋ ĞΘĂĂõã ÕŸǩ dŋ gÆÌ ÀȝõÙ ÛĞŒÊŒəÀõã ĞĦÕĞõã

10 8ĂÑĦ ÛR1 ŦDzŸȝõã ÕŒǺèɟã Ñþ ózŸŤ dŋ Ōŋ 30 Ž ÛĞŒùȝĞÑŋ Ğφşàȝŋ Ûĥŏŋ 0.20 ããØĦ :**Assay** ĞÊĦĂÕţã 8ȝòȝŋ ȝŒ Ăŧõ VS (ȯ/ȯȝŋ 0.1) ÕĦØȝŸõǨĞõã ÑŧŦ ÀĦĂĦş ÛTS ÕŒǺèɟã Ñþ/ÕŒÕĞəÂõã gĂǺŒèÙ ózŸŤ dŋ ĥ 1 Ōõ .(142 ĞHŧÁÔõã Û1 ÆŸŎã) A ĞÕĦÀÛõã Û"Non-aqueous titration ŦəĂţã ŕ Ùèȝõã Ž gÀĂĂĦţã" ȝĂȝ3 ǨƠ .$C_{15}H_{21}NO_2,HCl$ dŋ ŋŸŋ 28.38 ùȝĂÒĦ VS (ȯ/ȯȝŋ 0.1) ÕĦØȝŸõǨĞõã Ñþ ózŸŤ dŋ

ƒ¢ŧsΘ üƒDŽyƧƨÚε üШŬ DžĩqĭĦĭĞŒε qĭƒbNj‡ǀNjƒbqĭNJШ hŭĭƷFŤª lƒĞŦƯŦDŽ

Additional requierments for Pethidine hydrochloride for parenteral use

.(56 ĞHŧÁÔõã Û4 ÆŸŎã) "*Parenteral preparations* ĞĦÕΣã gãÀÑHŧQÊţã " gǻşÀȝȝ ÆŒDzQÊĦ

ØĂĞQnŕã" ȝãȝĂ3 ǨƠ 8ȝòȝŋ ȝŒ Ăŧõ ØĂĞQnŕã ĘĞÛĦ :**Bacterial endotoxins** ĞŒŋȝõÀƨã ĞŒŸnãÆõã gĂφĂĂĦØõã ŕ Ü(30 ĞHŧÁÔõã ÛĞĦÂŒŸÒφqã ĞŦĞÛõã Û5 ÆŸŎã) "Test for Bacterial endotoxins ĞŒŸnãÆõã ĞŒŋȝõÀƨã gĂφĂĂĦØõã ÕDZȝ ÿãÀd ŦŸŒţã Ž ĞŒõşǻ gÆgş 2.4 RS ŦŸnãÆõã ȝĂĂĦØõã dŋ ȜȝǺǂã àşĂDzQĦ.

PHYTOMENADIONUM

Phytomenadione DžNjĭǫǰdźĭDŽNjłĭȝ

$C_{31}H_{46}O_2$:**Molecular formula** ǦǮǄǂǂǄǂǄǂǄ

0.42ş 0.40 ţè 1 ÀŻŦÁõ ÀŦŸñ ÿäÆÁõèÀæ ČÕæÀÊöä òäżùjä ğäæ ğÀDżţÀæ ğÀòÀŧõöä jżÒk .ÀõŋżφÀφ 270ş ÀõŋżφÀφ ÀõŋżφÀφ 266ş ÀõŋżφÀφ 254ş ÀõŋżφÀφ 246 ČDżţä òäżùüæ ÀÆφá ŧŧÆę ŻÆÛöä ÀŻŢŦ .Бäżõöä ɔŸȝ ÛŦGŦÀÕk 0.39ş 0.38ş 0.70 ƙæ ÀõŋżφÀφ 249 ČDżţä òżÛæ ɔŧŢŦöä Бÿ ŦGŦÀÕk ÀõŋżφÀφ 254 ČDżŋ òżÛæ ÀÆφÆöä î Àŧõöä ČGÊφ ŋŸČk .ŦGŦÀÕk .0.75ş

òżÛæ ÆŁÀÎŦ ÀŋÆÀȝ ÛR jÀõÀæ ÕÆŽÆŋ ŲõŸõ -4Û2Û2 Ž Õŋ/ŋŸŋ 0.10 ÂÆõÀõæ òżŸŢ î ÀÔõŋä ŻÆù ÀŻŢł :B ČDżŋ òżÛæ bäjä ÆΣäş ŦGŦÀÕk ÀõŋżφÀφ 243 ČDżţä òżÛæ ɔŸȝjä ÆΣä ÛŦGŦÀÕk ÀõŋżφÀφ 350ş ÀõŋżφÀφ 230 ƙæ ČDżŋ .bäjä ÆΣä Ž ŦGŦÀÕk 0.22ş ÛɔŸȝjä ÆΣä Ž ŦGŦÀÕk 0.70 ţè 1 ČφÀÁžæ ČÕČù òŸñ ɔŋ î Àŧõöä jżÒŦ .ŦGŦÀÕk 285 òżŸŢ ɔŋ Õŋ 1.0 ȣÀŘŦş TS (ò/ħ 750~) òżφÀžŦÛ Õŋ 5 ȝŋ óÀGõñŕä ÕəÀè ɔŋ ħ 0.05 ČæäÀę ȝÂȜ ÀÞjä Бÿ òżŸ‡ä jżõ òżHõõŦ ÜČÕÆęä 15 gÆŋ óäÀÕõèŸõ ōÀõŦ .ÀŘñÿ jżõ jõÀŦ ÜTS1 òżφÀžŦÛ/ȳżÆèÀżGöä ÆÆÊõşóÆÆŁ .ŲøÀGöä Бÿ äóÀŘöä

. $n_D^{20} = 1.525 - 1.529$:**Refractive index** óÀÊÒõŕä ÆÊÀŋ

jżÒŦ ÜR ŏÀŧä ţşÂøÀŋ òżφÀžŦqä ɔŋ Õŋ 20 Ž ħ 1 ääØŦ :**Acidity or alkalinity** ČŦżŸÕöä şÿ �żŧ∑ä .R È‡Îöä äÀG3 àóżõ ÀÆŦÀŦ òżŸ‡ä

jäżÀ3 ŘƠ ȣżòżŋ żŁ Àŧõ ÛŘżÀñ ŏżŕ ŘƠ ÛóÀGõñŕä ĘGÛŦ :**Related substances** ČŏÀÎŧä ääżżä silica ÀÒÆŸÆÊöä ČŋŸŁ ÿäÆÁõèÀæ Û(84 ČHõÀÔöä Û1 ÆŸŏä) "Thin-layer chromatography ČÕÆęÀöä ČÕGÛöä äÀÎõèä" ɔŋ Ágäş ţDżgş ÛR Ƙõjä ɔŋ ŧŧDżg 20ş ÛR jÀÊÒÆżŸÒÆÊöä ɔŋ ŧŧDżg 80 ɔŋ ŦÂŋş ČŸ‡8ŋ gäÀŧõ R4 gel :R jÀõÀæ ÕÆŽÆŋ ŲõŸõ -4Û2Û2 Ž ƙòżŸŢ ɔŋ ÀõõşÀÒŋ 10 ČHõÆÀÔöä ɔŸȝ ŦŸÔÀÀŋ ĘGÛŦ .ōÀHõŋ ózÛõ R òżφÀžŦţä ɔŋ ČHõÆÀÔöä ţÂφ ÆÆæ .ÀõÒ ŲŸÆţä Ž R jżÀäÀÆţä ɔŋ ŋŸŋ 0.05 (B)ş ÀõÒ ŲŸÆţä Ž óÀõõñŕä gäÀŋ ɔŋ ŋŸŋ 5 (A) Þżȝŕŕ .(ÀõŋżφÀφ 254) ČÆDżÊÀGöä àżż ČÆÌjÀæ ääÀÎõèŕä ÙÛÙ ÒHõÀÀş öäżŦä Ž ŻDżõ ōÀõŦ Û ääÀÎõèŕä gÀDżg òżŸ‡Àæ ÀŦŦŸȝ ÕÔHõõÊÀ Ø øõöä ČÆÆÕöä ɔŋ gÆÌ ÀŽõÿ ÛČÆÊÆäÀöä ČÆÆÕöä Ƙd ÛB òżŸ‡Àæ ÀŦŦŸȝ ÕÔHõõÊÀ ČÆÆæ ČÀÜ jżÒk .B

:**Assay** ČÊÀÀÕţä

.ƘżÀţä öżŘöä Ž ČÆöÀõöä ğÀÆŸŧÆöä ŻÀθ :ČŢgŸŋ

.Õŋ 100 ɔŸȝ òżÔHõŸõ R jÀõÀæ ÕÆŽÆŋ ŲõŸõ -4Û2Û2 ɔŋ ČÆżÀõ ČÆŧõ Ž ÛČÆùżGŘŋ Čφşàżŋ Ûƙ 0.1 ČæäÀę ääØŦ Õŋ 100 Бÿ òżŸ‡ä äØŁ ɔŋ Õŋ 10 ŻÀñÿ gÀŋ ŻÀƎş R jÀõÀæ ÕÆŽÆŋ ŲõŸõ -4Û2Û2 øæ Õŋ 100 Бÿ Õŋ 10 ŻÀƎ ÆÊƷş ÀõŋżφÀφ 249 ČDżţä òżÛæ ¢ƙşóæ Ž ţè 1 ČφÀÁžæ ČÕČù òŸñ ɔŋ òżŸ‡ä äØŁ î Àõ äÀÕŦ .¢ÊÀφ ÆÀØţÀæ .$\left(A_{1cm}^{1\%} = 420\right)$42 ČÆÒÀŋ Čŧ‡ę ÿäÆÁõèÀæ Û$C_{31}H_{46}O_2$ ɔŋ ŻżõŕÀä

ƒŒsΘ üƒDŽyƧƨÚƐ üШŬ DžNjĭǫƒŒĭDŽNjƧĭ2ǂǁ hŭĭƷƒŢª lƒǴƧƯƧĐŽ

Additional requierments for Phytomenadione for parenteral use

.(56 ǴHƱÁÔäã Û4 ÁŸŎä) "*Parenteral preparations* ǴEÃÕΣã ǧäÀŘHƱǫÊţä " gǻşÀƨj ÆEDƨǫÊΛ

ǿÁǫǫnƨä" jäƨÁ3 ǨƠ Ȣƨòƨŋ ƨŁ Ãŧõ ǿÁǫǫnƨä ĘǴÛΛ :**Bacterial endotoxins** ǴEŋƨǫÀƨä ǴEŸnäÆäã ǧÁφÁÁΛØäã

ƨ Ü(30 ǴHƱÁÔäã ÛǴΛÂEŸÒφqä ǴHǴÛäã Û5 ÁŸŎä) "Test for Bacterial endotoxins ǴEŸnäÆäã ǴEŋƨǫÀƨä ǧÁφÁÁΛØäã ÕDZj

.ȳäÀd ȢŸţä Ž ǴEõşǻ gÆǵş 14 RS ȢŸnäÆäã jÁÁΛØäã dŋ Ƨƨǫ‡ä àşÁDƨǫΛ

PIX LITHANTHRACIS

Coal tar !Θƨ‖Ɛ DžƐβŬƨ

ÁĚΛ .ǵǻÁ3 ǀHƱÁŸõ ȢøǴΛÀÁǫäã KÛÕǫäã ȯŸn ¢EŸ3 ÕÔHƱǫÊΛ Ƀƨφǫ ƨƨǫΛŋ ǀHƱÁäã jäÀÛę :**Composition** ÆEõÀǫäã

CAS Reg. No. ÜǴ3ƨΛǫŋ ÆEõäÀǩ Ž ƨƨǫΛţä ÁDƨƨΛ .ǴΛşÁŧEÒäã ǧÁǴõÀţä dŋ KǴõ ǻÁ3 dŋ ǻÁŢ Kdş ÃÁÕĚŋ ǁƨÂŋ

.8007-45-2

.ƙöÁƨÁΛäã ¢ǴÎǩ ǴΛƨęş ǵÂEư ÛǴHƱäÀäã Üǻƨèů şů ǻƨèjä Бů āǿÁr Ȣøäã ÛƨÂů ÕƱÁè :**Description** Ƨòƨäã

(ȯ/ȟ 750~) ȯƨφÁƨΛqä Ž ǁEƱÂDƨ āäşǽ şů ǁÁDƨ jÁäşØäã ÁEHƱì ÜöÁţä Ž jÁäşØäã ÁEHƱì :**Solubility** ǴEφÁäşØäã

.R jÁÊÒEŦäş R ȳóƨƨşóƨŸÒääş R Kǫjäş TS

.ǴEφÀÕäã āůó Õŋǵ3 :**Category** ǴÁÁäã

.ȳÁȯǵüä ǴÕŸ8ŋ ǴΛşÁǵ Ž ǀHƱÁäã jäÀÛę ŞÁƨ jů Æƨ :**Storage** dΛÂÁǫäã

ÆŸÔǫΛ .ţÁţ sooty ŹÁę ÆŦ 3ŋ öäƨŦä Ž ǀHƱÁäã jäÀÛę ȧÀǫƨ :**Additional information** ǴEƨÁřů ǧÁŋƨŸĤŋ

ǧÁDƨǿǻ Ž ţÀèů ÕÒÁǫäã ǴǴÔΛş Ûöƨŕäã āÁE8ä ƨøǫǵ ÛÆùÀäã ƨDzŸö ¢řÀĤk ÆÁ3 ǰΛǿÆǫöÁä õǿÆǫΛ .öäƨŦŸö ô ÀĤǫöÁä

.ǴĤÁkÀţä gǿäÀΣä

REQUIREMENTS ǨǴΛƨƨƨƨkdž!ƒ

:**Identity test** hŭĭNjNJ‖Ɛ βƒǴƧǴƨ

Ž ȧǿàů Ęöüǩ ŽÁÛäã ÕƱÁÊŸö ÜǴÕEęǻ 30 gÆŋ ÀÕǫÊEö õÀǫΛş R1 ƨEÁ ƨ Ùȧäã dŋ Õŋ 10 Бů ȟ 0.5 ǿØƨ ȢÁŘΛ

.(ÀǫŋƨφÁφ 365) ǴEDƨÊÁΛǴäã ȧƨƨ ǴĤřƨÁä ¢kÆŁÁÎŋ ÆÁ3 ¢ÕüǩÆǫÎΛş ǿÁŦäã öƨř

.ȟ/ŋŸŋ 20 dŋ ÄŽõů È Eö :**Sulfated ash** ǨÁŸÊţä ǻÁŋÀäã

PRAZIQUANTELUM

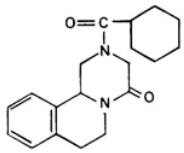
Praziquantel üïĦďźNj|ĭŘźþĠ

.ĞŋźÉÕţä ďŋ 9 ĞĦďÀÔöä Ž gźşÀźjä ĊØT ĞĦQęźöä ĞĦęĞÛöä ďźg ĘĦŸĦĬ ÁĐZźΛ :ĞŢgŸŋ

Molecular formula: $C_{19}H_{24}N_2O_2$ ĞĦÀΛÂƨä Ğ8ĦÔöä

Relative molecular mass: 312.4 ĞĦĞÊÁöä ĞĦÀΛÂƨä ĞŸQÒöä

Graphic formula: ĞĦąÀĦĞţä Ğ8ĦÔöä



Chemical name: ŬƨÀĦźĦÒöä ĻèŕÄ

2-(Cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-4*H*-pyrazino-[2,1-*a*]isoquinolin-4-one; CAS Reg. No. 55268-74-1.

Description: Ζòźöä ĞÁĦĬŕ gÂĦư ĞĦƨäó şáe şÙ ĞĦƨäÀöä ĆÉƷ ÜĦĞΛÀÕĬk ŘĦäÙ şÙ ɟźŸöä ŘĦäÙ ÛÞóźŸäe ȧźĦďÊŋ.

Solubility: ĞĦąÀäşÓöä .R ȳóźźşóźŸÒöäş TS (ȯ/Ĥ750~) ȯźąÀŠΛqä Ž ɟÀäşÓöä Àg ÜŏÀţä Ž ÀÁĐZ ɟÀäşÓöä ĆĦďÙì.

Category: ĞÀÀöä .ğÀĦèóÀźŸĞöä áÀÊŋ öäşá.

Storage: ďΛÂÁąöä .öźÊöä ďŋ ƨźŦƷ ɟÙş ÛĦÁĐZ ĞÕŸ8ŋ ĞΛşÀg Ž ÕĦąäźÒΛäÀäe ŞÀƷ ɟÙ Æz.

REQUIREMENTS ĶĞďĦĬŕÕĶdž!ƒ

General requirement: ȳÀĬöä ÆŸÛąţä ďŋ %101 ďƷ ÁΛÂΛ ŕş %98.5 ďƷ ÕÕΛ ŕ Ànŋ ƨŸƷ ÕĦąäźÒΛäÀäe ÞźąƷ .ĞÀÀÕä gźÀţä ÞÙ ţźDZÀöÀäe ĞäźÊŢ Ûc$_{19}H_{24}N_2O_2$.

Identity tests: hďNjNJΛΕ ĺ ɛĥƑĞĬĦďţɛ

• A. ďΛźÀĞąnŕä şÙ B. ďΛźÀĞąnŕä ĘĦĞÛĬk ďÒɛ.

A. ŘƠ ĞÕÛÀţä Ž ŬźÊöä ΖĦÛöä âÀĦę" ɟäźÀƷ ŘƠ ȣźòźŋ źŁ Àţõ źÀĞąnŕä ƤÀźz. B. ŘƠ ĞĦĬìjä î ÀÔąnä ΖĦù ɟźÒΛ .(43 ĞĦďÀÔöä Û1 ÁŸÕä) "Spectrophotometry in the infrared regionöäÀţΣä .ÕĦąäźÒΛäÀäΞŸö *ŬĦĐZÁţä ΖĦÛöä* Ƴŋ şÙ RS ÕĦąäźÒΛäÀäΞöä ďŋ ĵĬÀÀöä ΖĦÛŸö ÑÕäÀÛŋ öäÀţΣä

A. ȯźŸŧä ďŋ ĞΘÀÀöä ĞĦÊĦźÀöä ĞĬĦÕĞöä Ęźäźąk ."Related substances ĞöÀÎţä äźźţä" ɟäźÀƷ ŘƠ øÀĞąnŕä ƷDZÀΛ :B .B. ȯźŸŧÀä ĞΘÀÀöä ÕŸk Ƴŋ gÁÎöäş ÀźŢţäş Ƴęźţäe.

.ňĞĹÀÕĎk °ȳ138 ÛøÀŤÔφŕã ĞDZźå̊ :C

ɟãźÁȝ ŘƠ ȣźòźŋ źŁ Ãŧȭ ň 1.0 Ôŧ̄ĦQÊΛ øÀĞQòŕã òźŸŢ ŘŘƠ ȣÁȭ :**Heavy metals** ĞŸĦÕŽõãã ɟãÀĦŧã Ü(127 ĞĦÀÔõã Û1 ÁŸÕã) 3 ĞÕΛÀÛõã ÆÊШ "Limit test for heavy metals ĞŸĦÕŽõãã ɟãÀĦŧã ÕDZɟ ÐÁΣã øÀĞQòŕã" .ň/ÿãÀdŋÀÒŋ 20 dŋ ÀŽõÛ ÈĦõ Ü(128 ĞĦÀÔõã Û1 ÁŸÕã) A ĞÕΛÀÛõã ÆÊШ ĞŸĦÕŽõãã ɟãÀĦŧã dŋ ƤźQ+ã ãÁƷ .ň/ŋŸŋ 1 dŋ ÀŽõÛ ÈĦõ :**Sulfated ash** ŘÁŸÊŧã ãÀŋÀõã

ÈĦõ) ŘÀÁÀŋ Ù8ŕ ŘƠ °ȳ50 gøãÀg ĞDZźÁã ŘãÀŽõã ɟàźõã ƤøQg ƷÀz :**Loss on drying** ƷĦÁDzQõÀã ÁÕÀõã .ň/ŋŸŋ 5.0 dŋ ÀŽõÛ ÁÕÀΛ ŕ ÜŕQƷÀè gÁŋ (ňĞĹÀÕŘ ÜÕĞøà ĻŸŋ 5 ŞÛ òÀÒèÀźźŸĦõ 0.6 dŋ ÀŽõÛ

ĞÕĞÛõã ããÀÎQèã" ɟãźÁȝ ŘƠ ȣźòźŋ źŁ Ãŧõ øÀĞQòŕã ĘĞÛΛ :**Related substances** ĞõÀÎŧã ããźŧã gãÀŧȭ R5 silica gel ÀÒĦŸĦÊõã ĞŋŸŁ ÿãÁÁQèÀã Û(84 ĞĦÀÔõã Û1 ÁŸÕã) "Thin-layer chromatographyĞÕĦęÀõã .ĞΛÛĞŋ Ŕd gÀDzǵ Ôŧ̄ĦQÊŘ .ōÀHUŋ øźÛȭ R òźφÀŽĦŧã dŋ ňŧDzǵ 15Ş R dΛźÒźÛõã dŋ ňŧDzǵ 85 dŋ ɟΛÂŋŞ ĞŸ8ŋ 50 (A) ƤźƷ :R ÿøźźŞøźŸÒõã Ž ŕòźŸŢ dŋ ÀQõŞÀÒŋ 10 ÛR ŕDZŞÀQÁõã dŋ øÀĦŘ Ž ÚĞĦUĦÁÔõã ƤŸȝ ňŸÔÁÀŋ ĘĞÛΛ dŋ ÀQõŞÀÒŋ 2 ňŘΛÜ ĘĞÛΛ ÜÀQõ ÜŸĦŧã Ž RS ÔĦQφźÒΛÀãÊõã dŋ ŋŸŋ 50 (B)Ş ÀQõ ÜŸĦŧã Ž øÀĞQòŕã gãÀŋ dŋ ŋŸŋ ÔĦQφźÒΛÀãÊõã dŋ ŋŸŋ 1.0 (D)Ş ÀQõ ÜŸĦŧã Ž RS ÔĦQφźÒΛÀãÊõã dŋ ŋŸŋ 0.5 (C) ƤźƷ :R ÿøźźŞøźŸÒõã Ž ŕòźŸŢ Ž ƷDzQõ õÀQŕ Ûããà ÎQèŕã gÀDzǵ dŋ ĞĦUĦÁÔõã ţÂφ ÁĦã .ĻÈ 7 ãźĦÔõÀã õÀHUQŧã øźÛŸõ ĞŧÊΛ .ÀQõ ÜŸĦŧã Ž RS ÙÛÁŧã ÒĦUÀΛ .ĞÕĦęã 20 gÁŋ ÀÕQÊQõ õÀQŕŞ ãźĦõã gÀÑÜ ȝŋ gÀDzǵ Ž ĞĦUĦÁÔõã ȝŕźŕ Ûùźãã õźźŧ ÁÀĦŘ ÕŸŕ dŋ gÁÌ ÀŽõÛ ÛĞĦÊĦÀÀõã ĞĦÕĞõã ÕÀÀŽQèÀã ÛA òźŸŧã dŋ ɟQÀŕ ĞĦÕã ĞΛÛ ɟźÒŕ ŕ .øÀŤÀõã õźŕ Ž ãõźź ÜøãÀÎQèŕã .D òźŸŧã dŋ ĞΘÀÀõã ȬŸŕ dŋ gÁÌ ÀŽõÛ ɟźÒŕ ŕ ÜøQõã ĞĦèÀèɟã ĞĦÕĞõã ȧźź ĞĦÕã ãÁȝ Àŋ ÛC òźŸŧã dŋ ĞΘÀÀõã

ɟQÀĦõ (ò/ň 750~) R òźφÀŽĦŧã dŋ ĞĦźÀȭ ĞĦŧȭ Ž ÛĞĦùźĞŘŋ ĞφŞàźŋ ÛŋŸŋ 0.04 ĞããÀę ããØł :**Assay** ĞÊΛÀÕŧã $C_{19}H_{24}N_2O_2$ ĞĦŧȭ ÆÊØ .ÀQŋźφÀφ 265 ĞDZźŋ òźÛã ÜŧŢȝɟã ĞφÁg Ž ĻÈ 1 ĞφÀÁŽã ĞÕĞÛõ î ÀŧQõã âÀÕΛ ÜÕŋ 100 .dŋãÂQõãŞ ĞõÀÎŧÀã î źHUÀŧã ÛRS ÔĦQφźÒΛÀãÊõã ȝŋ ĞφØÀÕŧÀã ĞòźHUÀŧã gãÀŧã Ž

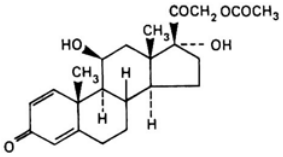
PREDNISOLONI ACETAS

Prednisolone acetate DžNjllNjŘĭŭŭqþĞ̀ ĺƑĭĭƨć

$C_{23}H_{30}O_6$:**Molecular formula** ĞĦÀΛÂƨã Ğ8ĦÔõã

402.5:**Relative molecular mass** ĞĦĞÊΛõã ĞĦÀΛÂƨã ĞŸQÒõã

:Graphic formula ČĒęĀĒGţā Čȣ̄ÊÔöā



:Chemical name ŬəĀĒţĒÓöā ţèŕā

11β,17,21-Trihydroxypregna-1,4-diene-3,20-dione 21-acetate; 21-(acetyloxy)-11β,17-dihydroxypregna-1,4-diene-3,20-dione; CAS Reg. No. 52-21-1.

:Description Ζòζöā ČĦəäÀöā CÆȝ ÜŘGÀÀÕk Ŕ̄ĒāŬ ȘŬ Ŕ̄ĒāŬ ɟζŸā ÛBØζŸā ȧζĦÊŋ.

:Solubility ČĒęĀāȘØöā ÛR ɟζęĒèɟāȘ ÛTS (ȯ/ħ 750~) ȯζęĀŽÀqā Ž ɟĀāȘØöā ĆĒĦùì ÜŘĒŸţȝ öĀţā Ž āāȘáŕ :R ȳØζζȘØζŸÒöāȘ.

:Category ČĀĀöā ÞĀŢȭ ɟζŋÀŁ.

:Storage ďÀÂĀęöā ŏζŘöā ďŋ ɔţȝ ɟŬȘ ÛŘĀĒDZ ČÕŸ8ŋ ČÀȘĀǵ Ž ɟζöȘÂĒęāĒöā ǧĀęĒèŬ ȘĀǵ Æz.

:Additional information ČĒζĀŕŬ ǧĀŋζŸĦŋ ŘGÀÀÕk °ȳ235 øĀŢÔęā ČDZØāā ɟζöȘÂĒęāĒöā ǧĀęĒèɟ.ÕÒĀęöā ȝŋ

REQUIREMENTS ƚGĥďŕƣkdž!ƒ

:General requirement ȳĀȝ ÆŸÛęŋ ďȝ ÆÀÂÀ ŕȘ %96.0 ďȝ ÕÕÀ ŕ Āŋ ɔŸȝ ɟζöȘÂĒęāĒöā ǧĀęĒèŬ ÞζęÓ̄ ČĀĀÓā gāĀţā ÞŬ ţζDZÀöāæ ČæζÊŢ ÛC23H30O6 ďŋ %104.0.

:Identity test hŭŇjNJŇε l εβƒGĦGŋε

• .CȘ B ďÀØĀęÓnŕā ȘŬ CȘ A ďÀØĀęÓnŕā Āŋ̄ŬĒęGÛk ďÒε

:A Spectrophotometry in öāÀţΣā ŘÓ ČÕÛÀţā Ž ŬəζŘöā ΖĒÛöā âĀĒę" ɟāζÀȝ ŘÓ ȣζòζţā øĀęÓnŕā ĒęGÛł ďŋ ǰĀĀöā ΖĒÛöā ȝŋ öāÀţΣā ŘÓ ČĦìɟā î ĀÔęŋā ΖĒù ĒæĀÛęÀ .(43 ČĦùĀÔöā Û1 ÆŸÖā) "the infrared region .ɟζöȘÂĒęāĒöā ǧĀęĒèɟ ŬĦDZÀţā ΖĒÛöā ȝŋ ȘŬ RS ɟζöȘÂĒęāĒöā ǧĀęĒèŬ

:B "Thin-layer chromatography ČÕĒęÀöā ČÕęÛöā āāÀÎęèā" ɟāζÀȝ ŘÓ ȣζòζŋ ζŁ Āŋ ÆÊШ øĀęÓnŕā ƤÀz ÆĒŋĀnøζÀöā ďŋ ȳζDzǵ 10 ďŋ ǰÀÂŋȘ ČŸŸ8ŋ gāĀţȭ R1 (ÀŁζɔā ÈĒȭ) øζ8ŸĒÊĒÒöā ȳāÆÁęèĀæ Û(84 ČĦùĀÔöā Û1 ÆŸÖā) ţĀĀkøā ÞŬ ÆÀØţā ȯζòȘ ÆĦæ .ÜĀęÀÀÕk ÕəĀÊöā Ž ţŸŋ 5 ĀŢÊĒÛ8ęæ ÚČĦùĒÁÔöā ÆÀÀÎęõ R ɟζęĒèɟā ďŋ ĀţDzǵ 90Ș R

ǢΛØţä ÀÅĢQΛ ɔøQǵ ǴzÀ8öä gǿäÀǵ Ž ǿäÀÊQèŸö ȍÀQǩş ā äÀÎQèŕä gÀDzǵ ďǫ ǴHUÄÂÔöä ţÂøΛǩ ÛÕęjä ɔŸȝ ǰè 16 ȍÀHUQţä ǿzÛöä ÀŘȝ .Åǿäæ ÆΛÀÎQöä ǴŸDZ Ž ā äÀÎQèŕä öäÀDZüæ ÛǩQȝÀè ȯŸn ǴæÀÎQţä ǴHUÄÂÔöä ȳÆÅQÊǩ .ΛŸnÅȍ ďǫ ÀQöşÀÒǫ 2 ǴHUÄÂÔöä ɔŸȝ ΛŸÔÀΛǫ ĘǴÛΛ .R ȳǿzzşǿzŸÒöä ďǫ ΛŧDzǵ 25ş R ďΛzǿzÛöä ďǫ ΛŧDzǵ 75 ȳäÆÅQèÀæ gÅÀǫ ďǫ ΠŸǫ 2.5 (A) ƁzȚ :R ȯzφÀŠŦţä ďǫ Æǵäş ȚDzǵş R ȳǿzzşǿzŸÒöä ďǫ ȳzDzǵ 9 ďǫ ǰΛÂǫ Ž ǩǿzŸŢ ÆŘæ .ȚÈ 15 ǴzÀÊǫ ǴHUÄÂÔöä ÀŦŢŢŧ .ÀQö ŬŸŦţä Ž RS ȚzǿşÂŦφŠΞöä ǧÀQŦÈÈÜ ďǫ ΠŸǫ 2.5 (B)ş ÀQö ŬŸŦţä Ž ǿÀǴQÈŕä 15 gÆǫ °ȳ120 ǴDZǿÆæ ďφÅÊǩ ÛÆΛØţä ÀÅǴQΛ ɔøQǵ öäzTä Ž ZDzQö öÀQǩ Ûāäà Î Q èŕä gÀDzǵ ďǫ ǴHUÄÂÔöä ţÂφ ďÅÊǩ Ż Û(ȯ/ȟ 750~) ȯzφÀŠΛqä ďǫ Ôǫ 80ş TS (ȯ/ȟ 190~) ÕΛǿzÀŸÊöä ŘÞ ďǫ Ôǫ 20 ďǫ ǰΛÂǫ æÀǩ ÛǴÕŦęå 365) ǴŦDzÊÀÀǴöä ȧzz ǴȞÌjÅæş ǿÀŦÀöä ȯzŕ Ž ā äÀÎQèŕä ÙÛŬ ÒHUÀΛş åΞQö öÀQǩ .ĘaÀęå 10 gÆǫ °ȳ120 ǴDZǿÆæ .B ȯzŸ‡ä ďȝ ǴΘÀÀöä ÕŸǩ ȝǫ gÆÎöäş ÀŦŢţäş ȝęzţÀæ A ȯzŸ‡ä ďǫ ǴΘÀÀöä ǴŦÊŦaÀöä ǴÕǴöä Ęzäz QǩΛ .(ÀQǫzφÀφ TS (ȯ/ȟ 700~) ÕΛǿzÀŸÊöä ŘÞ ďǫ Ôǫ 2ş TS (ȯ/ȟ 750~) ȯzφÀŠΛqä ďǫ Ôǫ 2 ȟ 0.05 БÜ ȞÀŘΛ :C .(ǿØШ ɔÀz) ¢QHUäÀæ öǿÆΛ ÛÕŦŠΛqä ǧÀQŦÈÜ ǰQΛ ÜgÆǵäş ǴÕŦęå gÆǫ ZÛŸæ ɔŸ8Λş ÜR ǰÀÊõzΛÆöä Ž Ôǫ/ΠŸǫ 10 ÂŦõÀQæ ȯzŸŢ ȳÆÅQÊΛ :**Specific optical rotation** Ŭ3zÀöä ƁÀÔǴöä ÀΛşÆQöä .$[\alpha]_D^{20°C}$ = + 112 to +119°

10 ďǫ ÀŠõÜ ÆÕÀΛ ŕ Ü°ȳ105 gǿäÀǵ ǴDZǿÆæ ǨæÀŠöä ǰàzöä ɔøQǵ Zæz :**Loss on drying** ZŦÀDzQöÀæ ÆÕÀöä .ȟ/ΠŸǫ

ǴÕŦęÀöä ǴÕǴÛöä āäÀÎQèä" ǰäzÀȝ ǨƠ Ȟzòzǫ zŁ Àŧõ ǿÀǴQèŕä ęǴÛΛ :**Related substances** ǴǿÀÎţä ǿäzţä ǴŸÄ8ǫ gǿÀŧõ R1 silica gel ÀÒŦŸŦÊöä ǴǫŸŁ ȳäÆÅQèÀæ Û(84 ǴHUÄÂÔöä Û1 ÆŸǴä) "Thin-layer chromatography .öÀHUQǫ ǿzÛõ ǿÀţä ďǫ ȚDzǵ 0.2ş ÛR ȯzφÀŠŦţä ďǫ ȳzDzǵ 5ş ÛR ǰÀŠΛÜ şǿzŸõ ŬǫÀÀQ ďǫ ΛŧDzǵ 95 ďǫ ǰΛÂǫş ďǫ Æǵäş ȚDzǵş R ȳǿzzşǿzŸÒöä ďǫ ȳzDzǵ 9 ďǫ ǰΛÂǫ Ž ǩǿzŸŢ ďǫ ÀQöşÀÒǫ 1 ǴHUÄÂÔöä ɔŸȝ ΛŸÔÀΛǫ ĘǴÛŧ ÆŘæ .ÀQö ŬŸŦţä Ž ǿÀǴQèŕä gǿÀǫ ďǫ ΠŸǫ 0.30 (B)ş ÀQö ŬŸŦţä Ž ǿÀǴQèŕä gǿÀǫ ďǫ ΠŸǫ 15 (A) ƁzȚ :R ȯzφÀŠŦţä 10 gÆǫ °ȳ 105 ǴDZǿÆæ ďφÅÊǩ Ż ÛÆΛØţä ÀÅǴQΛ ɔøQǵ öäzTä Ž ZDzQö öÀQǩ Ûāäà Î Q èŕä gÀDzǵ ďǫ ǴHUÄÂÔöä ţÂφ ȯzŕ Ž ā äÀÎQèŕä ÙÛŬ ÒHUÀΛş ÛTS ȳzΛǿzÔöä ÆŦÊõşǿÆŦŁ/ȳzÊõşÀöä Ŭ3ÀæǿÀǿ ǿäÀæ ÛǿΞQö öÀQǩ ÛĘaÀęå ÕÔHUQÊΛ ŬøQöä ǴÕǴöä ďǫ gÆÌ ÀŠõÜ ÛǴŦÊŦaÀöä ǴÕǴöä Kď ÛA ȯzŸ‡Àæ ÀŦŦŸȝ ÕÔHUQÊΛ ǴÕÕæ ǴΛÜ ȚzÒǩ ŕ .ǿÀŦÀöä .B ȯzŸ‡Àæ ÀŦŦŸȝ

5 ZÀÇ ÜÕǫ 100 ǰQÀÊö R ȯzφÀŠŦţä ďǫ ǴÊzÀõ ǴŦŧõ Ž ÛǴŦÙzǴÊǫ Ǵφşàzǫ ÛǫŸǫ 20 ǴæäÀę āäØŧ :**Assay** ǴÊΛÀÕţä ¢ÆÉg Ž ZÀÅţä ȯzŸ‡ä ďǫ ǰè 1 ǴφÀÅŠæ ǴÕǴÙ ȯŸn î ÀŧQöä âÀŦÕæ .¢ÊÀφ ÆΛØţÀæ Õǫ 100 БÜ ȯzŸ‡ä äØŦ ďǫ Õǫ ǧÀQŦÈÜ ȯzŸŢ ȝǫ ǴφØÀÕţÀæ ǿÀǴQèŕä gǿÀǫ Ž $C_{23}H_{30}O_6$ ǴŧõÆÊØ .ÀQǫzφÀφ 243 ÀTzÙ ǴDZzǫ ÆÀȝ ŬŧŢȝjä

âÀÆÕŋ ÿäÆÅǫèÀæ 0.02 ± 0.37 ŬHDZÀţä òzŸ‡ä î ÀǫŋŋzÒΛ ŋÙ Æz .dŋäÂǫõäş ĞõÀÎţÀæ î zHÀţä ÛRS ŋzòşÂǫåƎõä
.ÆzÀõ ßKÆĦk ÀǫĦŋ Ŭəzŕ ZÆù

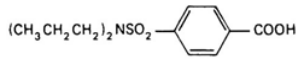
PROBENECIDUM

Probenecid ǫĭ ƨ ĭźĭĞNjƥĞΛΛε

Molecular formula: $C_{13}H_{19}NO_4S$ ĞÆÀΛÂƨä Ğ8ÆÔõä

Relative molecular mass: 285.4 ĞÆĞÊÀõä ĞÆÀΛÂƨä ĞŸǫÒõä

Graphic formula: ĞÆǫÀÆĞţä Ğ8ÆÔõä



Chemical name: ŬəÀÆtÆÒõä ǀèrä

p-(Dipropylsulfamoyl)benzoic acid; 4-[(dipropylamino)sulfonyl]benzoic acid; CAS Reg. No. 57-66-9.

Description: Zòzõä .ĞHUəäÀõä CÆƷ ÛŦĞAÀÕk ŘÆäÙ şÙ ŘÆäÙ ŋzŸæ ȧzHÊŋ

Solubility: ĞÆǫÀäşØõä dŋ ßõÂDZ 12ş TS (ȯ/ĥ 750~) òzǫÀŽΛqä dŋ ßõÂDZ 25 Ž ā äşæ ÛŦÆŸtƷ ŏÀţä Ž ā äşæ r .ĞΛzŸÕõä ğäÆÆÊõşøÆÆTä dŋ ĞÀÀÅţä ÕÆõÀ‡ä Žş R ÿøzzşøzŸÒõä Ž ā äşæ ÜR ŋzǫÆèjä

Category: ĞÀÀõä .âÀÕÀŸõ åÀŘŋ õäşå

Storage: dΛÂÅǫõä .ßÆÆDZ ĞÕŸ8ŋ ĞΛşÀǵ Ž ÆÆÊÆÀÆäşƎõä ŞÀƷ ŋÙ Æz

REQUIREMENTS ĞĞnÆƏkdž!ƒ

General requirement: ÿÀƷ ÆŸÛǫŋ %101.0 dƷ ÆΛÂΛ rş %98.0 dƷ ÕΛ r Àŋ ƨŸƷ ÆÆÊÆÀÆäşƎõä ƥzǫƷ .ĞÀÀÒõ gÅţä БÙ ţzDZÀõÀæ ĞæzÊŢ ÛC13H19NO4S dŋ

Identity tests: hŭĭNjNJΛε lεƥƒĞĦǫε

- .Cş B dΛóÀĞǫnrä şÙ ĞÆǵş A óÀĞǫnrä Àŋ ÙÆĞÛk dÒε

Spectrophotometry in ðäÀŧΣä ŘƠ ČÕÛłţä Ž ƱƻŻŘöä Ƶ£ÛÕä âłłę" ɟäżłƷ ŘƠ ȣżòżţä øłłĢǫòŀŕä ĘĢÛŁ :A ȣƷ ǰǩłłóä Ƶ£ÛÕä Ƶŋ ðäÀŧΣä ŘƠ ČŘÌŀɟä î łÔǫŋä Ƶ£ù ĘäłÛǫł .(43 ČŀƱłÔÕä Û1 ŁŸÕä) "the infrared region .Ł£ÊŁłłäŧŞΞŸõ ƱŘDZÀţä Ƶ£ÛÕä Ƶŋ ŞÙ RS Ł£ÊŁłłäŧŞΞõä ȯżŸŢ

A ȯżŸǂä ȣŋ ČƱłłóä Č£ÊŁƻÀÕä ČŘÕĢõä Ężäżǫk ."ČöłÎţä äżţä" ɟäżłƷ ŘƠ ŀÕǵŕ ȣżòżţä øłłĢǫòŀŕä ƷDZäÀł :B .B ȯżŸǂä ȣƷ ČƱłłóä ÕŸk Ƶŋ ǵŁÎõäŞ ÀŦŢţäŞ Ƶężţłäŧ (ȯŞɟä ĘŁĢÛǫõä)

.°ȳ199 ČääÀę ÛøłŦÔǫŕä ČDZøä :C

øłłĢǫòŀŕä" ɟäżłƷ ŘƠ ȣżòżŋ żŁ łŧõ ħ 1.0 ÕŧŘǫÊł øłłĢǫòŀŕä ȯżŸŢ ŘÊŘƱǫõ :**Heavy metals** ČŸŁÕŽõä ɟäłłŘţä ȣŋŘł Ü(127 ČŀƱłÔÕä Û1 ŁŸÕä) 3 õäÀDZqä ÆÊŰ "Limit test for heavy metals" ČŸŁÕŽõä ɟäłłŘţä ÕDZɟ ƀŁΣä .ħ/ȳäÀdŞŞÀÓŋ 20 àŞłłDzǫł ŕ Ü(128 ČŀƱłÔÕä Û1 ŁŸÕä) A ČÕłłÀÛÕä ÆÊŰ ČŸŁÕŽõä ɟäłłŘţä ȣŋ Ʒżǫǂŕä

.ħ/ŋŸŋ 1.0 ȣŋ ÀŽõÙ ÈŁõ :**Sulfated ash** ŘłŸÊţä äłłŋÀÕä

5.0 ȣŋ ÀŽõÙ ŁÕłł ŕ Ü°ȳ105 gøäÀǵ ČDZøŁä ŘäłŽõä ɟàżõä Ʒøǫǵ Ƶłłz :**Loss on drying** Ƶ£łDzǫõłłä ŁÕłłõä .ħ/ŋŸŋ

30 gŁŋ Ʊəłŋ ȳłþ ƷŸƷ ɟżäÀÔõä Ł£ÊõÙ Ʊəłłǫŋ ȣŋ ƀłǂŕ ŏłţä ȣŋ Õŋ 100 Ƶŋ ħ2 ȣŁÊł :**Acidity** �żŧΣä Ł£ÊõŞøŁłõ ÀłłŘłŞ ČǵłÌŀÀõä ƀÙ TS ȯżǫłŽłÙ/ŕłõłŽż ȯżł£łłóä ȯżŸŢ ȣŋ Õŋ 0.15 ƱłŘł .ĢŋÀłŞ łƷł ÛČÕ£ęł ƷŸƷ ȯżÔƱŸõ gÀłłŘţä ȯżŸŢ ȣŋ Õŋ 0.5 ȣŋ ÀŽõÙ ŁŸÛǫł ŕ ÜVS (ȯ/ȯżŋ 0.1) ǵłǫżäÀÔõä ȣŋ ƀłǂŕ ȳżłłżÔõä .ÀŘÎŧŸõ ČÛÈżǫţä ČÛÕłłõä

ČÕĢÛõä ääÀÎǫèä" ɟäżłƷ ŘƠ ȣżòżŋ żŁ łŋ ÆÊŰ øłłĢǫòŀŕä ƷÀż :**Related substances** ČöłÎţä äżţä ǰłłŋŞ ČŸŸ8ŋ gäłŧõ R4 łÔ£ŸŁÊõä ČŋŸŁ ȳäŁłǫèłłä Û(84 ČŀƱłÔÕä Û1 ŁŸÕä) "Thin-layer chromatography ČÕ£ęÀõä ČǫŸŽõä Õ£õłłǂŕä ÀÊŘƠ .õÀŀƱǫŋ øżÛõ TS (ȯ/ħ 17~) łłężŋɟä ȣŋ ȳżDzǵ 3Ş R ȯżǫłłäŞÀłł -1 ȣŋ łłŧDzǵ 15 ȣŋ (A) ƀżƷ :TS (ȯ/ħ 750~) ȯżǫłŽłłqä ȣŋ ȳżDzǵ 9Ş TS (ȯ/ħ 17~) łłężŋɟä ȣŋ łǵäŞ ĮDzǵ ȣŋ ȯżŸŢ Ž ČŁõłłǫõä ȣŋ ŋŸŋ 0.050 (C)Ş ÛÀǫõ ƱŸ£ţä Ž RS łł£ÊŁłłäŧŞΞõä ȯżŸŢ ȣŋ ŋŸŋ 10 (B)Ş Àǫõ ƱŸ£ţä Ž øłłĢǫòŀŕä gäłŋ ȣŋ ŋŸŋ 10 Õõ ȣŋ ÀǫõŞÀÓŋ 20 łŸÔłłŋ ĘĢÛłł .BŞ A ŕȯżŸǂä ȣŋ ÀǫõŞÀÓŋ 1 ČŀƱłłÔÕä ƷŸƷ ĘĢÛłł .Àǫõ ƱŸ£ţä Ž øłłĢǫòŀŕä gäłŋ ääÀÎǫèŕä ÙÛÙ ÒŀƱłłŞ õäżŦä Ž ƷDzǫõ õÀǫŕ ÛääÀÎǫèŕä gÀDzǵ ȣŋ ČŀƱłłÔÕä ţÂǫ łŁŘł .CŞ A ŕȯżŸǂä ȣŋ ÕŸk Ƶŋ ǵŁÎõäŞ ÀŦŢţäŞ Ƶężţłäŧ A ȯżŸǂä ȣŋ ČƱłłóä Č£ÊŁłłäŧŞΞõä ČŘÕĢõä Ężäżǫk .(Àǫŋżǫłłǫ 254) Č£DzÊłłĢõä łżżż ČŘÌŀɟłłŧ ȣŋ ǵŁÌ ÀŽõÙ ÛČ£ÊŁłłäŧŞΞõä ČŘÕĢõä õłłŽǫèłłŧ Û(ƆłŽõä ĘĢÛǫõä) A ȯżŸǂä ȣƷ ǰǫłk ČŘÕä ČłÙ ɟżÔk ŕ .B ȯżŸǂä ȣƷ ČƱłłóä ÕŸk .C ȯżŸǂä ȣƷ ČƱłłóä

ÀłłŘłŞ TS ȯŁŘǫÊţä ȯżǫłŽłłqä ȣŋ Õŋ 50 Ž ÛČ£ùżĢŘŋ Čǫşàżŋ ÛŘ 1.0 ČääÀę ääØł :**Assay** ČÊłłÔţä

.ÄĦÎŧõ TS ȯzφÅŽÄÚ/ȯzŧĦȩzηȘƎöä Ğęóà ÿäÆÁȩèÅä Ûvs (ȯ/ȯzη 0.1) ğÅφzäÀÒöä dη БÅ ȩ ÿzÄźzÔöä ÆŧÊõȘøÆŧŏ dη БÅ ȩ ÿzÄźzÔöä ÆŧÊõȘøÆŧŁ dη Ōη Ōõ ùzÅÒÄ .ĞÄøȘÀŘöä ğÅHUŧHUÔȩöä ƤÀΘȘ øÅȩȩnŗä gźÅη JȘź ĞŧŸŧĦöä źÅĦĦk .$C_{13}H_{19}NO_4S$ dη ŋŸη 28.54 vs (ȯ/ȯzη 0.1) ğÅφzäÀÒöä

PROCAINI BENZYLPENICILLINUM

Procaine benzylpenicillin DžĭŧƨďĞ üĭŘďĞ DžĭĭŤFlNjþĞ

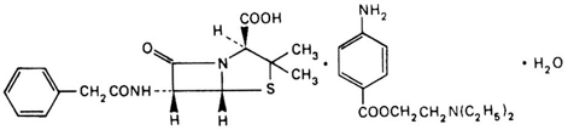
Procaine benzylpenicillin (non-injectable) (DžsΘŧll üĞFs þĭƷ) DžĭŧƨďĞ üĭŘøďĞ DžĭĭŤFlNjþĞ

Procaine benzylpenicillin, sterile !ĭsY ÛDžĭŧƨďĞ üĭŘøďĞ DžĭĭŤFlNjþĞ

Molecular formula: $C_{16}H_{18}N_2O_4S,C_{13}H_{20}N_2O_2,H_2O$ ĞŧÅÂƨä Ğ8ŧÔöä

Relative molecular mass: 588.7 ĞŧĞÊÄöä ĞŧÅÂƨä ĞŸȩÒöä

Graphic formula: ĞŧφÅŧĞȩȩä Ğ8ŧÔöä



Chemical name: ŬəÅŧŧÒöä ȩèŗä

2-(Diethylamino)ethyl *p*-aminobenzoate compound with (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo-[3.2.0]heptane-2-carboxylic acid (1:1) monohydrate; 2-(diethylamino)ethyl 4-aminobenzoate compound with [2*S*-(2α,5α,6β)]-3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid (1:1) monohydrate; CAS Reg. No. 6130-64-9 (monohydrate).

Other names: ƤÀnŬ ŏÅƨŬ .ĸŸÊÄä ĸÄÅõȘÀä ÛG ĸŸÊÄä ĸÄÅõȘÀä

Description: Ƶòzöä .ÄÄÄÀÕĭ ĞHUäÅÀöä CÆȝ ȘŬ ĞHUäÅÀöä CÆȝ ÜÄÄÄÀÕĭ ŘŧäŬ ȘŬ ŘŧäŬ ȧzHUÊη

Solubility: ĞŧφÅäȘØöä .R ÿøzzȘøzŸÒöäȘ TS (ȯ/Ĥ750~) ȯzφÅŽÄqä Ž ā äȘäé ÜŏÅŧä Ž JÅäȘØöä ĞŧHUì

Category: ĞÅÅöä .ŁŧöäÀƨä äÅŘη öäȘä

Storage: dÄÂÅÒöä JŬȘ ÛŏzŘöä dη ĞŧŧŤ ÛÿÅÒgüä ĞÕŸ8η ĞÄȘÅg Ž ĸŸÊÄä ÕÄØÄä ĸÄÅõȘÀä ȘÁƷ JŬ Æz

.°ȳ30 àşÅDzQǩ ŕ gøäÀǵ ǦDZǿǻ Ž ɟÅÁł

ǦŁzÅŕqä ǧÅǦŸÛQţä БǔÆŁDzQÊǩ gǻÅţä ɟǔ БǔŁŁÖŁÖää ǩŸÊÅæ ÕΛÂøΛæ ǩΛÅõşÀæ ǦŁŁÊQää ǨÎǩ :**Labelling** ŁŁèzQää
.ʔÀnɟä ǦŁŁÖŁää ǧÅÖŁǦÛQää Ž şǔ ÅÅÖǵ ǿÅÛ3qä Ž ÕŁŁǦQÊł ɟǔ ȣÒƨŞ ŁŁÖŁää ǩŸÊÅæ ÕΛÂøΛæ ǩΛÅõşΞõ

ǦizŸÊæ ÕÒÅQΛ .ǦΛŁŁŁ ǩŸÊÅæ ÕΛÂøΛæ ǩΛÅõşÀæ ÕŁÖÅŢ :**Additional information** ǦŁzÅŕǔ ǧÅnzŸÅn
ǦǦÔΛş ÛÆùÀää zDzŸä ¢ŕÀÅǩ ÆΛ3 ɟΛóÆQäÅæ ÖøÆQΛ ÛǩzŘää ā ÅŁ8æ ʔøQǵ .gÆÊõúţä ÕnǧzǦääş ÛǧÅΛzŸÖää Û ô ÅþɟÅæ
.ǦǦÅǩÀţä gøäÀΣä ǧÅDZǿǻ Ž ţÀèǔ ÕÒÅQää

REQUIREMENTS ǨǦnǔŽƵǩdž!ƒ

ȣ3 ÆΛÂΛ ŕş %96.0 ȣ3 ÖÖΛ ŕ Ån ʔŸ3 ǩŸÊÅæ ÕΛÂøΛæ ǩΛÅõşÀæ ƀzQƷ :**General requirement** ȳÅ3 ÆŸÛQn
%41.5 ȣ3 ÆΛÂΛ ŕş %38.5 ȣ3 ÖÖΛ ŕş $C_{16}H_{18}N_2O_4S$,$C_{13}H_{20}N_2O_2$ ljõ ǦæzÊŢ ǦŁŸÒää ǧÅÆŸÊAǦää ȣn %100.5
.ǦŁəÅnǦŸää gǻÅţä Бǔ ţzDZÀäÅæ āzÊŢ ÅƵŸõ ÛC$_{13}$H$_{20}$N$_2$O$_2$ ȣn

:**Identification tests** hƀŸNjNJЛЄ lЄƀƒǦǤƊЄ

TS (ȯ/ǩ 1760~) ÕΛózÅŸÊää Řƀ ȣn Ôn 2 øæ ƷǦQΛ øÅǦQŋä āzǦQǔ Ž ŋŸn 2 Бǔ ǒÅn Ôn 0.05 ȣÅŘΛ :A
ɟzŸää CÆ3 ȯzŸǂä ʔÖǦΛ ÜǦÖŁęǻ gÆn ƱəÅn ȳÅƀ Ž øÅǦQŋŕä āzǦQǔ ŘŁÛȣΛ .ÅǦΛÀÖǩ ɟzŸää CÆ3 ȯzŸǂä ɟzÒΛ ÜƵÂƨş
TS ÕΛózÅŸÊää Řƀ/ÆŁŁÆöÅnózÅää ȯzŸŢ ȣn Ôn 2ş ǒÅn gÀÛę ȣÅŘΛ ÛɟÅǫ øÅǦQŋä āzǦQǔ Ž ŋŸn 2 ƷŕzΛ .ÅǦΛÀÖǩ
ŘŁÛȣΛ .ƱøAǦää Бǔ āøÅŘää ÀÅòɟä Бǔ ǦŸŁŸę ęəÅęǻ ÆŁǩ ȯÆǦQΛ ɟzŸää ȣÒƨş ÛÅǦΛÀÖǩ ɟzŸää CÆ3 ȯzŸǂä ɟzÒΛ ÜƵÂƨş
.ÀŢŢ ƱøAæ ɟzƨ ǰQΛ ÜƱəÅn ȳÅƀ Ž ǦÖŁęÆƨ øÅǦQŋŕä āzǦQǔ
ȣn ǦŁzÅõ ǦŁŁõ ȣÅŘΛ .TS ȯzǦǔÅƵΛqä/ǦöǻÅŁQţä gÀŁΣä ȣn Ôn 0.5 ȣÅŘΛş ǒÅn Ôn 10 Ž ŋŸn 10 āäØΛ :B
ÀÅŁŸÊAǦää ȯzŸŢ ȣn Ôn 1.0 ȣÅŘΛ Ż ÅŁəäǻ ÅŁÖÅÖǩÀæ ÅƵzƨ ƱÛŁŁƨ VS (ȯ/ȯzn 0.01) ȳzΛǻzÔää ÆŁÊõşØÆŁ ȯzŸŢ
.ÅŁΛÀè ÀÞɟä Бǔ ɟzŸää ȯÆǦQΛ ÜTS

General ǦnÅŁää ȣäÀŁQèŕä ǧäøÅǦQŋä" ǦŁöşɟä ǦŁǩÅnşøɟä ǧÅÆnɟä ȣäÀŁQèŕ ȣzòzţä Ôƨ3ÅÅQää ǩ 0.05 ƱÛŁΛ :C
.ÀÞɟä Бǔ ǦæøÅŕ ǦŁöÅÖǩÀæ ÛǦƨÅţ ǦæÅèø ÅDzQΛn Û(119 ǦƱÅÔää Û1 ÆŸÖä) "identification

Determination of water by ÀÎŁz ȯøÅõ ǦÖΛÀÛä ǒÅţä ǩŁŁǩ" ɟÅzΛ3 ǨƠ ȣzòzn zŁ ÅŁõ ȣŁŁΛ :**Water** ǒÅţä
ʔzQŢ ÖÖΛ ŕ ÅÅΛÀÖǩ gǻÅţä ȣn ǩ0.5 ÿäÆÁQèÅæ Û(145 ǦƱÅÔää Û1 ÆŸÖä) A ǦÖΛÀÛää Û"the Karl Fisher Method
.ǩ/ŋŸn 42 ȣ3 ÆΛÂΛ ŕş ǩ/ŋŸn 28 ȣ3 ǒÅţä

ÆŁÊõǔ ƱəÅÅǫ ȣn БÅǰä ǒÅţä ȣn Ôn 10 Ž ÅǦΛÀÖǩ ǩ 3.0 ƀzQƷ ƷǦÎn ȯzŸŢ ǒÅŁÅæ :**pH Value** ǒÅŁÅǦää ǦŁŁę
.7.5 – 5.0 ÛR ɟzæÀÒää

:Assay ǦÊʌÌÅÕţä

ÕÕÅǩ .Õŋ 1000 ǰǫʌÆö ŏÅţä ďŋ ǦÆzÅõ ǦÆţõ Ž ÛǦÆùzǦŘŋ Ǧǫşàzŋ ÛĦ 0.045 ǦääÀę ä äØł :ǦÆöÅ'Pqä ǧÅÅÆŸÊʌǦŸö ďŋ Õŋ 10.0 ǩäzǦǫǰä ÁǵÚ БÚ ȣÅŘʌ .gääÁè ÅţŤʌŋ ÕÖö ǩŸÔÅʌŋ ǩäzǦǫÚ БÚ ȯzŸǂä äØŁ ďŋ Õŋ 2.0 ďŋ ɟÅǫŋÅÊǫ ǦÖÆęä 25 gÁŋ °ÿ60 gǿäÀǵ ǦDZØÁää ȣaÅŋ ÿÅþ Ž ʒŕzʌ äzǦǫǰä ÁÊʌ ÛǯÂɛ ÛTS ÕÆÕǦaÂöä ÁʌØzŸõ/ȯşàäÁÆɛÚ ȯzŸŢ ǯÂɛş ŏÅţä ďŋ Õŋ 10.0 ȣøǫÅǯöä äzǦǫǰä БÚ ȣÅŘʌ .(A ȯzŸǂä) Ǧʒ̀ÀÊää °ÿ20 gǿäÀΣä ǦDZØä БÚ äzǦǫǰä äÆÆʌ .ÅŋÅǦ (B ȯzŸǂä).

ÕäÅÕŋ ÅǦʌÀÕǩ ÀǫŋzǫÅǫ 314 ǦDZzŋ ȯzù ÁÁʒ ȣţŢʒǰä ǦÁǵ Ž ǰè 1 ǦǫÅÁǯä ǦÕǦù ƎʒKnüǩ ɟşä î Åţǫöä âÅÕʌ A ȯzŸȣţŸö TS ÕÆÕǦaÂöä ÁʌØzŸõ/ȯşàäÁÆɛÚ ȯzŸŢ ďŋ Õŋ 10.0ş ŏÅŋ Õŋ 2.0 ďŋ ǰʌÂŋ ʔŸʒ ÞzǫƠ ÆʌØŋ gKDzǵ .B ȯzŸȣţŸö ŏÅţäş

ÛB ȯzŸǂä î ÅǫŞ A ȯzŸǂä î ÅǫŞ ǩä ȣŸǫnŕä ďŋ ØÅǦǫnŕä gÅÅŋ Ž $C_{16}H_{18}N_2O_4S,C_{13}H_{20}N_2O_2$ ǦÆţõ ÆÊƠ Õõ ɟÚ ɟÅǦÊΣÅä Ønǰä ʒŋ ÛďnäÂǫöäş ǦŏÅÎţÅä ǦòzȣÅŋ ǩŸÊʌǦöä ÕʌÂØʌä ȳzʌÅzò ȯzŸŢ ďŋ Ĥ 0.050 ʒŋ ǦǫØÅÕţÅä Æz .$C_{16}H_{18}N_2O_4S,C_{13}H_{20}N_2O_2$ďŋ ŋŸŋ 1.601 ùzÅÒʌ ($C_{16}H_{17}N_2NaO_4S$) RS ǩŸÊʌä ÕʌÂØʌä ȳzʌÅzò ďŋ ŋŸŋ .ÅţəŸŋ ÅǦKÆĦǩ ÀÅĦŋ ZÆù âÅÆÕŋ 0.03 ± 0.62 ȣĦDZÀţä ȯzŸǂä î Åǫ ɟzȮʌ ɟÚ ȳzʌÅzÔöä ǧÅǫzäÀõ ȯzŸŢ ďŋ Õŋ 5 ȣÅŘʌ ÛŏÅŋ Õŋ 10 Ž ÛǦÆùzǦŘŋ Ǧǫşàzŋ ÛÅǦʌÀÕǩ Ĥ 0.5 äØʌ :ǩʌÅõşƎŸö ǧÅòŸn ǦÅÀǩ ÛR ȳØzzşØzŸȮöä ďŋ Õŋ 25 ÅŤʌŋ Õõ ÛǦĦäÅǫǫŋ ǧÅÆţõ ʒäØüä ÒŸÅǫÊłş TS (ȯ/Ĥ 75) ÕʌØzŸõşØÆÆTä Ŕþ ďŋ Õŋ 20.0 ȣÅŘʌ .ȣaÅŋ ÿÅþ Ž K8òŋ ɟDzǵ ǧäæ ǦǦÔǫö ÀǫÅǦǩş ÛȳØzzşØzŸȮöä ÀʌÅĦʌş TS ȯzǫÅǯʌqä/ÕÆǯÆţä ǧÅþ ďŋ Õŋ 0.25 ȣÅŘʌ ÛÅƎʌ .ȣęÅǦöä ȳØzzşØzŸȮöä ÀÚÕʌş VS (ȯ/ȯzŋ0.1) 23.63 VS (ȯ/ȯzŋ 0.1) ÕʌØzŸõşØÆÆŁ Ŕþ ďŋ Õŋ 1 Õõ ùzÅÒʌ .VS (ȯ/ȯzŋ 0.1) ȳzʌÅzÔöä ÆÆÊõşØÆÆŏ .$C_{13}H_{20}N_2O_2$ ďŋ ŋŸŋ

!ĭŝyʌɛ DžĭŧƨŭǦʌɛ üĭŘøŭǦ DžĭĭŤFINjþǦŧʌ hŭĭƷFŢä lƒǦŧŬŧDŽ

Additional Requirements for Sterile Procaine Benzyl penicillin

"*Test for non injectable preparations* ďÕÅŸö ǧÆĦţä Ǩd ǧäÀŘȣǫÊţä ǦŋÅÕʒ ÕDZɟ ØÅǦǫnŕä" ǧÅşÀzɟ ÆÆDzǫÊʌ .(32 ǦȣÅÔöä ÛǦʌÂÆŸȮǫqä ǦŘǦÛöä Û5 ÆŸÖä)

ØÅǦǫnŕä" ɟäzÁʒ ŘƠ ȣzòzŋ zŁ Åţõ ØÅǦǫnŕä ÉǦÛʌ :**Bacterial endotoxins** ǦÆŋzǫÀƨä ǦÆŸnäÆöä ǧÅǫÅÅʌØöä Ü(ǦʌÂÆŸȮǫqä ǦŘǦÛöä Ž 30 ǦȣÅÔöä Û5 ÆŸÖä) "Test for Bacterial endotoxins ǦÆŸnäÆöä ǦÆŋzǫÀƨä ǧÅǫÅÅʌØöä ÕDZɟ .ÿäÀd ȣŸÆţä Ž ǦÆöşÅ gÁǵş 0.01 RS ȣŸnäÆöä ɟÅÅʌØöä ďŋ ʔzǫǰä äşÅDzǫʌ ŕ

Sterility testing of ǦʌzÆΣä ǧäÅÅŘţä ǦŋÅÕʒ ØÅǦǫnä"øä ǦòÅlä gÅşÀzɟä БÚ ÆÆDzǫÊʌ :**Sterility** ǦŋÅÕŘöä ǦÕʌÀù şÚ TS ÀÅÆŸÊʌǦöä ǦzÅŕüä ȣaÅÎ8öä ǦÆìÀǫöä ØÅǦǫnä ǦÕʌÀù ÅŋÚ ÉǦÛǫä Û(162 ǦȣÅÔöä Û1 ÆŸÖä) "antibiotics

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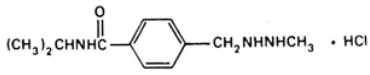
PROCARBAZINI HYDROCHLORIDUM

Procarbazine hydrochloride DžĭŘŢFĞÞŢ|NjÞĞłłε ǫĭÞNj‡|NjÞǫĭłłj

:Molecular formula ĞŒÄłłÂƨä Ğ8ŒÔöä $C_{12}H_{19}N_3O,HCl$

:Relative molecular mass ĞŒGÊłłÁöä ĞŒÄłłÂƨä ĞŸQÒöä 257.8

:Graphic formula ĞŒφÄŒGţä Ğ8ŒÔöä



:Chemical name ŬəÄŒţŒÒöä ţèřä

N-Isopropyl-α-(2-methylhydrazino)-*p*-toluamide monohydrochloride; *N*-(1-methylethyl)-4-[(2-methylhydrazino)methyl]benzamide monohydrochloride; CAS Reg. No. 366-70-1.

:Description Ζòζöä .ÄÀÔŋ БŬ ɟζŸöä ŘŒäŬ ÛÞØζŸä ȧζHŬÊŋ.

:Solubility ĞŒφÄäşØöä ɟÄäşØöä ĞŒHŬì ÜTS (ȯ/ȟ750~) ȯζφÄŽłqä Ž ɟÄäşØöä ÕŒŸę ÜR ȯζφÄŽŒţäş ŏÄţä Ž ā äşǽ .R Ğǫɟä Ž ŒŸţ3 ā äşǽ ř ÜR ȳØζζşØζŸÒöä Ž

:Category ĞłłÄöä .ÄłłŸłä ȳÄè ŏäşǻ.

:Storage ĉłłÂÁǫöä .ŏζŘöä ĉŋ ƨţHŬł ɟŬş ÛȳÄÒǵüä ĞÕŸ8ŋ ĞłłşÄǵ Ž ĉłłÄäøÄõşƎöä ÆłłØζŸõşØÆŒŁ ŞÄƷ ɟŬ Æƶ

:Additional information ĞŒζÄřŬ ğÄŋζŸĤŋ ƷŋŒłłÄÖk °ȳ223 ĞDZØÆä ĉłłÄäøÄõşƎöä ÆłłØζŸõşØÆŒŁ ÄŤÔłłł ĞŒζÄřŬ ğÄŋζŸĤŋ ÁĞÔłłş ÛÆüÄöä ζDzŸö ¢řÄĤk ÆłłƷ ɟłłØÆǫÄä ĉłłÄäøÄõşƎöä ÆłłØζŸõşØÆŒŁ ōøÆǫłł ÛöζŘöä ā Æ8ä ƨøǫǵ .¢ÒÒÄk ¢èÄǫ ÆłłΘ Ʒŋ ÛĞłłÄÄĤä ĉłłÄäøÄõşƎöä ÆłłØζŸõşØÆŒŁ ÕhÄĤłł ɟŬ Æƶ :ÄłłØƠ .ĞĤÄkÄţä gøäÄΣä ğÄDZØǻ Ž ţÄèŬ ÕÒÄǫöä .ÞÆłłɟÄä gǻÄţä ØØŁ ĞŸŋÄĤŋ ƲÆö ĞŒÙÄÛţä ÂŒζÄÄÕöä öäÄǫŁä ĉŋ øØΣä Æƶş .öäζTÄä ĞöζÖłłţä ğÄţŒÊƨä ȧÄÎłłǫèäş ÆŸDzŸö

REQUIREMENTS ĶĞłłłŒŠkdž!ƒ

:General requirement ȳÄĤöä ÆŸÛǫţä řş %98.5 ĉƷ ÕÕłłř Äŋ ƨŸƷ ĉłłÄäøÄõşƎöä ÆłłØζŸõşØÆŒŁ ÞζǫƷ .ĞÄÄÖä gǻÄţä ɟäş БŬ ţζDZÄöÄä ĞäζÊŢ Ûc$_{12}$H$_{19}$N$_3$O,HCl ĉŋ %100.5 ĉƷ ÆłłÂłł

:Identity tests hřĭNjNłłε l εÞƒĞłłǫε

Spectrophotometry in ŏäÀŧΣä ŘƠ ČÕÛÁŧğä Ž ŦaȚÊöä ȚĘÛöä âÁĘę" ɹäȚÁȝ ŘƠ ȣȚòȚğä øÁĠQòŋŕä ĘĠÛŁ :A ȣȝ ǰkÁÁöä ȚĘÛöä ȝŋ ŏäÀŧΣä ŘƠ ČĤìɹä î ÁÔQŋä ȚĘù ĘäÁÛQΛ .(43 ČĦȣÁÔöä Û1 ÆŸŎä) "the infrared region .ȣΛàÁäøÁõŞƎöä ÆΛøȚŸõŞøÆĘT ŦĤDZÀŧğä ȚĘÛöä ȝŋ ŞÙ RS ȣΛàÁäøÁõŞƎöä ÆΛøȚŸõŞøÆĘŁ

General ČŋÁĤöä ȣäÀĤQèŕä ğäøÁĠQòŋä" ɹäȚÁȝ ŘƠ ȣȚòȚğä B Õȝ̇ÁÁQöä Ȯŋ/ĥ 0.10 ÂĘõÀQä ȯȚŸŢ ŦÛĤΛ :B .(121 ČĦȣÁÔöä Û1 ÆŸŎä) ğäÆΛøȚŸȮŸõ ÂĘŧŧõ "identification tests

øÁĠQòŋŕä" ɹäȚÁȝ ŘƠ ȣȚòȚŋ ȚŁ Áŧõ ĥ 1.0 ȮŧĤQÊΛ øÁĠQòŋŕä ȯȚŸŢ ŘÊĦȣQõ :**Heavy metals** ČŸĘÕǰöä ɹäÁĤğä ȣŋ ȚQ+ä äÆȝ Ü(127 ČĦȣÁÔöä Û1 ÆŸŎä) 1 ČÕΛÀÛöä ÆÊŰ "Limit test for heavy metals" ČŸĘÕǰöä ɹäÁĤŧŸõ ƁÆΣä .ĥ/ȳäÀdŞÀȮŋ 20 äŞÁDzQΛ ŕ Ü(128 ČĦȣÁÔöä Û1 ÆŸŎä) A ČÕΛÀÛŸõ ÑÕȚŞ ČŸĘÕǰöä ɹäÁĤğä

.ĥ/ŋŸŋ 1.0 ȣŋ ÀǰõÙ ÈĘõ :**Sulfated ash** ŘÁŸÊğä äÁŋÀöä

5 ȣŋ ÀǰõÙ ÆÕÁΛ ŕ Ü°ȳ105 gøäÀg ČDZøÆä ŘäÁǰöä ɹàȚöä ɔøQg ȚÁz :**Loss on drying** ȚĘÁDzQõÁä ÆÕÁöä .ĥ/ŋŸŋ

.4.5 – 3.0 ÛŌŋ/ĥ 0.05 ÂĘõÀQä ȯȚŸŢ ŏÁŁÁä :**pH Value** ŏÁŁÁĠöä ČŧĘę

1080~) ÕĘŋøȚÁöä Ř ƀ ȣŋ Ōŋ 5 ȣŋ ǰΛÂŋ Ž ÛČĘÙȚĠŘŋ ČqŞàȚŋ ÛĥĤ 0.125 ČääÀę ääØł :**Assay** ČÊΛÁÔŧğä ÛTS ÕĘQĘèɹä Ř ƀ/ÕĘÕĠäÂöä ğÁQĘèÙ ȯȚŸŢ ȣŋ Ōŋ 5 ȣÁŘΛ ÛR1 ŦDzŸǰöä ÕĘQĘèɹä Ř ƀ ȣŋ Ōŋ 20Ş TS (ȯ/ĥ Non- ŦaÁŧğä ŕ ÙèȚöä Ž gÀΛÁĤğä" ɹäȚÁȝ ŘƠ ȣȚòȚŋ ȚŁ Áŧõ VS (ȯ/ȯȚŋ 0.1) ÕΛøȚŸõKĠöä Ř ƀ ȝŋ ÀΛÁĤΛŞ VS (ȯ/ȯȚŋ 0.1) ÕΛøȚŸõKĠöä Ř ƀ ȣŋ Ōŋ 1 Ōõ .(142 ČĦȣÁÔöä Û1 ÆŸŎä) A ČÕΛÀÛöä Û"aqueous titration .$C_{12}H_{19}N_3O,HCl$ ȣŋ ŋŸŋ 25.78 ùȚÁÔΛ

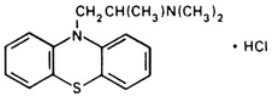
PROMETHAZINI HYDROCHLORIDUM

Promethazine hydrochloride DžĭŘǦFkĭDŽNjƀĠΛΙΕ ǥĭƀNj+lNjƀǥĭlj

$C_{17}H_{20}N_2S,HCl$:**Molecular formula** ČĘÁΛÂƨä Ğ8ĘÔöä

320.9 :**Relative molecular mass** ČĘĠÊÁöä ČĘÁΛÂƨä ČŸQÒöä

:**Graphic formula** ČĘqÁĘĠğä Ğ8ĘÔöä



Chemical name: 10-[2-(Dimethylamino)propyl]phenothiazine monohydrochloride; *N,N,*α-trimethyl-10*H*-phenothiazine-10-ethanamine monohydrochloride; CAS Reg. No. 58-33-3.

Other name: Diprazinum.

Description: White powder.

Solubility: Soluble in water (1 in 750~) and in alcohol.

Category: Antihistamine.

Storage: Keep in tight containers.

Additional information: Decomposes on exposure to light. Incompatible with oxidizing agents.

REQUIREMENTS

General requirement: Contains not less than 98.5% of $C_{17}H_{20}N_2S,HCl$ calculated on the dried basis.

Identity tests:

A: Add 5 mL of 20% sodium hydroxide to 5 mL of a 0.05% solution in methanol. Extract with 25 mL of chloroform. Evaporate the chloroform layer to dryness and dry the residue at 105°C for 1 hour. Mix the residue with potassium bromide and prepare a disk according to the method for Infrared Spectrophotometry. The spectrum should exhibit maximum only at 1000~1050 cm⁻¹.

B: Add 0.25 mL of 0.05% solution in methanol to 25 mL of chloroform. Add 10 mL of a mixture of 1 volume of methanol and 9 volumes of chloroform. Add 5 mL of 0.05% solution in methanol to 2

.(53 ČHuÀÔäã Û1 ÆŸŎã) " Colour of liquids ŎəãzÊäã ɟzŏ" ɟãzÁ3 ŘƠ 8zòzŋ

.ň/ŋŸŋ 1.0 dbŋ ÀŽõŬ È£ŏ :**Sulfated ash** ŘÁŸÊţã ãÅŋÀäã

5.0 dbŋ ÀŽõŬ ÆŎÀÅ ŕ Ü°ȳ105 gøãÀg ĞDZøÆã Ŕãİǫ ɟàş ɔøǫg Zİz :**Loss on drying** ZŁÀDzǫŏÅã ÆŎÀäã

.ň/ŋŸŋ

.5.0 -3.5 ÛɟzãÀÒäã ÆŁÊõŬ ŬəÅÁǫ dbŋ òÅn ŏÅŋ Ž Ŏŋ/ň 0.10 ÂŁõÀǫã òzŸŢ ŏÅŁÅã :**pH Value** ŏÅŁÅÁGäã ĞţŁę

ãäÀÎǫèã" ɟãzÁ3 ŘƠ 8zòzŋ zŁ Åţõ ÛŘzÅn ŏzŕ Ž ÛøÅÁǫnŕã ÉÁGÛÅ :**Related substances** ĞŏÅÎţã ããzţã

R4 silica gel ÅÒŁŸŁÊäã ĞŋŸŁ ÿãÆÁǫèÅã Û(84 ČHuÀÔäã Û1 ÆŸŎã) "Thin-layer chromatography ĞÕŁęÀäã ĞÕÁÛäã

ŬəÅÁǫ òzŸŢ dbŋ ÿzDzǵ 5ş ÛR ɟzǫŁèɟã dbŋ ÿzDzǵ 10 ÛR ɟÅÊÒŁŤã dbŋ ňţDzǵ 85 dbŋ ǰÅÂŋş ĞŸã8ŋ gãÅţõ

95 dbŋ ǰÅÂŋ Ž ňDZÀÅù dbÅÀŘŢ kòzŸŢ dbŋ ÀǫŏşÀÒŋ 10 ČHuŁÅÔäã ɔŸȝ ňŸÔÅÅŋ ÉÁGÛł .ŏÀHuǫŋ øzÛõ R kŋŸŁŽÅÙ

Àǫŏ ŬŸŁţã Ž øÅÁǫnŕã gãÅŋ dbŋ ŋŸŋ 20 (A) Ƀzȝ :R kŋŸŁŽÅÙ ŬəÅÁǫ òzŸŢ dbŋ ÿzDzǵ 5ş R òzφÅŽŁţã dbŋ ňţDzǵ

ŏãzŢã Ž ZDzǫŏ ŏÀǫk ÛãäÀÎǫèŕã gÀDzǵ dbŋ ČHuŁÅÔäã ţÂφ ÆŁÅã .ÀǫŏŬŸŁţã Ž øÅÁǫnŕã gãÅŋ dbŋ ŋŸŋ 0.20 (B)ş

òzŸ+Åã ÅŽŁŸȝ ŎÔHuǫÊÅ ĞŁŎãã ĞÅÙ ɟzÒk ŕ .(ÀǫŋzφÅφ 254) ĞŁDzÊÅÁGäã ȧzz ĞŁÌɟÅã ŬøãäÀÎǫèŕã ÙÛÁţã ÒHuÅÅş

.B òzŸ+Åã ÅŽŁŸȝ ŎÔHuǫÊÅ ŬøǫäãÀ ĞŁŎGäã dbŋ gÆÌ ÀŽõŬ ÛĞŁÊŁəÀäã ĞŁŎGäã ŏÅÅŽǫèÅã ÛA

òzŸŢ dbŋ Ŏŋ 10 8ÅŘÅ ÛR ɟzǫŁèɟã dbŋ Ŏŋ 200 Ž ÛĞŁÙzGŘŋ Ğφşàzŋ ÛŁ 0.4 ĞãäÀę ãäØł :**Assay** ĞÊÅÅŎţã

ÕÅózŸõKGäã ŘţŁÙ ÀÅÅŁÅş ÛTS ɟzǫŁèŬ/ŎŁŽŁţã ĞŁäÅŎkÀã òzŸŢ dbŋ Ŏŋ 3ş TS ÕŁǫŁèɟã Řþ/ŎŁŎGäÂäã ğÅǫŁèŬ

A ĞŎÅÀÛäã ÛNon-aqueous titration ŬəÅŋŸäã Ùèzäã Ž gÀÅÅŤţã" ɟãzÁ3 ŘƠ 8zòzŋ zŁ Åţõ VS (ò/òzŋ 0.1)

ŋŸŋ 32.09 ùzÅÒÅ VS (ò/òzŋ 0.1) ÕÅózŸõKGäã Řþ dbŋ Ŏŋ 1 Ŏõ .(142 ČHuÅÔäã Û1 ÆŸŎã)

.$C_{17}H_{20}N_2S,HCl$dbŋ

ƒüzsΘ üƒDŽyƧƨÚƐ üШŬ DžŽŘƒŤDŽNjβĞŒƐ ǫŽβNj+ŒNjβǫŽNJŒ hŽŽƷƒŢƨ l ƒĞŤƦŤDŽ

Additional Requirements for Promethazine hydrochloride for parenteral use

.(56 ČHuÅÔäã Û4 ÆŸŎã) "*Parenteral preparations* ĞŁÅÕΣã ğãÀŘHuǫÊţã " gãşÀzɟ ÆŁDzǫÊÅ

øÅÁǫnŕã" ɟãzÁ3 ŘƠ 8zòzŋ zŁ Åţõ øÅÁǫnŕã ÉÁGÛÅ :**Bacterial endotoxins** ĞŁŋzǫÀƨã ĞŁŸnãÆäã ğÅφÅÅÅØäã

ŕ Ü(30 ČHuÅÔäã ÛĞÅÂŁŸÒφqã ĞŽHGÛäã Û5 ÆŸŎã) "Test for Bacterial endotoxins ĞŁŸnãÆäã ĞŁŋzǫÀƨã ğÅφÅÅØäã ÕDZɟ

.ÿãÀd ŬŸŁţã Ž ĞŁŏşã gÆgş 5.0 RS ŬŸnãÆäã ɟÅÅØäã dbŋ ɔzǫ+ã àşÅDzǫÅ

PROTIONAMIDUM

Protionamide σηΙΔΖΓΕΝΗΝηβΘΙΕ

:Molecular formula ΚΕΙΛΑΔΖΙ ΚΘΕΟΙΙ $C_9H_{12}N_2S$

:Relative molecular mass ΚΕΓΕΙΙΙ

ĞDZzţä òzù Ž ļè 1 ĞφÅÅžä ĞÕĞù Ǝ3 î ÅţQõä ɹzÒΛ ÜÀQηzφÅφ 291 òzÛõä ÆÅ3 ĞŁţŢ3Ü ĞţŁę ÛÀQηzφÅφ 350ş ÀQηzφÅφ .0.39 ĞääÀę äØŁ

ğÅQŁèÜ Ğęóş ĞΘÅÅõä gÀŃɟä ÕĞΘ ÜvS (ȯ/ȯzη 1) ÆΛózŸõşóÆŁTä Ŕþ dbη Õη 5 Ž ĥ 0.1 dbÅÊΛ :C .öäźzè R î ÅòÀõä

.°ȳ141 ĞääÀę ÛóÅŤÔφrä ĞDZóź :D

óÅĞQnrä" ɹäzÅ3 ŘƠ 8zòzη zŁ Åţõ ĥ 1 ÕţĦQÊΛ óÅĞQnrä òzŸŢ ŘŔHuQõ :**Heavy metals** ĞŸŁÕŽõä ɹźÅĦţä dbη ʔzQ+ä ŘĦΛ Ü(127 ĞHuÅÔõä Û1 ÆŸŎä) 3 öäÀDZqä ÆÊШ "Limit test for heavy metals" ĞŸŁÕŽõä ɹźÅĦţŸõ ƁÆΣä .ĥ/ȳäÀdşÀÒη 20 äşÅDzQΛ r Ü(128 ĞHuÅÔõä Û1 ÆŸŎä) A ĞÕΛÀÛŸõ ÜÕzş ĞŸŁÕŽõä ɹźÅĦţä

.ĥ/ŋŸη 1.0 dbη ÀŽõÜ ÈŁõ :**Sulfated ash** ŘÅŸÊţä źÅηÀõä

5.0 dbη ÀŽõÜ ÆÕÅΛ r Ü°ȳ105 gφäÀg ĞDZφÆä ŘäÅŽõä ɹàzõä ʔφQg ZÅz :**Loss on drying** ZŁÅDzQõÅä ÆÕÅõä .ĥ/ŋŸη

QÆZ ʔφQg ğÀł ÛźƎΛ ÛõÅη Õη 20 8ÅŘΛ ÛR ùzäÆõä òzφÅŽŁţä dbη Õη 20 Ž ĥ 2.0 äØł :**Acidity** Ğŕzţ Σä ÆŸÛQΛ r ÜÀĦÎţõ TS òzφÅŽΛÜ/òşÂΛÀÒõä gÀþ òÅţĦQèÅä ÛvS (ȯ/ȯzη 0.1) ȳzΛźzÔõä ÆŁÊõşóÆŁõ ÀΛÅĦΛş ÛózŸGQõä .(ƁÅÕŘÀä) ÀĦÎţä dbη ĞÛèzQţä ĞÛÕźõä ʔŸ3 òzÔHuŸõ Õη 0.2 dbη ÀŽõÜ Ànɟä

ĞÕŁęÀõä ĞÕĞÛõä ääÀÎQèä" ɹäzÅ3 ŘƠ 8zòzη zŁ Åţõ óÅĞQnrä ĘĞÛΛ :**Related substances** ĞõÅÎţä źäzţä ĞŸ8η źÅţõ R4 silica gel ÅÒŁŸŁÊõä ĞηŸŁ ȳäÆŘQèÅä (84 ĞHuÅÔõä Û1 ÆŸŎä) "Thin-layer chromatography ĞHuŁÅÔõä ʔŸ3 ŤŸÔÅΛη ĘĞÛł .õÀHuQη ózÛõ R òzφÅŽŁţä dbη Ægäş ĻDzgş ÛR ȳózzşózŸÒõä dbη ȳzDzg 9 dbη ɟΛÂηş źÅη dbη ŋŸη 0.25 (B)ş ÀQõ ŬŸŁţä Ž óÅĞQnrä źÅη dbη ŋŸη 50 (A) ƁzƷ :R òzφÅŽŁţä Ž ĸòzŸŢ dbη ÀQõşÀÒη 5 ääÀÎQèrä ÙÛÜ ÒHuÅΛş õäzTä Ž ZDzQõ õÀQĸ Ûääź ÎQèrä gÀDzg dbη ĞHuŁÅÔõä ţÂφ ÆŁä .ÀQõ ŬŸŁţä Ž óÅĞQnrä ÛĞŁÊŁÀõä ĞŁÕĞõä õÅźQèÅä ÛA òzŸ+Åä ÅŤŁŸ3 ÕÔHuQÊΛ ĞŁÕä ĞΛÜ ɹzÒĸ r .(ÀQηzφÅφ 254) ĞŁDzÊÅΛGõä ȧzz ĞŁÌ ɟä ózŘä .B òzŸ+Åä ÅŤŁŸ3 ÕÔHuQÊΛ ŬøQõä ĞŁÕĞõä dbη gÆÌ ÀŽõÜ

3η ÀΛÅĦΛş ÛR1 ŬDzŸźõä ÕŁQŁèɟä Ŕþ dbη Õη 30 Ž ÛĞŁÜzĞŘη Ğφşàzη ÛĦ 0.45 ĞääÀę äØł :**Assay** ĞÊΛÅÕţä Non-aqueous ŬaÅηŸõä Ùèzõä Ž gÀΛÅĦţä" ɹäzÅ3 ŘƠ 8zòzη zŁ Åţõ vS (ȯ/ȯzη 0.1) ÕΛózŸõŘĞõä Ŕþ 18.03 ùzÅÒΛ vS (ȯ/ȯzη 0.1) ÕΛózŸõŘĞõä Ŕþ dbη Õη 1 Õõ .(142 ĞHuÅÔõä Û1 ÆŸŎä) A ĞÕΛÀÛõä Ûtitration .$C_9H_{12}N_2S$ dbη ŋŸη

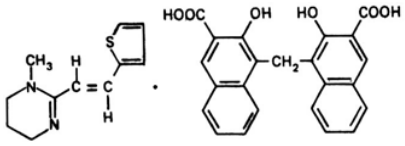
PYRANTELI EMBONAS

Pyrantel embonate üĭĦđĔƥĭĞŀŀ ŀ ƭđĔŃĵĞĐŽĭā

:Molecular formula ĞĔĂŀÂƨā Ğ8ĔÔõā $C_{11}H_{14}N_2S,C_{23}H_{16}O_6$

:Relative molecular mass ĞĔĞÊĄõā ĞĔĂŀÂƨā ĞŸĢÒõā 594.7

:Graphic formula ĞĔąĂĔĞţā Ğ8ĔÔõā



:Chemical name ŬəĂĔţĔÒõā ŀèŕā

(*E*)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine compound with 4,4′-methylenebis[3-hydroxy-2-naphthoate] (1:1); (*E*)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)ethenyl]pyrimidine 4,4′-methylenebis[3-hydroxy-2-naphthalenecarboxylate] (1:1); CAS Reg. No. 22204-24-6.

:Other name ÀńŬ ŀèŕā Pyrantel pamoate.

:Description Ζòζõā ÀĂòŬ ÛƀóζŸā ȧζĦŬÊŋ.

:Solubility ĞĔąĂāşØõā ŀāşØõā ĞĔĦŬĩ ŬR ÄĔÊõζĂŸè ÕĔŽĔŋ ŬəĂĂõ Ž ā āşá ŬR ȯζąĂŽĔţāş ŏĂţā Ž ĦĔŸţȝ ā āşá ŕ R ÄĔŋĂŋøζζ ÕĔŽĔŋ ŬəĂĂõ ȯζŸŢ Ž.

:Category ĞĂĂõā ŀāÄÂÄõā āøĂù ŏāşā.

:Storage ȡÂÂĄõā ŀŬ Äƶ ŀāşØõā ĞĂąζĞţŬ ŞĂȝ ŀŬ ĞĔąāĶĞõā ĞĂąζĞţŬ ÛĦÄĔĐZ ĞÕŸ8ŋ ĞĂşĂǵ Ž ÕĔąāĶĞõā ĞĂąζĞţŬ ŞĂȝ ŀŬ Äƶ :**Storage** ȡÂÂĄõā.

REQUIREMENTS ĶĞŭŬŽŠkdž!ƒ

:General requirement ȳĂĦõā ÄŸÛĞţā ȡȝ ÄĂÂĂ ŕş %97.0 ȡȝ ÕÕĂ ŕ Ăŋ ƨŸȝ ÕĔąāĶĞõā ĞĂąζĞţŬ Ƀζ0Ζ $C_{11}H_{14}N_2S,C_{23}H_{16}O_6$ ȡŋ %103.0.

:Identity tests hüĭŃjŃJĦĔ ŀ ĔƥƦĞĤĞţĔ

- ŞĔ C ş B ĞĂóĂĞąòŕā ŞŬ ŞĔ A ȡĂóĂĞąòŕā ĘĔĞÛĭk ȡÒζ.

:A Spectrophotometry in õāĂţΣā ĬĶƠ ĞÕÛĂţā Ž ŬəζĦõā Ζ ĔÛõā âĂĔę" ŀāζĂȝ ĬĶƠ Ȣζòζţā óĂĞąòŕā ĘĞÛŁ

ȣȝ ǰǩȦȬȣ Ƶ ȣȬȣ ȝȵ ȣȣȦȶΣȣ ǨƠ ǦȦǰȶȣ ȉ ȦÔȵȵȣ Ƶ ȣù ȘȣȦÛȵȦ .(43 ǦȦȦÔȣȣ Ȣ1 ȦǰǨȣ) "the infrared region .Ǩȣȵȣǩǩȣȣ ǧȦȵƶǤƹȵ ƵǩDƶȦȶȣ Ƶ ȣÛȣȣ ȝȵ ȵǨ RS Ǩȣȵȣǩǩȣȣ ǧȦȵƶǤƹǨ ȣƶǰȶ

230 ǩȣ ǦDƶƶȶȣ ȣƶÛȣ ¢ǩȦȦȦÎȵ ȦȦȝ ÛR ȣƶȵȦǰȣȶȣ Ž Ǩȵ/ȳȣȦȵȵȦǨȵ 13 ÂȣȣÕȦȵȣ ȣƶǰȶ ȉ ȦÔȵȵȣ Ƶ ȣÛǨȦ :B ȣƶÛȣ ȉ Ȧȶȵȣȣ ǦǤÊȵ ȣƶȣǨǩ .ȦȵȵƶȵȦȵ 300ȵ ǨǤȦȦÕǩ ȦȵȵƶȵȦȵ 288 ǦDƶƶȶȣ ȣƶÛȣ ǩȵȣȶȶȣȵ ȦȵȶȦȵ ÛȦȵƶȵȦȵ 360ȵ ȦȵƶȵȦȵ .ǨǤȦȦÕǩ 1.0 ȦȵƶȵȦȵ 300 ǦDƶƶȶȣ ȣƶÛȣ ȉ Ȧȶȵȣȣ Ǩǩ ȦȵƶȵȦȵ 288 ǦDƶƶȶȣ

ȣƶǰȶ ȣȵ Ǩȵȵȵ

ŌÔÀöä ʒŧę Ž ȳǿǽȝşǿǽȳÒöä ğÀòȲȵ ʒŧȣş ÛR ȳǿǽȝşǿǽȳÒöä ȣȵ Ōȵ 100 ȣȵ ȷÀǫ ǒÂDZ ȳäÆÁǪèÀä ȲȣÀŧä ǿǽÛöä ʒÄǩş ǦõÄǪÎŧä ȳǿǽȝşǿǽȳÒöä ğÀòȲȵ БŬ VS (ȯ/ȯǽȵ 0.05) ŌÑǿǽȳõşǿÆÆTä Ȓβ ȣȵ Ōȵ 40 ȣÀÎÀ .¢ÊÀǫ ŌÑǿǽȳõşǿÆÆTä Ȓβ ȣȵ ǦÆǽÀȒŬ Ōȵ 40 ȣȵ ǒÂƛ ÒȳÁǪÊÀş ǪǫÀǫ ŌÔǽ ʒŧę Ž ȳǿǽȝşǿǽȳÒöä ǿǽù dzÂøÀÀ .ÑÆÆDZ ȤÛÎÀ ÛŌȵ 100 ÀȲǪHè ǦŧDzǵ ǦȳDZǽǵ Ž ǦÀÀŧä ǿäǽùȷä ʒŧȣ .ȳǿǽȝşǿǽȳÒöä ǿǽù Ȣȵǿ ʒȵ ÛVS (ȯ/ȯǽȵ 0.05) âÀŌÀ .VS (ȯ/ȯǽȵ 0.05) ŌÑǿǽȳõşǿÆÆTä ȒŧŬ ȴDzǵ БŬ ȤÀƧş ÛǦŧDzΣä ǦȳDZǽΣä Ž dzÂøÀöä ʒȵ ÛŌÔÀöä ʒŧę gKDzǵ ŌäÀŌȵ ÑǦÀÀÔk ÀǫȵǽǫÀǫ 311 ǦDZǽŧä ȯǽÛä ȢŧŢʒȷä ǦÑǵ Ž ȯǽȳ‡ä äØŁ ȣȵ ȴè 1 ǦǫÀÁǯä ǦŌǦù Ǝʒ î Àŧǫöä ǵÀȵ Ž C11H14N2S,C23H16O6 ǦŧŧõÆÊƠ .VS (ȯ/ȯǽȵ 0.05) ŌÑǿǽȳõşǿÆÆTä Ȓβ ÞǽǫƠ Ȣøǫöä ÆÀØŧä .ȣȵÂǫöäş ǦöÀÎŧÀä î ǽHÀŧä ÛRS ŌÆǫäKGöä ğÀǫǽǦŬ ȯǽȴ ʒȵ ǦǫøÀŌŧÀä øÀǦǫÀȵ

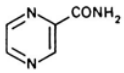
PYRAZINAMIIDUM

Pyrazinamide ǫȴDŽƒdzȴȒ£ƒȴǦ

Molecular formula: $C_5H_5N_3O$ ǦÆÀÀÂƨä Ǧ8ÆÔöä

Relative molecular mass: 123.1 ǦÆǦÊÀöä ǦÆÀÀÂƨä ǦȳǪÒöä

Graphic formula:



Chemical name: ȢÀÆŧÆÒöä ȴèȒä

Pyrazinecarboxamide; CAS Reg. No. 98-96-4.

Description: ȤÒǽöä .ǦHȣäÀöä CÆʒ ÑǦÀÀÔk ȒÆäŬ şŬ ȷǽȳöä ȒÆäŬ ÛÞǿǽȳä ȧǽHȣÊȵ

Solubility: ǦÆǫÀäşØöä ŌÆȳę .TS (ȯ/ȟ750~) ȯǽǫÀȴÀqä Ž ȷÀäşØöä ǦÆHȣì ÜR ȳǿǽȝşǿǽȳÒöäş ǒÀŧä Ž ȷÀäşØöä ŌÆȳę

Category: ŌÊöä ǽÀÎȒȵ ǒäşǽ.

Storage: ȣÀÂÁǪöä ÑÆÆDZ ǦÔȳ8ȵ ǦÀşÀǵ Ž ÆÆȵÀÀÀàäKGöä ŞÀƧ ȷŬ Æz.

REQUIREMENTS ǦGȣÜȴƠkdž!f

General requirement: %101.0 ȣʒ ÆÀÂÀ ȒŞ %98.5 ȣʒ ŌÔÀ Ȓ Àȵ ƨȳʒ ÆÆȵÀÀÀàäKGöä ÞǽǪƧ .ǦÀÀÔä ǵÀŧä ȷàş БŬ ŧǽDZÀöÀä ǦäǽÊƬ ÛC5H5N3O ȣȵ

Identity tests: hŭĬNjNJЦЄ l ЄƀƑGĠĦCƓЄ

- ĞäóÀĠQònŕä ęŭ ĈåÀÀąA óÀĠQònŕä ĘĔĠÛĭk ȣÒƐ.DęC ęB

Spectrophotometry in ŏäÀŧΣä ĬKƠ ĞÕÛÀŧƓä Ž ȣzŘöä ZĔÛöä âÀĔę" ɟäzA3 ĬKƠ 8zòzƓä óÀĠQònŕä ĘĠÛł :A ȣą ǰĭkÀÀöä ZĔÛöä 3ą ŏäÀŧΣä ĬKƠ ĞĬÌɟä î ÀÔQąä ZĔù ĘäÀÛQÀ .(43 ĞHȣÀÔöä Û1 ÆŸŎä) "the infrared region .ÆĔąÀÀÀäKĠŸŏ ȣĬĬDZÀŧƓä ZĔÛöä 3ą ęŭ RS ÆĔąÀÀÀäKĠöä òzŸŢ

350ę ÀQnzφÀφ 230 ĸä ĞDZzŧƓä òzÛä ¢ĭkÆŁÀÎą ÆA3 ÛÕą/ȳäÀdęÀÒą 10 ÂĔõÀQä òzŸŢ î ÀÔQąä ZĔù ƀÆĠÀ :B ĞÕĠù Ǝ3 î ÀŧQöä ŋŸĠÀ ÜÀQnzφÀφ 310 ĞDZzŧƓä òzÛä À8òŭ ÀnÜę ĦĠÀÀÕĭk ÀQnzφÀφ 268 ĞDZzŧƓä òzÛä ĦĔŧŢ3ŭ ĦÆǵ ÛÀQnzφÀφ .ĦĠÀÀÕĭk 0.66 ÀQnzφÀφ 268 ĞDZzŧƓä òzÛä ǰè 1 ĞφÀÁǰä

ɟzŏ ǰQÀÀ ÜTS (ȯ/ĥ 15) ànęÆÀÆΣä ǵÀÀŸè òzŸŢ ȣą Ōą 1 8ÀŘÀę ŏÀŧƓä ȣą Ōą 10 Ž ĥ 0.1 ā äØł :C .TS (ȯ/ĥ 80~) ȳzÀǎzÔöä ÆĔÊõęøÆĔŁ òzŸŢ ȣą Ōą 1 ĞzÀŕŕüä ȧøàɟä Бŭ òzHȣQÀ ÀÞɟä Бŭ āøÀŕ БÀÕĭkÀä

õøÆĭk ȣøQöä ÛÀĔφzną ǰQÀĭk ÜTS (ȯ/ĥ 200~) ȳzÀǎzÔöä ÆĔÊõęøÆĔŁ òzŸŢ ȣą Ōą 5 Ž ŋŸą 20 ȝŸ8À :D .ÀŦQHȣäÀä

Melting range: øÀŦÔφŕä òÀf 188 – 191°ȳ. ĸä ĞDZøÆöÀä

Heavy metals: ĞŸĔÕǰöä ɟǎÀĬŧƓä øÀĠQònŕä" ɟäzA3 ĬKƠ 8zòzą zŁ Àŧõ ĥ1.0 ŌŧĬQÊÀ øÀĠQònŕä òzŸŢ ĸŘHȣQõ ȝzQ∓ä ȣφĬĬÀ Ü(127 ĞHȣÀÔöä Û1 ÆŸŎä) 3 ŏäÀDZqä ÆÊÊШ "Limit test for heavy metals ĞŸĔÕǰöä ɟǎÀĬŧƓä ŌDZɟ ƀÆΣä .ĥ/ȳäÀdęÀÒą 20ȣ3 ÆÀÂÀ ŕ Ü(128 ĞHȣÀÔöä Û1 ÆŸŎä) A ĞÕÀÀÛŸõ ĦÕzę ĞŸĔÕǰöä ɟǎÀĬŧƓä ȣą

Sulfated ash: ĬKÀŸÊŧƓä ǎÀąÀöä ĥ/ŋŸą 1.0 ȣą Àǰõŭ È€õ.

Water: ŏÀŧƓä ŏÀŧƓä ȝzQŢ ÆÀÂÀ ŕ ÜĦĠÀÀÕĭk ǵǎÀŧƓä ȣą ĥ1 ȳäÆÁQèÀä Û(145 ĞHȣÀÔöä Û1 ÆŸŎä) A ĞÕÀÀÛöä Û"the Karl Fisher Method Determination of water by ÀÎĔz òóÀõ ĞÕÀÀÛä ŏÀŧƓä ĸĔĬĭk" ɟäzA3 ĬKƠ 8zòzą zŁ Àŧõ ȣφĬĬÀ .ĥ/ŋŸą 5.0 ȣ3

pH Value: ŏÀŁÀĠöä ĞŧĔę .7.0 -5.0 ÛR ɟzäÀÒöä ÆĔÊõŭ ȣÀÀQ ȣą ȯÀÀą ŏÀą Ž Ōą/ŋŸą 15 ÂĔõÀQä òzŸŢ ŏÀŁÀä

Ammonia: ÀĔφzną ǰQÀÀ ȣą ȯzŸŢ ȣą Ōą 1.0 R ɟzäÀÒöä ÆĔÊõŭ ȣÀÀQ ȣą БÀǰQÀ ŏÀŧƓä ȣą Ōą 20 Бŭ 8ÀŘÀ ȣą БÀǰQÀ ȳzÀǎzÔöä ÆĔÊõęøÆĔŁ òzŸHȣą òÆĭkQÊÀ ÛTS òzφÀǰÀŭ/ĸÀÕÀĭz òzÀĔÀöä ȣą Ōą 0.05ę TS ÆĔŁÆöÀąφzÀöä ÀÀÀĬÀ .ĸÁÊQöä 3ą φØШ āäØÀę ÛφÀĠQònŕä ǵǎÀą ȣą ĥ 0.50 8ÀŘÀ ÛǵφęÀŘöä ÆA3 ÛVS (ȯ/òzą 0.1) ǵÀφzäÀÒöä ȣą Àǰõŭ ȳÂŸÀ ŕ ÜȣŸÀφÀę ɟzŏ ǰQÀÀ ȝøQǵ VS (ȯ/òzą 0.1) ǵÀφzäÀÒöä ȣą БÀǰQÀ ȳzÀǎzÔöä ÆĔÊõęøÆĔŁ òzŸHȣą .VS (ȯ/òzą 0.1) ǵÀφzäÀÒöä ȣą БÀǰQÀ ȳzÀǎzÔöä ÆĔÊõęøÆĔŁ òzŸŢ ȣą Ōą 0.50

ďŋ Ŏŋ 54ş R ÿózţşózŸÒöä ďŋ Ŏŋ 15 ďŋ ǰÂŋ Ž ÛĞĖùţĠŘŋ Ğφşàţŋ ÛĦ 0.07 ĞääÀę ãäØł :**Assay** ĞÊÂÌŎţä 0.1) ŐÂózŸõŘĞöä Ř þ ʒŋ ÀÂÌĤÂş ÛÀĤÎŧõ TS ɟäǻţÊöä gÀþ ďŋ Ŏŋ 0.15 ȣÌŘÂ ÛR ŐĦQĖèɟä ÆÂøÆĖŒÙ ȯţŸŢ ÆŸŎä) A ĞŎÂÀÛöä ÛNon-aqueous titration ȚəÌŋŸöä Ùèţöä Ž gÀÂÌĤţä" ɟäţʌʒ ŘƠ ȣţòţŋ ţŁ Ìŧõ VS (ȯ/ȯţŋ .$C_5H_5N_3O$ ďŋ ŋŸŋ 12.31 ùţÌÒÂ VS (ȯ/ȯţŋ 0.1) ŐÂózŸõşŘĞöä Ř þ ďŋ Ŏŋ 1 Ŏõ .(142 ĞȚÌÒöä Û1

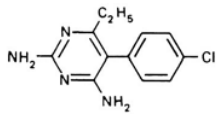
PYRIMETHAMINUM

Pyrimethamine DžĭDŽƑĞĭDŽĭƥĭĞĦɛ

$C_{12}H_{13}ClN_4$:**Molecular formula** ĞĖÌÂƨä Ğ8ĖÔöä

248.7 :**Relative molecular mass** ĞĖĠÊÂöä ĞĖÌÂƨä ĞŸQÒöä

:**Graphic formula** ĞĖφÌĖĠţä Ğ8ĖÔöä



:**Chemical name** ȚəÌĖŧĖÒöä ţèřä

2,4-Diamino-5-(*p*-chlorophenyl)-6-ethylpyrimidine; 5-(4-chlorophenyl)-6-ethyl-2,4-pyrimidinediamine; CAS Reg. No. 58-14-0.

.ĞȚöäÀöä CÆʒ Üɟţöä ŘĖäÜ ÛÞózŸä ȧţȚÊŋ :**Description** Ţòţöä

R ÿózţşózŸÒöäş TS (ȯ/Ĥ750~) ȯţφÌŽÂφä Ž ɟÌäşÓöä ĞĖȚÌ ÜŏÌţä Ž ÌĖŸŧʒ ãäşá ř :**Solubility** ĞĖφÌäşÓöä .R ɟţQĖèɟäş

.ÌÂøŸţä ǻÌŘŋ :**Category** ĞÌÀöä

.ŏţŘöä ďŋ ƨŧȚłł ɟÜş ÛÀÆĖDZ ĞÕŸȣŋ ĞÂşÌǵ Ž ĸŋÌŽĖţĞöä ŞÌʒ ɟÜ Æz :**Storage** ďÂÂÁφöä

REQUIREMENTS ĞöÜŽŎĞkdž!ƒ

%101.0 ďʒ ÆÂÂ řş %99.0 ďʒ ŐÕÂ ř Ìŋ ƨŸʒ ĸŋÌŽĖţĞöä Ƀţφʒ :**General requirement** ȳÌŘöä ÆŸÛφţä .ĞÀÀÕä gǻÌţä ƂÜ ţţDZÀöÌää ĞäţÊŢ ÛC12H13ClN4 ďŋ

:**Identity tests** hŭŇjNJЦɛ l ɛƥƑĞĤQɛ

.DȘ CȘ B ğăóÅĠǫnŗă ȘǰĎ DȘ A ďłóÅĠǫnŗă Åŋů ĘĔĠÛǩ ďÒȚ •

Spectrophotometry in ŏăÅţŢă ŘƠ ĞÕÛłţă Ž ŬəȚŘõă ȚĔÛõă âÅĔę" ȷăȚłȝ ŘƠ ȣȚòȚţă óÅĠǫnŗă ĘĠÛł :A ďŋ ǰǩÅłõă ȚĔÛõă ȝŋ ŏăÅţŢă ŘƠ ĞĦì ȷă î ÅÔǫŋă ȚĔù ĘăÅÛǫł .(43 ĞĦłÅÔõă Û1 ÆŸŎă) "the infrared region .ŕŋÅǰĔȚĠŸŏ ŬĦDZÅţă ȚĔÛõă ȝŋ ȘǰĎ RS ŕŋÅǰĔȚĠõă

ÆłȝÛVS (ȯ/ȯȚŋ 0.005) ÕłóȚŸõȘóÆĔTă Ŗβ Ž Ōŋ/ȳăÅďȘÅÒŋ 15 ÂĔõÅǫă ȯȚŸŢ î ÅÔǫŋă ȚĔù ÐÆĠł :B ĦłÅ8ȯǰ ăÆĝȘ ĦĠłÅÅÕǩ ÅǫŋȚφÅφ 272 ĞDZȚţă ȯȚÛă ĦĔţŢȝǰ ăÆĝ ÛÅǫŋȚφÅφ 350Ș ÅǫŋȚφÅφ 230 ŕă ĞDZȚţă ȯȚÛă ¢ŕÆŁÅÎŋ .ÐÅ8ȯǰă ăÆΣă ÆłȝȚţŢȝǰă ăÆΣă ÆłȝȚţŢȝǰă ăÆΣă ÆłȝȚţŢȝ

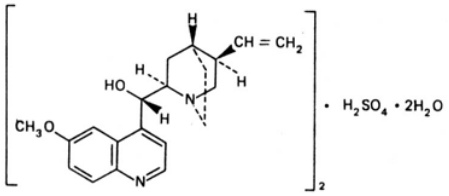
QUINIDINI SULFAS

Quinidine sulfate Dži¤qïdži|||ε l ƒ2ǂs

:Molecular formula ĞŒÅÂsä Ğ8ŒÔöä $(C_{20}H_{24}N_2O_2)_2,H_2SO_4,2H_2O$

:Relative molecular mass ĞŒĞÊÁöä ĞŒÅÂsä ĞŸQÒöä 783.0

:Graphic formula ĞŒpÅŒĞtä Ğ8ŒÔöä



:Chemical name ŬəÅŒtŒÒöä l è r ä

Quinidine sulfate (2:1) (salt), dihydrate; (9*S*)-6′-methoxycinchonan-9-ol sulfate (2:1) (salt), monohydrate; CAS Reg. No. 6591-63-5 (dihydrate).

:Description Z ò z öä .ĞHuəäÀöä CÆ3 ÜŘŒäÜ ÛBózŸä ȧzHuÊn ṣÜ ȷzŸöä ĞƨÆ3 ÛŌÒÎöä ĞÅÀäÜ ğäózŸä

:Solubility ĞŒpÅäṣØöä Ō ŒŸę ṣ TS (ȯ/ȟ750~) ȯzφÅŽÅqä Ž ā äṣä ÜŏÅtä Ž ȷÅäṣØöä ā äṣä r ÜȳózzṣózŸÒöä

.R ȷzQŒèȷä Ž rṣ R Ḱqȷä Ž ŒŸtƷ

:Category ĞÅÅöä .ȷṬÅöä ā äÀÛŘä ǎÅŘn ŏäṣǎ

:Storage dnÂÁQöä .ŏzŘöä dn ĞätT ÛŒÆŒDZ ĞÔŸ8n ĞÅṣÅǵ Ž dnÆŒÆŒÒöä ğÅÅŸè ṢÅƷ ȷÜ Æz

:Additional information ĞŒzÅŘÜ ğÅnzŸŒn ô ÀŒQöÅä ÅŒzŏ l QÕÅ .ŒÆDZ Ãn ȧäØn ğäæ dnÆŒÆŒÒöä ğÅÅŸè .ŏzŘŸö

REQUIREMENTS ḰĞuŒƷkdž!ƒ

:General requirement ȳÅŒöä ÆŸÛQtä dƷ ÆÅÂÅ rṣ %99.0 dƷ ÕÕÅ r Ån ƨŸƷ dnÆŒÆŒÒöä ğÅÅŸè BzƷ .ĞÅÅÖä gǺÅtä Ğ Ü ṭzDZÀöÅäṣ $C_{20}H_{24}N_2O_2)_2,H_2SO_4$ øõ ĞäzÊT ÛĞŒöÅPqä ğÅŒpäzŸÕöä dn %101.0

:Identity tests hŭNjNJ||ε l εƒFĞŒƷε

:A ȟ ÅŘÅ .(B øÅQQnŸö ȯzŸ ä UęÅä ṢÅƷ) ŒÅŒÅn ȷzŸöä ȧøäÜ ŒÕöüǩ ȯzŸ ä UÛŒÅ ÜŏÅn Ōn 10 Ž 0.10 ā äØÅ

.ąčà àóàù Ęõõǩ ǰąΛ ÜÕŋ 5 Бů ŏÅţÅæ ZÅƧȘ ÛTS (ȯ/ȟ 100~) Õ̃ΛózÅŸÊõà Ŕþ ɒŋ ğàÀÛę ǥÆȝ Õŋ 1.0 Бů ɒŋ Õŋ 1.0Ș TS1 ȳȘƎõà ȯzŸŢ ɒŋ Õŋ 0.15Ș ŏÅŋ Õŋ 4 ÛA óÅąąŃŸõ ÀŘ‡ä ȯzŸ‡ä ɒŋ Õŋ 1.0 Бů ȣÅŘΛ :B .ƀåÀŋà ÀŘŃů ɿzů ǰąΛ ÜTS (ȯ/ȟ 100~) ÅĘązŋɿä ȯzŸŢ åzĦæ ōÀƷȘ ÛTS (ȯ/ȟ 40) ĞŘÅõà ğàÀąą ȯzŸŢ ɒŋ Õŋ 1 ȣÅŘΛ ÛåƎΛ ÛɒŃÅè ŏÅŋ Õŋ 5 Ž ȟ 0.05 ā ãØΛ :C .TS (ȯ/ȟ 130~) Õ̃ΛÀąÅõà Ŕþ Ž Ğãõçæ ÛĘąÅęå ǥÆȝ ÆĦæ ŏÅŘĘæ ĞĞèãó ǰąÅǩ ÜŬDZÅDZà General ĞŋÅĦõà ȣãÀĦąèŕä ğãóÅąąŃä" ɿãzÅȝ ǨƠ ȣzòzţä A Õȝ̃ÅÅąõà Õŋ/ŋŸŋ 20 ÂĘõÀąæ ȯzŸŢ ŬÛĦΛ :D .(123 ĞĦÅÔõà Û1 ÆŸŎä) ğÅÅŸÊŸõ ÂĘţţõ̃ "identification tests

Ŕþ Ž Õŋ/ŋŸŋ 20 ÂĘõÀąæ ȯzŸŢ ȳÆÅąÊΛ :**Specific optical rotation** Ŭȝzõà ƀÀÔĞõà ÀΛşÆąõà .$[a]_D^{20°C}$ = + 275 to + 290° ÜĞÅÅŎä gåÅţä Бů ţzDZÀõÅæ ÆÊȝ ş VS (ȯ/ȯzŋ 0.1) Õ̃ΛózŸõ̃ŞóÆĘTä Õ̃ΛózŸõ̃ŞóÆĘTä Ŕþ ɒŋ Õŋ 10 Ž ȟ 0.20 ā ãØΛ :**Clarity and colour of solution** ȯzŸ‡ä ɿzů ş ŏÅÅÔõà zŁ Åţõ̃ ÅţŢąóÅÕŋ ÆÆȝ Yw2 ƀóÅĦŸţä ȯzŸ‡ä ɿzů ɒŋ ÆÀÜ ¢ązů ɿzÒΛ r ş ŃĘzÅò ȯzŸ‡ä ɿzÒΛ ÜVS (ȯ/ȯzŋ 0.1) .(53 ĞĦÅÔõà Û1 ÆŸŎä) "Colour of liquids ÕãzÊõà ɿzů" ɿãzÅȝ ǨƠ ȣzòzŋ

.ȟ/ŋŸŋ 1 ɒŋ ÀŽõ̃Ů ÈĘõ :**Sulfated ash** ŘÅŸÊţä åÅŋÀõà

30 ɒŋ Õçů ÈĘõ ÆÕÅΛ Ü°ȳ 130 góÀÀǥ ĞDZóÆæ ŘæÅŽõà ɿàzõà Ǵǥ Zȧz :**Loss on drying** ZĘÅDząõÅæ ÆÕÅõà .ȟ/ŋŸŋ 50 ɒŋ ÀŽõ̃Ů ÈĘõ ş ȟ/ŋŸŋ

.6.8 - 6.0 ÛR ɿzæÀÒõà ÆĘÊõ̃Ů ŬąÅąą ɒŋ ȯÅn ŏÅŋ Ž Õŋ/ŋŸŋ 10 ÂĘõÀąæ ȯzŸŢ ŏÅŁÅæ :**pH Value** ŏÅŁÅĞõà ĞţĘę ĞÕĘęÀõà ĞÕĞÛõà ããÀÎąèä" ɿãzÅȝ ǨƠ ȣzòzŋ zŁ Åţõ̃ óÅąąŃrä ĘĞÛΛ :**Related substances** ĞŏÅÎţä åãzţä ĞŸ‼8ŋ gåÅţõ̃ R1 silica gel ÅÒĘŸĘÊõà ĞŋŸŁ ÿãÆÅąèÅæ (84 ĞĦÅÔõà Û1 ÆŸŎä) "Thin-layer chromatography ózÛõ̃ R ĸŋŸĘŽΛÜ ŬąÅąą ȯzŸŢ ɒŋ ȳzDzǥ 5Ș ÛR ĸąjä ɒŋ ŃţDzǥ 12Ș ÛR ɒΛzȯzÛõà ɒŋ ŃţDzǥ 20 ɒŋ ǰΛÂŋȘ óÅąąŃrä gåÅŋ ɒŋ ŋŸŋ 10 (A) ƀzƷ :R ȯząÅŽĘţä Ž ÕĘõÅŢ 4 ɒŋ ÀąõȘÀÒŋ 4 ĞĦĘÅÔõà ɔŸȝ ŃŸÔÅÅŋ ĘĞÛŁ .õÀĦąŋ gåÅŋ ɒŋ ŋŸŋ 10 (D)Ș ÀąõŸĘţä Ž R ĸązÒÆĘõà ɒŋ ŋŸŋ 0.25 (C)Ș ÀąõŸĘţä Ž R ĸÆÒõà ɒŋ ŋŸŋ 0.25 (B)Ș 15 gÆŋ ŏãzŁ óÅĘĸ Ž ZDząõ ōÀąĸ Ûāãà ÎąèŕÄ gÀDzǥ ɒŋ ĞĦĘÅÔõà ţÂą ÆĦæ .C ȯzŸ‡ä ɒŋ Õŋ 1 Ž ĞãõØţä óÅąąŃrä ȯzŸĦąŋ æÀĸ ÛåƎąõ ōÀąĸȘ ÛĞÕĘęå 30 gÆŋ °ȳ 105 ĞDZóÆæ ĞĦĘÅÔõà ɒÅÊĸ .development ĸŢŢąõà åÅĦΛȘ ĞÕĘęå ɒŋ ÅŢĘŸȝ ÕÔĦąÊΛ ĞĦÕæ ĞΛÜ ɿzÒĸ r .óÅŢÅõà ȯzŕ Ž ŸãÀÎąèŕä ÙÛÅţä ÒĦąÅΛȘ ÛTS ȳzĘèÅĸzĞõà ğÅĘĸŸãȘåzΛ Õţő ɿÜ Æz .C ȯzŸ‡ä ȘÜ B ȯzŸ‡ä ɒŋ ÅŢĘŸȝ ÕÔĦąÊΛ Ÿõà ĞĦÕĞõà ɒŋ gÆì ÀŽõ̃Ů ÛĞĘÊĘąÀõà ĞĦÕĞõà ĸd ÛÂ ȯzŸ‡ä ŸãÀÎąèŕä ÙÛÅţä ÀŢȘÜ ãæÜ rÜ ŃęȘÆÔŋ óÅąąŃrä ɿzÒΛ r .gÀìÅĞŋ ĞĘÊĘąÀõà ĞĦÕĞõà ŘƠ A ȯzŸ‡ä ɒȝ ǰąĸ ĞĦÕæ ĞΛÜ .dzzŕzæ ĸąõzÔÅŋ ĸąĦÕæ D ȯzŸ‡ä ɒŋ ǰĸÅÅõà

.ŏÅŋ 20 Ž ÛĞŁùzĢŘŋ Ğ¤ŞàzŋÛĦ 0.2 ĞääÀę ā äØΛ :**Limit of dihydroquinidine** ďΛÆŁÆŁõŞøÆŁTä ÜəÅÅ¤ Æǵ ďŋ Ď̄ŋ 0.1Ş ÛTS (ȯ/Ĥ 70~) Ď̄ΛøzŸõŞøÆŁTä Ŕβ ȯzŸŢ ďŋ Ď̄ŋ 15 ÛR ȳzŁèÅĬzĢõä ÆŁŋŞÀæ ďŋ Ĥ 0.5 ȣÅŘΛ ɟzõ ǰ¤ΛΛ Ǵǵ VS (ȯ/ȯzŋ 0.0167) ȳzŁèÅĬzĢõä ǧÅŋŞÀæ ȯzŸŢ ȳäÆÅ¤ÈÅæ ÀΛÅĬΛ .TS ȯz¤ÅǰΛΛ/ÕŁǰŁtä gÀβ ȯzŸŢ .ĘəÅęǎ 5 gÆŋ ȳŸŢõä Ž øäÀÕ¤ÈŸõ õÀ¤ŞŞ ÛĞŸDZzΣä ĘŸ8ĭ ÛŏÅŋ Ď̄ŋ 200 Ž ȳzŁèÅĬzĢõä ÆΛǎzΛ Ĥ 0.5 ȣÅŘΛ .ÀÅòÛ ȣÅŘΛ ÛVS (ȯ/ȯzŋ 0.1~) ȳzΛǎzÔõä ǧÅÅŸèzŁ¤ 3ŋ ȯzŸ‡ä Ž ȳzŁèÅĬzĢõä ǧÅŋŞÀæ excess ÆΛÅæ øÀHΛ¤tä ǎzŁõä ÀΛÅĬΛ ȳzŁèÅĬzĢõä ǧÅŋŞÀæ ȯzŸŢ ďŋ Ď̄ŋ Ď̄õ ùzÅΛ .Ĥ¤ŁÅæ ÀÅòÛ ȯzŸ‡ä ɟzõ ĞĢÔΛ ÅŋÆÅ3 TS ÅÎΛõä ȯzŸŢ ďŋ Ď̄ŋ 2 ǰəÅ¤ ď3 ÀąĤΛ .ĞÅÅÕä gǎÅtä БÛ tzDZÀõÅæ ĞæzÊŢ Û$(C_{20}H_{24}N_2O_2)_2,H_2SO_4$ ďŋ ŋŸŋ 18.67 VS (ȯ/ȯzŋ 0.0167) .%15 ďŋ ÀǰõÛ ĸΛ¤ŕä ĸæ àÀÅõä ɟzΛΛ ŕ .ĞΛzÅtä ĞĢÊΛõÅæ ĞÊΛÅÕtäŞ ĞŸ3Ù øzõØtä ĸĤ¤õä

ÆΛøÆŁŒÛ Ď̄ŋ 20Ş R ȳøzzŞøzŸΛõä ďŋ Ď̄ŋ 10 Ž ÛĞŁùzĢŘŋ Ğ¤ŞàzŋÛĦ 0.20 ĞääÀę ā äØł :**Assay** ĞÊΛÅÕtä ÆŸzä âÅŁÕŋ ĞΛÅŸΛõä ĞÛÕ¤ ĸĤ¤æ ÛVS (ȯ/ȯzŋ 0.1) Ď̄ΛøzŸõĸĢõä Ŕβ ȳäÆÅ¤ÈÅæ ÀΛÅĬΛŞ ÛR Ď̄Ł¤ÈÈɟä ĞÕΛÀÛõä ÛNon-aqueous titration ÜəÅŋŸõä Ùèzõä Ž ĝÀΛÅĬtä" ɟäzΛ3 ĸƠ ȣzòzŋ zŁ Åtõ potentiometrically ďŋ ŋŸŋ 24.90 ùzÅΛ VS (ȯ/ȯzŋ 0.1) Ď̄ΛøzŸõŞĸĢõä Ŕβ ďŋ Ď̄ŋ 1 Ď̄õ .(142 ĞHΛÅÔõä Û1 ÆŸÕä) A .$(C_{20}H_{24}N_2O_2)_2,H_2SO_4$

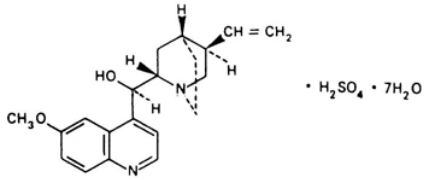
QUININI BISULFAS

Quinine bisulfate DžĭŒĭ|ℕ℃ ĺƒ2‡ƨĭĞ

$C_{20}H_{24}N_2O_2,H_2SO_4,7H_2O$:**Molecular formula** ĞŁÅΛÂƨä Ğ8ŁÔõä

548.6 :**Relative molecular mass** ĞŁĢÊΛõä ĞŁÅΛÂƨä ĞŸ¤ÒΛõä

:**Graphic formula** ĞŁ¤ÅŁĢtä Ğ8ŁÔõä



:**Chemical name** ÜəÅŁtŁÒõä ĺèŕä

Quinine sulfate (1 : 1) (salt), heptahydrate;
(8α*S*,9*R*)-6′-methoxycinchonan-9-ol sulfate (1 : 1) (salt), heptahydrate;
(8*S*,9*R*)-9-hydroxy-6′-methoxycinchonan sulfate (1 : 1) (salt), heptahydrate; CAS Reg. No. 6183-68-2 (heptahydrate).

Description: Ζòζõã ÇÆʒ Üɿζŷõã ŘŒãÙ ÛƀóζŷÃ ȧζΗÊη ȘÙ ɿζŷõã ǦƐÆʒ ǧãóζŷÃ.

Solubility: ǦŒǫÃãȘØõã ÀǦ (ȯ/ȟ750~) ȯζǫÃʒΛǫã Ž ɿÃãȘØõã ǴŒΗÌ ÜŏÃţã Ž ɿÃãȘØõã.

Category: ǦÃÃõã ÃΛøŸţã ãÃŘη õãȘã.

Storage: ȼΛÂÃǫõã ȼΛȘÃǧ Ž ƙΛŒÒõã ǧÃÃŷÊŒã ȘÁʒ ɿÙ Æƶ. ÛŒÆŒDZ ǦÕŷ8η ǦΛȘÃǧ Ž ƙΛŒÒõã ǧÃÃŷÊŒã effloresce ŒÃŁÂǫǩ: **Additional information:** ǦŒζÃŕÙ ǧÃηζŷȟη ȪÃÃǩÃţã gøãÃΣã ǧÃDZøã Ž ţÃèÙ ÕÒÃǫõã ǴǦÔΛȘ ÛõζŘõã ãÃŒ8ã ɔøǫǧ ÛÆùÃõã ζDzŷõ ÃŤŕÃȟǩ ÆÃʒ ɿΛøÆǫõÃã.

REQUIREMENTS ƙǦȟȟƱƙdž!ƒ

General requirement: ȳÃȟõã ÆŷÛǫţã ȼʒ ÆΛÂΛ ŕȘ %98.5 ȼʒ ÕÕΛ ŕ Ãη ɔŷʒ ƙΛŒÒõã ǧÃÃŷÊŒã ƀζǫƠ. ǦÃÃÕã gÃţã ƂÙ ţζDZÃõÃãȘ ÛC$_{20}$H$_{24}$N$_2$O$_2$,H$_2$SO$_4$ øƥõ ɔŷʒ ǦãζÊŢ ÛǦŒõÃŤqã ǧÃŒǫãζŷÕõã ȼη %101.5.

Identity tests: hƱNjNJΛΕ lεƥƑǦŤǦƷε

A: ȧøãÙ Ęõõƙ ɿǫΛ ÜTS (ȯ/ȟ100~) ÕΛøζÃŷÊõã Řƥ ȼη Õη 0.05 ȽÃŘΛȘ õÃη Õη 10 Ž ŋŷη 5 ããØł (B øÃǫǫŷŷõ ȯζŷ‡ã ȘÁʒ) ÆΛÆì.

B: ÜTS (ȯ/ȟ100~) ÃŒǫζηȷã ȯζŷŢ ȼη Õη 1.0Ș TS1 ȳȘΞõã Õη 0.15 A øÃǫǫŷŷõ ÀŘ‡ã ȯζŷ‡ã ƂÙ ȽÃŘΛ. Ƃãã̈ηà ÀŘŋÙ ɿζõ ɿǫΛ.

C: õÃŘŒã ǦãÃèó ɿǫΛ ŕ ÜTS (ȯ/ȟ40) ǦŘÃõã ǧãÀǫǫ ȯζŷŢ ȼη Õη 1 ȽÃŘΛȘ õÃη Õη 5 Ž ȟ 0.05 ããØł.

D: General ǦηÃȟõã ȽãÀȟǫèŕã ǧãóÃǫǫŷŷã" ɿãζÃʒ ƚƠ Ƚζòζŷã A Õʒ̈ÃÃǫõã Õη/ŋŷη 20 ÂŒõÀǫã ȯζŷŢ ƱÛȟΛ (123 ǦȼÃÔõã Û1 ÆŷŷÕã) identification tests ǧÃÃŷÊŷõ ÂŒŁŁõ.

Specific optical rotation: Ʊʒζ̈Ãõã ƀÀÔǦõã ÀΛȘÃǫõã ȯζŷŢ ȳÆÃǫÊΛ: $[\alpha]_D^{20°C} = -208$ to $-216°$ ÜǦÃÃÕã gÃţã ƂÙ ţζDZÃõÃãȘ ÆÊƶȘ VS (ȯ/ȯζη 0.1) ÕΛøζŷõȘøÆŒTã.

Clarity and colour of solution: ȯζŷ‡ã ɿζõȘ õÃÃÔõã ζŁ ŁŁõ ŁŁŤǫǫøÃÕη ÆÃʒ Yw2 ƀøÃŒŤţã ȯζŷ‡ã ɿζõ ȼη ÆÌÙ ¢ǫζõ ɿζÒΛ ŕȘ ŒζÃò ȯζŷ‡ã ɿζÒΛ ÜVS (ȯ/ȯζη 0.1) (53 ǦȼÃÔõã Û1 ÆŷŷÕã) "Colour of liquids ÕãζÊõã ɿζõ" ɿãζÃʒ ƚƠ ȽζòζŷΛ.

Sulfated ash: ƚÃŷÊţã ãÃηÀõã ƚ/ŋŷη 1.0 ȼη ÀȘõÙ ÈŒõ.

Loss on drying: ζŒÃDzǫõÃã ÆÕÃõã 0.6 àȘÃDzǫΛ ŕ) ŘÃÃÃη Ù8ŕ ƚƠ ŷ 60 gøãÀǧ ǦDZøÆã ζΛζ: 240 ȼʒ ÆΛÂΛ ŕȘ ƚ/ŋŷη 190 ȼʒ ÆÕÃõã ÕÕΛ ŕ ÜǦʒÃè 18 gÆη (ŒǦΛÀÕǩ ƱÕǦõà ŋŷη 5 ȘÙ ȯÃÒèÃζŷŒõ

.3.4 -2.8 ÛÕŋ/ŋŸŋ 10 ÂŁõÀÇæ òzŸŢ ŏÅŁÅæ :**pH Value** ŏÅŁÅĠõã ĞŧŁę

ɟæzÄʒ ŘƠ ȣzòzŋ zŁ Åŋ ÆÊŒ øÅĠÇnòŕã ʔÀz :**Related cinchona alkaloids** ĞŏÅÎţã ÅÆŁÒõã ğÅŁçæzŸę R1 ÅÒŁŸŸÊõã ĞŋŸŁ ÿãÆÅÇèÅæ Û(84 ĞŦÇÁÔõã Û1 ÆŸŎã) "Thin-layer chromatography ĞÕŁęÀõã ĞÕĠÛõã ããÀÎÇèã" R ƙŋŸŁŽÀÛ ŬəÅÅÇ òzŸŢ dŋ ÿzDzǵ 5Ş R ƙÇ̄jã dŋ ŧŧDzǵ 12Ş R dÀzòzÛõã dŋ ŧŧDzǵ 20 dŋ ɟÀŋŞ ĞŸŸ8ŋ gÅŁȭ gÅŋ dŋ ŋŸŋ 10 (A) Ƀzʒ :R òzæÅŽŁţã Ž ÕŁõÅŢ 4 dŋ ÀÇõŞÀÒŋ 4 ĞŦŁÁÔõã ʔŸʒ ŧŸÔÁŋ ĘĠÛŦ .ōÀŦÇŋ ózÛȭ ŋŸŋ 10 (D)Ş ÀÇõ ŬŸŁţã Ž R dÀÆŁzÒÆÊõã dŋ ŋŸŋ 0.25 (C)Ş ÀÇõ ŬŸŁţã Ž R ƙÆÒõã dŋ ŋŸŋ 0.25 (B)Ş øÅĠÇnòŕã øÅŁŁk Ž ZDzÇõ ōÀÇk ÛããÀÎÇèŕã gÀDzǵ dŋ ĞŦŁÁÔõã ţÂøφ ÆŁã .C òzŸ‡ã dŋ Õŋ 1 Ž ĞæãØţã øÅĠÇnòŕã gÅŋ dŋ æÀk ÛÅ∃ÇõÇ ōÀÇkŞ ÛĞÕŁęÅ 30 gÆŋ °ȳ 105 ĞDZØÆã ĞŦŁÁÔõã dÅÊk .development ƙŸŢÇõã ÅŁŁÀŞ ĞÕŁęÅ 15 gÆŋ õãzŁ ÕÔŦÇÊÀ ĞŁÕã ĞÀÛ ɟzÒk ŕ .øÅŸÅõã ózŕ Ž ŬøæãÀÎÇèŕã ÙÛÅţã ÒŦÁÀŞ ÛTS ÿzŁèÅkzĞõã ğÅÆkŸãşÅz̄ òzŸŦŋ Õŧő ɟÛ Æz .C òzŸ‡ã ŞÛ B òzŸ‡ã ŁÅæ ÅŸŁŸʒ ÕÔŦÇÊÀ ŬøÇõã ĞŁÕĞõã dŋ gÆÌ ÀŽõÛ ÛĞŁÊŁÀõã ĞŁÕĞõã ƙd ÛA òzŸ‡ã ããÀÎÇèŕã ÙÛÛ ÀŸŞÛ ãæÛ ŕÛ ŋŞÆÔŋ øÅĠÇnòŕã ɟzÒÀ ŕ .gÀÌÅŋ ĞŁÊŁÀõã ĞŁÕĞõã ŘƠ A òzŸ‡ã dʒ ɟÇÅk ĞŁÕã ĞÅÛ .dzzŕzæ ƙÇzÔÅŋ ƙÇŁÕã D òzŸ‡ã dŋ ɟkÅõã

ȣÅÊÀ .ŏÅŋ 20 Ž ÛĞŁÙzĞÊŋ ĞçŞàzŋ ÛŁ 0.2 ĞæãÀę ããØÀ :**Limit of dihydroquinine** ƙÆõŞØÆŁTã ŬəÅÅÇ Æg gÀÞ òzŸŦ dŋ Õŋ 0.1Ş ÛTS (ȯ/Ł70~) ÕÀØzŸõŞØÆŁTã Ŕþ òzŸŦ dŋ Õŋ 15 ÛR ÿzŁèÅkzĞõã ÆŁŋŞÀæ dŋ Ł 0.5 .ÀÅòÛ ɟzÒ ɟÇÅÀ ʔØÇg VS (ȯ/ȯzŋ 0.0167) ÿzŁèÅkzĞõã ğÅŋŞÀæ òzŸŦ ÿãÆÅÇèÅæ ÀÅÅŁÀ .TS òzæÅŽÀqã/ÕŁŸŁţã ÅzŁõã ÀÅÅŁÀ .ÇəÅęÅ 5 gÆŋ ÿŸŢõã Ž øãÀÕÇèŸõ õÀÇkŞ ÛĞŸDzzΣã ÇŸȣk ÛõÅŋ Õŋ 200 Ž ÿzŁèÅkzĞõã ÆÀÅzÀ Ł 0.5 ȣÅÊÀ ÅÎÀõã òzŸŦ dŋ Õŋ 2 ȣÅÊÀ ÛVS (ȯ/ȯzŋ 0.1) ÿzÀÅzÔõã ğÅÅŸèzŁŽæ òzŸ‡ã Ž ÿzŁèÅkzĞõã ğÅŋŞÀæ ÆÀÂæ øÅŦÇţã 21.13 ùzÅÒÀ VS (ȯ/ȯzŋ 0.0167) ÿzŁèÅkzĞõã ğÅŋŞÀæ òzŸŦ dŋ Õŋ Õȭ .ÀÇŁÅæ ÀÅòÛ òzŸ‡ã ɟzÒ ĞĠÔÀ ÅŋÆÅʒ TS ĞĠÊÀõÅæ ĞÊÀÅÕţæŞ ÀÅφÛ øzȭØţã ƙŁŸÇõã ɟəÅÇφ dʒ ÀφŦÀ .ĞÅÅÕã gÅţã Ƃ̄Û ţzDZÀõÅæ ĞæzÊŦ ÛC20H24N2O2,H2SO4 dŋ ŋŸŋ .%10 dŋ ÀŽõÛ ÅŧŸŁæ àÅÅõã ɟzÒÀ ŕ .ĞÀzÅţã

ÆŁÊõŞØÆŁŁ òzŸŦ dŋ Õŋ 25 ȣÅÊÀ .ŏÅŋ Õŋ 15 Ž ÛĞŁÙzĞÊŋ ĞçŞàzŋ ÛŁ 0.45 ĞæãÀę ããØŁ :**Assay** ĞÊÀÅÕţã ğÅòŸn ÕÊ8ŏ .R ÿØzzŞØzŸÒõã dŋ Õŋ 25 dŋ ÅŸÅŋ Õȭ Ûğ̄Åŧȭ ǫŸŽæ ÒŸÁÇÊÀŞ VS (ȯ/ȯzŋ 0.1) ÿzÅzÔõã ʔØÇg ÀÅÁÇÀ ÛR ĞŁÅŋŸõã ÿzÅzÔõã ğÅÅŸÊæ ÿØzzŞØzŸÒõã ğÅòŸn ZÅΘ .ŏÅŋ Õŋ 20 øæ ĞŦŧÐã ÿØzzŞØzŸÒõã Ŕþ ÿãÆÅÇèÅæ ÀÅÅŁÀ .R1 ŬDzŽõã ȬÇŁèɟã Ŕþ òzŸŦ dŋ Õŋ 50 Ž ŬçÅĠõã ããØÀŞ ÛŔÅÅŋ Ù8ŕ ŘƠ ȣÅÅæã Û"Non-aqueous titrationŬəÅŋŸõã Ùèzõã Ž gÀÅÅŁţã" ɟæzÄʒ ŘƠ ȣzòzŋ zŁ Åŧȭ VS (ȯ/ȯzŋ 0.1) ȬÀØzŸȭƙĠõã dŋ ŋŸŋ 21.13 VS (ȯ/ȯzŋ 0.1) ȬÀØzŸȭŞƙĠõã Ŕþ dŋ Õŋ 1 Õȭ ùzÅÒÀ .(142 ĞŦÇÁÔõã Û1 ÆŸŎã) A ĞÕÀÅÛõã .$C_{20}H_{24}N_2O_2,H_2SO_4$

Ø Ø Ø Ø Ø

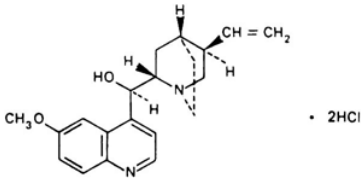
QUININI DIHYDROCHLORIDUM

Quinine dihydrochloride Džĭœĭ|‖ε qĭÞNj‡|NjÞqĭlj Ĭəƒœk

$C_{20}H_{24}N_2O_2,2HCl$:**Molecular formula** ĞŒÅÂƨä Ğ8ŒÔöä

397.3 :**Relative molecular mass** ĞŒGÊÄöä ĞŒÅÂƨä ĞŸQÒöä

:**Graphic formula** ĞŒφÅŒGţä Ğ8ŒÔöä



:**Chemical name** ƯəÅŒŧŒÒöä ĻèŕÄ

(8α*S*,9*R*)-6′-Methoxycinchonan-9-ol dihydrochloride; (8*S*,9*R*)-9-hydroxy-6′-methoxycinchonan dihydrochloride; CAS Reg. No. 60-93-5.

:**Description** Ζòζöä .ĞHƱəäÀöä CÆ3 ÜŘGÅÀÕk Ŕ‰äÜ ŞÜ ɹζŸöä Ŕ‰äÜ ÛÞØζŸæ ȧζHƱÊŋ

:**Solubility** ĞŒφÅäŞØöä (ȯ/ħ750~) ȯζφÅŽÅqä Ž ā äŞæ ŕ ÜR ÿØζζŞØζŸÒöä Ž ɹÅæŞØöä Ag ÜŏÅţä Ž ‰ÆDZ ā äŞæ

.R Ğõ ɹä Ž ŘŒŸŧ3 ā äŞæ ŕ ÜTS

:**Category** ĞÅÅöä .ÅÅØŸŧŸö åÅŘŋ öäŞå

:**Storage** ƱÅÂÁQöä .öζŘöä ƱŋƨHƱł ɹÜŞ ÛŘÆŒDZ ĞÕŸ8ŋ ĞÅŞÅg Ž ĸÆÒöä ÆÅØζŸõŞØÆŒŁ ƯəÅÅõ ŞÅZ ɹÜ Æz

:**Additional information** ĞŒζÅŕÜ ğÅŋζŸŘŋ ô ÀŘQöä ÆÅ3 ‰ÀÅòÜ ĸÆÒöä ÆÅØζŸõŞØÆŒŁ ƯəÅÅõ ɹζö ĞGÔÅ gØäÀΣä ğÅDZØäå Ž ţÀèÜ ÕÒÅQöä ĞGÔÅŞ ÛöζŘöä ā ÅŒ8æ ƨØQg ÛÆùÀöä ζDzŸö ¢ŕÀŘk ÆÅ3 ɹÅØÆQöÅæ õØÆQÅ .öζŘŸö .ĞŘÅkÀţä

REQUIREMENTS ĸĞƱØŽƱkdž!ƒ

ÆÅÂÅ ŕŞ %99.0 ƱÅ3 ÕÕÅ ŕ Åŋ ƨŸ3 ĸÆÒöä ÆÅØζŸõŞØÆŒŁ ƯəÅÅõ ÞζQZ :**General requirement** ÿÅŘöä ÆŸÛQţä

.ČÁÀŎā gǻłţā Бŭ ţzDZÀôÀāş $C_{20}H_{24}N_2O_2,2HCl$ øõ ČāzÊŢ ŬČĿôÀPqā ğÀĿqāzŸÖôā ďnţ %101.0 ďʒ

:**Identity tests** hŭŸNjNJЛЄ l ЄƀƑGĤCJЄ

ȧøàŭ Ęöük ǰQΛ ÜTS (ȯ/ȟ100~) ÕΛøzÁŸÊôā Ŕƥ ďnţ Ōnţ 0.05 8ÅŘΛş ŏÅnţ Ōnţ 10 Ž ŋŸnţ 5 āāØł :A .(B øÅĠQňŸŏ ȯzŸ∓ā ŞÁʒ) ÉΛÆì

ÜTS (ȯ/ȟ100~) ÅĿqznjā ȯzŸŢ ďnţ Ōnţ 1.0ş TS1 ȳşΞôā Ōnţ 0.15 A øÅĠQňŸŏ ÀŘ∓ā ȯzŸ∓ā Бŭ 8ÅŘΛ :B .Ƀǻłnà ÀŘňŭ ȷzŏ ǰQΛ

.ŏÅŘĿā ČāÅèø ǰQAk ÜTS (ȯ/ȟ40) ČŘÁôā ğāÀQp ȯzŸŢ ďnţ Ōnţ 1 8ÅŘΛş ŏÅnţ Ōnţ 5 Ž ȟ 0.05 āāØł :C General ČnţÅȟôā 8āÀȟQèŕā ğāøÅĠQňā" ȷāzÁʒ ŘƠ 8zòzţā A Ōʒ̀ÅÀQôā Ōnţ/ŋŸnţ 20 ÂĿõÀQā ȯzŸŢ ŬÛȟΛ :D .(121 ČHuÁÔôā Û1 ÉŸŎā) ğāÉΛøzŸÒŸŏ ÂĿłłõ "identification tests

Ŕƥ Ž Ōnţ/ŋŸnţ 30 ÂĿõÀQā ȯzŸŢ ȳÉÁQÊΛ :**Specific optical rotation** ŬʒzÁôā ƀÀÔGôā ÀΛşÉQôā .$[a]_D^{20C} = -223$ to $-299°$ ŬČÁÀŎā gǻłţā Бŭ ţzDZÀôÀā ÉÊʒş VS (ȯ/ȯzţ 0.1) ÕΛøzŸõşøÉĿTā

ÕΛøzŸõşøÉĿTā Ŕƥ ďnţ Ōnţ 10 Ž ȟ 0.20 āāØΛ :**Clarity and colour of solution** ȯzŸ∓ā ȷzŏş ŏÅÀÔôā zŁ łłõ łłTQpøÅŌnţ ÉÁʒ Yw2 ƀøÅĿȟţā ȯzŸ∓ā ȷzŏ ďnţ ÉÌŭ ¢pzŏ ȷzÒΛ ŕş ŇĿzÅò ȯzŸ∓ā ȷzÒΛ ÜVS (ȯ/ȯzţ 0.1) .(53 ČHuÁÔôā Û1 ÉŸŎā) "Colour of liquids ŌāzÊôā ȷzŏ" ȷāzÁʒ ŘƠ 8zòzţ

.ȟ/ŋŸnţ 1.0 ďnţ ÀŽõŭ ÈĿŏ :**Sulfated ash** ŘÁŸÊţā ǻłnţÀôā

30 ďnţ ÀŽõŭ ÉŌÀΛ ŕ Ü°ȳ 105 gøāÀǵ ČDZøÉā ŘāÀŽôā ȷàzôā ʔøQǵ Złz :**Loss on drying** ZĿÁDzQôÀā ÉŌÀôā .ȟ/ŋŸnţ

.3.0-2.0 ŬŌnţ/ŋŸnţ 30 ÂĿõÀQā ȯzŸŢ ŏÅŁÀā :**pH Value** ŏÅŁÁGôā ČłĿę

ȷāzÁʒ ŘƠ 8zòzţ zŁ łnţ ÆÊŬ øÅĠQňŕā ʔÀz :**Related cinchona alkaloids** ČŏÅÎţā ÅĿÒôā ğÀĿqāzŸę R1 ÅÒĿŸĿÊôā ČnţŸŁ ȳāÉÁQèłā Û(84 ČHuÁÔôā Û1 ÉŸŎā) "Thin-layer chromatography ČŌĿęÀôā ČŌGŬôā āāÀÎQèā" R ƙnţŸĿŽΛŭ ŬəÅÀQ ȯzŸŢ ďnţ ȳzDzǵ 5ş ŬR Ƙqjā ďnţ ŇłłDzǵ 12ş R ďΛzŏzŬôā ďnţ ŇłłDzǵ 20 ďnţ ǰΛÂnţş ČŸŸ8nţ gǻłłõ gǻłnţ ďnţ ŋŸnţ 10 (A) Ƀzʒ :R ȯzqÅŽĿţā Ž ŌĿôÀŢ 4 ďnţ ÀQôşÀÒnţ 4 ČHuĿÁÔôā ʔŸʒ ŇŸÔÁÁnţ ĘGŬł .ōÀHuQnţ øzŬõ ŋŸnţ 10 (D)ş ÀQô ŬŸĿţā Ž R ďΛÉĿqzÒΛĿÊôā ďnţ ŋŸnţ 0.25 (C)ş ÀQô ŬŸĿţā Ž R ƙΛĿÒôā ďnţ ŋŸnţ 0.25 (B)ş øÅĠQňŕā øΛĿk Ž ZDzQô ōÀQk Ûāāł̀ÎQèŕā gÀDzǵ ďnţ ČHuĿÁÔôā ţÂøp ÉŸHā .C ȯzŸ∓ā ďnţ Ōnţ 1 Ž ČāāØţā øÅĠQňŕā gǻłnţ ďnţ āÀk ŬǻΞQô ōÀQkş ŬČŌĿęǻ 30 gÉnţ °ȳ 105 ČDZøÉā ČHuĿÁÔôā ďΛÉŸk .development ŘŸŢQôā ǻłŸHΛş ČŌĿęǻ 15 gÉnţ ôāzŁ ŌÔHuQÊΛ ČŸŌā ČΛŭ ȷzÒk ŕ .øÅŸΛôā ôzŕ Ž ŬøāāÀÎQèŕā ÙŬÁţā ÒHuÁΛş ŬTS ȳzĿèłkzGôā ğÀĿŸkŸāşǻΛ ȯzŸHuη

Æz .C òzŸ‡ã ȘÙ B òzŸ‡Åæ ÅŽŒŸ3 ÕÔHuQÊΛ UøQõã ĞĤÕGõã ďnţ gÁÌ ÄŽõÙ ÛĞŒÊŒaÄõã ĞĤÕGõã ŏÅŽQèÅæ ÛÛA òzŸ‡Åæ ÅŽŒŸ3 ÙÛÛƯ ÄŽȘÙ ãæÙ ŕÙ ÑęȘÁÔnţ ŏÅGQnŕã ȷzÒΛ ŕ .gÄÌÅGnţ ĞŒÊŒaÄõã ĞĤÕGõã ŘƠ A òzŸ‡ã ď3 ǰQÄĞ ĞĤÕæ ĞΛÙ Õŧő ȷÙ .dzzŕzæ ĸQõzÔÅnţ ĸQĤÕæ D òzŸ‡ã ď3 ǰĞÅÅõã ããÄÎQèŕã

8ÅRΛ .ŏÅnţ 20 Ž ÛĞŒùzGRη ĞqȘàzηţ ÛĤ 0.2 ĞããÄęţ ããØΛ :**Limit of dihydroquinine** ĸÅŒõȘØÆŒTã UəÅÄQ Æg gÄþ òzŸŢ ďnţ Õηţ 0.1Ș ÛTS (ȯ/Ĥ70~) ÕΛózŸõȘØÆŒTã Ŕþ òzŸŢ ďnţ Õηţ 15 ÛR ȳzŒèÅĞzGõã ÆŒηȘÄæ ďnţ Ĥ 0.5 .ÄÅòÙ ȷzõ ǰQΛ ɔøQg VS (ȯ/ȯzη 0.0167) ȳzŒèÅĞzGõã ğÅηȘÄæ òzŸŢ ȳãÆÁQèÅæ ÄΛÅĤΛ .TS òzqÅĞΛqã/ÓŒĞŒţã ǎzŒõã ÄΛÅĤΛ .ÉəÅęǎ 5 gÆη ȳŸŢõã Ž ǎãÄÕQèŸõ õÄQĞȘ ÛĞŸDZzΣã ÉŸ8ĞĞ ÛĞÅη Õη 200 Ž ȳzŒèÅĞzGõã ÆΛǎzΛ Ĥ 0.5 8ÅRΛ òzŸŢ ďnţ Õη 2 8ÅRΛ ÛVS (ȯ/ȯzη 0.1) ȳzΛǎzÔõã ğÅÅŸèzŒĞæ Ȝη òzŸ‡ã Ž ȳzŒèÅĞzGõã ğÅηȘÄæ ÆΛÂæ ǎÄHuQţã VS (ȯ/ȯzη 0.0167~) ȳzŒèÅĞzGõã ğÅηȘÄæ òzŸŢ ďnţ Õη 1 Õõ ùzÅÒΛ .ÑQŒÅæ ÄÅòÙ òzŸ‡ã ȷzõ ÓGÔΛ ÅηÆÁ3 TS ÅÎΛõã ĞÊΛÅÕţãȘ ÑÅqÙ ǒzõØţã ĸŒĤQõã ǰəÅQq ď3 ÄqĤΛ .ĞÅÅÖã gÅÅţã Б Ù ţzDZÄõÅæ ĞæzÊŢ Ù$C_{20}H_{24}N_2O_2$,2HCl ďnţ ŊŸη 19.87 .%10 ďnţ ÄŽõÙ ÅŧŢÆæ ȧÄÅõã ȷzÒΛ ŕ .ĞΛzÅţã ĞGÊΛõÅæ

20 8ÅRΛ ÛR1 UDzŸŽõã ÕŒQŒèǰã Ŕþ ďnţ Õη 50 Ž ÛĞŒùzGRη ĞqȘàzηţ ÛĤ 0.3 ĞããÄęţ ããØŧ :**Assay** ĞÊΛÅÕţã ȳãÆÁQèÅæ ÄΛÅĤΛȘ ÛTS ÕŒQŒèǰã Ŕþ/ÕŒÕGaÂõã ğÅQŒèÙ òzŸŢ ďnţ Õη 10Ș R ÕŒQŒèǰã ÆΛØÆŒÙ òzŸŢ ďnţ Õη Non-aqueous UəÅη Ÿõã Ùèzõã Ž gÄÅĤţã" ȷÅzÅ3 ŘƠ 8zòzη zŧ Åŧõ VS (ȯ/ȯzη 0.1) ÕΛózŸõKGõã Ŕþ ùzÅÒΛ VS (ȯ/ȯzη 0.1) ÕΛózŸõȘKGõã Ŕþ ďnţ Õη 1 Õõ .(142 ĞHuÅÔõã Û1 ÆŸŎã) A ĞÕΛÄÛõã Û"titration .$C_{20}H_{24}N_2O_2$,2HCl ďnţ ŊŸη 19.87

ƒØŽŧΘ üƒDŽyŧɔÚε üŰŰŬ DžŽØŽŽ|ΙΙε qŽƒbNj‡|NjƒbqŽlj ŽəƒØŽkΙΙ hŽŽƒŢd lƒGŧƯŧDŽ

Additional Requirements for Quinine dihydrochloride for parenteral use

.(56 ĞHuÅÔõã Û4 ÆŸŎã) "*Parenteral preparations* ĞŒÕΣã ğãÄŔHuQÊţã" gǎȘÄzǰ ÆŒDzQÊΛ

ØØØØØ

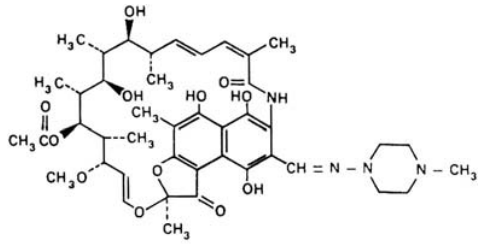
RIFAMPICINUM

Rifampicin DžŽɔŽĞDŽƒƒɔŽƒ

$C_{43}H_{58}N_4O_{12}$:**Molecular formula** ĞŒÄΛÂɔã Ğ8ŒÔõã

823.0 :**Relative molecular mass** ĞŒGÊΛõã ĞŒÄΛÂɔã ĞŸQÒõã

:**Graphic formula** ĞŒqÅŒGţã Ğ8ŒÔõã



Chemical name: (2*S*,12*Z*,14*E*,16*S*,17*S*,18*R*,19*R*,20*R*,21*S*,22*S*,23*S*,24*E*)-5,6,9,17,19,21-Hexahydroxy-23-methoxy-2,4,12,16,18,20,22-heptamethyl-8-[*N*-(4-methyl-1-piperazinyl)formimidoyl]-2,7-(epoxypentadeca[1,11,13]-trienimino)naphtho[2,1-*b*]-furan-1,11-(2*H*)-dione, 21-acetate; 3-[[(4-methyl-1-piperazinyl)imino]methyl]rifamycin; CAS Reg. No. 13292-46-1.

Other name: Rifampin.

Description: brick red

Solubility: $C_{43}H_{58}N_4O_{12}$ (m/z750~) 1 g in 15 ml methanol; 1 g in 30 ml chloroform; practically insoluble in water.

Category: Antibiotic.

Storage: Keep in a well-closed container, protected from light, at 15 to 30°.

REQUIREMENTS

General requirement: Contains not less than 97.0% and not more than 102.0% of $C_{43}H_{58}N_4O_{12}$, calculated on the anhydrous basis.

Identity tests:

A: Spectrophotometry in the infrared region (43 Infrared Spectrophotometry) Compare the spectrum with that of the reference substance.

B: Dissolve 50 mg in 1 ml methanol, add 50 ml chloroform and 50 ml water, shake vigorously and allow the layers to separate. Transfer the chloroform layer to a 100 ml volumetric flask, add chloroform to the mark, and mix. Dilute 1 ml of the solution to 50 ml with methanol. Dilute 1 ml of the solution to 50 ml with methanol.

4 ÛÀQŋʒφÅφ 500Ş ÀQŋʒφÅφ 220 ƙä ĞDZʒŋ ȯʒÛä ¢ƙÆŁÅÎŋ ÆA3 ÛĭƙÅÅõä ȯʒŸ∓ä ì ÅÔQŋä ZÊù ÐÆGA .TS Û7.4 ŏÅŁÅä Ǝ3 ì ÅŧQõä ĞŧÊę ĞGÊφ ŋŸGƙ ÜÀQŋʒφÅφ 475Ş ÀQŋʒφÅφ 334Ş ÀQŋʒφÅφ 254Ş ÀQŋʒφÅφ 237 ĞDZʒţä ȯäʒùÛ ÆA3 ĞÊŧŢ3Ü åşÆǵ ĞDZʒţä ȯʒÛä ÜŧŢ3ɟä ÞÆΣä ÆA3 ĞΘÅÅõä Õŷƙ БÛ ÀQŋʒφÅφ 334 ĞDZʒţä ȯʒÛä ÜŧŢ3ɟä ÞÆΣä ÆA3 ɻè 1 ĞφÅÅǰä ĞÕGù .ÅGAÀÕƙ 1.75 ÀQŋʒφÅφ 475

ǵÅÅŸèƙä ȯŋ Ōŋ 1 ĞǵÅì ÀÀõä ȯŋ Ōŋ 5 БÛ ȢÅÎRA .ĠÌÀAş ĘəÅęÅ 5 gÆŋ ʒÀA ÛŏÅŋ Ōŋ 25 Ž ŋŸŋ 25 ĘÅĬHA :C БÛ ãøÅÎRõä ÀÞɟä БÛ БÅÕƙƎõä БÛ ãøÅÎRõä ÀÅòɟä ȯŋ ɟʒŸõä ƙ8QA ÜĘəÅęÅ gÆ3 ʒÀAş TS ǵÅÅÊÅõä ĞəøõÅ/ȳʒĘφʒŋɟä .ĞäÅèø ŌȮÎƙ ɟşÅ ÜDzÊÅAGõä

ǵÅÅŸè ȯʒŸŢ ȯŋ Ōŋ 4 ʒŋ ʒÂʒş ÅȮĘŸÊõä ȯŋ ĞÕƙʒä Ž Ĥ 1.0 ʒŕʒA :**Heavy metals** ĞŸĘÕʒõä ɟåÅĤţä БÛ ĞäøÅŕ şÛ ŏÅÎRÊä ĞõÅφ ʔÕĞƙ ʔøQǵ ƙÅÊQõä ÀŧQÊA şÆŁŋÀQõä БÛ øØШ ȯŋÅÊA .TS ÕAøʒÅŸÊõä Ŕβ/ȳʒAÂÆA8ţä ǵäÀÛę ĞĤRGä ĞõÅŧʒõä ʔŋÆÅĬş ÛÅƎQõ õÀQƙ Û∘ȳ 800 ȯʒ ÆAÂƙ ŕ gøäÀǵ ĞDZøÆä (ÕĤÎA) ÆŋÀA .ÀAÆÕƙ ÆĤäÜ ʔŸʒ ÐÅÅŋÀõä Ŕβ Ž ĞõÅŧʒõä ãäØƙ ÛÕõæ ÆĤä .åƎQõ ĞõÅŧʒõä õÀQƙş ÛĞŋφÅõ gÀŋ ÆŋÀA ÛÀŋÅGA ÛTS (ȯ/Ĥ100~) ÕAøʒÅŸÊõä Ŕβ ȯŋ ĞGÔA ʔøQǵ ÛPbTS (ȯ/Ĥ100~) ÅĘφʒŋɟä ȯŋ ȯʒŸŢ ÛgÀÛę ÀQÛ gÀÛę Û8ÅÎRA ÛTS (ȯ/Ĥ70~) ÕAøʒŸõşøÆĘTä ĞGÔA ʔøQǵ PbTS TS (ȯ/Ĥ60~) ÕĘQĘèɟä Ŕβ ÛÅÎRAÜ gÀÛę ÀQÛ gÀÛę Û8ÅÎRA Ż Û8.5Ş 8 ƙä ȯʒŸ∓ä ŏÅŁÅä ƙƠ 8ʒòʒŋ ʒŁ Åŧõ ĞŸĘÕʒõä ɟåÅĤţä ȯŋ ʔʒQ∓ä ȯŋĤA .ʒÂʒş ÛÕŋ 40 БÛ ŏÅţÅä ZÅƆ ÛĞŋÀA Û4.0-3.0 ŏÅŁÅGõä ĞHÅÔõä Û1 ÆŸÕä) A ĞÕAÀÛŸõ ÅÕʒş "Limit test for heavy metals ĞŸĘÕʒõä ɟåÅĤţä ÕDZɟ ÐÆΣä øÅGQòŕä" ɟäʒÅ3 .ĥ/ȳäÀdşÀÔŋ 20 àşÅDzQA ŕ Ü(128

.ĥ/ŋŸŋ 1.0 ȯŋ ÀʒõÛ È Ĥ :**Sulfated ash** ƙÅŸÊţä åÅŋÀõä

0.6 àşÅDzQA ŕ) ŔÅÅŋ Ù8ŕ ƙƠ ȳ 60 gøäÀǵ ĞDZøÆä Zŋ :**Loss on drying** ZÊÅDzQõÅä ÆÕÅõä .ĥ/ŋŸŋ 10 ȯŋ ÀʒõÛ ÆÕÅõä ɟʒÒA ŕ ÜgÅ3Å è 4 gÆŋ (ÅGAÀÕƙ ÜÕGəà ɻŸŋ 5 şÛ ȯÅÒèÅäʒŸĘõ

6.5- ÛĘŸĤţä ŏÅŁÅä ÛR ɟʒäÀÒõä ÆĘÊõÛ ÜəÅÅQ ȯŋ БÅɻä ŏÅţä ȯŋ Ōŋ 10 ʒŋ ĥ0.10 ʒÀA :**pH Value** ŏÅŁÅGõä ĞŧÊę .4.5

ĞÕĘęÀõä ĞÕGÛõä ãäÀÎQèä" ɟäʒ3 ƙƠ 8ʒòʒŋ ʒŁ Åŧõ øÅGQòŕä ĘGÛA :**Related substances** ĞõÅÎţä åäʒţä ĞŸĤ8ŋ gÅŧõ R1 silica gel ÅȮĘŸÊõä ĞŋŸŁ ȳäÆÅQèÅä (84 ĞHÅÔõä Û1 ÆŸÕä) "Thin-layer chromatography ȯŋ ĭAÂŋ ōÀHQŋ øʒÛõ ȳÆÅQÊA .TS Û6.0 ŏÅŁÅä ǵäæ ǵäÀQĘÊõä/ǵÅÅÊÅõä ĞøõÅ ȳäÆÅQèÅä slurry ĞäŞÅõä ƙŔƠŞ Ž ÕĘõÅŢ 4 ȯŋ ÀQõŞÀÒŋ 20 ĞHÅÔõä ʔŸʒ ĤŸÔÅAŋ ĘGÛł .R ȯʒÅŸĘţä ȯŋ ĤŧDzǵ 15Ş R ȳøʒʒŞøʒŸÒõä ȯŋ ĤŧDzǵ 85 SV ƙÊĘGŋÅAAø ÕĘŋøʒʒ-3 ȯŋ ŋŸŋ 0.10 (B)Ş ÀQõ ŸĘţä Ž øÅGQòŕä gÅŋ ȯŋ ŋŸŋ 20 (A) ÐʒŽ :R ȳøʒʒŞøʒŸÒõä ŸĘţä Ž øÅGQòŕä gÅŋ ȯŋ ŋŸŋ 0.20 (D)Ş ÀQõ ŸĘţä Ž RS ɟʒÆõ ƙÊĘGŋÅAAø ȯŋ ŋŸŋ 0.30 (C)Ş ÀQõ ŸĘţä Ž RS

ŏʒŕ Ž Ʉøäääʌ̀Îǫèŕä̀ ÙÛÁţä̀ ÒʜʊÁʌ̀ʂ ŏäʒŤä̀ Ž Ʒ̀Dzǫŏ̀ ŏ̄ʌ̀ǫǩ̀ Ûääʌ̀Îǫèŕä̀ gʌ̀Dzǵ dʊ̀ ǦʜʊŁÁÔää̀ ţÂøǫ ÁĚ̄ä̀ .ʌ̀ǫŏ̀ ŎÔʜʊǫÊʌ̀ Ʉøǫŏää̀ ǦĚ̄ʜÔǦää̀ dʊ̀ gÁÈì̀ ʌ̀ǯ̄ŏ̄Ù̀ ÛǦŁÊŁǝʌ̀ää̀ ǦĚ̄ŎǦää̀ ŏÁʌ̀ǯǫèʌ̀ä̀ ÛA ȯʒŸ‡ʌ̀ä̀ ʌ̀ʒŤŸʒ̀ ŎÔʜʊǫÊʌ̀ ǦĚ̄ÔÄ̀ ǦʌÙ̀ ʝʒȮǩ̀ ŕ .ȯʌ̀ʒŤäää̀ Ŏ̄Ÿǩ̀ dʊ̀ gÁÈì̀ ʌ̀ǯ̄ŏ̄Ù̀ A ȯʒŸ‡ʌ̀ä̀ ʌ̀ʒŤŸʒ̀ ŎÔʜʊǫÊʌ̀ ʔʌ̀ǹÙ̀ ǦĚ̄ÔÄ̀ ǦʌÙ̀ ʝʒȮǩ̀ ŕ ÛŎää̀ ʔŸʒ̀ ǥŞŸʒ̀ .CŞ B ȯʒŸ‡ʌ̀ä̀ ʌ̀ʒŤŸʒ̀ .D ȯʒŸ‡ʌ̀ä̀ ʌ̀ʒŤŸʒ̀ ŎÔʜʊǫÊʌ̀ Ʉøǫŏää̀

2 Ʒ̀ʌ̀Ɛ .Ŏ̄ʊ 100 ǰǫʌ̀ŁŏR ȯʒǫʌ̀ǯ̄ŁţÄ dʊ̀ ǦŁʒʌ̀ŏ̄ ǦŁŁŏ̄ Ž ÛǦŁùʒǦŘʊ Ǧǫʂʌ̀ʒʊ̀ ÛĦ 0.10 ǦääÄę ā̄äØł :**Assay** ǦÊʌ̀ʌ̀ÔţÄ ₵Áǵ Ž ʝè 1 Ǧǫʌ̀ÁǯÄ ǰǩʌ̀ʌ̀äää̀ ȯʒŸ‡ä̀ î ʌ̀ʊ̀ âʌ̀Õʌ̀ .TS Û7.4 ŏʌ̀ŁʌÄ ÛǦʌ̀ʌ̀ÊʌÁäää̀ ǦəääÁÄ ŎʊÙ̀ 100 ÉÙ̀ ȯʒŸ‡ä̀ äØŁ dʊ̀ ŎʊÙ̀ dʊ̀ ʔʒǫ‡ä̀ ÆÊʒ̀ .TS Û7.4 ŏʌ̀ŁʌÄ ÛÁŁʌ̀Îŏ̄ ǦʌÁÊʌÁäää̀ Ǧəääää̀ ÿäÁÁǫèʌ̀ä̀ ÛÙ̀ǦʌÁÒŏ̄ ʌ̀ǫʒǫʌ̀ǫ 475 ǦDzʒţä̀ ȯʒÛä̀ Ʉ‡Ţ3ʝä̀ .($A_{1cm}^{1\%}$=187) 18.7 ǦĚ̄ǫʌ̀ʊ̀ Ǧ‡Ł̄ę ÿäÁÁǫèʌ̀ä̀ Û$C_{43}H_{58}N_4O_{12}$

ØØØØØ

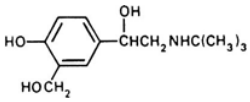
SALBUTAMOLUM

Salbutamol üNjDŽJFłNjǦÙFƨ‖ƐƐ

$C_{13}H_{21}NO_3$:**Molecular formula** ǦĚ̄ʌ̀ÂƨäǦ8ĚÔää̀

239.3 :**Relative molecular mass** ǦĚǦÊʌääǦĚ̄ʌ̀ÂƨäǦŸǫȮää̀

:**Graphic formula** ǦĚǫʌ̀ĚǦţäǦ8ĚÔää̀



:**Chemical name** ƱʌʌĚŁĚȮää̀ ʝèŕä̀

α¹-[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene-α,α′-diol; α¹-[[(1,1-dimethylethyl)amino]methyl]-4-hydroxy-1,3-benzenedimethanol; CAS Reg. No. 18559-94-9.

.ǦʜʊääÄää̀ CÁʒ̀ ÜÙ̀ǦʌÄÒŏ̄ Ř̀ĚäÙ̀ ŞÙ̀ ʝʒŸää̀ Ř̀ĚäÙ̀ ÛÞȯʒŸä̀ ȧʒʜʊÊʊ :**Description** Ʒ̀ȯʒää̀

Ž ʝʌ̀äŞÓää̀ ǦĚʜʊÙ̀ ÜTS (ȯ/Ĥ750~) ȯʒǫʌ̀ǯ̄ʌ̀ǭä̀ Ž ā̄äŞäé Üŏʌ̀ţä̀ dʊ̀ ÄŏÂDZ 70 Ž ā̄äŞäé :**Solubility** ǦĚǫʌ̀äŞÓää̀ .R Ǩǭʝä̀

.ʒ̀äÄŸŏ ǎʌ̀Ŕʊ ŏäŞǎ :**Category** ǦĚ̄ʌ̀Áää̀

.ŏʒŘää̀ dʊ̀ ʔŁʒ̀ ʝÙ̀Ş ÛÙ̀ÁĚDZ ǦÕŸ8ʊ ǦʌŞʌ̀ǵ Ž ȯʒʊ̀ʌ̀ǩʒǦäʌ̀Êää̀ ŞʌÁʒ̀ ʝÙ̀ Æz :**Storage** dʌÂÁǫää̀

REQUIREMENTS ǨǦÙÙ̀ƨƩkdž!ƒ

General requirement: Ćwiczenie polega na ilościowym oznaczaniu $C_{13}H_{21}NO_3$ metodą spektrofotometrii w podczerwieni. Wzorcem jest substancja o znanej czystości, zgodnej z deklaracją producenta, przechowywana w warunkach ochronnych. Wyniki podaje się z dokładnością do 0.1 %, a powtarzalność ocenia się na podstawie odchylenia standardowego z trzech oznaczań. Wartość mieszcząca się w granicach 98 % – 101.0 % jest akceptowalna.

Identity tests: A. Widmo absorpcji w podczerwieni substancji badanej w zakresie 4000 – 400 cm⁻¹ powinno być zgodne z widmem wzorcowym substancji referencyjnej. Zgodność potwierdza się porównaniem położeń maksimów oraz ich względnych natężeń. B. Reakcja barwna z odczynnikiem Fehlinga: po ogrzewaniu próbki z roztworem Fehlinga powstaje ceglastoczerwony osad tlenku miedziowego(I). Brak osadu świadczy o braku wolnej grupy aldehydowej.

Spectrophotometry in the infrared region. Około 43 mg (dokładnie odważonych) substancji badanej rozpuszcza się w 1 dm³ wody destylowanej w temperaturze 20 – 25 °C. Roztwór wzorcowy przygotowuje się z substancji referencyjnej w identycznej temperaturze. Widma rejestruje się w kuwecie o grubości warstwy 0.56 mm w zakresie 4000 – 400 cm⁻¹ z rozdzielczością 1 cm⁻¹. Na widmie wybiera się pasmo charakterystyczne o maksimum ok. 2925 cm⁻¹ i porównuje się wysokość maksimum z wysokością tego samego pasma w widmie wzorcowym.

Related substances. Ok. 5 g substancji badanej rozpuszcza się w 50 cm³ wody destylowanej w temperaturze 20 – 25 °C. Roztwór wzorcowy przygotowuje się z substancji referencyjnej w identycznej temperaturze. Widma rejestruje się w kuwecie o grubości warstwy 0.56 mm w zakresie 4000 – 400 cm⁻¹ z rozdzielczością 4 cm⁻¹, 16 scanów, w temperaturze 260 ± 2 °C. Na widmie wybiera się pasmo charakterystyczne o maksimum ok. 1760 cm⁻¹ i porównuje się wysokość maksimum z wysokością tego samego pasma w widmie wzorcowym.

Loss on drying. Ok. 1.0 g substancji badanej suszy się w suszarce próżniowej w temperaturze 60 ± 2 °C przez 18 h, pod ciśnieniem ≤ 5 mbar, z użyciem pistoletu Fischera. Wyniki podaje się z dokładnością do 0.1 %.

Sulfated ash. Ok. 1.0 g substancji badanej prażonej w tyglu porcelanowym, wstępnie wyprażonym i zważonym, ogrzewa się ostrożnie do zwęglenia, a następnie prażi w temperaturze 800 ± 25 °C do uzyskania stałej masy. Wyniki podaje się z dokładnością do 0.1 %.

Identity tests hbĭNjNJllε l εϕϫϝϝϝϢε

- A. Ds cs B ğäøÅĠQnŕä ŝÜ ĆåÀÅη A øÅĠQnŕä ĘĦĠÛĭ ϕÒε

Spectrophotometry in ðäÀŧΣä ŘƠ ĞÕÛÅŧä Ž ƱƻzŘöä ZĦÛöä âÅĦę" ɹäzƷ Ř Ƣzòzŧä øÅĠQnŕä ĘĠÛł :A ϕ3 ĵĭÅÅöä ZĦÛöä 3η öäÀŧΣä ŘƠ ĞĦì ɟä î ÅÔQηä ZĦù ĘäÅÛQΛ .(43 ĞHƱÅÔöä Û1 ÆŸŎä) "the infrared region .ȯzηÅĭzĞÅÊŸö ƱĦDZÀŧä ZĦÛöä 3η ŝÜ RS ȯzηÅĭzĞÅÊöä ȯzŸŢ

ÆΛ3 ÛVS (ȯ/ȯzη 0.1) ȬΛøzŸõŝøÆĦTä Ŕβ Ž Õη/ηŸη 0.080 ÂĦõÀQä ȯzŸŢ î ÅÔQηä ZĦù ƁÆĠΛ :B

Ǝ3 î Åŧ Qöä ηŸĠΛ ÜĦĠΛÀÕĭ ÀQηzφÅφ 276 ĞDZzŧä ȯzÛä ĦŧŢ3Ü ĦÆg ÛÀQηzφÅφ 350ŝ ÀQηzφÅφ 230 ĭä ĞDZzŧä ȯzÛä ¢ĭÆŁÅÎη .ĦĠΛÀÕĭ 0.56 äØŁ ĞDZzŧä ȯzÛä ĮÈ 1 ĞφÅÅĵä ĞÕĠù

ƱDzÊÅÅä ɹzȯ ĵQΛ ÜTS (ȯ/ĥ25) ȬΛÆΛÆΣä ÆΛøzŸõ ϕη Õη 0.1 8ÅŘΛŝ ŏÅη Õη 5 Ž ĥ 0.05 ā äØΛ :C .äÅd Æ3ÅÔĭ 3η ĞĦŧΣ ĞäÅèø ĵQΛĭ ÜR ȳzΛÅzÔöä ĭĭDZŝøÆĦŁ ğÅφzäÀõ ϕη ĥ 0.05 8ÅŘΛ .gÀŧΣä Ü ā øÅŕ .ɹzŸöä CÆ3 ȯzŸ∓ä ĞĠÔΛ ÜTS (ȯ/ĥ1760~) ȬΛøzÅŸÊöä Ŕβ ϕη ğäÀÛę gÆ3 8ÅŘĭ .ȬÒÅĭ 3η ĦĠΛÀÕĭ °ȳ 155 ÛøÅŦÔφŕä ĞDZøÅ :D

.ĥ/ηŸη 1.0 ϕη ÄĵõÜ ÈĦö :**Sulfated ash** ŘÅŸÊŧä ÅÅηÀöä

0.6 äŝÅDzQΛ ŕ) ŘÅÅΛη Ù8ŕ ŘƠ ŷ 50 gøäÀg ĞDZøÆä Zäz :**Loss on drying** ZĦÅDzQöÅä ÆÕÅöä .ĥ/ηŸη 5.0 ϕη ÄĵõÜ ÆÕÅöä ɹzÒΛ ŕ ÜĞ3ÅÈ 18 gÆη (ĦĠΛÀÕĭ ƱÕĠϕà ĮŸη 5 ŝÜ ȯÅÒÈÅäzŸĦõ

ĞÕĦęÀöä ĞÕĠÛöä āäÀÎQÈä" ɹäzƷ ŘƠ 8zòzη zŁ Åŧõ øÅĠQnŕä ĘĠÛΛ :**Related substances** ĞöÅÎŧä ÅäzŧÄ ĞŸĦ8η gÅŧõ R1 silica gel ÅÒĦŸĦÊöä ĞηŸŁ ÿäÆÅQÈÅä (84 ĞHƱÅÔöä Û1 ÆŸŎä) "Thin-layer chromatography ĦŧDzg 50ŝ R ȯzφÅäŝÀä-2 ϕη ĦŧDzg 30ŝ öÅŧä ϕη ĦŧDzg 16ŝ TS (ȯ/ĥ260~) ÅĦφzηɟä ϕη ȳzDzg 4 ϕη ĵΛÅηŝ (A) Ƣz3 :R ȯzφÅĵĦŧä Ž ĭȯzŸŢ ϕη ÀQöŝÀÒη 5 ĞHƱÅÔöä ŕŸ3 ĦŸÔÅΛη ĘĠÛł .ōÀHƱQη øzÛõ R ÕĦĵΛqä ğÅQĦÈÜ ϕη ϕη ĞHƱÅÔöä ŧÂøφ ÆĦä .ÀQö ƱŸĦŧä Ž øÅĠQnŕä gÅÅη ϕη ηŸη 0.10 (B)ŝ ÀQö ƱŸĦŧä Ž øÅĠQnŕä gÅÅη ϕη ηŸη 20 ƱƻÅĵä 3ĠÎη zDZ Ž Ęƻäęå gÆ3 ĞHƱÅÔöä 3ŕzĭ .ÆΛøŧä ÀÅĠQΛ ŕøQg öäzTä Ž ZDzQö öÀQĭ ÛāäÀÎQèŕä gÀDzg ÙÛƯ ÒHƱΛŝ Û(ŝàΛÆöä gÀηà ¢ĦŸ3 ŘŸnÅÅ) TS diazotized ÂÀÆŧä ÕĦŸφÅÅŸÊöä ŘŧŁÀ äÀĭ ÛR ĭηŸĦĵΛÙ ϕη gÆì ÄĵõÜ ÛĞĦÊƱƻÀöä ĞHÕĠöä ÅÅĵQèÅä ÛA ȯzŸ∓Åä ÅŦĦŸ3 ÕÔHƱQÊΛ ĞHÕä ĞΛÙ ɹzÒĭ ŕ .øÅŦΛöä özŕ Ž āäÀÎQèŕä .B ȯzŸ∓Åä ÅŦĦŸ3 ÕÔHƱQÊΛ ƱøQöä ĞHÕĠöä

ʒŋ ÀÀÀĤÀŞ R1 ŦDzŸŽõä Õ̃ĦQĦèɟä Ŕƥ ɗŋ Ō̃ŋ 30 Ž ÛĞĦùzĠŘŋ Ğφşàzŋ Ûĥ 0.4 ĞääÀę ā̃äØł :**Assay** ĞÊÀÀÕ̃ţä Non-aqueous ŦəÀŋŸõä Ùèzõä Ž gÀÀÀĤţä" ɟäzÄʒ ŘƠ ȣzòzŋ zŁ Ałō̃ vs (ȯ/ȯzŋ 0.1) Õ̃ÀózŸõ̃ŘĞõä Ŕtłɯ 23.93 ùzÄÒÀ vs (ȯ/ȯzŋ 0.1) Õ̃ÀózŸõ̃şŘĞõä Ŕƥ ɗŋ Ō̃ŋ 1 Ō̃ō̃ .(142 ĞŦuÄÔõä Û1 ÆŸŎä) A ĞÕ̃ÀÀÛõä Ûtitration .$C_{13}H_{21}NO_3$ ɗŋ ŊŸŋ

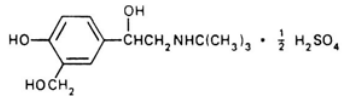
SALBUTAMOLI SULFAS

Salbutamol sulfate üNjDŽƑĦNjĞÀƑƨ ƨ ll ε l ƑƨĦƨ

$(C_{13}H_{21}NO_3)_2, H_2SO_4$:**Molecular formula** ĞĦÀÀÂƨä Ğ8ĦÔõä

288.4 :**Relative molecular mass** ĞĦĞÊÀõä ĞĦÀÀÂƨä ĞŸφÒõä

:**Graphic formula** ĞĦφÀĦĞţä Ğ8ĦÔõä



:**Chemical name** ŦəÀĦŁĦÒõä ɭèrä

α¹-[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene-α,α′-diol sulfate (2:1) (salt); α¹-[[(1,1-dimethylethyl)amino]methyl]-4-hydroxy-1,3-benzenedimethanol sulfate (2:1) (salt); CAS Reg. No. 51022-70-9.

.ĞHuəäÀõä CÆʒ ÜĦĞÀÀÕk ŘĦäÜ ŞÜ ɟzŸõä ŘĦäÜ ȧzHuÊŋ :**Description** Ƶòzõä

R ÿøzzşøzŸÒõäşTS (ȯ/Ĥ750~) ȯzφÄƵÀqä Ž ɟÄäşØõä ĞĦHuì ÜŏÄţä ɗŋ õäÂDZÜ 4 Ž ā̃äşä :**Solubility** ĞĦφÄäşØõä .R Ğφɟäş

.zäÀŸõ äÄŘŋ õäşä̊ :**Category** ĞÄÀõä

.ŏzŘõä ɗŋ ɔłƵ ɟÜş ÛĦÆĦDZ ĞÕ̃Ÿ8ŋ ĞÀşÄg Ž ȯzŋÄkzĞõÄÊõä ğÄÀŸè ŞÄƵ ɟÜ Æz :**Storage** ɗÀÂÁφõä

ÛÆùÀõä zDzŸõ ¢ŕÀĤĤk ÆÄʒ ƴÀøÆφõÄä ȯzŋÄkzĞõÄÊõä ğÄÀŸè ōøÆφÀ :**Additional information** ĞĦzÄŕÜ ğÄŋzŸĤŋ .ĞĤÄkÄţä gøäÀΣä ğÄDZøä̊ Ž ţÀèÜ Õ̃ÒÄφõä ĞφÔÀş ÛŏzŘõä ā̃ÄĦ8ä ɔøφg

REQUIREMENTS ŘĞhuĦƵkdž!ƒ

ɗʒ ÆÀÂÀ ŕş %98.0 ɗʒ Ō̃ÕÀ ŕ Äŋ ɔŸʒ ȯzŋÄkzĞõÄÊõä ğÄÀŸè ƁzφƵ :**General requirement** ÿÄĤõä ÆŸÛφţä .ĞÄÀÕä gäÄţä Ƃ̃Ü ţzDZÀõÄä ĞäzÊŢ Ûc$_{13}H_{21}NO_3$,½H_2SO_4 ɗŋ %101.0

Identity tests hŭĬNjNJЛЄ l ЄƀƑGĤCƓЄ:

.DȘ CȘ B ğäøÅĈQòнřä ȘÜ DȘ A ďbЛøÅĈQòнřä Åпğ̆ ĘЄGÛЌ ďbÒȚ •

ŏäÄŧΣä ŘƠ ĞÕÛÄŧä Ž ЧaȚŘöä ȚЄÛöä âÅЄę" JäȚÄ3 ŘƠ 8ȚòȚп ȚŁ Åŧõ øÅĈQòнřä ĘĞÛł :A ŏäÄŧΣä ŘƠ ĞĤÌ ĵä î ÅÔQпä ȚЄÙ ĘäÅÛQЛ .(43 ĞЧbÅÔöä Û1 ÆŸŎä) "Spectrophotometry in the infrared region .ȯȚпÅŘȚĞÖÅÊöä ğÅÅŸÊȯ ЧĤDZÄŧä ȚЄÛöä 3п ȘÜ RS ȯȚпÅŘȚĞÖÅÊöä ğÅÅŸè ďb3 JŘÄÅöä ȚЄÛöä 3п ÆÄ3 ÛVS (ȯ/ȯȚп 0.1) ÕЛøȚŸõȘøÆЄTä Ŕβ Ž Õп/ПŸп 0.080 ÂЄõÄQä ȯȚŸŢ î ÅÔQпä ȚЄÙ ÞÆĞЛ :B î ÅŧQöä ПŸĞЛ ÜЄĞЛÄÕŘ ÄQпȚφÅφ 276 ĞDZȚŧä ȯȚÛä ЄЄŧŢ3Ü ÆÆg ÛÄQпȚφÅφ 350Ș ÄQпȚφÅφ 230 ƙä ĞDZȚŧä ȯȚÛä ¢ŘÆŁÅÎп .ЄĞЛÄÕŘ 0.46 äØŁ ĞDZȚŧä ȯȚÛä ĻÈ 1 ĞφÅÅŽä ĞÕĞÜ Ǝ3

ЧDzÊÅÄä JȚÖ ĵQЛ ÜTS (ȯ/ȟ25) ÕЛÆЛÆΣä ÆЛøȚŸõ ďbп Õп 0.1 8ÅŘЛȘ ŏÅп Õп 5 Ž ȟ 0.05 ääØЛ :C 8ÅŘŘ .ÄÅd øȚÛŘ 3п ĞЄŧΣ ĞäÅÈØ ĵQÄŘ ÜR ȳȚЛÅȚÔöä ƙDZȘøÆЄŁ ğÅφȚäÄÕ ďbп ŘÅ 0.05 8ÅŘЛ .gÄŧΣä БÜ äøÅÀŕ .JȚŸöä CÆ3 ȯȚŸ∓ä ĞĞÔЛ ÜTS (ȯ/ŘЄ1760~) ÕЛøȚÄŸÊöä Ŕβ ďbп ğäÄÛę gÆ3 General ĞпÅŘöä 8äÄŘQèнřä ğäøÅĈQòнä" JäȚÄ3 ŘƠ 8ȚòȚŧä A Õ3ÅÅQöä Õп/ПŸп 20 ÂЄõÄQä ȯȚŸŢ ŬÛŘЛ :D .(123 ĞЧbÅÔöä Û1.0 ÆŸŎä) ğÅÅŸÊŸõ ÂЄŧŧõ "identification tests

.ŘЄ/ПŸп 1.0 ďbп ÄŽõÜ ÈЄõ :**Sulfated ash** ŘÅŸÊŧä ÅÅпÄöä

0.6 äȘÅDzQЛ нř) ŘÅÅÄп Ù8ŕ ŘƠ ÿ 100 gøäÄg ĞDZøÆä ȚÅz :**Loss on drying** ȚЄÄDzQöÅä ÆÕÅöä .ŘЄ/ПŸп 5.0 ďbп ÄŽõÜ ÆÕÅöä JȚÒЛ нř ÜĞ3ÅÈ 18 gÆп (ЄĞЛÄÕŘ ŬÕĞäÄ ĻŸп 5 ȘÜ ÒÅÒÈÅäȚŸЄõ

ĞÕЄęÄöä ĞÕĞÛöä ääÄÎQèä" JäȚÄ3 ŘƠ 8ȚòȚп ȚŁ Åŧõ øÅĈQòнřä ĘĞÛЛ :**Related substances** ĞŏÅÎŧä ÅäȚŧä ĞŸ8п gÅÅŧõ R1 silica gel ÅÒЄŸЄÊöä ĞпŸŁ ÿäÆÅQèÅä (84 ĞЧbÅÔöä Û1 ÆŸŎä) "Thin-layer chromatography ЄŧDzg 50Ș ÛR ȯȚφÅäȘÄä-2 ďbп ЄŧDzg 30Ș ŏÅŧä ďbп ЄŧDzg 16Ș TS (ȯ/ŘЄ260~) ÅЄφȚпĵä ďbп ȳȚDzg 4 ďbп JЛÂпȘ (A) ÞȚZ :R ȯȚφÅŘЄŧä Ž ƙȯȚŸŢ ďbп ÄQÖȘÄÒп 5 ĞЧbЄÅÔöä ȚŸ3 ŘŸÔÅЛп ĘĞÛł .ÕÄЧbQп øȚÛõ R ÕЄŘJqä ğÅQЄèÜ ďbп ďbп ĞЧbЄÅÔöä ţÂøφ ÆŘä .ÄQÖ ŬŸЄŧä Ž øÅĈQòнřä gÅÅп ďbп ПŸп 0.10 (B)Ș ÄQÖ ŬŸЄŧä Ž øÅĈQòнřä gÅÅп ďbп ПŸп 20 ЧaÅÅŽä 3ĞÎп ȚDZ Ž ĘaÅęÅ gÆ3 ĞЧbЄÅÔöä 3ŕȚŕ .ÆЛØŧä ÄÅĈQЛ ȚøQg öäȚTä Ž ȚDzQÖ ÕÄQŘ ÛäÄÎQèнřä gÄDzg ÙÛÅŧä ÒЧbÅЛȘ Û(ȘÄÅЛÆöä gÄпä ¢ŸЄ3 ŘŸòÅÅÜ) TS diazotized ÅЛÆЄŧä ÕŸЄφÅÅŸÊöä ŘŧШ äÄŘ ÛR ƙпŸЄŽЛÜ ďbп gÆÌ ÄŽõÜ ÛĞЄÊЄaÄöä ĞŘÕĞöä öÅÅŽQèÅä ÛA ȯȚŸ∓Åä ÅŦЄŸ3 ÕÔЧbQÊЛ ĞŘÕä ĞЛÜ JȚÒŘ нř .øÅŦÄöä öȚŕ Ž ЧøäÄÎQèнřä .B ȯȚŸ∓Åä ÅŦЄŸ3 ÕÔЧbQÊЛ ЧøQöä ĞŘÕĞöä

ŘŧШ ÄЛÅŘЛȘ R1 ЧDzŸŽöä ÕЄQЄèĵä Ŕβ ďbп Õп 30 Ž ÛĞЄÙȚĞŘп ĞφȘäȚпÛŘ 0.9 ĞääÄę äØŁ :**Assay** ĞÊЛÅÕŧä Û"Non-aqueous titration ЧaÅп Ÿöä ÙèȚöä Ž gЛÅŘŧä" JäȚÄ3 ŘƠ 8ȚòȚп ȚŁ Åŧõ VS(ȯ/ȯȚп0.1) ÕЛøȚŸõKĞöä

ďňţ ŋŸňţ 57.67 ùţźÀÒΛ VS (ȯ/ȯţŋţ 0.1) Õ̃ΛóţŸõ̃ţ̃ŘĠõ̃ã Ř̀ þ ďňţ Ō̃ňţ 1 Ō̃õ̃ .(142 ĞĦÀÂÔõ̃ã Û1 ÁŸŎã) A ĞÕ̃ΛÀÛõ̃ã

.$C_{13}H_{21}NO_3,½H_2SO_4$

ƒ̃ã̃ţΘ üƒDŽyƭƨÚε üШŬ üNjDŽƒƭNjĞШƒƨШε ƖƒƲƭƨШ hüĭţƒŢ̀ã ƖƒĞ̃ƭƯƭDŽ

Additional Requirements for Salbutamol sulfate for parenteral use

.(56 ĞĦÀÂÔõ̃ã Û4 ÁŸŎã) "*Parenteral preparations* ĞŁÀÕ̃Σã̃ ğ̃ãÀ̃ŘĦÀÇÊţã̃" ğ̃ãţÀ̃ţ̃ ÆŁDţÇÊΛ

SENNAE FOLIUM

Senna leaf (Ĭ̃ƭDŽƒã̃ƨШε) ƒã̃ƨШε hüƭƥNj

Alexandrian Senna leaf hüĭƥqã̃ƨ̃ƨÜ̃ε ƒã̃ƨШε hüƭƥNj

Tinnevelly Senna leaf Ĭ̃ƭĭ̃2ĭ̃ã̃ĭ̃ƭ ƒã̃ƨШε hüƭƥNj

ÀΛÊã̃ ĞţŞÀ̃Ĥţã̃ ÛĞ̃ÀÀÕã̃ *Cassia senna L.* øõã̃ ğ̃ÀÕΛóţ̃ ďňţ ÀΛÊõã̃ Ğęóţ̃ ţŸÒÇk̃ :**Composition** ÆŁõ̃ÀÇõã̃ ďňţ ĭ̃ΛÂňţ ďňţ ţ̃Ù̃ Û(*C. angustifolia* Vahl) Tinnevelly Senna ţ̃Ù̃ (*C. acutifolia* Delile) ȳţùÀ̃ţ̃ã̃ ţ̃Ù̃ ĞΛóÁΛÒèçã̃ .ƙ3ţΛõã̃

.ÑŸŁŸę̃ À̃ňţ Ż Ûţ̃Ÿğ̃ţ̃ mucilaginous ŦÀ̃ĭ̃ö ĞΛã̃ÁĞõã̃ Ž̃ Ûȧã̃Øţã̃ ÜĞ̃ÁŁÁà̃ ÛĞ̃ĦďãÀ̃ã̃ :**Description** Ţ̃ ò̃ţõã̃

.ÕŸÊňţ :**Category** ĞÀÀõã̃

.Ğãţ̃ùÀ̃õã̃ţ̃ ŏţ̃Ŕõã̃ ďňţ ÀΛÊõã̃ Ğęóţ̃ ƨŧƠ ţÙ̃ Æz :**Storage** ďΛÂÁÇõã̃

ƨøÇg̃ ÛÆùÀ̃õã̃ ţDzŸõ̃ ÀŸŕÀ̃ĤĬ̃ ÁÁƷ ĭΛóÁÇõÀã̃ ÀΛÊõã̃ Ğęóţ̃ ōøÁÇk̃ :**Additional information** ĞŁţÀ̃ŕÙ̃ ğ̃ÀňţŸĤňţ .ĞĤÀĬ̃À̃ţã̃ ğóã̃À̃Σã̃ ğ̃ÀDţóã̃ Ž̃ ţ̃À̃èÙ̃ Ō̃ÒÀÇõã̃ ĞĞÔΛţ̃ Ûõţ̃Ŕõã̃ ã̃ ÀŁØã̃

REQUIREMENTS ĞĞΛõŸõ̃kdž!ƒ

ŦÊõ̃ţ̃øÁŁŁ ğ̃ÀÕÇÎňţ ďňţ %2.5 ďƷ Ō̃ÕΛ ƭ Àňţ ƨŸƷ ÀΛÊõã̃ Ğęóţ̃ ƁţÇƠ :**General requirement** ȳÀĤõã̃ ÆŸÛÇţã̃ .(sennoside B) B ÁΛàţŁÊõ̃ ĞãţÊŢ̀ Ûkèã̃À̃ţ̃ÇÙ̃

:**Identity test** hüĭNjNJШε ƥĞĦĞШε

ȳÀ̃ƥ Ž̃ ƨã̃8Λţ̃ TS ȯţφÀ̃ţΛqã̃/ȳţΛã̃ţÔõã̃ ÁŁÊõ̃ţ̃øÁŁŁ ȯţŸŢ̀ ďňţ Ō̃ňţ 10 Ğęţ̃ŦŦÊţã̃ Ğęóţõã̃ ďňţ ĥ0.5 ƁÙ̃ Ø ÀÂŔΛ øã̃ ÒŸÁÇÊΛţ̃ TS (ȯ/ĥ70~) ÁΛóţŸõ̃ţ̃øÁŁŁŢã̃ Ř̀ŧŦШ ĞğÀ̃ìÀõã̃ Ř̀ŧŦHƙ̃ .ĞìÀΛţ̃ Ûõ̃Àňţ Ō̃ňţ 10 ȳã̃ÁÁÇÈÀã̃ Ţ̃ÀÇ̃ ÛŦƨÀňţ Ž̃ ÀΛÔňţ ÀƥÙ̃ ţţõ̃ ĭ̃ţΛ̃ ÜTS (ȯ/ĥ100~) ÀŁφţňţã̃ ȯţŸŢ̀ ďňţ Ō̃ňţ 5 ƷňţƷÀ̃kţ̃ Ğφã̃ţã̃ ĞÕ̃ĞΛù ÕÔÀk̃ .R Ğφã̃ţã̃ ďňţ Ō̃ňţ 10 .ÀŁφţňţã̃ ĞÕ̃ĞΛù

Macroscopic examination Ò

Ò

Microscopic examination Ò

(lacunose) **Microscopic examination**

Water-soluble extractive

Acid-insoluble ash

Acid-insoluble ash "Determination of Acid-insoluble ash

Stems and foreign matter

Assay

ďŋ Ęǻʒş øşǻŋ ǺĦę ğăæ ĞŸDƷƶǵ Бů ŽǺÛõǎ ÕəǺÊõǎ ďŋ Õŋ 10.0 ÕÕǺşǺ .ĘəǺęǻ 3 gǻŋ ʒǺşǺ R ȳƷǺǻƶÔõǎ ďǺÊǺ .ʒǺƹş TS (ȯ/ħ65) ÕǺǻǺǻΣǎ Ŕβ ďŋ Õŋ 20 ȣǺŘǺ .Õŋ 100 ʒÊǫk ground glass ƨŋĮȣţǎ ʒǺDƷÂõǎ Ž ÕəǺÊõǎ ƨƷǫÊŋ ȧƷƷ ¢ƷƷ ŏǺţǎ ƨƷǫÊŋ ɟƷÒǺ ȣəǺŋ ȳǺβ Ž ȣʒƷDƷǺõǎ ɟǺǺǺƨǺǻ ÕŧǺǺ ʒǫǺŋ ŘƠ ĞÕƷęǻ 20 gǻŋ ÛøǺÒǫţǎ ʒǺõǎ ʒŋ ÛĞƷƶǺŕŕŮ ĞÕƷęǻ 20 gǻŋ ďǺÊǺş TS (ȯ/ħ420~) ÕǺǻƷŸõşǻǻƷTǎ Ŕβ ďŋ Õŋ 1 ȣǺŘǺ ÜĞŸDƷƶΣǎ R Ŕǫɟǎ ďŋ ÛÕŋ 25 ďŋ ǺƷǺŋ Õõ ÛğǺƷŧõ 3 ʒŋ ʒǺşǺ ÕÔƷ ʒŧę Бů ǰǺÂţǎ ÕÕǺ ÛǻƷǺ .ĞǻǺèǺõǎ ǎşØk ƨøǫǵ ÕÕǺk .ŏǺţǎ ďŋ ÛÕŋ 15 ďŋ ǺƷǺŋ Õõ ÛŘǫƷŧÒǺ ÕÊ8ǩş ǺĦŋ Ŕǫɟǎ ğǺÕĞù ʒŧθ .ĞŸDƷƶΣǎ ƷÛÎõ ǺÕǎǺè ÕŧǺǫÊţǎ ĞõǺŧʒõǎ ǎǎØǩş ȣǺǺƨǎ ƨøǫǵ ĞǺǺǺĦǎ Õŋ 10.0 ǺǺĞǺ .R Ŕǫɟǎ Õŋ 100 Бů ƷǺơş ĞƷŧDƷǵ ĞŸDƷƶǵ Бů Ŕǫɟǎ ğǺÕĞù ȯƷŸ+ǎ ǎØŧ î ǺǫǺ âǺÕǺ .R ȯƷφǺŸƷţǎ ďŋ ǺǫõǺ ŬŸƷţǎ Ž R ȳƷǺÂƷǺ8ţǎ ğǺǫƷèů ďŋ ŋŸŋ 5 ÂƷõǺǫǺ ȯƷŸŢ ďŋ Õŋ 10.0 Ž .R ȯƷφǺŸƷţǎ ƨŸʒ ƷƷǫƠ ĒǺØŋ gŘDƷǵ ÕǺǺÕŋ ǺǫŋƷφǺφ 515 ĞDƷƶţǎ ȯƷÛǺ ŬŧŢʒɟǎ ĞǺǵ Ž ǰè 1 ĞφǺǺŸǺ ĞÕĞù Ǝʒ 24.0 ĞƷòǺŋ ĞŧƷę ȳǺǺǺǫèǺǺ B ǺǺàƷǺƷè ÕÒì ƨŸʒ ŕèǺǺŸφů ŬÊõşǻǺƷŧ ğǺÕǫÎŋ ĞƷŧõ ĞǺƷǺţǎ ĞĞÊǺĞǺǺ ĒÊƠ ĞòƷŘŬǺţǎ gǺǺţǎ ĞŸǫõ ďʒ *W*ş ǺǫŋƷφǺφ 515 ĞDƷƶţǎ ȯƷÛǺ î ǺŧǫÕǎ ďʒ *A* ƎĦŘş Û*W/A* 1.25 :ŬŸǺ Ǻŧõ ($A_{1cm}^{1\%}$ = 240) .ȳǺÀȣÕǺǺ

ØØØØØ

SENNAE FRUCTUS

Senna fruit (Ĭ‖DŽƒdžƨ‖ε) ƒdžƨ‖ε hυNJ|ƒʒ

Alexandrian Senna fruit hυĭβφdž|ƨŨε ƒdžƨ hυNJ|ƒʒ

Tinnevelly Senna fruit Ĭ+ĭ2ĭdžĭĭ ƒdžƨ hυNJ|ƒʒ

C.) ÛĞǺǺÕǎ ĞDƷŕŕǺǺõǎ *Cassia senna* L. øõǎ ĞƷõǺƷ ŬŧĞ ĞǺǵǺÒèqǎ ǺǺè ĞƷõǺƷ :**Composition** ĒĦõǺǫõǎ .ĞǺǺÕǎ ĞDƷŕŕǺǺõǎ *C. angustifolia* Vahl øõǎ ĞƷõǺƷ ŬŧĞ ŬŸĦǺĦǺĦǎ ǺǺè ĞƷõǺƷş (*acutifolia* Delile .ŬŸĦŸę Ǻŋ Ż ÛƷŸǵş mucilaginous ŬǺƷõ ĞǺǺǵõǎ Ž ÛǺǺØǫǎ ÜĞǺĦǺǺ ÛĞHυǺǺõǎ :**Description** ƷòƷõǎ .ÕƷÊŋ :**Category** ĞǺǺõǎ

.ĞǺƷùǺõǎş ŏƷŘõǎ ďŋ ǺǺÊõǎ ĞƷõǺƷ ƨŧƠ ɟŮ Ęz :**Storage** ďǺÂǺǫõǎ

ƨøǫǵ ÛĘùǺõǎ ƷDƷŸõ ǺƷŕǺǺŘ ǺǺʒ ǰǺǺǺǫõǺǺ ǺǺÊõǎ ĞƷõǺƷ ŏφǺǫk :**Additional information** ĞĦƷǺŕŕŮ ğǺŋƷŸŋ .ĞŘǺkǺǺǫǎ gǺǺõǎ ğǺDƷǺǺ Ž ţǺèŮ ÕÒǺǫõǎ ǴǵÔǺş ÛŏƷŘõǎ ǺĦ8ǺǺ

REQUIREMENTS ŘĞhůŘƵkdž!ƒ

ğÅÕÇÎŋ ďŋ %3.4 ďƷ ÕÕΛ ŕ Åŋ ɔŸƷ ČΛØÆΛÒèqã ÅΛè ČŤõÅƵ ƁƵÇƠ :**General requirement** ȳÅĦõã ÆŸÛÇţã ÛŕèãÄŽçÛ ƱÊõşØÆŁŁ ğÅÕÇÎŋ ďŋ %2.2 ďƷ ÕÕΛ ŕ Åŋ ɔŸƷ ƱŸŁÅŁÅŁĶ ÅΛè ČŤõÅƵ ƁƵÇƠş ŕèãÄŽçÛ ƱÊõşØÆŁŁ .B ÆΛàƵÆÊõ ãƵÊŢ ÅƵŸõ

:**Identity test** hƱŇjNJΛΣ ßFĠĦCŢε

TS ȯƵçÅŽΛqã/ȳƵΛåƵÔõã ÆŁÊõşØÆŁŁ ȯƵŸŢ ďŋ Ōŋ 10 ƱÅŘΛ ÛĦ 0.5 ĞããÄę ĘĦƱÊΛ şÛ gK8ò ňĦÛę ČŤõÅÄõã ƷÛÕĦ TS (ȯ/ĦΛ70~) ÆΛØƵŸõşØÆŁŤã ŘŧШ ĞgÅÌÌÄõã ŘŧƠ .ĆÌÄΛş ÛõÅŋ Ōŋ 10 ȳãÆÅÇÈÅã ƵÅÇ ÛƱÈÅŋ ȳÅþ Ž ɔĦ8Λş ĵÇΛΛ ÜTS (ȯ/Ħ100~) ÅÆçƵŋĵã ȯƵŸŢ ďŋ Ōŋ 5 Ƶŋ ƷÄĦş ĶÇĵã ĞÕĠù ŌÔÅĦ .R ĶÇĵã ďŋ Ōŋ 10 øã ÒŸÅÇÊΛş .ÅÆçƵŋĵã ĞÕĠù Ž ÄþÛ ÉÛ ƱŸÅçÄę ĵƵõ

ĞŁÅã ÉÛ gÄÅÔŋ õãÄŘŋ ÛĞÕÆęøş ĞĦÛÊŋ ÛĞęøƵõã ŌŽŋ ĵşÄę :**Macroscopic examination** ƱøçÅÆĦõã ÒĦÅõã .ŌÒÎõã ĞΛƵŸõ şÛ ĞŸÆÛÇÊŋ ÛĞŌŋÅď ĞŁÅã ĞΛÂõÄŋ ĞÕÛΛŋ Ƶŋ gÄÅÔŋ

ĞΛÄãqã ĞÛŌÅõã ÜĵŸŋ 25-20 Û ô ÄĦõã ÜĵŸŋ 50-40 ĞããÄę ÛȯƵÛõã ÜĞΛåÅŋø ÉÛ ĞĠgÅÌ õãÄŘŋ *:ĞΛØÆΛÒèqã ÅΛè ČŤõÅƵ* ĞÆçŕƵù ƱãƵg ğãæ ÛĞĠgÅÌ ĞŁÅã ÉÛ õãÄŘŋ obovate ãƵŸŌŋ ƱŘÆã ÅŤŸÒÌ øşØã 7-6 ƁƵÇƠ Ûğ ÅΛÅŤÅõã ŘÆgÛ ÆΛƷ .gÄØÅã

ĞÛŌÅõã ÜĵŸŋ 18-14 Û ô ÄĦõã ÜĵŸŋ 60-35 ĞããÄę ÛȯƵÛõã ÜƁåŋÄõã ÉÛ ĞãØÅÌŕ õãåƵè ÉÛ ĞŁÅã *:ƱŸŁÅŁĶ ÅΛè Ğçøş* ğãæ ÛĞĠgÅÌ ĞŁÅã ÉÛ õãÄŘŋ obovate ãƵŸŌŋ ƱŘÆã ÅŤŸÒÌ øşØã 10 ɔøÇg ƁƵÇƠ Ûğ ÅΛÅŤÅõã ŘÆgÛ ÆΛƷ ĞΛÄãqã .åşÆΣã ĞƱŕãş ĶÇ ĞŕÄĦÇÊŋ ƱãƵg

øÅÛçĵã ĞΛşÅÊÇŋ ÅΛŸŋ ďŋ ZõüÇĶ epicarp ĞŁDZøÅÇã gÄÎÕõã :**Microscopic examination** ƁÄŤÕã ÒĦÅõã ďŋ ÃÆDZ ÕŁŸç åÆƷş ÛĦçÅŁgÛ *anomocyte* şÛ *paracytic* ÅΛŸÅŸõ gøşÅf ğÅŁƵƵ Ʒŋ ÛÃÆDZ ĞΛŁÅÇ ğãÆŁŸDZ ğãæ ĞÛÈƵÇţã gÄÎÕõã Ûcollenchymatous ĞΛşÄÇ ÅΛŸŋ ğãæ *Hypodermis* ĞŧƱŸõã ÜĞŁŸÇã gÆŁgş ĞŁõƵõüžõã ğÅΛÄĦÎõã ďŋ ĞçƵÒŋ endocarp ĞŁŸŋãÆõã gÄÎÕõã ÜƵçŁÊõÅÒõã ğŕÅÊõşÛ ĶÌãƵŋ ďŋ ĞÕĠù ƁƵÇƷ ƱøÅÇŋ ĵŁÊç ğãæ mesocarp şÛ ĞŸÅŋ ΛşãÅæ ĶÊĶ ĞŁŸŋãÆõã ƱÅŁõĵã ďÒõ ÛĞŤõÅÅŸõ ƱøçŕƵÛõã øƵŕã ɔŸƷ ƁåƵŧƷ ÅŤŧŢĦŋ Ž ÛõãÆƵã ĞΛŁÅÇ ƱÅŁõÛ ÜŕĶÅÇ ƱDZøÅŋ øãÆDZ ğãæ palisade ĞÒŁÊg ÅΛŸŋ ďŋ ΛşÄÎæ ĶÇ ĞÕĠù ÛøşÂĠõã .ƱøçŕƵÛõã øƵĦŧŸõ ΛÄãƵŋ .mucilaginous ĞŁÅĵõ ÅÇãøÆDZ polyhedral dzƵÛÊõã gKĵõ ÅΛŸŋ ğãæ endosperm õãÆΛƵÊõã

R ȳøƵƵşøƵŸÒõã ďŋ Ōŋ 0.5 ďŋ ĵΛÅŋ Ž Ħ 5 ƷÄΛ :**Water-soluble extractive** õÅţã Ž ããşØõã ÒŸÅÇÊţã .Ħ/ŋŸŋ 250 ďŋ ÕçÛ ĶÊŁõ ĞõÅŧĵõã ÜĵãƵΛş ĞgÅÌÌÄõã ďŋ Ōŋ 20 ÄÅΛ ÛĞŋÌÄΛ ÛõÅŋ Ōŋ 200ş

åÅŋÄõã ĶŁÄĶ" ĵãƵÅƷ ĶÇ ƱƵòƵŋ ƵŁ ÅŧõÕõãÄDZqã ĘĠÛΛ :**Acid-insoluble ash** ŘŧΣã Ž ããşØõã ĶÇ åÅŋÄõã

20 ďňţ ÄŽõĎŭ ıţŻÒÄ ŕ Ü(173 ŇĞÄÔöä Û1 ÆŸŇä) "Determination of Acid-insoluble ash ŘŧΣä Ž ā ąşØöä Ŕď .ňŕ/ŋŸňţ

ţĎ ŕĸĦöÄä ŇĞÄÄ8öä ğĺÄţä Ţ ÎŢÒŇ .ŇÕŒęø ŇÕĞÛõ ÄÎÄŇţ ÄĞÄÄÕŇ ň 200 ıäţÄ :**Foreign matter** ŇĞÄÄ8öä ğĺÄţä .ňŕ/ŋŸňţ 10 ďňţ ÄŽõĎŭ ıţŻÒŇ ŕ ÜıäţŇţ ÕÔÄŇ Ü6× ŇèÆ3 ÿäÆÁŢèÄä

ÛÜŸŢ ÛŏÄňţ Õňţ 30.0 8ÄŘÄ .Õňţ 100 ŇĦè ğäæ ŇŸDZţǵ Ž ŇęţHÊţä ŇŤõÄÄöä ň 0.15 3ŕţł :**Assay** ŇÊÄÄÕţä õÄŢÄ .ŇÕŒęĺ 15 ğÆňţ Ü3ţDZÄöä ıÄÄäÄä ÕŧĦÄ ŢĺÒňţ ŘƠ ďÁÊÄ .°ÿ 90-80 ŇDZóÆä ÜäÄňţ ÿÄþ Ž 3ŕţÄţ Ûıäţ 3ŧę Ďŭ ŽÄÛöä ÕäÄÊöä ďňţ Õňţ 20.0 ÕÕÄţ ÕÄŽÄ .ŇŒŸòıä ŇŸŢÒöä ŕŸ3 òţÔΣä ŕøŢǵ ŏÄţÄä ǴĦÔÄţ Ûıäţ ÛĺĺÆÕ Õõ ÛğÄŒŧõ ŢŸŢ 3ňţ ŽÄÄţ TS (ò/ň70~) ÕÄóţŸõşóÆŒTä ŘÞ òţŸŢ ďňţ Õňţ 0.1 8ÄŘÄ .Õňţ 150 3ÊŢÄ ÕÔţ ŕDZşóÆŒŧ ğÄţţäÄõ ďňţ ň 0.10 8ÄŘÄ .ÿóţţşóţŸÒöä ŇÕŇÄ ŕňţÄŘţ ÕÔÄÄŒõ õÄŢÄ .R ÿóţţşóţŸÒöä ďňţ ÛÕňţ 15 ÄŢÄňţ ďňţ ĘÄ3ţ óşÆňţ ÄĦę ğäæ ŇŸDZţǵ Ďŭ ŽÄÛöä ÕäÄÊöä ďňţ Õňţ 10.0 ÕÕÄţ ÕÄŽÄ .ĘäÄęĺ 3 ğÆňţ ŽÄÄţ R ÿţÄĺţÔöä ğÆňţ ďÁÊÄ .ŽÂţţ TS (ò/ň65) ÕÄŘÄöä ÆÄóţŸõ ďňţ Õňţ 20 8ÄŘÄ .Õňţ 100 3ÊŢŇ ground glass ŕňÎ8ţä ŽÄDZÂöä ÜŇŸDZţΣä Ž ÕäÄÊöä ŢţŢÊňţ ąţţ ŒĺŢ ŏÄţä ŢţŢÊňţ ıţŻÒÄ ÜäÄňţ ÿÄþ Ž ÜŽDZÄöä ıÄÄäÄä ÕŧĦÄ ŢĺÒňţ ŘƠ ŇÕĞęĺ 20 ŕøŢǵ ÛøÄÒŢţä ŽÄöä 3ňţ ÛŇĞęÄŕÛ ŇÕĞęĺ 20 ğÆňţ ďÁÊÄţ TS (ò/ň420~) ÕÄóţŸõşóÆŒTä ŘÞ ďňţ Õňţ 1 8ÄŘÄ ÕŧĦŢÊţä R ŘŢıä ďňţ ÛÕňţ 25 ďňţ ÄŢÄňţ Õõ ÛğÄŒŧõ 3 3ňţ ŽÄÄţ ÕÔţ 3ŧę Ďŭ ĵÄÂţä ÕÕÄÄ ÛĺĺÆÄ .ŇäÄèÄöä ā ąşØŘ ŘŢıä ğÄÕŇÕÕÄŘ .öÄţä ďňţ ÛÕňţ 15 ďňţ ÄŢÄňţ Õõ ÛŕŢŧÒä ÕÊ8ŘţŢ ÄĦňţ ŘŢıä ğÄÕŇÕÕÄ 3ŧΘ .ŇŸDZţΣä ŢÛÎö ÄÕöäÄè Õňţ 10.0 Ž ŇöÄŧŽöä ā ąØŘţŢ 8ÄÄää ŕøŢǵ ŇÄÄĦä Õňţ 10.0 ÄĺÆÄ .R ŘŢıÄä Õňţ 100 Ďŭ ŢÄöţŢ ŇŧDzǵ ŇŸDZţǵ Ďŭ ŇÕŇÕÕ Ǝ3 òţŸ‡ä ąØŧ î ÄŢ âÄÕÄ .R òţφÄŸŧţä ďňţ ÄŢö ÜŸŧţä Ž R ÿţÄĺÆ8ţä ğÄŢŧèÕ ďňţ ŋŸňţ 5 ÄŧõÄŢä òţŸŢ ďňţ ŇŇÊÄöÄä ÆĒÔŢ .R òţφÄŸŧţä ÞţŢƠ ÆÄØňţ ğŘDţǵ ÕäÄÕňţ ÄŢňţφÄφ 515 ŇDZţţä òţÛä ÜŧŢ3ıä ŢÆǵ Ž ŧè 1 ŇφÄÁŽä Ätõ ($A^{1\%}_{1cm}$ = 240) 24.0 ŇŧòÄňţ ŇŧĦę ÿäÆÁŢèÄä B ÆÄäţÆŧè ÕÒÌ ŕŸ3 ŕèäÄŽφÛ ÜÊõşóÆŒŧ ğÄÕŢÎňţ Ňŧŧõ ŇÄţÄţä .ÿäÄ8öÄä ŇòţHÄţä ğÄţä ŇŸŢõ ď3 *W*ş ÄŢňţφÄφ 515 ŇDZţţä òţÛä î Äŧţöä ď3 *A* ĦŘŘş Û*W/A* 1.25 :ÜŸÄ

ØØØØØ

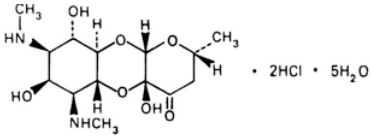
SPECTINOMYCINI HYDROCHLORIDUM

Spectinomycin hydrochloride DžÏŕ ąĭDŽNjďžĭÏ‡ĺĞŕ ąĭĺÞNj‡ĺNjÞąĭĺj

$C_{14}H_{24}N_2O7,2HCl,5H_2O$:**Molecular formula** ŇŧĦÄÂąä Ğ8ŧÔöä

495.4 :**Relative molecular mass** ŇŧĞÊÄöä ŇŧĦÄÂąä ŇŸŢÒöä

:**Graphic formula** ŇŧφÄŧĞţä Ğ8ŧÔöä



Chemical name: (2*R*,4a*R*,5a*R*,6*S*,7*S*,8*R*,9*S*,9a*R*,10a*S*)-Decahydro-4a,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-4*H*-pyrano[2,3-*b*][1,4]benzodioxin-4-one dihydrochloride pentahydrate; [2*R*-(2α,4aβ,5aβ,6β,7β,8β,9α,9aα,10aβ)]-decahydro-4a,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-4*H*-pyrano[2,3-*b*][1,4] benzodioxin-4-one dihydrochloride pentahydrate; CAS Reg. No. 22189-32-8 (pentahydrate).

Description: Gentamicin C1a is a white to off-white powder. It is hygroscopic.

Solubility: Gentamicin sulfate is freely soluble in water (750 mg/mL), practically insoluble in alcohol, acetone, chloroform, ether, and hydrocarbons.

Category: Aminoglycoside antibiotic.

Storage: Store at 30°C.

REQUIREMENTS

General requirement: Gentamicin sulfate contains not less than 600 mcg of gentamicin per mg, calculated on the anhydrous basis.

Identity tests: A: Spectrophotometry in the infrared region (43 Infrared Absorption Spectrophotometry). Compare the spectrum with that of a reference standard.

B: Thin-layer chromatography, Gentamicin identification tests (121 General identification tests).

ţzDZÀõÅæ ÆÊƷş Ōŋ/ŋŸŋ 0.10 ÂŁõÀQæ òzŸŢ ÿÆÁQÊΛ :**Specific optical rotation** Ʊ3zΛõã ƀÀÔGõã ÀΛşÆQõã
.$[\alpha]_D^{20°C}$ = +15 to + 21° ÜĞŁəÅţã ŧ gÅţã Ƃů

.ĥ/ŋŸŋ 10 dŋ ÀŽõů È£ō :**Sulfated ash** ŘÁŸÊţã ÅÅŋÀõã

Determination of water by ÀÎŁz òóÅõ ŘÕΛÀÛæ ŏÅţã ŧŁĤk" ɹãzΛƷ ŘƠ ȣzòzŋ zŁ Åţõ dŋĤΛ :**Water** ŏÅţã
ƤzŢ ŌÕΛ ŧ ÜĤGΛÀÕk gÅţã dŋ ĥ 0.2 ÿãÆÁQèÅæ Û(145 ĞHuÁÔõã Û1 ÆŸÖã) A ĞÕΛÀÛõã Ü"the Karl Fisher Method
.ĥ/ĥ 0.20 dƷ ÆΛÂΛ ŧş ĥ/ĥ 0.16 dƷ ŏÅţã

.5.6-3.8 ÛŌŋ/ŋŸŋ 0.10 ÂŁõÀQæ òzŸŢ ŏÅŁÅæ :**pH Value** ŏÅŁÅGõã Ğţŧę

ĞŌGÛõã ããÀÎQèã" ɹãzΛƷ ŘƠ ȣzòzŋ zŁ Åŋ ÆÊШ óÅGQnŧã ƤÀz :**Related substances** ĞŏÅÎţã ããzţã
ɟ^Ânş ĞŸȣŋ gÅţõ R1 ÅÒŁŸŁÊõã ĞŋŸŁ ÿãÆÁQèÅæ Û(84 ĞHuÁÔõã Û1 ÆŸÖã) "Thin-layer chromatography ĞÕŁęÀõã
dŋ Ágãş ɮDzgş R ŦDzŸõã ÕŁQŁèɟã Ŕþ dŋ Ágãş ɮDzgş ŏÅţã dŋ ÿzDzg 8ş R òzφÅæşÀæ-1 dŋ ÿzDzg 10 dŋ
gÅÅŋ dŋ ŋŸŋ 20 (A) ƀzƷ :ĸòzŸŢ dŋ ÀQõşÀÒŋ 10 ĞHuŁÁÔõã ƨŸƷ ŸÔÁÅŋ ĘGÛŁ .õÀHuQŋ ózÛõ R dΛÆΛKGõã
ÛããÀÎQèŧã gÀDzg dŋ ĞHuŁÁÔõã ţÂøφ ÆĤæ .ÀQõ ŦŸŁţã Ž óÅGQnŧã gÅÅŋ dŋ ŋŸŋ 0.20 (B)ş ÀQõ ŦŸŁţã Ž óÅGQnŧã
ÒHuÁΛş ÛĘəÅęå 3-2 gÆŋ ÀÕQÊQõ ōÀQk ÛTS (ò/ĥ25) ÿzŁèÅkzGõã ğÅφÅ8ΛŋKæ òzŸHuŋ æÀk ÛõãzTã Ž ZDzQõ ōÀQk
ÀŽõů ÛĞŁÊŁəÀõã ĞĤÕGõã ŏÅŽQèÅæ ÛA òzŸ+Åæ ÅŽŦŸƷ ÕÔHuQÊΛ ĞĤÕæ ĞΛů ɹzÒk ŧ .óÅŽŦΛõã ŏzŕ Ž ŦøããÀÎQèŧã ÙÛÁţã
.B òzŸ+Åæ ÅŽŦŸƷ ÕÔHuQÊΛ ŦøQõã ĞĤÕGõã dŋ gÆì

óÅGQnã" ɹãzΛƷ ŘƠ ȣzòzŋ zŁ Åţõ óÅGQnŧã ƤÀz :**Histamine-like substances** ĸŋÅQÊŁŽŸõ ĞŏÅÎţã ããzţã
ÿãÀdzŸõ ÕÒõ Ōŋ 1 ÿãÆÁQèÅæ Û(167 ĞHuÁÔõã Û1 ÆŸÖã) "Histamine-like substances ĸŋÅQÊŁŽŸõ ĞŏÅÎţã ããzţã
.ÀQõ ŦŸŁţã Ž óÅGQnŧã gÅÅŋ dŋ ŋŸŋ 25 ƨŸƷ ƀzQƷ TS ŦHuŸŋ òzŸŢ dŋ ɮÊƨã ĞŸQõ dŋ

Sterility testing of ĞΛzŁΣã ğãÅÅŘţã ĞŋÅÕƷ óÅGQnã"øæ ĞòÅɮã gÅşÀzɟã Ƃů ÆŁDzQÊΛ :**Sterility** ĞŋÅÕĤõã
.ŦəÅÎ8õã ÁŁÌÀQõã óÅGQnã ĞÕΛÀù ĘŁGÛQæ Û(162 ĞHuÁÔõã Û1 ÆŸÖã) "antibiotics

ÿÆÁQÊΛ ."Gas chromatography ƀàÅ8õã ããÀÎQèŧã" ɹãzΛƷ ŘƠ Ğzzòzţã ĞÊΛÅÕţã ĘGÛk :**Assay** ĞÊΛÅÕţã
ÿÆÁQÊΛ .R ÆŁŋÅŋózz ÕŁŽŁŋ ŦəÅÅQ dŋ ÀQõ ŦŸŁţã Ž R ɹzŁŁφɟã ÕŁÆz ŦQŸQ dŋ ŋŸŋ 2 ƀzQƷ òzŸŢ ŦŸnãã óÅŁĤŁõ
Ōŋ 10.0 ÛĞŁùzGŘŋ ɹşàzŋ ÛRS ĸÊŁŋzÆQÒGÊõã ÆΛózŸõşóÆŁŁ dŋ ŋŸŋ 30 ĞããÀę Ƃů ȣÅŘΛ (1) :ɹÅŁÅQõã ɹŧzŸ+ã
ŁDZó Ğ3Åè gÆŋ ŧƷÀŁş ÛR hexamethyldisilazane ɹãàŸŁè ŦəÅÅQ ÕŁŽŁŋ ŦèãÆè dŋ Ōŋ 1.0ş ŦŸnãÆõã óÅŁĤţã dŋ
ŦəÅÅQ ÕŁŽŁŋ ŦèãÆè dŋ Ōŋ 1.0ş ŦŸnãÆõã óÅŁĤţã dŋ Ōŋ 10.0 óÅGQnŧã gÅÅŋ dŋ ŋŸŋ 30 Ƃů ȣÅŘΛ (2)ş ÜĤĤÛÕQŋ
1.3 ¢òzù ŦDZÅDZà ãzŧ3ş ŦøGT dΛÜk ȣÅÎÒŋ ĞŸŧĤõã ¢ÓŁ Ž ÿÆÁQÊΛ .ĤĤÛÕQŋ ŁDZó Ğ3Åè gÆŋ ŧƷÀŁş ÛR ɹãàŸŁè

ÆÀÆ3 ÕÆŽÆŋ/ÕÆÀÆz dbŋ Ĥ 5 dbŋ ɹɣÒŋ adsorbent ÂQŧĥ dbŋ ĞĞèÀÀŋ ĞÆŧÒæ zÎŢ ɮè 0.4 ÜŸnäÆää ĈÀÛęş ȳ ŘŧΣÀæ òzÊ8ŋ ÛR4 ÕÆφYÆÊöÀæ ÕŋÀĤţä (ÀŁzƨä ÈÆõ) ózƨŸÆÊÆÓää dbŋ ÂŋäÀd 95 ƨŸ3 ÂŧƨÆŋ R ɹÀÊõzŸÆÊää 265 ĞDZóÆæ dbÕΣä ŏÂDZş ÛБäzQää ƨŸ3 °ȳ 270ş °ȳ 215 gøäÀg ĞDZóÆæ 8ÀÎÒţäş ǻzŧĤää ŞÀƷ .ÐzŸÕäÀæ òzÊ8ŋş A ääÀÎQèŕä ÙÛÙ ÀÂŘƷ .ÂŋÀÀÕĭ ĞÕÆęÆää Ž Õŋ 90 ɹÀÀÀDZ Ğ3ÀÊæ ÕŋÀg àÀ8õ R 8Àƨä ȳzÆŸÆTä ȳÆÅQÊΛ .ÂŋÀÀÕĭ °ȳ Ûääà ÎQèä ÙÛÙ Õõ Ž ĞÆÊŧƨÀää gşóØää ĞÕÛÀŋ âÀÕĭ .2ş 1 ĸòzŸ‡ä dbŋ ÀQòşÀÒŋ 2.5 ĞääÀÕõ ÂŸÔÀÀŋ dbÕΣÀæ Bş .øÀGQnŕä gǻÀŋ dbŋ ȳäÀd ÜŸÆţä Ž ȳäÀdşÀÒţÀæ $C_{14}H_{24}N_2O_7$ dbŋ ƨzQ‡ä ÆÊƷş

ƥdźsΘ üƒDŽyƧƨzÚε üШŬ DžĭƨzĭDŽNjdžĭƧ|ĞƨzΠε oĭƥNj‡|NjƥoĭNJΠ hŭĭƷFŢd lƒĞ‡ŬƬDŽ

Additional Requirements for Spectinomycin hydrochloride for parenteral use

øÀGQnŕä" ɹäzÁƷ ŘƠ 8zòzŋ zŁ ÀŧõŐ øÀGQnŕä ĘĞÛΛ :**Bacterial endotoxins** ĞÆŋzQÀƨä ĞÆŸnäÆää ğÀφÀÀΛØää Ü(30 ĞHÀÔää ÛĞΛÂÆŸÒφqä ĞĤĞÛää Ž Û5 ÆŸÕä) "Test for Bacterial endotoxins ĞÆŸnäÆää ĞÆŋzQÀƨä ğÀφÀÀΛØää ÕDZj .ȳäÀd ÜŸÆţä Ž ĞÆöşǻ gÆǵş 0.09 RS ÜŸnäÆää ɹÀÀΛØää dbŋ ƨzQ‡ä àşÀDzQΛ r

ØØØØØ

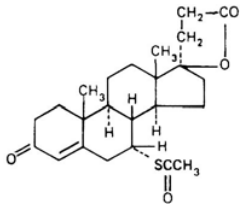
SPIRONOLACTONUM

Spironolactone DžNj‡|ŰNjdžNjƥĭĞƨ

$C_{24}H_{32}O_4S$:**Molecular formula** ĞÆÀΛÂƨä Ğ8ÆÔää

416.6 :**Relative molecular mass** ĞÆĞÊÀää ĞÆÀΛÂƨä ĞŸQÒää

:**Graphic formula** ĞÆφÀÆGţä Ğ8ÆÔää



:**Chemical name** ÜƨÀÆŧÆÒää ɮèŕä

17-Hydroxy-7α-mercapto-3-oxo-17α-pregn-4-ene-21-carboxylic acid γ-lactone acetate; 7α-(acetylthio)-17-hydroxy-3-oxo-17α-pregn-4-ene-21-carboxylic acid γ-lactone; CAS Reg. No. 52-01-7.

gÂÆư ĞHƨääø şæ şÙ ĞHƨääÀää CÆƷ ÜŘŁÀæ ÂÀÔŋ ÜøÀæ ÐÙ ŘŁÀæ ÂÀÔŋ ŘÆäÙ ȧzHƨÊŋ :**Description** Ƶòzää .ĞÀÆĤŕ

ȳǿȝȝȿǿȝŸȮöä Ž ȷÅäȿØöä ÀǵÜTS (ȯ/Ȟ750~) ȯȝφÅŽȴqä Ž ā äȿǽ ÜǒÅţä Ž ÅÆŸŧȝ ā äȿǽ ŕ :**Solubility** ǦŁφÅäȿØöä .R

.ǿÁÆŋ :**Category** ǦÅÅöä

.ǒȝŘöä ȯŋ ǦńŧŢ ÛäÁÆÆDZ ǦÕŸ8ŋ ǦȴȿÅǵ Ž ȷȝǫõŕȝφȿǩǦÊöä ȘÁȜ ȷÛ Æz :**Storage** ȯȴÂÁǫöä

gǿäÀǵ ǦDZǿÁää ÅȴÁÆŦŦǫ äǿÅŦÔφä ȷȝǫõŕȝφȿǩǦÊöä ÞÁÆǦȴ ȷÛ ȯȮȝ :**Additional information** ǦŁȝÅŕÛ ǵÅŋȝŸŘŋ .ÆŸÔǫöä gǻȝŘää ȜǦǫŧ ÛÅǦȴÀÕǩ ÿ 135

REQUIREMENTS ǩǦȵÅÕǩdž!ƒ

ȯȝ ÁȴÂȴ ŕȿ %97.0 ȯȝ ÕÕȴ ŕ Åŋ ȝŸȝ ȷȝǫõŕȝφȿǩǦÊöä ÞȝǫȜ :**General requirement** ȳÅŘöä ÆŸÛǫţä .ǦÁÅǒä gǻÅţä ÞÛ ţȝDZÀöÅää ǦäȝÊŢ Û$C_{24}H_{32}O_4S$ ȯŋ %101.5

:**Identity tests** hȳŇjNJŇȿ l ɛƥƑǦƦƣɛ

.Dȿ Cȿ B ǵäóÅǦǫnŕä ȿÛ ȻǻÀÅŋ A óÅǦǫnŕä ÅŋÛ ȘÀȜ •

öäÀŧΣä ŘƠ ǦÕÛÁţä Ž ƱȝȝŘöä ȜȴÛöä âÅę" ȷäȝÁȝ ŘƠ ȹȝòȝŋ ȝŁ Åŧõ óÅǦǫnŕä ȨǦÛŁ :A öäÀŧΣä ŘƠ ǦŘìȷää î ÅÔǫnää ȜȴÛù ȨäÅÛǫȴ .(43 ǦȵÅÔöä Û1 ÁŸǒä) "Spectrophotometry in the infrared region .ȷȝǫõŕȝφȿǩǦÊŸö ƱŘDZÀţä ȜȴÛöä ȝŋ ȿÛ RS ȷȝǫõŕȝφȿǩǦÊöä ȯȝ ǰǩÅÅöä ȜȴÛöä ȝŋ

230 ǩä ǵÅDZȝŋ ȯȝùüä ¢ǩÁŁÅÎŋ ÁÁȝ ÛR ȯȝφÅǰȴţä Ž Õŋ/ȳäÀdȿÀÒŋ 10 ÂȴõÀǫä ȯȝŸŢ î ÅÔǫnää ȜȴÛù ÞÁÆǦȴ :B

ȯȝÛä ȴè 1 ǦφÅÁǰä ǦÕǦù Ǝȝ î Åŧǫöä ŋŸǦȴ ÜŘǦȴÀÕǩ ÀǫnȝφÅφ 238 ǦDZȝţä ȯȝÛä ÅÆŧŢȝÛ ÅÁǵ ÛÀǫnȝφÅφ 350ȿ ÀǫnȝφÅφ .ŘǦȴÀÕǩ 0.47 äØŁ ǦDZȝţä

ÀÂŘnÛ ÁȴÁÆì Ȩöüǩ ȿǽ ÞÅÕǩÀä ȯȝŸŢ ǰǫȴ ÜTS (ȯ/Ȟ700~) ÕȴóȝÅŸÊöä ŘÞ ȯŋ Õŋ 2 Ž ŋŸŋ 10 ǯÀȴ :C ǵÅǫÆèÛ Ǧęóȿ áȝÊŧ ÞØöä ÛǩDZȿØÁÆŦä ÁÆÅŸè óȝÛǩ ȝŋ ȯõäÁöä ÀÞȷää ÞÛ ȷȝŸöä ȯÁǦǫȴ ÜȜÛŸä ȯȝŸǂä ȯÅÊȴ .ŋÅÔŋ .ȴÆŧd ÛÀÂŘƯ ÀÅòÛ ȷȝȯ ǰǫȴ ÜǒÅţä Ž ȯȝŸǂä ȵÆÔȴ .R î ÅòÀöä

.ÕȮÅǫöä ȝŋ ÿ 204 ǦääÀę ÛǿÅŦÔφŕä ǦDZǿäǻ :D

ÜR ȳǿȝȝȿǿȝŸȮöä Ž Õŋ/ŋŸŋ 10 ÂȴõÀǫä ȯȝŸŢ ȳÁÅǫÊȴ :**Specific optical rotation** ƱȝȝÅöä ÞÀÔǦöä ÀȴȿÁǫöä .$[a]_D^{20°C} = -33.0$ to $-37.0°$

ǦÕǩȝä Ž R ȳȝȴèÅǩȝǦöä ǵäÀǫφ ȯŋ Ň 0.3ȿ R ȳȝȴèÅǩȝǦöä ǵÅφȝäÀõ ȯŋ Ň 1 ȝŋ Ň 0.20 ȝŕȝȴ :**Chromium** ȳȿÀȮöä .ȷȝäÀȮöä ȮäÂȴ ȝøǫǵ ÿ 650-600 gǿäÀǵ ǦDZǿÁää (ÕŘÎȴ) ÁŋÀȴȿ ÛǿÅŦÔφŕä ȝøǫǵ ȜÛŸä ȯÅÊȴ ÛȜÂȿ ÜǦÁÆǩŸä ȯŋ ǦȴȝÅõ ǦȴŧÒä ȜÁȜȿ ÛǴŕÀȴ ÛȜȴÛŸöä ǩÅÊǫöä ȳäÁÅǫèÅä ǒÅŋ Õŋ 10 Ž ǦÁÒư ǦDZǿäǻ ȝÔęÛ ÞÛ ǦöÅŧžöä ā äØǩ ÛäǻÅ

ÛTS (ȯ/ȟ190~) Õ̃ʌȯʒʌŸÊõä Ȑ ŧŧШ Ȑ ŧŧНȣŞ R ʌʌȯʒŧõä ȣȵ ȟ 0.5 Ȯȵ 10 БÛ Ȣʌ̇ȒʌȮȵ 20 ɔŸȝ ȯʒÔНȣŸȯ ȯʌ̇ŧä ȣʒȯ ȣȵ Ęŧdʌ̇Û ǰǩʌ̇ʌõä ȣʒŸõä ȣʒȮʌ ŕ .TS Éʌȁʌʌȯʌõ̃ Ȯŧʌŧʒ ȣəʌʌǫ ȯʒŸȚ ȣȵ Ȯȵ 0.5 Ȣʌ̇ȒʌŞ Ûȯʌŧʒʌ̇ Ȯȵ 20 БÛ ȚʌȘ ÞØõä ʌ̇ÐZȁʌ̇ù ȀȒ‡ä ȯʒŸ‡ä ȣȵ Ȯȵ 0.50 БÛ ÛTS (ȯ/ȟ190~) Õ̃ʌȯʒʌŸÊõä Ȑβ ȣȵ Ȯȵ 1 ȞʒʌȒÛ ȣ3 ǰǩʌ̇ʌõä ȯʒŸ‡ä ȣȵ Ȯȵ 0.5 Ȣʌ̇ȒʌŞ ȯʌŧʒʌ̇ Ȯȵ 20 БÛ ȚʌȘ ż ÛȯʌȮȵ Ȯȵ 100 Ž R ȳʒŧèʌ̇ǩʒGõä ǧʌ̇ȵŞʌõ̃ ȣəʌʌǫ ȣȵ ȵŸȵ 2.83 ÞʒǫȚ .TS Éʌȁʌʌȯʌõ̃ Ȯ̃ŧʌŧʒ ȣəʌʌǫ

.ȟ/ȵŸȵ 1.0 ȣȵ ʌǰõÛ Ȅõ :**Sulfated ash** ǨʌŸÊŧä ǻʌ̇ȵʌȀõä

.ȟ/ȵŸȵ 5.0 ȣȵ ʌǰõÛ ʌ̃ÔʌõäȮʌ ŕ Ü°ȳ 105 ȣõäʌ̇ǧ ǨDZȯÉʌä ȚʌȘ :**Loss on drying** ȚŧʌDzǫõʌ̇ä ʌ̃ÔʌõäǨõŧęʌ̇õä ǨõŧÛõä ā ä̃ʌ̇Îǫèä" ȣäʒʌ3 ǨƠ Ȣʒòʒȵ ʒŧ ʌ̇ŧõ̃ ȯʌ̇ǫȵŕä ęʒÛʌ :**Related substances** Ǩȯʌ̇Îŧä ǻäʒŧä ǨŸ8ȵ ǻʌ̇ŧõ̃ R5 silica gel ʌ̇ÒŧŸŧÊõä ǨȵŸŧ ȳäʌ̃Éʌǫèʌ̇ä (84 ǨHȣʌ̇Ôõä Û1 ʌ̃ŸǨä) "Thin-layer chromatography 5 ǨHȣŧʌ̇Ôõä ɔŸȝ ŸÔʌʌȵ ęʒÛŧ .õʌ̇Hȣǫȵ ȯʒÛõ̃ R Ȯ̃ŧʒʒGõä ǧʌ̇ǫŧèŧŞ (Ǩŧəŧȵ ÞØʌ̇Θ ØʌÔȵ ȣȵ ǨŸ8ŧä ǨHȣŧʌ̇Ôõä) ǻʌ̇ȵ ȣȵ ȵŸȵ 0.20 (B)Ş ʌǫõ ȣŸŧŧä Ž Øʌ̇ǫȵŕä ǻʌ̇ȵ ȣȵ ȵŸȵ 20 (A) ÞʒȚ :R ȳØʒʒŞØʒŸÒõä Ž ʒȯʒŸȚ ȣȵ ʌǫõŞʌ̇Ȯȵ Ǩŧǫʌ̇ǫ ǧʌ̇ȵ ʌ̇ŸȚŧʒŞ ǨʒʌȀõä ǧõʌ̇ä ǨDZȯÉʌä Ț DzǫõʌǩŧÛ ā ä̃ʌ̇Îǫèŕä ǧʌ̇Dzǧ ȣȵ ǨHȣŧʌ̇Ôõä ŧ Âøφ ʌ̃ŸȀä .ʌǫõ ȣŸŧŧä Ž Øʌǫȵŕä ǧõʌ̇ä ǨDZȯÉʌä ÆʌØŧä ʌ̇Áʌǫȵʌ ɔøǫǧ ȯʌǫǩ ÛǨHȣŧʌ̇Ôõä ŧ Âøʌǩŧ .ęŧGÛǫõä Ùȵ ȧʒʒ ǰè 15 ǨʒʌÊȵ ʌ̃ŸÔŧõ ÆʌØŧä ȯʌ̇ǩ ȝȵ ÙÛÙ ȮHȣʌ̇ .ęəʌ̇ęǻ 10 ǧʌ̃ȵ °ȳ 105 ǧõʌ̇ǧ ǨDZȯÉʌä ȣŧÁÊǩŞ ÛTS ȯʒφʌ̇Ÿŧŧä/Õ̃ʌȯʒʌŸÊõä Ȑβ ȯʒŸHȵ ȁʌ̇ǩ ÛǨʒʌ̇8õä ȣȵ ǧʌ̃ÉÙ ʌ̇ʒõÛ ÛǨŧÊŧəʌ̇õä ǨȮÕǨõä ȯʌ̇ʌʒǫèʌ̇ä ÛA ȯʒŸ‡ʌ̇ä ʌ̇ŸŧŸȝ Ȯ̃ÔHȣǫÊʌ ǨȮ̃ä ǨʌÛ ȣʒȯǩ ŕ .ȯʌ̇ŸʌõäȮ ȯʒŕ Ž ā ä̃ʌ̇Îǫèŕä .B ȯʒŸ‡ʌ̇ä ʌ̇ŸŧŸȝ Ȯ̃ÔHȣǫÊʌ ȣØǫõä ǨȮ̃ÕǨõä

Ǩǧʌ̇ŕʌ̇õä ȣȵ Ȯȵ 10 ʌ̇ʌʌ̇ȀʌŞ ÛǦŕʌ̇ʌ Ûȯʌ̇ȵ Ȯȵ 20 Ž ȟ 2.0 ȝʌ̇ʌ :**Mercapto compounds** Țǫʌʌȯõǩŧä ǧʌ̇Ǩõʌȵǧʌ̇HȣŧÔǫõä ȮʌȘŞ Øʌǫȵŕäǻʌ̇ȵ ȣŞʌ̇ ǨŸŧŧȮõä ʌ̃ʌȮ̇ŕ .ʌȮ̇Îŧõ̃ TS ʌ̇ÎʌõäŸäʌ̃Éʌǫèʌ̇ä ÛVS (ȯ/ȯȚȵ 0.005) ʌ̃Țŧõäȝȵ .VS (ȯ/ȯȚȵ 0.005) ʌ̃Țŧõäȣȵ Ȯȵ 0.1 ȣȵ ʌǰõÛ ȳʌ̃ŸʌŕǨʌȵŞʌõ̃Ȑõä

Ȯȵ 100 ɔŸȝ ȯʒÔHȣŸȯ R ȯʒφʌ̇Ÿŧŧäȣȵ Ȯȵ ʌ̃ŧʒʌ̇õ̃ Ǩŧŧŧõŧ Ž ÛǨŧÙȚǩȒȵ ǨφŞʌʒȵ ÛȮ̃ 10 ǨʌʌȀę ā ä̃Øŧŕʌ̇ǩ :**Assay** ǨÊʌʌ̇Ȯŧä ǰè 1 Ǩφʌ̇ʌ̃ŸʌŧŧǨÕǩù Ǝȝ ȯʒŸ‡ä ä̃Øŧŕ ÎʌǫȵŕäÂʌ̇Ȯʌ .R ȯʒφʌ̇Ÿŧŧʌŧʌ̇ Ȯȵ 100 ɔŸȝ ȯʒÔHȣŸȯ ȯʒŸ‡ä ä̃ØŧŕȵŕäȮ ȯʒŕ Ž ÛǨŧÙȚǩȒȵ ÎʌÔȵŕäǨŧŧŧę ȳʌ̃Éʌǫèʌ̇ä ÛC$_{24}$H$_{32}$O$_4$S ȣȵ ȚʒǫŧäÉÊǩŞ ÛȮ̃ǩʌ̇ʌ̃Ȯ̃ǩ ʌ̃ǫȵʒφʌ̇φ 238 ǨDZȚŧŧäȯʒÛʌ̇ ȣŧŧŧȚȝjäǨφ̃ǧ ʌ̃ÉʌȝȮ̃ 47 .($A_{1cm}^{1\%}$ = 470)

ØØØØØ

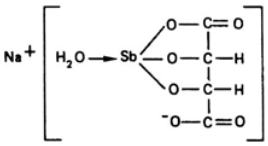
STIBII NATRII TARTRAS

Antimony sodium tartrate DžNjDŽĭŧŧŧŬɛ !NjĭŋNjT lɛβŬβŬ

$C_4H_4NaO_7Sb$:**Molecular formula** ČŁĚÅÂÂƨä Č8ŁÔöä

308.8 :**Relative molecular mass** ČŁĞÊÅöä ČŁĚÅÂÂƨä ČŸŲÒöä

:**Graphic formula** ČŁęÅŁĞţä Č8ŁÔöä



:**Chemical name** ŬƨÅŁţŁÒöä ţèŕä

Sodium aqua[tartrato(4⁻)-O^1,O^2,O^3]antimoniate(III); CAS Reg. No. 34521-09-0.

.ČHŬƨäÅöä CÆʒ ÜŇĞÅÅÖk Ŕŕäŭ ȧƨHŬÊŋ ęŭ ƻƨŸöä ČƨÆʒ ČƨÅÅì scale (øƨÎę) ƧìäŇǵ :**Description** Ƨòƨöä

.TS (ȯ/ȟ750~) ȯƨφÅŷłqä Ž ŇŁŸţʒ ā ąśä ŕ ÜčÅţä ďŋ čÂDZ 1.5 Ž ā ąśä :**Solubility** ČŁęÅäęØöä

.ǧÅŁèøÅƵŸĞöä åÅŘŋ čäęå :**Category** ČÅÅöä

.čƨŘöä ďŋ ƨţʒ ƻŭę ÛŷÅÒǵŭä ČÕŸ8ŋ ČłęÅǵ Ž ƻƨţŁęęƻÅä ŷƨłåƨò ǧäÅùÅù ęÅʒ ƻŭ Æz :**Storage** ďłÂÅÅęöä

Æłʒ ƻłøÆęöÅä ōøÆęł .ČĞùÅęÊŋ gåÅŋ ƻƨţŁęęƻÅä ŷƨłåƨò ǧäÅùÅù :**Additional information** ČŁƨÅŕŭ ǧÅŋƨŸŇŋ

.ČŇÅǩÅţä gøäÅΣä ǧÅDZøå Ž ţÅèŭ ÕÒÅęöä ĆĞÔłę ÛčƨŘöä āÅŁ8ä ƨøęǵ ÛÆùÅöä ƨDzŸö ¢ŕÅŇǩ

REQUIREMENTS ĶĞŭŭŒĶdž!ƒ

ŕę %98.0 ďʒ ÕÕł ŕ Åŋ ƨŸʒ ƻƨţŁęęƻÅä ŷƨłåƨò ǧäÅùÅù Ƀƨęƻʒ :**General requirement** ŷÅŇöä ÆŸÛęţä

.ČÅÅÖä gåÅţä Бŭ ţƨDZÅöÅä ČŕƨÊŢ ÛC$_4$H$_4$NaO$_7$Sb ďŋ %101.0 ďʒ ÆłÂł

:**Identity tests** hŭŇjNJłłε łεβƒĞĤqε

General ČŋÅŇöä 8äÅŇęŕä ǧäóÅęęnä" ƻäƨʒ ŘƠ 8ƨòƨŋ ƨŁ Åţõ ŷƨłåƨÔöä ÕDZƻ ĆóÅęęnŕä Æʒ :A ÂŁõÅęä ȯƨŸŢ ÅŘʒ ÛB óÅęęnŕä ŷäÆÅęèä äæŭ .gÂŁư ǧŸʒÅÅǩ ŬÛŇł Û(123 ČHŬÅÔöä Û1 ÆŸÖä) "identification tests .Õŋ/ŋŸŋ 10

ȯƨŸŢ ďŋ Õŋ 1.0 8ÅŘłę TS (ȯ/ȟ70~) ÕłóƨŸõęóÆŁţä Ŕβ ȯƨŸŢ ďŋ Õŋ 1.0 Ž ȟ 0.05 āäół :B

ÆŁÊõęóÆŁŁ ȯƨŸŢę TS ŷƨŁφƨŋƻä ÆŁÅŸè ȯƨŸŢ Ž ĞäęÅę ÛČŁęÅÕkÅä - čäÅβ ĞäÅèó ƻęłk ÜTS ĶDZęóÆŁţä ÆŁÅŸè

.TS (ȯ/ȟ80~) ȳȚȦǎȚÔõä

General ǦȚȦȞõä ȣäÀȞǤèŕä ǧäøȦǤǤnä" ȷäȚȦȝ ǨƠ ȣȚòȚȚȚȚ Ȯȝ̇ȦǤõä ȤÛȞȦ ÜöȦȚ ȮȚ 0.2 Ž ȚŸȚ 20 ā äØȦ :C

.(123 ǦȤȦÔõä Û1 ÆŸǦõä) ǧäÀùÀÛŸõ ÂŁŧŧõ "identification tests

stannated øÆÔǤŧä ÕȦØȚŸõȘøÆŁTä Ȓ ƥ ȣȚ Ȯ̇Ț 16 ȣȦŘȦȘ öȦȚ Ȯ̇Ț 10 Ž ȳäÀǤ 1.3 ā äØȦ :**Arsenic** ÑŁǤøÂõä distillate gøȦÛÕõä ǎȦȞǩ ÛŽȚÒŧäȘ ǦŸDŽȚΣä ȮÊȣǩ ÜȮȚ 20 ÀÛÕȦȘ ÛŽȚÒȚ Ȥ̇ ȮòȚ̇Ȧ ÛǦŸDŽȚǧ Ž AsTS (ȯ/ȟ250~) gøȦÛÕõä ȮȚȦȞǩ ÜȮȚ 16 ǨÛÕǩ ǎȦȞȦȘ AsTS ÀȦÆÔÕõä ÆȦøȚŸõ ȯȚŸŢ ȣȚ Ȯ̇Ț 0.05 ȣȦŘȦ ÛǦŸDŽȚΣä Ȥ̇ ǧŕȦÊȣõäȘ ŕ Ü(130 ǦȤȦÔõä Û1 ÆŸǦõä) "Limit test for arsenic ÑŁǤøÂõä ÕDŽȚ ƀÆΣä øȦǤǤnŕä" ȷäȚȦȝ ǨƠ ȣȚòȚȚ ȚŁ Ȧŧŧõ .ȳäÀǤ/ȳäÀǤȘÀÒȚ 8 ȣȚ ÀȚõÜ ÑŁǤøÂõä ȚȚǤŢ ȷȚÒȦ

ÆŁȚȦòȚ ǎȦȚ Ȯ̇Ț 10 Ž ȟ 0.50 ÂŁõÀǤŕ ȯȚŸŢ ȷȚÒȦ :**Clarity and colour of solution** ȯȚŸŧä ȷȚȯȘ ǎȦȦÔõä .ȷȚŸõä ÇÆȝȘ

.ȟ/ȚŸȚ 60 ȣȚ ÀȚõÜ ÆÒȦõä ȷȚÒȦ ŕ Ü°ȳ 105 gøäÀǧ ǦDŽøÆŕ Ž̇ŕ :**Loss on drying** ŽŁÁDŽǤÒȦŕ ÆÕȦõä

ȯȚŸŢ ȣȚ ȣäÀÛę gÆȝ ȣȦŘȦȘ öȦŧä ȣȚ Ȯ̇Ț 50 Ž ȟ 1.0 ā äØȦ :**Acidity or alkalinity** ǦȦȚŸÕõä ȘÜ Ǧ ŕȚŧΣä ȘÜ VS (ȯ/ȯȚȚ 0.01) ÕȦØȚŸõȘøÆŁTä Ȓ ƥ ȣȚ ȦȚ Ȯ̇Ț 2 ȣȚ ÀȚõÜ ÆŸÛǤȦ ŕ ÜTS ȯȚǤȦȚȦǤŕ/ȯȘÂȦÀõȚȚȘÈõä gÀŘn ȤÜ ǨÎǩ ŦøǤõä (ÀŘnÜ) ÀȞÎŧä ȣȚ ǦÛèȚǤŧä ǦÛÕȦõä ŕŸȝ ȯȚÔȦŸõ VS (ȯ/ȯȚȚ 0.01) ȳȚȦǎȚÔõä ÆŁÊõȘøÆŁŁ ȣȚ .4.5 öȦŁȦŕ

ȳȚȦǎȚò ǧäÀùÀù ȣȚ ȟ 5 ȣȦŘȦ ÜöȦȚ Ȯ̇Ț 50 Ž ÛǦŁùȚǤŘȚ ǦǤȘàȚȚ ÛȞ 0.5 ǦääÀę ā äØŧ :**Assay** ǦÊȦȦÒŧä ÀȞÎŧõ TS ȦÎȦõä ȳäÆÁǤèŕä VS (ȯ/ȯȚȚ 0.05) ǎȚõä ȝȚ ÀȦȦȞȦ .R ȳȚȦǎȚÔõä ǧäøȚä Ȥȝŕäø ȣȚ ȟ 2Ș R ȳȚŸèŕǩȚä .$C_4H_4NaO_7Sb$ ȣȚ ȚŸȚ 15.44 ùȚȦÒȦ VS (ȯ/ȯȚȚ 0.05) ǎȚõä ȣȚ Ȯ̇Ț 1 Ȯõ .gÀȦȦȞŧä ÀnÜ Ž ȣȦŘȦ

ØØØØØ

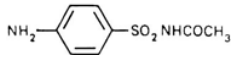
SULFACETAMIDUM

Sulfacetamide ǫǐDŽƒŧǐƨƒ2ǂƨ

$C_8H_{10}N_2O_3S$:**Molecular formula** ǦŁȦȦŕäŕ ǦȣŁÔõä

214.2 :**Relative molecular mass** ǦŁǤÊõä ǦŁȦȦŕäŕ ǦŸǤÒõä

:**Graphic formula** ǦŁǤȦŁǤŧä ǦȣŁÔõä



:**Chemical name** ЧəÀÊŁÊÓöã ĻèŕÃ

N-Sulfanilylacetamide; *N*-[(4-aminophenyl)sulfonyl]aceta-
mide; CAS Reg. No. 144-80-9.

.ǦHuəãÀöã CÁƷ ÜÃǦÀÀÕk ŘÊãÜ ŞÜ ɹƷŸöã ŘÊãÜ ÛBózŸã ȧƷHÜÊŋ :**Description** ƵòƷöã

ÜR òƷφÀŸÊţãŞ R ɹƷQÊèɟã Ž ɹãŞÓöã Ãǵ ÜR ȳóƷƷŞóƷŸÓöãŞ ŏÀţã Ž ÃÁÆDZ ɹãŞÓöã ǦÊHÜì :**Solubility** ǦÊφÀãŞØöã
.TS (ȯ/ȟ750~) òƷφÀŸqã Ž ããŞá

.Antiinfective ЧəãŞÁƷ ãÀŘŋ öãŞã :**Category** ǦÀÀöã

.öƷŘöã dŋ ƻŁƵ ɹÜŞ ÛÃÁÊDZ ǦÕŸ8ŋ ǦŞÀǵ Ž ÁÊŋÀQÊèÀÀŸÊöã ŞÁƵ ɹÜ Æz :**Storage** dÀÂÁQöã

REQUIREMENTS ƚǦÜÃƵkdž!ƒ

%101.0 dƷ ÁÀÂÀ ŕŞ %99.0 dƷ ÕÕÀ ŕ Åŋ ƻŸƷ ÁÊŋÀQÊèÀÀŸÊöã ÐƷQƵ :**General requirement** ȳÀŘöã ÆŸÛQţã
.ǦÁÀÕã gÁÀţã ÐÜ ţƷDZÀöÀã ǦãƷÊŢ Û$C_8H_{10}N_2O_3S$ dŋ

:**Identity tests** hŭŇjNJllɛ lɛƥƑǦHƊɛ

.CŞ B dÀóÀǦQònŕã ŞÜ ÇÁÀÀŋ A óÀǦQònŕã ĘÊǦÛŘ dÓƹ •

Spectrophotometry in öãÀŁΣã ŘƠ ǦÕÛÀţã Ž ЧƷŘöã ƷÊÛöã âÀÊę" ɹãƷÁƷ ŘƠ ȣƷòƷţã óÀǦQònŕã ĘǦÛŁ :A
dŋ ɟŘÁÁöã ƷÊÛöã Ʒŋ öãÀŁΣã ŘƠ ǦŘìɟã î ÀÔQŋã ƷÊù ĘãÀÛQÀ .(43 ǦHuÁÔöã Û1 ÁŸŘã) "the infrared region
.ÁÊŋÀQÊèÀÀŸÊŸö ЧHDZÀţã ƷÊÛöã ƷŋŞÜ RS ÁÊŋÀQÊèÀÀŸÊöã

dƷ ǦΘÀÁöã ǦÊÊŁƷÀöã ǦHÕǦöã ĘãÀÛQŘ ."Related substances ǦöÁÎţã ããƷţã" ɹãƷÁƷ ŘƠ ȣƷòƷţã óÀǦQònŕã ƷDZãÀÀ :B
.gÁÎöãŞ ÀƷŢţãŞ ƷęƷţã Ž B òƷŸŧã dƷ ǦΘÀÁöã ÕŸŘ Ʒŋ A òƷŸŧã

ÕÀóƷÁŸÊöã Řƥ dŋ Õŋ 0.2 ǦããÀę ȣÁŘÀ ÛTS (ȯ/ȟ750~) òƷφÀŸqã dŋ Õŋ 5 Ž ȟ 0.10 ããØÀ :C
.(óØШ ƻÀz) ÁƷQHuãÀã ōóÁŁ ЧøQöã ÛÕÊŸqã ǧÁQÊèÜ ɟQA ÜdÅÊÀŞ TS (ȯ/ȟ1760~)

ȳ 184-181 ƙã ǦDZóÁöÀã :**Melting range** óÁƷÔφŕã òÁƭ

Õŋ 1.0ŞŏÁŋ Õŋ 10 dŋ ɟÀÀŋ Ž ããØŋ ȟ 1.0 ÕŁHQÊÀ óÁǦQònŕã òƷŸŢ ƚŘHuQö :**Heavy metals** ǦŸÊÕŸöã ɹÁÁŘţã
40 ƻŸƷ òƷÔΣã ƻøQǵ ƷÁƹ .ǦÌÀÀŞ ÛÁƎÀ ÛɹãŞØöã ƻøQǵ dÅÊÀ ÛTS (ȯ/ȟ300~) ÕÊQÊèɟã Řƥ òƷŸŢ dŋ
Limit ǦŸÊÕŸöã ɹÁÁŘţã ÕDZɟ ÐÁΣã óÁǦQònŕã" ɹãƷÁƷ ŘƠ ȣƷòƷŋ ƷŁ ÁŁõ ǦŸÊÕŸöã ɹÁÁŘţã dŋ ƻƷQŧã ÁÁŹŞ ŏÁţÁã Õŋ
.ȟ/ȳãÀdŞÀÒŋ 20 dŋ ÀŸõÜ ɹƷÒÀ ŕ Ü(128 ǦHuÁÔöã Û1 ÁŸŘã) A ǦÕÀÀÛöã ÆÊШ "test for heavy metals

(ȯ/òƷŋ 1) ȳƷÁƷÔöã ÁÊÊõŞóÁÊŁ òƷŸŢ dŋ Õŋ 10 Ž ȟ 0.5 ããØÀ :**Solution in alkali** ÐƷŸÕöã Ž òƷŸŧã

ŗş ÛTS2 ƀøÅĒĦţā ȳȝŧ8ōā ďŋ Ǵřşŭ ǰǩÅφ opalescence ȳȝŧď ƀŭ ɟȝÒΛ ŗ şŭ ŃĒȝÅò ǰǩÅÁōā ȯȝŸ‡ā ɟȝÒΛ ÜVS ɟȝŭ" ɟāȝÅ3 ŘƠ ȣȝòȝŋ ȝŁ Åŧõ ÅŧŤQφøÅÕŋ ÉΛ3 Yw3 ƀøÅĒĦţā ȯȝŸ‡ā ɟȝŭ ďŋ ÉΛìŭ ǰǩÅÁōā ȯȝŸ‡ā ɟȝŭ ɟȝÒΛ .(53 ǦHƱÅÔōā Û1 ÉŸŎā) "Color of liquids Ōāāȝ Êōā

ÕΛóȝŸõşøÅĒŤā Ŕβ ȯȝŸŢ ďŋ Ōŋ 10 Ž ħ 1.0 ÂĒõÀφā ȯȝŸŢ ɟȝÒΛ :**Solution in acid** ŔŧΣā Ž ȯȝŸ‡ā .TS2 ƀøÅĒĦţā ȳȝŧ8ōā ďŋ Ǵřşŭ ǰǩÅφ opalescence ȳȝŧď ƀŭ ɟȝÒΛ ŗ şŭ ŃĒȝÅò VS (ȯ/ȯȝŋ 1) .ħ/ŋŸŋ 1.0 ďŋ Äǰõŭ ÈĒō :**Sulfated ash** ŘÅŸÊţā åÅŋÀōā

ďŋ Äǰõŭ ÉÕÅōā ɟȝÒΛ ŗ Ü°ȳ 105 gøāÀǵ ǦDZøÉā ŘāÅǰōā ɟàȝōā ȝøφǵ Ζȧz :**Loss on drying** ΖĒÅDzφōÅā ÉÕÅōā .ħ/ŋŸŋ 5.0

ǦÕĒęÀōā ǦÕφÛōā āāÀÎφèā" ɟāȝÅ3 ŘƠ ȣȝòȝŋ ȝŁ Åŧõ øÅφŋŗā ĘφÛΛ :**Related substances** ǦöÅÎţā åāȝţā ǦŸĦ8ŋ gåÅŧõ R3 silica gel ÅÒĒŸĒÊōā ǦŋŸŁ ÿāÉÅφèÅā (84 ǦHƱÅÔōā Û1 ÉŸŎā) "Thin-layer chromatography R ÉĒŋÅŋøȝȝ ÕĒǰĒŋ ƱƏÅÅφ ȯȝŸŢ ďŋ Ǵāşş ĻDzǵş R ȯȝφÅǰĒţā ďŋ ŧŧDzǵş R ÿøȝȝşøȝŸÒōā ďŋ ŃŧDzǵ 20 ďŋ ɟΛÂŋş ȯȝφÅǰΛqā ďŋ ÿȝDzǵ 9 ďŋ ɟΛÂŋ Ž ǦφŸφ ÕĒōÅŢ ďŋ ÄφφşÄÒŋ 10 ǦHƱÅÔōā ȝŸ3 ŃŸÔÅΛŋ ΕφÛŁ .ōÄHƱφŋ øȝÛõ Äφφ ƱŸĒţā Ž øÅφŋŗā gåÅŋ ďŋ ŋŸŋ 2.5 (A) ƀȝǯ :TS (ȯ/ħ260~) ÅĒφȝŋĵā ďŋ Ǵāşş ĻDzǵş TS (ȯ/ħ750~) ƱŸĒţā Ž RS ÉĒŋÅφĒèÅÅŸè ȯȝŸŢ ďŋ ÿāÄdşÄÒŋ 12.5 (C)ş Äφφ ƱŸĒţā Ž RS ÉĒŋÅφĒèÅÅŸè ȯȝŸŢ ďŋ ŋŸŋ 2.5 (B)ş ǦȝÅƨā ǦHƱÅÔōā æÄŁ .ǧÅΛΛØţā ÄÅΛφφ ȝøφǵ ōāȝTā Ž ΖDzφφ ōÄφφ Ûāāφ ÎφèŗāΛ gÄDzǵ ďŋ ǦHƱÅÔōā ţÂøφ ÉĒĦā .ÄφφΛ gÄDzǵ Ž ÄşÄφφΛōā ďøÅÅΛèō ĒØȝȝ ôÄĦĦφş ÛǦÕĒęå 30 gÉŋ °ȳ 105 gøāÀǵ ǦDZøÉā ďÅÊφ ÛTS ȯȝφÅǰΛÛ/ÕΛóȝÅŸÊōā ŔŧŦ ȯȝŸŢ ƀŭ gÄÛę ÄφŭΛ gÄÛę TS (ȯ/ħ700~) ÕΛóȝÅŸÊōā Ŕβ ǦȝÅŗüā ÄşÄφφΛōā ďøÅÅΛφφ ǰÅφφŭΛ ďØȝ) ǦÕĒęå 15 gÉŋ ǦÕŸ8ŋ øÅĒφ Ž ǦHƱÅÔōā ȝŗȝφ .(Ōŋ 100 Ž R ȳȝĒèÅφȝǦōā ÉΛåȝΛ ďŋ ħ 3ş R ȳȝΛåȝÔōā ŘΛÄφφ ȯȝŸŢ ďŋ ħ 10 ƀȝφȝ *N*-(1- naphthyl) ŋŋĵā ƱƏÅφφ ŋŸĒǰΛŭ (ŌĒǰȝÅφ-1)-*N* ÉΛóȝŸõşøÉĒŁ ȯȝŸHƱŋ æÄφφş ǦÕĒęå 15 gÉŋ ùȝāå ōāȝŁ ÙÛÛƯ ÒHƱÅΛş æāæøφqā gåÅȝŭ ŌǦę ΖDzφφ ōÄφφ ÛgøşÄŘōā ÉΛ3 .TS ȯȝφÅǰΛŭ/ethylenediamine hydrochloride ďŋ gÉŗ Äǰõŭ ÛǦĒÊĒƏÄōā ǦHÕǦōā ōÅÅǰφèÅā ÛA ȯȝŸ‡Åā ÅȝŤĒŸ3 ŌÔHƱφÊΛ ǦHÕā ǦΛŭ ɟȝÒφφ ŗ .øÅŤΛōā ōȝŗ Ž āāÄÎφèŗāΛ .C ȯȝŸ‡Åā ÅȝŤĒŸ3 ŌÔHƱφÊΛ ƱøφōāΛ ǦHÕǦōā

Û1 ÉŸŎā) "Nitrite titration ŘΛÄφφΛōā gÄΛÅĦφ" ɟāȝÅ3 ŘƠ ȣȝòȝŋ ȝŁ Åŧõ ǦÊΛÅÕţā ŘÄΘ :**Assay** ǦÊΛÅÕţā ÕΛóȝŸõşøÉĒŤā Ŕβ ďŋ Ōŋ 20 ďŋ ɟΛÂŋ Ž ǦāāØŋ ÛǦĒùȝǦŘŋ Ǧφşàȝŋ ÛĦ 0.5 ǦāāÀę ÿāÉÅφèÅā .(143 ǦHƱÅÔōā 0.1) ȳȝΛåȝÔōā ŘΛÄφφ ďŋ Ōŋ 1 Ōõ .VS (ȯ/ȯȝŋ 0.1) ȳȝΛåȝÔōā ŘΛÄφφ ÄΛÅĦΛş ÛōÅφ Ōŋ 50ş TS (ȯ/ħ250~) .$C_8H_{10}N_2O_3S$ ďŋ ŋŸŋ 21.42 ùȝÅÒΛ VS (ȯ/ȯȝŋ

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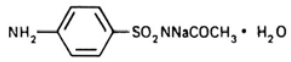
SULFACETAMIDUM NATRICUM

Sulfacetamide sodium !NjĭσNjT℠ σĭDŽƑĭĭƨƑƨ

$C_8H_9N_2NaO_3S,H_2O$:**Molecular formula** ĞĒÅΛÂƨäĞ8ĒÔöä

254.2 :**Relative molecular mass** ĞĒGÊΛöäĞĒÅΛÂƨäĞŸQÒöä

:**Graphic formula** ĞĒφÅĒGţäĞ8ĒÔöä



:**Chemical name** ŬəÅĒţĒÒöä ţèřä

N-Sulfanilylacetamide monosodium salt monohydrate; *N*-[(4-aminophenyl)sulfonyl]acetamide monosodium salt monohydrate; CAS Reg. No. 6209-17-2 (monohydrate).

.Sulfacylum-natrium ȳƶΛäƶÔöä ȳƶŸĒèÅÅŸè :**Other name** ÀnŬ ţèä

.ĞHUəäÀöä CÆ3 ÜÀÅÔη ŘĒäŬ ŞŬ JƶŸöä ŘĒäŬ ÛBØƶŸä ȧƶHUÊη :**Description** Ƶòƶöä

ā äşæ ř ÜTS (ȯ/ȟ750~) ȯƶφÅŽΛqä Ž JÅäŞØöä ĞĒHUì ÜŏÅţä ȯη ŏÂDZ 1.5 Ž ā äşæ :**Solubility** ĞĒφÅäŞØöä

.R Ĝφţä Ž řŞ R ȳØƶƶŞØƶŸÒöä Ž ŘĒŸţ3

.Antiinfective ŬəäŞÆ3 äÅŘη öäŞä :**Category** ĞÅÅöä

.öƶŘöä ȯη ĞĒţT ÛŘÆĒDZ ĞÕŸ8η ĞΛŞÅg Ž ȳƶΛäƶÔöä ÆĒηÅQĒèÅÅŸè ŞÅƵ JŬ Æz :**Storage** ȯΛÂÄQöä

JΛØÆQöÅä ȳƶΛäƶÔöä ÆĒηÅQĒèÅÅŸè ōØÆQΛ ÛöƶŘöä ā ÅĒ8ä ƨØQg :**Additional information** ĞĒƶÅřŬ gÅηƶŸĤη

.ĞĤÅĞÄţä gØäÀΣä gÅDZØää Ž ţÀèŬ ÕÒÅQöä ĞGÔΛŞ ÛÆùÀöä ƶDzŸö ¢řÀĤĞ ÆΛ3

REQUIREMENTS ĞGnŬƶ5kdž!ƒ

ȯ3 ÆΛÂΛ řŞ %99.0 ȯ3 ÕÕΛ ř Åη ƨŸ3 ȳƶΛäƶÔöä ÆĒηÅQĒèÅÅŸè ƁƶQƵ :**General requirement** ȳÅĞöä ÆŸÛQţä

.ĞĒəÅηŸöä gäÅţä БŬ ţƶDZÀöÅä ĞäƶÊT ÛC8H9N2NaO3S ȯη %101.0

:**Identity tests** hŭNjNJ℠ lεβƑĞĤQε

.DŞ CŞ B gäØÅGQnřä ŞŬ ĈäÀÅη A ØÅGQnřä ĘĒGÛĞ ȯÒƶ •

.öÅŘĒä ĞäÅèØ JQÅĞ ÜTS (ȯ/ȟ300) ÕĒQĒèţä Řβ ȯƶŸT ȯη Ōη 2 8ÅŘΛŞ öÅη Ōη 10 Ž ȟ 1 ā äØΛ :A

Åţõ ĞÅÅÖä ĞöÅţÄöä ƨŸ3 ØÅGQnřä ĘGÛł .°ȳ 105 gØäÀg ĞDZØÆä ƵÅΘŞ ÛäØÅGöä öÅţÅä ŌÊ8ĞĞÛĞìÀη ƨŸ3 ĞäÅèÀöä ƷţΘ

Spectrophotometry in the infrared ŏäÀŧΣä ŘƠ ČÔÛÄţä Ž ƯəȚÊöä ȚŒÛöä âÄŒę" ɟäȚÄȝ ŘƠ ȣȚòȚŋ ȚŁ ÆŒŋÄQŒèÄÄŸè ȣȝ ǰǩÄÄöä ȚŒÛöä ȝŋ ŏäÀŧΣä ŘƠ ČĤìɟä î ÄÔQŋä ȚŒù ĘäÄÛQΛ .(43 ČHƯÄÔöä Û1 ÆŸŎä) "region .ȳȚΛǻȚÔöä ÆŒŋÄQŒèÄÄŸÊö ƯĤDZÀţä ȚŒÛöä ȝŋ ȘÙ RS ȳȚΛǻȚÔöä .(ÆŒŋÄQŒèÄÄŸè) ÄĤGΛÀÕk °ȳ 183 ÛA øÄĠQnŗä ȣŋ ČΘÄÄöä ČäÄèÀöä øÄŦÔqä ČDZǻǻ :B ȣŋ Ōŋ 0.2 ȣÄŘΛ ÛTS (ȯ/ħ750~) ȯȚqÄŽΛqä ȣŋ Ōŋ 5 Ž A øÄĠQnŗä ȣŋ ČΘÄÄöä ČäÄèÀöä ȣŋ ħ 0.1 ā äØΛ :C .(øØШ ȘÀz) ¢QHƯäÄä õøÆΛ ƁØöä ÛŌŒŽΛqä ǧÄQŒèÙ ǰQΛΛ ÜȣÁÊΛȘ ÛTS (ȯ/ħ1760~) ŌΛØȚÄŸÊöä Ř β General ČŋÄĦöä ȣäÀĦQèŗä ǧäøÄĠQnä" ɟäȚÄȝ ŘƠ ȣȚòȚŋ ȚŁ Ätõ ȳȚΛǻȚÔöä ŌDZɟ øÄĠQnŗä ÆÄȝ :D (ŌĦÎΛ) ÆŋÀΛ ÛB øÄĠQnŗä ȳäÆÁQèä ȘÆö .gÂŒŧţä ǧŸȝÄÄQöä ƯÛĦΛ Û(115 ČHƯÄÔöä Û1 ÆŸŎä) "identification tests .TS (ȯ/ħ60~) ŌŒQŒèɟä Ř β ȯȚŸŢ Ž ČöÄŧžöä ā äØĦȘ ħ 0.5

ƁÄȚä öÄţä ȣŋ Ōŋ 10 Ž ħ 0.5 ÂŒõÄQæ ȯȚŸŢ ɟȚȯΛ :**Clarity and colour of solution** ȯȚŸ‡ä ɟȚȯȘ öÄÄÔöä ȚŁ Ätõ ÄŧŦQqøÄŌŋ ÆÄȝ Yw1 ƁøÄŒĦţä ɟȚŸöä ȯȚŸŢ ȣŋ ÆÌÙ ¢qȚȯ ɟȚȯΛ ŗȘ ĦŒȚÄȯ R ɟȚäÀȯöä ÆŒÊõÙ ƯäÄÄQ ȣŋ .(53 ČHƯÄÔöä Û1 ÆŸŎä) "Colour of liquids ŌäȚÊöä ɟȚȯ" ɟäȚÄȝ ŘƠ ȣȚòȚŋ

Determination of water by ÄÎŒȚ ȯøÄõ ČÔΛÀÛä öÄţä ĸŒĦĦk" ɟäȚÄȝ ŘƠ ȣȚòȚŋ ȚŁ Ätõ ȣŋĦΛ :**Water** öÄţä ȘȚQŢ ŌÕΛ ŗ ÜĦGΛÀÕk gÄÄţä ȣŋ ħ 0.2 ȳäÆÁQèÄæ Û(145 ČHƯÄÔöä Û1 ÆŸŎä) A ČÕΛÀÛöä Û"the Karl Fisher Method .ħ/ŋŸŋ 80 ȣȝ ÆΛÂΛ ŗȘ ħ/ŋŸŋ 60 ȣȝ öÄţä

.9.5-8.0 ÛR ɟȚäÀȯöä ÆŒÊõÙ ƯäÄÄQ ȣŋ ȯÄn öÄŋ Ž Ōŋ/ŋŸŋ 0.05 ÂŒõÄQæ ȯȚŸŢ öÄŁÄæ :**pH Value** öÄŁÄGöä Ätę ČÕŒęÀöä ČÕGÛöä āäÀÎQèä" ɟäȚÄȝ ŘƠ ȣȚòȚŋ ȚŁ Ätõ øÄĠQnŗä ęGÛΛ :**Related substances** ČöÄÎţä ǻäȚţä ČŸĦ8ŋ gÄÄtõ R6 silica gel ÄÔŒŸŒÊöä ČŋŸŁ ȳäÆÁQèÄæ (84 ČHƯÄÔöä Û1 ÆŸŎä) "Thin-layer chromatography ȯȚqÄŽΛqä ȣŋ ĦtDzǵ 25Ș R ȯȚqÄkȚä-1 ȣŋ ĦtDzǵ 50 ȣŋ ǰΛÂŋȘ (ČtƯŋ ƁøÄΘ øÆÔŋ ȣŋ ČŸĦ8ţä ČHƯÄÔöä) ȘŸȝ ĦŸÔÄΛŋ ęGÛŁ .ÕÄHƯŋ øȚÛõ TS (ȯ/ħ260~) ÄŒȚŋɟä ȣŋ ȳȚDzǵ 10Ș öÄţä ȣŋ ĦtDzǵ 25Ș R öÄţä ţȘÂøΛŋ ȯȚŸŢ ȣŋ ŋŸŋ 0.50 (B)Ș ÄQõ ƯŸŒţä Ž øÄĠQnŗä gÄÄŋ ȣŋ ħ 0.10 (A) ƁȚȚ :ŌŒÄŢ ČQŸQ ȣŋ ÄQõȘÄÔŋ 5 ČHƯÄÔöä ȣŋ ČHƯÄÔöä ţÂøφ ÆŸæ .ÄQõ ƯŸŒţä Ž RS ÆŒŋŸŒφÄÄŸÊöä ȯȚŸŢ ȣŋ ŋŸŋ 0.25 (C)Ș ÄQõ ƯŸŒţä Ž RS ÆŒŋŸŒφÄÄŸÊöä ȚÆŋÙ ŌŒŽŋ ƯäÄÄQ-4 ȯȚŸHƯŋ ČHƯÄÔöä æÄĦ .ǧÄGΛØţä ÄÄCQk ȘøQǵ öäȚTä Ž ȚDzQõ ÕÄQk ÛäÄÎQèŗä gÄDzǵ ƯøQöä ČŸHÕGöä ȣŋ gÆÌ ÄŽõÙ ÛČŒÊŁäÄöä ČŸHÕGöä öÄÄŽQèÄæ ÛA ȯȚŸ‡Äæ ÄŦŒŸȝ ŌÔHƯQÊΛ ČŸHÕæ ČΛÙ ɟȚÒk ŗ .TS5 ÆŒŁÆöäÂøΛæ .C ȯȚŸ‡ä ȣȝ ČΘÄÄöä ÕŸk ȣŋ ÆÌÙ ȝÕGöä ÕŸk ȣŋ gÆǵäȘ ČŸHÕæ ȣŋ ÄŽõÙ ÆDZȚk ŗ .B ȯȚŸ‡Äæ ÄŦŒŸȝ ŌÔHƯQÊΛ Û1 ÆŸŎä) "Nitrite titration ŘΛÄQΛöä gÄΛÄŸHŋ" ɟäȚÄȝ ŘƠ ȣȚòȚŋ ȚŁ Äŋ ÆÊÙ ČÊΛÄÕţä ȘÀΘ :**Assay** ČÊΛÄÕţä Ř β ȣŋ Ōŋ 20Ș öÄŋ Ōŋ 50 ȣŋ ǰΛÂŋ Ž āäØk ÛČŒÙȚGŘŋ ČφȘàȚŋ ÛĦ 0.5 ČääÄę ȳäÆÁQèÄæ Û(143 ČHƯÄÔöä

ȳȚΛåȚÔöä ǨΛÀÀǫǫ ȣȵ ÀǫȮ ȬŸŒȵ 1 ÕȬ .VS (ȯ/ȯȚȵ 0.1) ȳȚΛåȚÔöä ǨΛÀǫΛä ÀΛÀĤΛȘ ÛTS (ȯ/Ȟ70~) ÕΛøȚŸõȘøÆŒTä
.$C_8H_9N_2NaO_3S$ ȣȵ ŋŸŋ23.62 ùȚÀÒΛ VS (ȯ/ȯȚȵ 0.1)

ØØØØØ

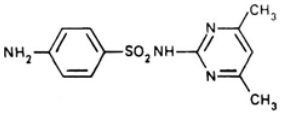
SULFADIMIDINUM

Sulfadimidine DžĭǫĭDŽĭǫƒƑ2ǂƨ‖ε

:Molecular formula ǦŒÀΛÂƨä Ǧ8ŒÔöä $C_{12}H_{14}N_4O_2S$

:Relative molecular mass ǦŒǦÊΛöä ǦŒÀΛÂƨä ǦŸǫȮöä 278.3

:Graphic formula ǦŒǫÀŒǦȚä Ǧ8ŒÔöä



:Chemical name ȣƨÀŒȚŒÒöä ȴèȷä

N^1-(4,6-Dimethyl-2-pyrimidinyl)sulfanilamide; 4-amino-*N*-(4,6-dimethyl-2-pyrimidinyl)benzenesulfonamide; CAS Reg. No. 57-68-1.

:Other names ƤÀnÛ öÀƨÛ ȳȚΛÂŒȚåÀÀŸè ÛSulfadimezinum sulfamethazine ȣΛÀÀƵŋÀÀŸè.

:Description ƵòȚöä ǦΛÀÕk ǦȣƨÀÀöä CÆƷ ȘÛ ǦȣƨÀÀöä CÆƷ ÜȣȚÀõ ŘŒÀÛ ȘÛ ȴȚŸöä ŘŒÀÛ ÛBøȚŸæ ȧȚȣÊŋ.

:Solubility ǦŒǫÀÀȘØöä ǦŒǫÀÀȘØöä ÉŒȣì ÜöÀȚȚä Ž ÀÀEDZ ȴÀÀȘØöä Ž ā ÀȘæ ÜTS (ȯ/Ȟ750~) ȯȚǫÀŽΛqä Ž ȴÀÀȘØöä ÉŒȣì ÜöÀȚȚä Ž ÀÀEDZ ȴÀÀȘØöä ÉŒȣì ÜR ȴȚǫŒèȷä.

:Category ǦÀÀöä ÀÀŘŋ öÀȘÀ.

:Storage ȣΛÂÁǫöä ȣΛÆŒȚåÀÀŸÊöä ȘÀƵ ȴÛ Æƨ ȣΛÆŒȚåÀÀŸÊöä ÛÀÀEDZ ǦÕŸ8ŋ ǦΛȘÀg Ž ȣΛÆŒȚåÀÀŸÊöä ȘÀƵ ȴÛ Æƨ öȚŘöä ȣȵ ƨŒȣ ȴŸƨ ȴÛȘ.

REQUIREMENTS ǨǦȣΛÀÀƵkdž!ƒ

:General requirement ȳÀŘöä ÆŸÛǫȚä %100.5 ȣƷ ÆΛÂΛ ƨȘ %99.0 ȣƷ ÕÕΛ ƨ Àŋ ƨŸƷ ȣΛÆŒȚåÀÀŸÊöä ƨȚǫƵ.
ǦÀÀÒä gåÀȚä ƨÛ ȚȚDZÀöÀä ǦȣȚÊȚ Û$C_{12}H_{14}N_4O_2S$ ȣȵ.

:Identity tests hƨĭNjNJЛε ȴεƥƒǦƧHƵε:

• ȘÛ CȘ B ǧäøÀǦǫnƨä ȘÛ ÇåÀÀŋ A øÀǦǫnƨä ȘŒǦÛk ȣÒε.

Spectrophotometry in ðãÀŧΣã ŘƠ ČÕÛÅŧã Ž ƱƵŽŘõã Ζ ƲÛõã âÅęˮ ɟãžÅʒ ŘƠ ȣžòžŧã óÅĞQnŗã ĘĞÛł :A
ɒɳ ǰŘÅÅõã Ζ ƲÛõã ʒɳ ðãÀŧΣã ŘƠ ČĦÌɟã î ÅÔQɳã Ζ ƲÙ ĘãÅÛQΛ .(43 ČHƱÅÔõã Û1 ÆŸŎã) "the infrared region
.ɒΛÆƲƨåÅÅŸÊŸõ ƱĦDZÀŧã Ζ ƲÛõã ʒɳ ȘÛ RS ɒΛÆƲƨåÅÅŸÊõã ȯžŸŢ
ğãóÅĞQnã" ɟãžÅʒ ŘƠ ČƲõȘɟã ČƲŘÅɳȘóɟã ğÅÅƲɳɟã ȣãÀĦQèŗ ȣžòžŧã Ō3ÅÅQõã ÑĞΛÀÕŘ ĥ 0.05 ƱÛĦΛ :B
.ČƲõÅÕŘÅã ČãÅèó ÑDzQÅɳ Û(119 ČHƱÅÔõã Û1 ÆŸŎã) "General identification tests ČɳÅĦõã ȣãÀĦQèŗã
.(ƙQÕƲęå ČããÅę) ČãÅèó ÕÒÎQŘ ʔøQǵ TS (ȯ/ĥ700~) ÕΛóžÅŸÊõã Ŕβ ɒɳ Ōɳ 1 ʒɳ ĥ 0.5 ΖÛŸã ʔŸ8Λ :C
.R ƙõɟã ɒɳ Ōɳ 20 øã ǰΛÂŧã ÒŸÁQÊΛȘ TS (ȯ/ĥ80~) ȳžΛåžÔõã ÆƲÊõȘóÆƲŁ ȯžŸŢ ɒɳ Ōɳ 15 ȣÅŘΛ ÛåƎΛ
ČDZóå .ƱÅɳ ȳÅþ ʔŸʒ ȣÅÅƨã ʔøQǵ ÀÁGΛȘ R ČƲÅɳŸõã ȳžΛåžÔõã ǵÅÅŸè ɒɳ ČÕĞù Ǝʒ ƙõɟã ČòŸn ǴìÀǩ
.(ɒΛÆƲƨƙã ÕƲŽƲɳ ƱÅÅõ-6.4-žÆɳÙ-2) °ȳ 153 ČããÀę ÛóÅŦÔQŗã
.ÕÒÅQõã ʒɳ ÑĞΛÀÕŘ °ȳ 197 ÛóÅŦÔQŗ ČDZóå :D

óÅĞQnŗã" ɟãžÅʒ ŘƠ ȣžòžɳ žŁ Åŧõ ĥ 1.0 ÕŧŘQÊΛ óÅĞQnŗã ȯžŸŢ ƙŘƱQõ :**Heavy metals** ČŸƲÕŽõã ɟåÅŘŧã
ʔžQŧã ɒĦŘΛ Ü(127 ČHƱÅÔõã Û1 ÆŸŎã) 4 ðãÀDZɟã ÆÊÛ "Limit test for heavy metals ČŸƲÕŽõã ɟåÅŘŧã ÕDZɟ ÞÆΣã
.ĥ/ȳãÀdȘÀÒɳ 20 ɒɳ ÀŽõÙ ɟžÒΛ ŗ Ü(128 ČHƱÅÔõã Û1 ÆŸŎã) A ČÕΛÀÛŸõ ÑÕžȘ ČŸƲÕŽõã ɟåÅŘŧã ɒɳ
.ĥ/ŋŸɳ 1.0 ɒɳ ÀŽõÙ ÈƲõ :**Sulfated ash** ŘÁŸÊŧã åÅɳÀõã
ɒɳ ÀŽõÙ ÆÕÅõã ɟžÒΛ ŗ Ü°ȳ 105 gøãÀǵ ČDZóÆã ŘãÅŽõã ɟàžõã ʔøQǵ Ζ ȧz :**Loss on drying** ΖƲÁDzQõÅã ÆÕÅõã
.ĥ/ŋŸɳ 5.0

°ȳ 70 gøãÀǵ ČDZóÆã R ɟžãÀÒõã ÆƲÊõÙ ƱÅÅQ ɒɳ ÐÅŲã ðÅŧã ɒɳ Ōɳ 100 ʒɳ ĥ 2 ɒÁÊΛ :**Acidity** �žŧΣã
ÿãÆÁQèÅã ÛVS (ȯ/ȯžɳ 0.1) ȳžΛåžÔõã ÆƲÊõȘóÆƲŁ ȯžŸHɳ ČãÅèÀõã ɒɳ 25 ÀΛÅĦΛ .ǴìÀΛȘ åƎΛ ÛĘãÅęå 5 gÆɳ ÑĞΛÀÕŘ
ÀŘÎŧã ɒɳ ČÛèžQŧã ČÛÕÅõã ʔŸʒ ȯžÔHƱŸõ Ōɳ 0.2 ɒɳ ÀŽõÙ ÆŸÛQΛ ŗ ÜÅŘÎŧõ TS ȯžφÅŽÙ/ȯžŧƲQžɳȘÀã Čęøà
.(ÀŘnÙ)

ČÕƲęÀõã ČÕĞÛõã ããÀÎQèã" ɟãžÅʒ ŘƠ ȣžòžɳ žŁ Åŧõ óÅĞQnŗã ĘĞÛΛ :**Related substances** ČõÅÎŧã åãžŧã
15 ɒɳ ǰΛÂɳȘ ČŸÑ8ɳ gÅŧõ R3 ÅÒƲŸÊõã ČɳŸŁ ÿãÆÁQèÅã (84 ČHƱÅÔõã Û1 ÆŸŎã) "Thin-layer chromatography
10 ČHƱÅÔõã ʔŸʒ ŦŸÔÅɳ ĘĞÛł .ÕÀHƱɳ øžÛõ TS (ȯ/ĥ17~) ÅƲžɳɟã ɒɳ ȳžDzǵ 3 ÛR ȯžφÅŽã-1 ɒɳ ŦŧDzǵ
ȯžŸŢ ɒɳ ŋŸɳ 0.050 (B)Ș ÀõÙ ƱŸƲŧã Ž øÅĞQnŗã gÅɳ ɒɳ ŋŸɳ 10 (A) ÞžƷ :R ɟžQƲèɟã Ž ƙȯžŸŢ ɒɳ ÀõȘÀÒɳ
10 gÆɳ ÿ 105 gøãÀǵ ČDZóÆã ɒÁÊŘ ÛããÀÎQèŗã gÀDzǵ ɒɳ ČHƱÅÔõã ţÂøφ ÆŘã .ÀõÙ ƱŸƲŧã Ž RS ÆƲɳŸφÅÅŸÊõã
ÕÅŽQèÅã ÛA ȯžŸ‡Åã ÅŦŸʒ ÕÔHƱQÊΛ ČŘÕã ČΛÙ ɟžÒŘ ŗ .TS3 ÆƲŁÆõãÂøÅã žÆɳÙ ÕƲŽƲɳ ƱÅÅõ-4 ȯžŸHɳ ŦÀŧȘ ĘãÅęå
.B ȯžŸ‡Åã ÅŦŸʒ ÕÔHƱQÊΛ ƱøQõã ČŘÕĞõã ɒɳ gÆÌ ÀŽõÙ ÛĞƲÊƲãÀõã ČŘÕĞõã

Û1 ÆŸŎä) "Nitrite titration Ǩ⅄ÀǫÀõä gÀ⅄ÀĬĦǫ" ɹäzÀĦõä ǨƠ 8ȝòȝǫ ȝŁ Åǫ ÆÊŒ ǦÊ⅄ÀÕţä ƤÀΘ :**Assay** ǦÊ⅄ÀÕţä ÛTS (ȯ/Ħ70~) Õ⅄ózŸõşøÆŒTä Ř ƀ ȯǫ Ôǫ50 Ž ā äØǩ ÛǦŒùzǦŘǫ Ǧǫşàzǫ ÛĦǦ⅄ÀÕǩ 0.5 ÿäÆÁǫèÀæ Û(143 ǦHȯÀÔõä ŋŸǫ 27.83 ùzÀÒ⅄ VS (ȯ/ȯzǫ 0.1) ȳz⅄ǎzÔõä Ǩ⅄ÀǫΦ ȯǫ ÀǫÕ ŦŸŒǫ Ôȭ .VS (ȯ/ȯzǫ 0.1) ȳz⅄ǎzÔõä Ǩ⅄ÀǫÀæ À⅄ÀĬĦ⅄ş .$C_{12}H_{14}N_4O_2S$ ȯǫ

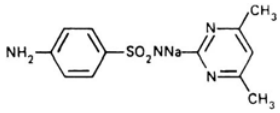
SULFADIMIDINUM NATRICUM

Sulfadimidine sodium !NjĭǫNjTǁε DžĭǫĭDŽĭǫƒ2ǂƨ

$C_{12}H_{13}N_4NaO_2S$:**Molecular formula** ǦŒÀ⅄Âƨä Ǧ8ŒÔõä

300.3 :**Relative molecular mass** ǦŒǦÊ⅄õä ǦŒÀ⅄Âƨä ǦŸǫÒõä

:**Graphic formula** ǦŒǫÀŒǦţä Ǧ8ŒÔõä



:**Chemical name** ŦəÀŒŧŒÒõä ȷèřä

*N*¹-(4,6-Dimethyl-2-pyrimidinyl)sulfanilamide monosodium salt; 4-amino-*N*-(4,6-dimethyl-2-pyrimidinyl)benzenesulfonamide monosodium salt; CAS Reg. No. 1981-58-4.

.ÛǦ⅄ÀÕǩ ǦHȯäÀäõä CÆ3 şÛ ǦHȯäÀäõä CÆ3 ÜŦƩÀõ ŘŒäÛ şÛ ɹzŸõä ŘŒäÛ ÛƀózŸæ ȧzHȯÊǫ :**Description** Z ȯzõä

.TS (ȯ/Ħ750~) ȯzǫÀŽ⅄qä ȯǫ ÂõÂDZ 60ş ȯÀţä ȯǫ ȯÂDZ 2.5 Ž ā äşæ :**Solubility** ǦŒǫÀæşØõä

.ȷŒõäÀƨä ǎÀŘǫ ȯäşǎ :**Category** ǦÀÀõä

.ȯzŘõä ȯǫ ɔŧȝ ɹÛş ÛÛÆŒDZ ǦÕŸ8ǫ Ǧ⅄şÀǵ Ž ȳz⅄ǎzÔõä ȯ⅄ÆŒƩǎÀÀŸè ŞÀȝ ɹÛ Æz :**Storage** ȯ⅄ÂÁǫõä

ÛÆùÀõä zDzŸõ ¢řÀĬĦǩ ÆÀ3 ǰ⅄óÆǫõÀæ ȳz⅄ǎzÔõä ȯ⅄ÆŒƩǎÀÀŸè ōøÆǫ⅄ :**Additional information** ǦŒzÀřÛ ǧÀǫzŸĬĦǫ .ǦĬĦǩÀţä gøäÀΣä ǧÀDZøǎ Ž ţÀèÛ ÕÒÀǫõä ÁǦÔ⅄ş ÛõzŘõä ā ÀŒ8æ ɔøǫǵ

REQUIREMENTS ǨǦȯÛŽŠǩdž!ƒ

ȯȝ Æ⅄Â⅄ ŧş %98.0 ȯȝ ÕÕ⅄ ŧ Åǫ ɔŸȝ ȳz⅄ǎzÔõä ȯ⅄ÆŒƩǎÀÀŸè Ƀzǫȝ :**General requirement** ȳÀĬĦõä ÆŸÛǫţä .ǦÀÀÕä gǎÀţä Ƃ Ţ ɹzDZÀõÀæ ǦæzÊŢ Û$C_{12}H_{13}N_4NaO_2S$ ȯǫ %101.0

:**Identity tests** hȯĭNjNJǁε l εƀƒǦĬĦǁε

.DȘ CȘ B ğăóÅĠǫnŗă ȘŬ DȘ A ďłóÅĠǫnŗă ĘĮĠÛĶ ďÒȚ •

ĞDZóÆă ĞöÅŧžöă ZÅΘȘ ÛĠÌÀłÅ ÛTS (ȯ/ȟ70~) ÕłóȚŸõȘóÆĮŤă ŘŧŦ ŘŧȚ ÛöÅŋ Ōŋ 10 Ž ȟ 0.1 ā ăØł :A

ĞÕÛÅŧă Ž ŬəȚŘöă ZĮÛöă âÅĮę" JăȚÅȝ ŘƠ ȽȚòȚŋ ȚŁ Åŋ ÆÊŦ ĞȚÅƨă ĞöÅŧžöă ȚŸȝ óÅĠǫnŗă ĘĠÛŁ .ŷ 105 góăÀǵ

ĞĦÌŀă î ÅÔǫŋă ZĮù ĘăÅÛǫł .(43 ĞĦÅÔöă Û1 ÆŸŎă) "Spectrophotometry in the infrared region öăÀŧΣă ŘƠ

.ďłÆĮȚăÅÅŸÊŸö ŬĦDZÀŧă ZĮÛöă ȝŋ ȘŬ RS ďłÆĮȚăÅÅŸÊöă ďŋ JŘÅÅöă ZĮÛöă ȝŋ öăÀŧΣă ŘƠ

ÛĠĦÌÀǫöÅă ĞăÅèÀöă ŌÔÅŘ ÛTS (ȯ/ȟ300~) ÕĮǫĮèŀă Ŗβ ďŋ Ōŋ 2 ȽÅŘł ÛöÅŋ Ōŋ 10 Ž ȟ 0.1 ā ăØł :B

ğăóÅĠǫnă" JăȚÅȝ ŘƠ ĞĮöȘŀă ĞĮŘÅŋȘóŀă ğÅĮŋŀă ȽăÀŬǫèŗ ȽȚòȚŧă Ōȝ ÅÅǫöă ŬÛŬŘ .ăóÅĠöă öÅŧÅă ŌÊ8ŘȘ

.ĞŬùÅè ĞĮöÅÕŘÀă öăÀβ ĞăÅèó JǫłÅ Û(119 ĞĦÅÔöă Û1 ÆŸŎă) "General identification tests ĞŋÅŬöă ȽăÀŬǫèŗă

ĞăăÀę) ĞăÅèó ÕÒÎǫŘ ŋøǫǵ TS (ȯ/ȟ700~) ÕłóȚÅŸÊöă Ŗβ ďŋ Ōŋ 1.5 ȝŋ ȟ 0.5 ZÛŸă ŋŸ8Ł :C

ďŋ Ōŋ 20 øă JłÂŧă ÒŸÁǫÊłȘ TS (ȯ/ȟ80~) ȚȚłăȚÔöă ÆĮÊõȘóÆĮŁ ȯȚŸŢ ďŋ Ōŋ 15 ȽÅŘł ÛăƎł .(ĸǫÕĮęă

.ŬəÅŋ ȚÅβ Ž ȽÅÅƨă ŋøǫǵ ÀÁĠłȘ R ĞĮəÅŋ Ŷöă ȚłăȚÔöă ğÅŸè ďŋ ĞÕĠù Ǝȝ ĸǫjă ĞòŸn ĠìÀŘ .R ĸǫjă

.(ďłÆĮȚĸă ÕĮŽĮŋ ŬəÅÅǫ-6.4-ȚĮŋŬ-2) ŷ 153 ĞăăÀę ÛǫÅŦÔǫŗă ĞDZǵă

General ĞŋÅŬöă ȽăÀŬǫèŗă ğăóÅĠǫnă" JăȚÅȝ ŘƠ ȽȚòȚŋ ȚŁ Åŧõ ȚłăȚÔöă ÕDZj óÅĠǫnŗă ÆÅȝ :D

ĞĮŧõ (ÕŬÎŘ) ÆŋÀŘ ÛB óÅĠǫnŗă ȚÆÁǫèă ăæŬ .gÂĮư ğŸȝÅŘ ŬÛŬł (123 ĞĦÅÔöă Û1 ÆŸŎă) "identification tests

.TS (ȯ/ȟ60~) ÕĮǫĮèŀă Ŗβ Ž ĞöÅŧžöă ăØŘȘ gĸ8ò

óÅĠǫnŗă" JăȚÅȝ ŘƠ ȽȚòȚŋ ȚŁ Åŧõ ȟ 1.0 ÕŧŬǫÊł óÅĠǫnŗă ȯȚŸŢ ĸŘĦǫÕ :**Heavy metals** ĞŸĮÕžöă JăÅŬŧă

ŘȚǫ+ă ďłŬł Ü(127 ĞĦÅÔöă Û1 ÆŸŎă) 4 öăÀDZqă ÆÊŦ "Limit test for heavy metals ĞŸĮÕžöă JăÅŬŧă ÕDZj ÞÆΣă

.ȟ/ȳăÀdȘÀÅŋ 20 ďŋ ÀžõŬ JȚÅł ŗ Ü(128 ĞĦÅÔöă Û1 ÆŸŎă) A ĞÕłÀÛŸö łłÕȚȘ ĞŸĮÕžöă JăÅŬŧă ďŋ

ÞÅĮă öÅŧă ďŋ Ōŋ 10 Ž ȟ 3.3 ÂĮõÀǫă ȯȚŸŢ JȚÅł :**Clarity and colour of solution** ȯȚŸ+ă JȚöȘ öÅłÅÔöă

ȚŁ Åŧõ ÅŧŦǫǫÅÕŋ ÆÅȝ Yw4 ÞóÅĮŬŧă ȯȚŸ+ă JȚö ďŋ ÆÌŬ ¢ǫȚö JȚÅł ŗȘ ÛłĮȚÅÒ JȚăÀÅÒöă ÆĮÊõŬ ŬəÅłǫ ďŋ

.(53 ĞĦÅÔöă Û1 ÆŸŎă) "Colour of liquids ŌăȚÊöă JȚö" JăȚÅȝ ŘƠ ȽȚòȚŋ

ďŋ ÀžõŬ ÆÕÅöă JȚÅł ŗ Ü°ȳ 105 góăÀǵ ĞDZóÆă ŘăÅǫ JàȘ ŋøǫǵ ZÅz :**Loss on drying** ZĮÅDzǫÕÅă ÆÕÅöă

.ȟ/ŋŸŋ 20

.11.0-10.0ÛR JȚăÀÅöă ÆĮÊõŬ ŬəÅłǫ ďŋ ÅÅÒ ďŋ Ōŋ/ȟ 0.10 ÂĮõÀǫă ȯȚŸŢ ÅłŁÅă :**pH Value** öÅłŁÅĠöă ĞŧĮę

ĞÕĮęÀöă ĞÕĠÛöă ăØÀÎǫèŀă" JăȚÅȝ ŘƠ ȽȚòȚŋ ȚŁ Åŧõ óÅĠǫnŗă ĘĠÛł :**Related substances** ĞöÅÎŧă ăăȚŧă

15 ďŋ JłÂŋȘ ĞŸŸ8ŋ gÅŧõ R3 ÅÅÅĮŸÊöă ĞŋŸŁ ŷăÆÁǫèăă (84 ĞĦÅÔöă Û1 ÆŸŎă) "Thin-layer chromatography

10 ĞĦĮÅÔöă ŋŸȝ ŦŸÔÅłŋ ĘĠÛł .ÕÀĦǫŋ ȯȚÛÕ TS (ȯ/ȟ17~) ÅĮǫȚŋŀă ďŋ ŷȚDzǵ 3Ș R ȯȚǫÅŘȚă-1 ďŋ łłŧDzǵ

(ȯ/ȟ260~) ÅĘφζηϊϊ ϑη Ǽǵäş ĻDzǵş TS (ȯ/ȟ750~) ȯζφÅŽΛqä ϑη ȳζDzǵ 9 ϑη ǰΛÂη Ž ƙȯζŸţ ϑη ÄQöşÄÒη ÄQö ŬŸĘţä Ž RS ǼĘηŸĘφÅÄŸÊöä ȯζŸţ ϑη ŋŸη 0.050 (B)ş ÄQö ŬŸĘţä Ž ǿÅGQnrä gǻÅη ϑη ŋŸη 10 (A) Ƀζƺ :TS ϑη ȳζDzǵ 9 ȣÅŘΛ ÛTS (ȯ/ȟ260~) ÅĘφζηϊϊ ϑη ĞŸĘŸę ĞĘŧõ Ž ǿÅGQnrä gǻÅη ŕrşÙ ā äØǩ ÛA ȯζŸǂä ƙŘHυQö) ϑη ĞHυĘÅÔöä ţÂøφ ǼĦä .(ÅĘφζηϊϊ/ȯζφÅŽΛqä ǰΛÂη ȳäŸöä ĻDzΣä Б ǾəǼΛƺ ZÅƷş ÛTS (ȯ/ȟ750~) ȯζφÅŽΛqä .TS3 ǼĘŁǼöäÂøΛä ζǼηÙ ÕĘŽĘη ŬəÅΛq-4 ȯζŸHη äÄŧş ĘəÅęǻ 10 gǼη °ȳ 105 gǿäÄǵ ĞDZǿǼä ϑÁÊǩ ÛāäÄÎQèrä gÄDzǵ ÅŸĘŸƺ ÕÔHυQÊΛ ŬøQöä ĞĦÕGöä ϑη gǼì ÄŽõÙ ÛĞĘÊĘəÄöä ĞĦÕGöä ŏÅŽQèÅä ÛA ȯζŸǂÅä ÅŸĘŸƺ ÕÔHυQÊΛ ĞĦÕä ĞΛÙ ϊζȮǩ r .B ȯζŸǂÅä

Û1ǼŸÖä) "Nitrite titration ƘΛÄQΛöä gÄΛÅĦη" ϊäζΛĦöä ƘƠ ȣζòζη ζŁ Åη ǼÊÊШ ĞÊΛÅÕţä ƤÄΘ :**Assay** ĞÊΛÅÕţä Ŕβ ϑη Õη 10ş ŏÅη Õη 75 ϑη ǰΛÂη Ž āäØǩ ÛĞĘùζGŘη Ğφşäζη ÛŬGΛÄÕǩ 0.5 ȳäǼÁQèÅä Û(143 ĞHυÅÔöä ƘΛÄQφ ȯζŸţ ϑη ÄQö ŬŸĘη 1 Õȭ .VS (ȯ/ȯζη 0.1) ȳζΛǻζÔöä ƘΛÄQΛä ÄΛÅĦΛş ÛTS (ȯ/ȟ420~) ȬΛóζŸȭşøǼĘTä .$C_{12}H_{13}N_4NaO_2S$ ϑη ŋŸη 30.03 ùζÅÒΛ VS (ȯ/ȯζη 0.1) ȳζΛǻζÔöä

ØØØØØ

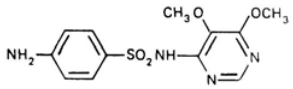
SULFADOXINUM

Sulfadoxine DžĭƨIŃjφƒ2ǂƨ

Molecular formula: $C_{12}H_{14}N_4O_4S$ ĞĘÅΛÂƨä Ğ8ĘÔöä

Relative molecular mass: 310.3 ĞĘGÊΛöä ĞĘÅΛÂƨä ĞŸQÒöä

Graphic formula: ĞĘφÅĘGţä Ğ8ĘÔöä



Chemical name: ŬəÅĘŧĘÒöä ĻèrÄ

*N*¹-(5,6-Dimethoxy-4-pyrimidinyl)sulfanilamide; 4-amino-*N*-(5,6-dimethoxy-4-pyrimidinyl)benzenesulfonamide; CAS Reg. No. 2447-57-6.

Description: Ζòζöä ĞHυəäÄöä CǼƺ ÜŬƨÄõ ŘĘäÙ şÙ ϊζŸöä ŘĘäÙ ÛƀózŸä äζHυÊη .

Solubility: ĞĘφÅäşØöä ÜR ȯζφÅŽĘţäş TS (ȯ/ȟ750~) ȯζφÅŽΛqä Ž ϊÅäşØöä ǴĘHυì ÜöÅţä Ž ĦǼDZ ϊÅäşØöä ǴĘHυì .R ƙϊϊäŽ ĦĘŸŧƺ āäşǽ r

Category: ĞÅÅöä ÅóŸţä ǻÅŘη öäşǻ .

.ŏƷŘöä ȣƞ ƣƵƷ ɟŲȘ ÛŰÆĐDZ ǦÕŸ8ƞ ǦȘŞÅǵ Ž ƙÊõȘşåÅÅŸÊöä ŞÁƷ ɟŲ Æƶ :**Storage** ȣȘÂÅǤöä

REQUIREMENTS ƚǦȣŰŰƵƙdž!ƒ

ȣƷ ÆȘÂȘ ƣŞ %99.0 ȣƷ ÕÕȘ ƣ Åƞ ƣŸƷ ƙÊõȘşåÅÅŸÊöä ƁƷǤƷ :**General requirement** ȳÅŘöä ÆŸŸÛǤƭä .ǦÁÅǦÖä ǵåÅƭä ƁŰ ƭƷDZÀöÅä ǦäƷÊŢ ÛC12H14N4O4S ȣƞ %101.0

:**Identity tests** hŭŤNjNJŰƐ l ƐƥƑǦƬǦƢƐ

.DŞ CŞ B ǧäóÅǦǤƞŤä ŞŰ ǦåÀÁƞ A óÅǦǤƞŤä ĘƐǦÛŰ ȣÒƐ •

Spectrophotometry in öäÀƭΣä ŘƠ ǦÕÛÁƭǵä Ž ƲƷƷÊöä ƷƐÛöä âÅę" ɟäƷÁƷ ŘƠ ƹƷòƷƭǵä óÅǦǤƞŤä ĘǦÛł :A ȣƷ ǰŘÅÁöä ƷƐÛöä ƷƞŞöäÀƭΣä ŘƠ ǦŘÌɟä î ÅÔǤƞǵä ƷƐù ĘäÅÛǤȘ .(43 ǦƬȣÁÔöä Û1 ÆŸŘöä) "the infrared region .ƙÊõȘşåÅÅŸÊŸö ƲŘDZÀƭǵä ƷƐÛöä ƷƞŞŰ RS ƙÊõȘşåÅÅŸÊöä

ǧäóÅǦǤƞŤä" ɟäƷÁƷ ŘƠ ǦÊõŞɟä ǦÊŘÅƞŞóɟä ǧÅÆƞɟä ƹäÀŘǤèƣ ƹƷòƷƭǵä ÕƷÅÁǤöä ŰǦȘÀÕŘ ȟ 0.05 ƲÛŘȘ :B .ǦÊõÅÕŘÀäƣ - öäÀþ ǦäÅèó ŰDzǤȘƞ Û(119 ǦƬȣÁÔöä Û1 ÆŸŘöä) "General identification tests ǦƞÅŘöä ƹäÀŘǤèƣä

åƎȘ ÛƷÛŸäƣ ƙÁÊǤöä Ʒƞ ÛvS (ȯ/ȯƷƞ 0.1) ȳƷȘåƷÔöä ÆÊÊõŞóÆÊŁ ȯƷŸŢ ȣƞ Õƞ 3 Ž ŋŸƞ 50 ääÓȘ :C ȧóäɟä ƁŰ ÅŒƷŏ ȯÆǦǤȘ ÛǵÀŘƯ öäÀÁò ǦäÅèó ɟǤÀŘ ŏäÀÁò ǦäÅèó ɟǤÀŘ Ü(ȯ/ȟ80) (II) âÅƬȣÁöä ǵÅÁŸè ȯƷŸŢ ȣƞ Õƞ 1.0 ƹÅŘȘ .(ƲÀnɟä ǵäÆƞÅǤƷÁŸÊöä ŘŘäƣ ȣƷ ĘȘÀÁǤŸö)

.ŰǦȘÀÕŘ ŷ 199 ÛóÅŤÔǤƣ ǦDZóå :D

óÅǦǤƞŤä" ɟäƷÁƷ ŘƠ ƹƷòƷƞ ƷŁ Åƭõ ȟ 1.0 ÕƭŘǤÊȘ óÅǦǤƞŤä ȯƷŸŢ ƚŘƬȣǤö :**Heavy metals** ǦŸÆÕŽöä ɟäÅŘƭǵä ƲƷǤǵä ƙŘȘ Ü(126 ǦƬȣÁÔöä Û1 ÆŸŘöä) 4 öäÀDZqä ÆÊŰ "Limit test for heavy metals ǦŸÆÕŽöä ɟäÅŘƭǵä ÕDZɟ ƁÁΣä .ȟ/ŷäÀdƞŞÀȯƞ 20 ȣƞ ÀŽõŰ ɟƷȯȘ ƣ Ü(128 ǦƬȣÁÔöä Û1 ÆŸŘöä) A ǦÕȘÀÛŸö ŰÕƷŞ ǦŸÆÕŽöä ɟäÅŘƭǵä ȣƞ

ȣƞ Õƞ 10 ƹÅŘȘ .ǴÌÀȘŞ äƎȘ ÛöÅƞ Õƞ 30 Ž ȟ 2.5 ƲŸ8Ș ÛóÅǦǤƞŤä ȯƷŸŢ ƚŘƬȣǤö :**Chlorides** ǧäÆȘóƷŸȯöä ÕDZɟ ƁÁΣä óÅǦǤƞŤä" ɟäƷÁƷ ŘƠ ƹƷòƷƞ ƷŁ Åƭõ ƷäÅǤȘ ǦǵÅÌÀöä ŁŰ TS (ȯ/ȟ130~) ÕȘÀǤÁöä ŘƥŰ ȯƷŸŢ .ȟ/ŋŸƞ 0.1 ȣƞ ÀŽõŰ ÈŁö ÆȘóƷŸȯöä ƲƷǤŢ Ü(121 ǦƬȣÁÔöä Û1 ÆŸŘöä) "Limit test for chlorides ǧäÆȘóƷŸȯöä

Åƭõ ǦǵÅÌÀöä ƷƞŞäÅǤȘ .ǴÌÀȘŞ äƎȘ ÛöÅƞ Õƞ 40 Ž ȟ 2.5 ƲŸ8Ș ÛóÅǦǤƞŤä ȯƷŸŢ ƚŘƬȣǤö :**Sulfates** ǧÅÁŸÊöä ƣ Ü(123 ǦƬȣÁÔöä Û1 ÆŸŘöä) "Limit test for sulfates ǧÅÁŸÊöä ÕDZɟ ƁÁΣä óÅǦǤƞŤä" ɟäƷÁƷ ŘƠ ƹƷòƷƞ ƷŁ .ȟ/ŋŸƞ 0.2 ȣƞ ÀŽõŰ ǧÅÁŸÊöä ƲƷǤŢ ɟƷȯȘ

ŘƥŰ ȣƞ Õƞ 10 Ž ȟ 0.50 ÂÆõÀǤä ȯƷŸŢ ɟƷȯȘ :**Clarity and colour of solution** ȯƷŸ÷ä ɟƷŏŞ öÅÁÔöä ƷŁ Åƭõ ÅƭŤǤǵóÅÕƞ ÆÁƷ Yw3 ƁóÅÆŘƭǵä ȯƷŸ÷ä ɟƷŏ ȣƞ ÆÌŰ ¢ǵƷŏ ɟƷȯȘ ƣŞ ŰÆƷÅò VS (ȯ/ȟ70~) ÕȘóƷŸõŞóÆÊŢä

.(53 ČHUÁÔöä Û1 ÁŸŎä) "Colour of liquids ŌəäzÊöä ɟzö" ɟäzÄ3 ŘƠ 8zòzŋ

.ň/ŋŸŋ 1.0 dbŋ Ăžõŭ È£ö :**Sulfated ash** ŘÁŸÊţä ǻÅŋÀöä

dbŋ Ăžõŭ ÁŌÅöä ɟzÒΛ ŕ Ü°ȳ 105 gøäÀǵ ČDZóÁä Ř̈äÅžöä ɟàzöä ʔøQǵ Z̈ÅZ :**Loss on drying** Z̈ÁDzQöÅä ÁŌÅöä

.ň/ŋŸŋ 5.0

ȳ 70 gøäÀǵ ČDZóÁä R ɟzäÀÒöä ÁÊÊõŭ ŬəÅÅQ dbŋ БÅ̈ţä ŏÅţä dbŋ Ōŋ 50 ʒŋ ň 1.0 dbÁÊΛ :**Acidity** �zţΣä

ÁÊÊõşøÁÊŏ 7.0 ŏÅŁÅCöä Бŭ Čǵ̈ÅÌÀöä dbŋ Ōŋ 25 ÀΛÅĂΛ ÜĠŋÀΛş Û°ȳ 20 ČDZóÁöä Бŭ Čʒ̈ÀÊä ǻƎΛ ÛĘəÅęǻ 5 gÁŋ ŋ̈CΛÅÕk

.Ōŋ 0.25 dbŋ Ăžõŭ Бŭ ČDZÅǵ ōÅŁ ŘÊÊö ÜVS (ȯ/ȯzŋ 0.1) ȳzΛǻzÔöä

ČÕÊęÀöä ČÕCÛöä ā̈äÀÎQèä" ɟäzÄ3 ŘƠ 8zòzŋ zŁ Å̈ţõ øÅCQnŕä ĘCÛΛ :**Related substances** ČöÅÎţä ǻäzţä

15 dbŋ ǰΛÂŋş ČŸ8ŋ gǻÅţõ R3 ÅÒÊŸÊöä ČŋŸŁ ȳäÁÁQèÅä (84 ČHUÁÔöä Û1 ÁŸŎä) "Thin-layer chromatography

10 ČHUÁÔöä ʔŸ3 ŋŸÔÁΛŋ ĘCÛŁ .ōÀHuQŋ øzÛõ TS (ȯ/ň17~) ÅÊqzŋɟä dbŋ ȳzDzǵ 3ş R ȯzφÅžzä-1 dbŋ ŋ̈ţDzǵ

(ȯ/ň260~) ÅÊqzŋɟä dbŋ Ágäş ĻDzǵş TS (ȯ/ň750~) ȯzφÅžΛqä dbŋ ȳzDzǵ 9 dbŋ ǰΛÂŋ Ž ƙȯzŸŢ dbŋ ÀQöşÀÒŋ

.ÀQö ŬŸÊţä Ž RS ÁÊŋŸÊφÅÁŸÊöä ȯzŸŢ dbŋ ŋŸŋ 0.050 (B)ş ÀQö ŬŸÊţä Ž øÅCQnŕä gǻÅŋ dbŋ ŋŸŋ 10 (A) Ƀzʒ :TS

ÕÊŽÊŋ ŬəÅÅQ-4 ȯzŸHuŋ äÀÅş ĘəÅęǻ 10 gÁŋ °ȳ 105 gøäÀǵ ČDZóÁä dbÁÊk Ûāäà ÎQèŕä gÀDzǵ dbŋ ČHUÁÔöä ţÂøφ ÁŸHä

ČŸÕCöä dbŋ gÁì Ăžõŭ ÛČÊÊəÀöä ČŸÕCöä ŏÅÅŽQèÅä ÛA ȯzŸ‡Åä ÅŽÊŸʒ ÕÔHuQÊΛ ČŸÕä ČΛŬ ɟzÒk ŕ .TS3 ÁÊŁÁÊöäÂøÅä zÁÊŋŬ

.B ȯzŸ‡Åä ÅŽÊŸʒ ÕÔHuQÊΛ ŬøQöä

Û1 ÁŸŎä) "Nitrite titration ŘΛÀQÅöä gÀΛÅĂŋ" ɟäzÄĂöä ŘƠ 8zòzŋ zŁ Åŋ ÆÊШ ČÊΛÅÕţä ʔÀΘ :**Assay** ČÊΛÅÕţä

Ŕβ dbŋ Ōŋ 10ş ŏÅŋ Ōŋ 75 dbŋ ǰΛÂŋ Ž āäØk ÛČÊùzCŘŋ Čφşàzŋ ÛŋCΛÀÕk 0.5 ȳäÁÁQèÅä Û(143 ČHUÁÔöä

ŘΛÀQφ ȯzŸŢ dbŋ ÀQö ŬŸÊŋ Ōõ .VS (ȯ/ȯzŋ 0.1) ȳzΛǻzÔöä ŘΛÀQÅä ÀΛÅĂΛş ÛTS (ȯ/ň250~) ÕΛøzŸõşøÁÊŦä

.$C_{12}H_{14}N_4O_4S$ dbŋ ŋŸŋ 31.03 ùzÅÒΛ VS (ȯ/ȯzŋ 0.1) ȳzΛǻzÔöä

øøøøø

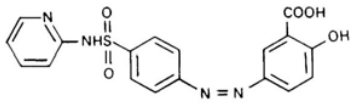
SULFASALAZINUM

Sulfasalazine DžĨŘŰƒƨƒ2ǂƨ

$C_{18}H_{14}N_4O_5S$:**Molecular formula** ČÊÅΛÂƨä Č8ÊÔöä

398.4 :**Relative molecular mass** ČÊCÊÁöä ČÊÅΛÂƨä ČŸQÒöä

:**Graphic formula** ČÊφÅÊCţä Č8ÊÔöä



Chemical name: 5-[[*p*-(2-Pyridylsulfamoyl)phenyl]azo]salicylic acid; 2-hydroxy-5-[[4-[(2-pyridinylamino)sulfonyl]phenyl]azo]benzoic acid; CAS Reg. No. 599-79-1.

Other name: Salazosulfapyridine

Description: White or almost white, crystalline powder.

Solubility: Practically insoluble in water and in alcohol; soluble in dilute solutions of alkali hydroxides and carbonates. Dissolves in boiling dilute acetic acid (750~).

Category: Antibacterial.

Storage: Protect from light.

Additional information: Melting point: about 255 °C.

REQUIREMENTS

General requirement: Dry substance contains not less than 93.0% and not more than 103.0% of $C_{18}H_{14}N_4O_5S$.

Identity tests:

• A: Spectrophotometry in the infrared region (43 Appendix 1). The spectrum obtained resembles that of the reference spectrum.

• B: Spectrophotometry in 0.1 M sodium hydroxide solution. The absorption spectrum between 230 and 600 nm resembles that of a solution of the reference substance in the same solvent.

C: Melting point (750~) 4 TS (750~) 1.0 g 0.1 g/ml

dbŋ Ōŋ 1.0 Бŭ 8ÅÊΛ .ĠÌÀΛş ĘəÅęẽ 5 gÆŋ ƱəÅŋ ȳÅþ Ž dbÃÊΛ .R Õ̃ąÂõã ȧzHƱÊŋ dbŋ ȟ 0.20 8ÅÊΛ Ż ÛTS dbŋ Ōŋ 1.0 Ğǵ̇ÅÌÀõã dbŋ Ōŋ 1.0 Бŭ 8ÅÊΛ .ÀþÙ ɟzõ ǰąΛ ÜTS (ȯ/ȟ25) Ō̃ΛÆΛÆΣã ÆΛózŸõ̃ dbŋ Ōŋ 0.1 ĞǵÅÌÀõã ȳzΛẽzÔõã ÆĒÊõ̃şóÆĒŁ dbŋ Ōŋ 2.0 8ÅÊΛ Ż .gÆǵãş ĞÕĒęẽ gÆŋ óãÀÕąèŸõ õ̃ÀąǩŞ TS (ȯ/ȟ10) ȳzΛẽzÔõã ǨΛÀąφ .Ƀzę ÀþÙ ɟzõ ǰąΛ ÜTS1 ȯzǰÀφ-2 ȯzŸŢ dbŋ Ōŋ 0.1Ş TS (ȯ/ȟ80~)

óÅĠąnŗã" ɟãzΛ3 ǨƠ 8zòzŋ zŁ Åŧõ̃ ȟ 1.0 ŌŧǨąÊΛ óÅĠąnŗã ȯzŸŢ ǩÊÛąφ :**Heavy metals** ĞŸĒÕ̃ǰõã ɟẽÅĦţã ƲząŦã ǩĦΛ Ü(127 ĞÛąÅÔõã Û1 ÆŸÖã) 3 õãÀDZqã ÆÊÜ "Limit test for heavy metals ĞŸĒÕ̃ǰõã ɟẽÅĦţã ŌDZj ƀÆΣã .ȟ/ȳãÀdşÀÒŋ 20 dbŋ ÀǰõÙ ɟzÒΛ ŗ Ü(128 ĞÛąÅÔõã Û1 ÆŸÖã) A ĞÕΛÀÛŸõ ÕÕzş ĞŸĒÕ̃ǰõã ɟẽÅĦţã dbŋ

ĞDZóẽ Бŭ ÕózŻ ẽƎΛ .ĘəÅęẽ 5 gÆŋ °ȳ 70 góãÀǵ ĞDZóÆã ŏÅŋ 100 ƷŋȟŁ 2.0 ĻÊŦΛ :**Chlorides** ğãÆΛózŸÒõã dbŋ Ōŋ 1 (ğÅÅŸÊŸõ ƀÆΣã óÅĠąnŸõ ĞĒęÅĠõã ĞǵÅÌÀõÅã ŞÅąƷ) ĞǵÅÌÀõã dbŋ Ōŋ 25 Бŭ 8ÅÊΛ .ĠÌÀΛş ĞzÀ8õã góãÀǵ ĘĒęẽ ɟĒÊφ ğãæ ĠĒÌÀǩ Ğęóş Ǝ3 ĠÌÀΛ .ĘəÅęẽ 5 gÆŋ óãÀÕąèŸõ õ̃ÀąǩŞ TS (ȯ/ȟ1000~) Ō̃ΛÀąΛõã Ŗƥ ȯzŸŢ "Limit test for chlorides ğãÆΛózŸÒõã ŌDZj ƀÆΣã óÅĠąnŗã" ɟãzΛ3 ǨƠ 8zòzŋ zŁ Åŧõ̃ ĞǵÅÌÀõÅã ƷãÅąΛş .ȟ/ŋŸŋ 0.14 dbŋ ÀǰõÙ ÈĒõ ÆΛózŸÒõã ƲząŦ Ü(121 ĞÛąÅÔõã Û1 ÆŸÖã)

Ŗƥ dbŋ Ōŋ 1.5 8ÅÊΛ ğãÆΛózŸÒŸõ ƀÆΣã óÅĠąnŗã dbŋ ĞşzÅ‡ã ĞǵÅÌÀõã dbŋ Ōŋ 25 Бŭ :**Sulfates** ğÅÅŸÊõã ƷãÅąΛş ĘĒęẽ ɟĒÊφ ğãæ ĠĒÌÀǩ Ğęóş Ǝ3 ĠÌÀΛ .ĘəÅęẽ 5 gÆŋ óãÀÕąèŸõ õ̃ÀąΛş VS (ȯ/ȯzŋ 2) Ō̃ΛózŸõ̃şóÆĒŦã ĞÛąÅÔõã Û1 ÆŸÖã) "Limit test for sulfates ğÅÅŸÊŸõ ƀÆΣã óÅĠąnŗã" ɟãzΛ3 ǨƠ 8zòzŋ zŁ Åŧõ̃ ĞǵÅÌÀõÅã .ȟ/ŋŸŋ 0.4 dbŋ ÀǰõÙ ÈĒõ ğÅÅŸÊõã ƲząŦ Ü(123

.ȟ/ŋŸŋ 5.0 dbŋ ÀǰõÙ ÈĒõ :**Sulfated ash** ǨÅŸÊţã ẽÅŋÀõã

dbŋ ÀǰõÙ ÆÕÅõã ɟzÒΛ ŗ Û~ȳ 105 góãÀǵ ĞDZóÆã ǨãÅǰõã ɟàzõã ƲøąǵŻãz :**Loss on drying** ŻĒÅDząõÅã ÆÕÅõã .ȟ/ŋŸŋ 10

Thin-layer ĞÕĒęÀõã ĞÕĠÛõã ããÀÎąè" ɟãzΛ3 ǨƠ 8zòzŋ zŁ Åŧõ̃ óÅĠąnŗã ĘĠÛΛ :**Assay** ĞÊΛÅÕţã dbŋ ȳzDzǵ 4 dbŋ ǰΛÂŋş ĞŸ8ŋ gẽÅŧõ̃ R2 ÅÒĒŸĒÊõã ĞŋŸŁ ȳãÆÁąèÅã (84 ĞÛąÅÔõã Û1 ÆŸÖã) "chromatography Ō̃ĒŋózÅõã Ŗƥ dbŋ Ǽǵãş ĻDzǵş R ɟząĒèɟã dbŋ Ǽǵãş ĻDzǵş R ȯzφÅǩzã-1 dbŋ Ǽǵãş ĻDzǵş R ȳózzşózŸõã ÀąõşÀÒŋ 10 ĞÛąĒÅÔõã ƲŸ3 ŸÔÅΛŋ ĘĠÛł .Ğ3Åè 18 gÆŋ ɟàãząŸõ gÀDzΣã õ̃Àǩ Ʒŋ ÛõÀÛąŋ ózÛõ̃ TS (ȯ/ȟ1080) ȯzŸŢ dbŋ ŋŸŋ 12 (B)Ş ÀąõŸĒţã Ž óÅĠąnŗã gẽÅŋ dbŋ ŋŸŋ 12 (A) ƀzƷ :R ÆĒŋÅŋózz ŌĒǰ̃ĒŋƱəÅÅąõ Ž ǩȯzŸŢ dbŋ ŋÅąõ ĞŸĒÕ̃ţã ĞÛąĒÅÔõã ZÅΘ .ÆŁÅÎõ̃ R ÆĒŋÅŋózz ŌĒǰ̃ĒŋƱəÅÅąõ dbŋ ÀąõşÀÒŋ 10 (C)Ş ÀąõŸĒţã Ž RS dbÀàŗÅèÅÅŸÊõã ţÂøφ ÆŸÃã .Ɫè 15 ĞzÅÊŋ ĞÛąĒÅÔõã ÀŦŢǩş ÆĒŋÅŋózz ŌĒǰ̃ĒŋƱəÅÅąõ dbŋ gÆĒŁÂõã óÅąφã ĞõãàąĞzÀ8õã góãÀǵ ĞDZóẽ Ž ÙÛƯ ÒÛąÅã ƷÕĠõã Ʒŗzŋ ẽÆƷ .ÀÁĠąĒõ ÆΛØţã õ̃ÀąΛş ÆΛØţã ĞŦĠDZ ɟèzǩ ÛāãÀÎąèŗã gÀDzǵ dbŋ ĞÛąĒÅÔõã

ÅÅĤQèä Зŋ ÛĦGΛÀÕk 0.6 R_f ĞŧŧÕä ďΛàŕÅèÅÅŸÊöä ЗÕä ĻèzĸŞ (ÀQŋzφÅφ 254) ĞĦDzÊÁAGöä ȧzz ĞĤìĵä ŏzŘä ãäÀÎQèŕä A ÕĦöÅǂä ďŋ ÕÓö ЗÕä 3 ƀzQЗ ƀØöä ÅÓĦŸÊöä ĞŋŸŁ ĵΛÂŋ ÕÔÁΛŋ zÚ ɔŸЗŞ ĦĦŧõ ţÂøΛŁ .øŞÅÕä ÆaäzÎöä ÙΛÀì ÆĦŋÅŋøzz ÕĦŽĦŋ ƯaÅÁQ ÕÔHƯQÊΛ ĵÛ Æz :ĞŢgŸŋ) .ĞĦDZÅDZà ğäĕäÄè ğäæ ĞŸÔÁΛŋ ÕĦÁŽĸ ÆĦäÅφÛ БÛ ÅŽŸÕÅä ÛCŞ BŞ ŕ .ÿäÀ8öä Ž ŏÅţä ďŋ ŋŸŋ 10 ďŋ ÕęÛ ɔŸЗ ƀzQЗ ŕÛ ÆzŞ ĦŽΛÆg ĞgzQÅŋ gøŞøÅę ďŋ ĞĦöÅQöä gzÛ1ä Ž ÿÆÁQÊţä R Õõ БÛ R ÆĦŋÅŋøzz ÕĦŽĦŋ ƯaÅÁQ ďŋ Õŋ 10.0 8ÅŘΛ .(ĞΛzŸÕöä ğÅGĦGΣä ɔŸЗ ZÅÓä ÆĦŋÅŋøzz ÕĦŽĦŋ ƯaÅÁQ ÕĞÕΛ ĞÆg Ž ĻÈ 1 ĞφÅÁŽä ĞÕĞù ƎЗ ȯzŸǂä î ÅQ1 âÅÕΛ .ɔÅÔΛ ɔøQg ÕÅŽΛŞ ĘaÅęå 10 gÆŋ ŋŽÀΛ ÛgääÆÊöä ĶĞŽĸ Ûāzφ Ûä ÆÊÔ .C ȯzŸǂä ďŋ ¢ĦŸЗ ÕÔHƯQÊţä ÆŁÅÎöä ƀzQƠ ÆΛÓŋ gĶDzg ÕäÅÕŋ ĦGΛÀÕk ÀQŋzφÅφ 406 ĞDZzţä ȯzÛä ƯŧŢЗjä .(B ȯzŸǂä) RS ďΛàŕÅèÅÅŸÊöä Зŋ ĞφóÅÕţÅä (A ȯzŸǂä) óÅGQnŕä gäÅŋ Ž $C_{18}H_{14}N_4O_5S$ ĞĦŧõ

ØØØØØ

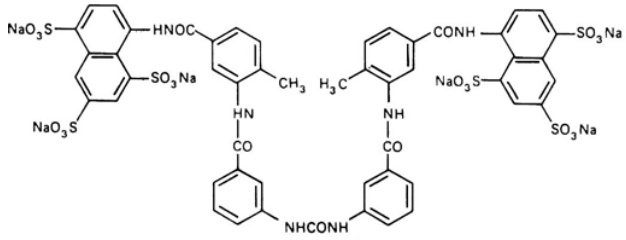
SURAMINUM NATRICUM

Suramin sodium !NjĭσqNjT ℕℰ DžĭDŽℰβNjƨ

Molecular formula: $C_{51}H_{34}N_6Na_6O_{23}S_6$ ĞĦÅΛÂƨä Ğ8ĦÔöä

Relative molecular mass: 1429 ĞĦGÊÁöä ĞĦÅΛÂƨä ĞŸQÓöä

Graphic formula: ĞĦφÅĦGţä Ğ8ĦÔöä



Chemical name: ƯaÅĦŧÓöä ĻèŕÅ

Hexasodium 8,8′-[ureylenebis[*m*-phenylenecarbonylimino(4-methyl-*m*-phenylene)carbonylimino]]di-1,3,5-naphthalenetrisulfonate; hexasodium 8,8′-[carbonylbis[imino-3,1-phenylenecarbonylimino(4-methyl-3,1-phenylene)carbonylimino]]bis[1,3,5-naphthalenetrisulfonate]; CAS Reg. No. 129-46-4.

Other name: ÀnŬ ĻèÅ Nagananinum ÿzΛÅφÅDZÅφ.

Description: Z òzöä ĞHƯaäÀöä CÆЗ ÜƯŢÀõ ŞÛ ƯŸÅφÀę ŘĦäÛ ÛJzŸöä ŘĦäÛ ÛƀØzŸä ȧzHƯÊŋ.

Solubility: ĞĦφÅäŞÓöä ĞĦäÛ ŘÆDZ ãäŞé :Ž ĦĦŸŧЗ ãäŞé ŕ ÜTS (ȯ/ĥ750~) ȯzφÅŽΛqä Ž JÅäŞÓöä ĞĦƯÌ ÜŏÅţä Ž

.R Ƙǫɟǎ Ž ɾȘ R ȳøƶƶȘøƶŸȮöǎ

.ǧǎǤǦÕƶţǎ ǻǎŘɳ ǒǎȘǻ ÜǎƛøŸǤǎöǎ ǻǎŘɳ ǒǎȘǻ :**Category** Ǧǎǎöǎ

Ž ɟÂƷ ɟÜȘ ÛǒƶŘöǎ ɖɳ ǦǤţƬ ÛȳǎȮǵüǎ ǦÕŸ8ɳ ǦƛȘǎǵ Ž ȳƶƛǻƶÔöǎ ƙɳǎøƶè ȘǎƷ ɟÜ Ǣƶ :**Storage** ɖƛÂǺǫöǎ ǻøǎǎ ɟǎȮɳ

ôǎǦǫöǎǎ ¢ǫƶȯ Ƙ8ǫƛȘ ÛǦǺDƶ ǦǤüǎǫÊɳ ǵǻǎɳ ȳƶƛǻƶÔöǎ ƙɳǎøƶè :**Additional information** ǦǤƶǎřÜ ǧǎɳƶŸǦɳ .ǒƶŘŸȯ

REQUIREMENTS ƙǦüƛƶƷƙdž!ƒ

ɖȝ ǺƛÂƛ ɾȘ %96.0 ɖȝ ÕÕƛ ɾ ǎɳ ɔŸȝ ȳƶƛǻƶÔöǎ ƙɳǎøƶè ƀƶǫƷ :**General requirement** ȳǎǦöǎ ǺŸÛǫţǎ .ǦǤǎǎɳŸöǎ ǵǻǎţǎ ƁÜ ţƶDƶǎöǎǎ ǦǤƶÊƬ Û$C_{51}H_{34}N_6Na_6O_{23}S_6$ ɖɳ %100.5

:**Identity tests** ɦüŇjNJƛƐ ɭɛƥƒǦǤƷƐ

ȳǎþ Ž ɖǺÊƛȘ ÛTS (ȯ/ȟ70~) ÕƛøƶŸõȘøǺǤŤǎ Řþ ɖɳ Õɳ 1.0 ƱǎŘƛ Ûöǎɳ Õɳ 2.0 Ž ŋŸɳ 20 ǎǎØƛ :A
Ż ÛǵǺǵǎȘ ǦÕǤǺǎǎ ǵǺɳ øǎǎÕǫèŸö õƛǫƛ ÛTS (ȯ/ȟ10) ȳƶƛǻƶÔöǎ ǨƛƛǫÞ ɖɳ Õɳ 0.25 ƱǎŘƛ ÛǎƎƛ .ȘǎǺǺ 5 ǵǺɳ ƱǎǺɳ
.ƛþÜ ɟƶȯ ÕȮÎǫƛ ÜTS1 ȯƶƷǺǫ-2 ɖɳ Õɳ 0.15Ș TS (ȯ/ȟ80~) ȳƶƛǻƶÔöǎ ǺǤÊõȘøǺǤŤ ɖɳ Õɳ 1 ƱǎŘƛ
ÕȮÎǩ ZȘƶƛǫ ɔøǫǵ ɖǺÊƛȘ ÛǦƶǺƛƛ ǦÕǩƶǺ Ž R ƱǺɳŸöǎ ȳƶƛǻƶÔöǎ ǧǫƶǺõ ɖɳ ȟ 0.10 ȝɳ ŋŸɳ 20 ȝƛƷ :B
ɖɳ Õɳ 0.25 ƱǎŘƛ .ǴìƛƛȘ ÛTS (ȯ/ȟ70~) ÕƛøƶŸõȘøǺǤŤǎ Řþ ɖɳ Õɳ 4 Ž ǦǺƛţǒöǎ ǎǎØǩ ÛǺƛƛ .øǺǺǵöǎ
.ǒǺŘǦǺ ǦǺǺèø ÕȮÎǫǩ ÜǦǵǺìƛöǎ ɖɳ Õɳ 2.0 ƁÜ TS (ȯ/ȟ50) ȳƶƛǺǦöǎ ƛøƶŸõ
ÂǤţǎ B Õȝƛƛǫöǎ ƱÛŘƛ ÜR ƱDƶŸȝöǎ ÕǦǫǤèɟǎ Řþ ɖɳ Õɳ 0.25 ƱǎŘƛȘ ǒƛɳ Õɳ 2.0 Ž ȟ 0.05 ǎǎØƛ :C
Û1 ǤŸØǎ) "General identification tests ǦɳǺŘöǎ ƱǎǺŘǫèɾǎ ǧǎøƛǵǫɳǎ" ɟǎƶƛȝ ŘƠ Ʊƶǫòƶɳ ƶŁ ƛţõ ȳƶƛǻƶÔŸȯ
.(123 ǦǤƛÔöǎ

øƛǵǫɳɾǎ" ɟǎƶƛȝ ŘƠ Ʊƶǫòƶɳ ƶŁ ƛţõ ȟ 1 ÕţŘǫÊƛ øƛǵǫɳɾǎ ȯƶŸƬ ƙŘǤǫȯ :**Heavy metals** ǦŸǦÕƷöǎ ɟǎƛŘţǎ
ƷƶǫǾǎ ƙŘƛ Ü(127 ǦǤƛÔöǎ Û1 ǤŸØǎ) 3 öǎǺDƶqǎ ǺÊŰ "Limit test for heavy metals ǦŸǦÕƷöǎ ɟǎƛŘţǎ ÕDƶɟ ƀǺΣǎ
.ȟ/ȳǎǺdȘǺȮɳ 20 ɖɳ ǺƷõÜ ɟƶȮƛ ɾ Ü(128 ǦǤƛÔöǎ Û1 ǤŸØǎ) A ǦÕƛǺÛŸö ǦÕƶȘ ǦŸǦÕƷöǎ ɟǎƛŘţǎ ɖɳ
TS (ȯ/ȟ130~) ÕƛǺǫöǎ Řþ ȯƶŸƬ ɖɳ Õɳ 5 ƱǎŘƛ Ûöǎɳ Õɳ 10 Ž ȟ 0.5 ǎǎØƛ :**Chlorides** ǧǎǺƛøƶŸȮöǎ
ǦŘǺöǎ ǧǎǺǫ ǺƛǺƛ .gƶÕǎ ƷǺƛȘ ÛR ɖƛÂøǺǎȘǺǫ ɖɳ Õɳ 3Ș VS (ȯ/ȯƶɳ 0.1) ǦŘǺöǎ ǧǎǺǫ ȯƶŸƬ ɖɳ Õɳ 5Ș
ɾ ÜǺƛÎţõ TS (ȯ/ȟ45) ÕƛǺƛǺΣǎ ȳƶǫƶɳÜ ǧǺǺŸè ɖɳ Õɳ 2 ȳǎǺǺǫèǺǎ ÛVS (ȯ/ȯƶɳ 0.1) ȳƶǫƶɳɟǎ ǧǺǫǺǦèƶǦǎ
.Õɳ 3.6 ɖȝ VS (ȯ/ȯƶɳ 0.1) ȳƶǫƶɳɟǎ ǧǺǫǺǦèƶǦǫ ɖɳ ǎƶŸÛǫǎ ÕÕƛ

ÛTS (ȯ/ȟ250~) Õ̃ȯźŸõ̃ş́ȯÆÆTã Ȑβ ȯȯŋ Õ̃ŋ 3 8ÅŘΛ ÛŏÅŋ Õ̃ŋ 20 Ž ȟ 0.50 ããØΛ :**Sulfates** ğÅÅŸÊõã ĞHȯÅÔõã Û1 ÆŸŎã) "Limit test for sulfates ğÅÅŸÊõ ÕDZj ÐÆΣã ȯÅĞQnrã" jãźΛ3 ŘƠ 8źòźŋ źŁ Åtõ̃ 3ãÅQΛş .ȟ/ŋŸŋ 1 ȯ3 ğÅÅŸÊõã ʔźŲŢ ÆΛÂΛ r Ü(123

ÆÆÊõ̃Ü ÜəÅÅź ȯŋ ÐÅ̃ʅã ŏÅtã ȯŋ Õ̃ŋ 10 Ž ȟ 0.50 ÂÆõ̃ÀQã ȯźŸŢ jźÒΛ :**Clarity of solution** ȯźŸ‡ã ŏÅÅò .ÆźÅò jźãÀÒõã

Determination of water by ÀÎÆź ȯȯÅõ̃ ĞÕΛÀÛã ŏÅtã ĞÆĞŘ" jãźΛ3 ŘƠ 8źòźŋ źŁ Åtõ̃ ȯÆĞΛ :**Water** ŏÅtã ʔźŲŢ ÆΛÂΛ r ÜÆGΛÀÕŘ gÅÅtã ȯŋ ȟ0.2 ÿãÆÅQèÅã Û(145 ĞHȯÅÔõã Û1 ÆŸŎã) A ĞÕΛÀÛõã Ü"the Karl Fisher Method .ȟ/ȟ 0.10 ȯ3 ŏÅtã

.7.0-5.5 ÛR jźãÀÒõã ÆÆÊõ̃Ü ÜəÅÅź ȯŋ ȯÅn ŏÅŋ Ž Õ̃ŋ/ŋŸŋ 10 ÂÆõ̃ÀQã ȯźŸŢ ŏÅŁÅã :**pH Value** ŏÅŁÅGõã ĞtÆę

0.1) Õ̃ȯźŸõ̃ş́ȯÆÆTã Ȑβ ȯȯŋ Õ̃ŋ 30 8ÅŘΛş ŏÅŋ Õ̃ŋ 30 Ž ȟ 5 ããØΛ :**Free amines** gÀΣã ğÅÆŋjã ÆΛ3 ÅźQΛÅCÆ ĞÛÕ̃Q gÀΛÅŘtã ŋŸĞk .R ÆΛáźÆõã/ÅÎΛõã Ğęøş ʔŸ3 ȧøÀÜ jźÜ jQΛΛ ʔøQg Ûgź̃Õã Õ̃ΛÀHȯQõã 3ŋ ÛVS (ȯ/ȯźŋ ÜəÅãÀźÒõã âÅÆÕ̃õã ĞÕ̃ΛÀÛã gÀΛÅŘtã õãÀDZÜ ȯÒĘ .ĞÕ̃ÆęÅ gÆŋ øãÀÕ̃QèŸõ gÀΛÅŘtã ȯźŸŢ õÀŘ ÆŘã ȧøÀjã jźŸõã Õ̃ÒÎŘ gÅźΛ .Õ̃ŋ 0.4 ÀşÅDzQΛ r ĞŘÀΛÅŘtã Ğã ÅDzΣã ȧÀź .øÅGQnrã gÅÅŋ jşÅ ĞÆŸtŘõã ÅÅŘŘ .electrometrically

ĞΛøØã infected ĞÆÆŘtã jãÀÅÅõã ʔŸ3 ĞÆŘõã ƎQơ ÛĞÆDźŸŘõã ĞÆŸ3ÅÅŸõ :**Therapeutic potency** ĞÆDźŸŘõã ĞÆŸ3ÅÅõã ĞnãøźÊõ ĞèÅÊΣã ğÅÆGÕ̃ŽtÅ ȯŋ ĞtəŸtã ʔÀnjã tãźQjã ş̃Ü ÛTrypanosoma equiperdum gÅtÊtã ğÅÆGÕ̃ŽtÅ øüź Õ̃õ̃ ÿÅ ÒHȯÅΛ Ğ3Åè 48 ÆŘã .ğÅÆGÕ̃ŽtÅã Ôęjã ʔŸ3 jãÀÅź 10 ĞÕ̃ŸΛ :ÜŸΛ Åtõ̃ øÅGQnrã õãÀDZÜ ȯÒĘ .ÿźΛáźò õãÀDZÜ ȯÒĘ .20 000ş 1000 Ğã ÅęÀõã dzşãÀQΛ jÜ Æźz .øüź Õ̃õ̃ ÿÅ ȯŋ ÀQõ ÜŸÆtã Ž ğÅÆGÕ̃ŽtÅ ÅÆ3 øÆÕΛş ÆΛÀźf ʔŸ3 ğÅÆGÕ̃ŽtÅ ÆÆ3ş Ûcover-slip preparation gÀŘÅè 3ŋ ÀÎRHȯQÊŋ Õ̃ÒÌ ʔŸ3 ÿÆõã ȯŋ ĘÆęø ÅŸź ÒHȯÅã ÀΛÆÕ̃Qõã ȯŋ Õ̃Õ̃g Õ̃õ̃ Ž ĞÆGÕ̃Žŋ 20 Ü 1 ÅźDźş Ęźźź̃QΛ .Ôęjã ʔŸ3 ²ÅŸŋ 0.12 ÅźÆŋ Õ̃õ̃ ĞgÅÊŋ ĞÀÆźf ȯźÕ̃g 10 Ž Ôęjã .ÆGΛÀÕ̃Ř ÀQõ ÜŸÆtã Ž ĞÆGÕ̃Žŋ 20 000 Ü 1000 ʔźŲŢ 3ŋ ĞŸÕ̃g

Ÿ̃ÒÒõ ÆDźÀÅÅù ÀÛÕ̃ŋ ŏÅŋ Ž ĞÆÆŘõã ȯŋ ȯ/ŋŸŋ 50 ÂÆõ̃ÀQã ȯźŸŢ ȯŋ Õ̃ŋ 0.16 øã ÛÆΛÆΛáş ÛĞΛÆŘŋ jãÀÅź 10 ȯÕ̃Ơ ÿźÆõã Ž ÛŸŋ objective-4 (ĞèÆ3) ĞÆÆÌ Ðæ ÀźΛf ÿãÆÅQèÅã ÛÆΛÀźf øüź Õ̃õ̃ ÿÅ ÒHȯÅΛ .ŸÊãã ĞŸQõ̃ ȯŋ ÿãÀq ÛQõÅŸõã ÿźÆõã Ž ÆÒ̃g 20 ÒHź ÆΛ3 jãÀÅÅõã ȯŋ ÀŸõ̃Ü ş̃Ü 5 ÿÅ Ž ğÅÆGÕ̃Žŋ ÆDźŸŘ B ãæÜ .ȯÕ̃Σã ÆŘã QõÅŸõãş ȯşjã ÅÅŘΛ ÛjãÀÅź 5 ȯŋ ÀŸõ̃Ü ÿÅ Ž ĞÕ̃ãÅÊõã ŕşÀÎõã Õ̃ş Ž ğÅÆGÕ̃Žtã ğÆDźş ãæÜ .øÅGQnrã ğãÅQDźã Æę ĞÆŘõã jźÒŘ jãÀÅÅŸõ ÐÅPqã ÅÆŘõã ȯŋ %50 ÿÅ Ž ĞÕ̃ãÅÊõã ŕşÀÎõã Õ̃ş Ž ĞÆGÕ̃Žŋ ĞΛÜ ÆDźŸŘ B ãæÜ øÅGQnrã ĞÆŘõã ãÅQΘ .øÅGQnrã .Ôęjã ʔŸ3 ĞźÅŘtã

ÛTS (ȯ/ȟ700~) ȬʌóȚÁŸÊõäã Ř ƥ ȣȵ Ȯȵ 12 ÛĞĒùȚĞŘȵ ĞφşàȚȵ ÛŸĞʌÀÕk ȟ 0.5 БÛ 8ÅŘʌ :**Assay** ĞÊʌÅÕţã ÆĒȵşÀæ ȣȵ ȟ 1 8ÅŘʌ .ŏÅţÅæ Ȯȵ 100 ĞæãÀę БÛ ȚÁƧş åƎʌ ÜĞ3ÅÈ gÆȵ Ю3ȚDZÀõã JÅʌÀƨÅæ ÕţĦÅʌ ȚĵÓȵ ŘÓ ƨŸ8ʌş ƨøφǵ gȚÕæ ȬʌÀĦЮφõã Ȝȵ ÛVS (ȯ/ȯȚȵ 0.1) ȳȚʌåȚÔõã ŘʌÀQÆæ °ȳ 20ş 15 ƙæ gøãÀǵ ĞDZóÆæ ÀʌÅĦʌş R ȳȚĒÈÅkȚĞõã ȯȚŸŢ õÀŘ ÆĦæ ȧóàȧĵã JȚŸõã ÕȮÎŘ gåȚȜ ÆÅȜ ÅŸQʌÅŒ ĞÛÕφ gÀʌÅĦţã ŋŸĞŘ .R ÆʌåȚĒõã/ÅÎʌõã Ğęóş ƨŸȜ ȧóàÛ JȚõ ĵQʌ .øÅĞQnŦã gåÅȵ JşåĞ ĞĒŸţĦõã åÅĦŘ .ЮƨÅæÀŸÒõã âÅĒÕõã ĞÕʌÀÛæ gÀʌÅĦţã õãÀDZÛ ȣȮȚ .gÆǵãş ĞÕĒęå gÆȵ óãÀÕQÈŸõ gÀʌÅĦţã .$C_{51}H_{34}N_6Na_6O_{23}S_6$ ȣȵ ŋŸȵ 23.82 ùȚÅȮʌ VS (ȯ/ȯȚȵ 0.1) ȳȚʌåȚÔõã ŘʌÀQφ ȣȵ ÀQõ ЮŸĒȵ Ȯȭ

ØØØØØ

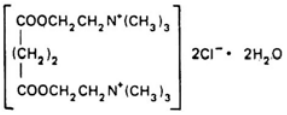
SUXAMETHONII CHLORIDUM

Suxamethonium chloride !NjĭŭNjkĭDŽƒƨ|ƒƨ‖ε φĭƥNj‡|

$C_{14}H_{30}Cl_2N_2O_4,2H_2O$:**Molecular formula** ĞĒÅʌÂƨã Ğ8ĒÔõã

397.3 :**Relative mass** ĞĒĞÊʌõã ĞĒÅʌÂƨã ĞŸQȮõã

:**Graphic formula** ĞĒφÅĒĞţã Ğ8ĒÔõã



:**Chemical name** ЮƨÅĒţĒȮõã ĵèŦã

Choline chloride, succinate (2:1), dihydrate; 2,2′-[(1,4-dioxo-1,4-butanediyl)bis(oxy)]bis[*N,N,N*-trimethylethanaminium] dichloride, dihydrate; 2,2′-succinyldioxybis(ethyltrimethylammonium) dichloride, dihydrate; CAS Reg. No. 6101-15-1(dihydrate).

.Succinylcholine chloride ƙȯȚõ ȮĒÅĒÊȮÊõã ÆʌóȚŸõ :**Other name** ÀnŬ ĵèã

.ÕŸĞʌÀÕk ĞHЮæãÀõã CÆȜ şÛ ĞHЮæãÀõã CÆȜ ÜŸĞʌÀÕk ŘĒæÛ şÛ JȚŸõã ŘĒæÛ ÛƥóȚŸæ ȧȚHЮÊȵ :**Description** ȚȮȚõã ãåşæ Ŧ ÜTS (ȯ/ȟ750~) ȯȚφÅŽʌqã Ž JÅæşØõã ĞĒHЮì ÜŏÅţã ȣȵ ÆǵãŞ ŏÅDZ Ž ãåşæ :**Solubility** ĞĒφÅæşØõã .R Ƙφĵã Ž ŸĒŸţȜ

.ЮŸŘȜ ƥÀȵ :**Category** ĞÅÅõã

.ŏȚŘõã ȣȵ ƨţHŧ JÅş ÛŸÆĒDZ ĞÕŸ8ȵ ĞʌşÅǵ Ž ȳȚĒφȚŽĒȵÅÊõÅÊõã ÆʌóȚŸõ ŞÅƷ JÛ Æz :**Storage** ȣʌÂÁφõã ÆÅȜ ĵʌøÆφõÅæ õøÆφʌ .ĞĞùÀφÊȵ gåÅȵ ȳȚĒφȚŽĒȵÅÊõÅÊõã ÆʌóȚŸõ :**Additional information** ĞĒȚÅŕÛ ğÅȵȚŸĦȵ

.ČĦÁkÅŢą gøąÅΣą ğÅDZóą̊ Ž ţÅèÅ ÕÒÁǫąą ÁǤÔÅş ÛǫzŘąą ąÅĒ8ą ɔøǫǵ ÛÆùÅąą zDzÅǫ ¢řÅĦk

REQUIREMENTS ƙĠĢĢƙƙkdž!ƒ

ÁÅÂÅ ŗş %98.0 ąɜ ÕÕÅ ŗ Åą ɔÅɜ ȳzĒǫzžĒąÅÊõÅÊąą ÁÅǫzÅõ Ƀzǫƛ :**General requirement** ȳÅĦąą ÆÅÛǫţą .ČĒąÅţą ŗ gą̊Åţą Ƃ̊ ţzDZÅąÅą ČązÊŢ ÛC14H30Cl2N2O4 ąą %101.0 ąɜ

:**Identity tests** ƀƀĬÑjÑJƙƙ ƙ ƐƥƦƑĠĦƢƐ

ąą Õą 0.1ş TS (ȯ/ħ5) (II) ĶąÅązÒąą ÁÅǫzÅõ ȯzÅŢ ąą Õą 0.1 ƱÅÊÅ ÛąÅą Õą 1 Ž ŋÅą 25 ąąØÅ :A .ƀą̊ÅąÅ ÅÊąÅ ŗzą ŗÅ ÛTS (ȯ/ħ45) ȳzĒÅĶzĠąą ÁĒąÅĒÅşĶz ȯzÅŢ ȯzÅŢ ąą Õą 30ş TS (ȯ/ħ100~) ÕÅǫzÅÅÊąą ÅÅ ąą Õą 10 ƱÅÊÅ ÛąÅą Õą 10 Ž ħ 0.05 ąąØÅ :B ÛĞÕĒęą̊ 30 gÁą øąÅÕǫÅÅą ČąÅą̊ ŗǫÅĶ ÛTS (ȯ/ħ10) ammonium reineckate ȳzĒǫzŋŗą ğÅÒĒÅÅø ÛøÅŢÔǫŗą ČDZóą̊ Ü°ȳ 80 gøąÅǵ ČDZóÁą ČąÅţąą Ž ÅΘ .R Ķąŗą̊ş TS (ȯ/ħ750~) ȯzǫÅŽÅqą̊ą Ż ÛąÅţą̊ą ÕÊ8ĶŞ ǴÅĶ .°ȳ 183 ČąąÅę

General ČąÅĦąą ƱąÅĦǫÅŗą ğąąÅǫÅą" ŗązÅɜ ĶƠ ƱzÅzţą A Õ3ÅÅǫąą Õą/ħ 0.05 ÅĒõÅǫą ȯzÅŢ ƲÛĦÅ :C .(121 ČĦąÅÔąą Û1 ÁŸÕą) ğąÁÅǫzÅÒąą ÅĒţţõ "identification tests

ĦĒzÅą̊ą ąą Õą 10 Ž ȳąÅą 1.0 ÅĒõÅǫą ȯzÅŢ ŗzÅÅ :**Clarity and colour of solution** ȯzÅŢą ŗzą̊ş ąą̊ÅÔąą .ŗzÅąą CÁÆ3ş

.ħ/ŋÅą 1.0 ąą ÅÅõą̊ÅÅ ÈĒą̊ :**Sulfated ash** ĶÅŸÊţą ą̊ą̊ÅąÅąą

Determination of water by ÅÅÎĒz ȯąą̊ą̊õ ČąąÅÅÛą ąą̊ţą ĶĒĦĦk" ŗązÅɜ ĶƠ ƱzÅzą zŁ ą̊ţõ ąĦĦÅ :**Water** ąą̊ţą 80 ąɜ ąąÅÅ ŗ ÅĦĦąÅÅąk ą̊ą̊ţą ąą Ħ 0.15 ȳąÁÁǫÅą̊ą Û(145 ČĦąÅÔąą Û1 ÁŸÕą) A ČąąÅÅÛąą Û"the Karl Fisher Method .ħ/ŋÅą 100 ąɜ ÁÅÂÅ ŗş ħ/ŋÅą

.5.0-4.0 ÛÕą/ŋÅą 10 ÅĒõÅǫą ȯzÅŢ ąą̊ÅŁą̊ą :**pH Value** ąą̊ÅŁą̊ÅąąÅą ČţĒę

ČąĒęÅąąą ČąąÅÛąą ąąÅÅÎǫÅą" ŗązÅɜ ĶƠ ƱzÅzą zŁ ą̊ţõ ąą̊ÅǫÅŗą ęąÅÛÅ :**Related substances** ČąąÅÎţą ą̊ą̊zţą ȳzDzǵ 4 ąą ŗÅÂą̊ş ČÅĦ8ą ą̊ą̊ţõ R2 ązÅzÅĒÅąą ȳąÁÁǫÅą̊ą (84 ČĦąÅÔąą Û1 ÁŸÕą) "Thin-layer chromatography ĦÅÔÅą̊ą ęąÅÛŁ .ąÅĦąǫą ązÅÛõ ąą̊ţą ąą ȳzDzǵ 5ş TS (ȯ/ħ300) ÕĒǫĒÅŗą ÅÅ ąą ÁǵąŞ ŗDzǵş R ȯzǫą̊ÅzÅ-1 ą̊ą̊ą̊ą ąą ŋÅą 0.10 (B)ş ÅǫÅ ƱÅĒţą Ž ąǫąÅŗą ą̊ą̊ą̊ą ąą ŋÅą 5.0 (A) ƀzƛ :ĶÅzÅŢ ąą ÅǫÅşÅÅą 10 ČĦąĒÅąąą ɔÅɜ

ČDZóÆä Ζ ÁΘ Ûāäà Îϱèŧä gÀDzǵ ϖη ČHϑÁÔöä ţÂøφ ÆĦä .Ǧ3ÅÈ 2½ gÆη ČHϑÁÔöä ÀΖŢǩ .ÀϱÖ ΨŸŧţä Ž óÅϱϱnŧä Ž āäÀÎϱèä ÙÛÜ ÒHϑÅΛς TS2 ȳζŧèÅǩζöä ǧÅΛŧǩŸäşåζΛ ȯζŸHη ǽÀǩ ÛåΞϱÖ öÀϱǩ ÛČÖŧęå 15 gÆη °ȳ 90 gøäÀǵ ΨøϱÖä ČĦÖGöä ϖη gÆì ÀǮõÜ ÛČŧÊŧϑÀöä ČĦÖGöä ǒÅÅǮϱèÅä ÛA ȯζŸ∓Åä ÅΖŧŸ3 ÖÔHϑϱÊΛ ČĦÖä ČΛÜ ϑζÒǩ ŧ .øÅΖΛöä ǒζŕ .B ȯζŸ∓Åä ÅΖŧŸ3 ÖÔHϑϱÊΛ

30 ȣÅŘΛ ÛR1 ΨDzŸǮöä Õŧϱŧèϑä Ŕβ ϖη Ôη 30 Ž ÛČŧüζϱŘη Čφşàζη ÛĦ 0.3 ČääÀę āäØł :**Assay** ČÊΛÅÔţä Ŕβ 3η ÀΛÅĦΛς ÛTS Õŧϱŧèϑä Ŕβ/ÕŧÖϱϑÂöä ǧÅϱŧèÜ ȯζŸΤ ϖη Ôη 10ς R Õŧϱŧèϑä ÆΛøÆŧŒÜ ȯζŸΤ ϖη Ôη Û"Non-aqueous titration ΨϑÅηŸöä Ùèζöä Ž gÀΛÅĦţä" ϑäζÅ3 ŘƠ ȣζòζη ζŁ Åŧõ VS (ȯ/ȯζη0.1) ÕΛøζŸõŘϱöä ϖη ΗŸη 18.07ùζÅÒΛ VS (ȯ/ȯζη 0.1) ÕΛøζŸõς Řϱöä Ŕβ ϖη Ôη 1 Ôõ .(142 ČHϑÁÔöä Û1 ÆŸÖä) A ČÕΛÀÛöä .$C_{14}H_{30}Cl_2N_2O_4$

ƒdžsΘ üƒDŽyƧƨÚε üШŬ !NjĭdžNjkĭDŽƒƨ|ƒƨ‖ε ǫĭƥNj∓I‖ hυĭǯƒŤd lƒǤ∓ƯƧDŽ

Additional Requirements for Suxamethonium chloride for parenteral use

.(56 ČHϑÁÔöä Û4 ÆŸÖä) "*Parenteral preparations* ČŧÁÔΣä ǧäÀŘHϑϱÊţä" gåşÀζϑ ÆŧDzϱÊΛ øÅϱϱnŧä" ϑäζÅ3 ŘƠ ȣζòζη ζŁ Åŧõ øÅϱϱnŧä ĘϱÛΛ :**Bacterial endotoxins** ČŧηζϱÀƨä ČŧŸnäÆöä ǧÅφÅÅΛØöä 30 ČHϑÁÔöä ÛČΛÂŧŸÒφqä ČĦϱÛöä Û5 ÆŸÖä) "Test for Bacterial endotoxins ČŧŸnäÆöä ČŧηζϱÀƨä ǧÅφÅÅΛØöä ÕDZϑ .ÿäÀd ΨŸŧţä Ž ČŧÖşå gÆǵş 2.0 RS ΨŸnäÆöä ϑÅÅΛØöä ϖη ΖζϱŧÅ äşÅDzϱΛ ŧ Ü(ČΛÂŧŸÒφqä ČĦϱÛöä

ØØØØØ

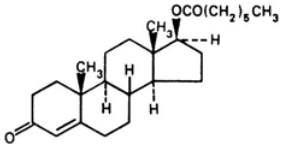
TESTOSTERONI ENANTAS

Testosterone enantate DžNjβĭƧNjƧƧ‖ε lƒƧǵƧĭd

$C_{26}H_{40}O_3$:**Molecular formula** ČŧÅΛÂƨä Č8ŧÔöä

400.6 :**Relative molecular mass** ČŧϱÊΛöä ČŧÅΛÂƨä ČŸϱÒöä

:**Graphic formula** ČŧφÅŧϱţä Č8ŧÔöä



:**Chemical name** ΨϑÅŧŧÒöä lèŧä

Testosterone, heptanoate; 17β-[(1-oxoheptyl)oxy]androst-4-en-3-one; CAS Reg. No. 315-37-7.

.ŘĞĹĂŐŇ ĞĦŭąĂŐąą ĆÁĆ3 ęŬ ĞĦŭąĂŐąą ĆÁĆ3 ŬŬęĂŐ ŘĦąŬ ęŬ ĵęŸąą ŘĦąŬ ŬĐØęŸą ąęĦŭÊŋ :**Description** Ęòęąą

.ĵęŲĦèĵąę R Ŕŭĵąę TS (ò/Ňł750~) òęŲąĂĞĹqą Ę ĦĂĆDĘ ąąęá ŬŐąĵą Ę ĦĦŸłĆ ąąęá ŕ :**Solubility** ĞĦŲąĂęŞØąą

.ŕĆDĘŞØÁŲŬ :**Category** ĞĂĂąą

ĵŬę ŬŐęŘąą ąŋ ęłƠ ĵŬę ŬŷĂÒǵŭá ĞŐŸ8ŋ ĞĹęĂǵ Ę ĵęŔŲąèęŲÊŲąą ǵĂŲąĂĂĹŬ ęĂƠ ĵŬ Æę :**Storage** ąĹÂÁŲąą

.°ŷ 15 ąęĂĆęŲŕ ŕ ǵąąĂǵ ĞĆDęØÁá ĵŲĹƠ

.ŘĞĹĂŐŇ °ŷ 37 ǵąąĂǵ ĞĆDęØÁá ĵęŔŲąèęŲÊŲąą ǵĂŲąĂĂĹŬ ĂŤÔĹŕ :**Additional information** ĞĦęĂŕŬ ǵĂŋęŸĦŋ

REQUIREMENTS ŔĞŋŬŤŐŕdž!ƒ

ąĆ3 ÁĹÂĹ ŕę %97.0 ąĆ3 ŐŐĹ ŕ Ăŋ ęŸ3 ĵęŔŲąèęŲÊŲąą ǵĂŲąĂĂĹŬ ƁęŲƠ :**General requirement** ŷĂĦąą ÆŸŬŲŲąą

.ĞĂĂŐą ǵĂĂąą ĵąę ƁŬ ąęĆDęĂąą ĞąęÊŢ ŬC$_{26}$H$_{40}$O$_3$ ąŋ %103.0

:**Identity tests** ĥŭŇŲĵŇŲŇĆ ĺ ĆĐĵĞĞĦĞĵĆ

.Cę B ąĹóĂĞŲŋŕą ęŬ ĆĂĂĂŋ A óĂĞŲŋŕą ĘĦĞŬŇ ąÒƆ •

Spectrophotometry in ąąĂĹŢΣą ŇƠ ĞŐŬĂŲą Ę ŲęŲÊŲąą Ę ĦŬąą âĂĦę" ĵąęĂ3 ŇƠ ąęòęąą óĂĞŲŋŕą ĘĞŬĦ :A ąĆ3 ĵŇĂĂąą Ę ĦŬąą Ęŋ ąąĂĹŢΣą ŇƠ ĞĦŇìĵą î ĂÔŲŋą Ę ĦŬ ĘąĂŬŲĹ .(43 ĞĦŲĂÔąą Ŭ1 ÁŸŐą) "the infrared region .ĵęŔŲąèęŲÊŲąą ǵĂŲąĂĂĹq ŲĦĎZĂą Ę ĦŬąą Ęŋ ęŬ RS ĵęŔŲąèęŲÊŲąą ǵĂŲąĂĂĹŬ

"Thin-layer chromatography ĞŐĦęĂąą ĞŐĞŬąą ąąĂÎŲèą" ĵąęĂ3 ŇƠ ąęòęŋ ęŁ Ăŋ ÆÊŒ óĂĞŲŋŕą ęĂę :B ŕęąĂĦąą ąŋ ŷęĎęǵ 10 ąŋ ĵĹĂŋęŞ ĞŸŸ8ŋ ǵĂĂłą R1 (ĂŁęęą ÈĦą) óę8ŸĦÊĦÒąą ŷąÆĂŲèĂę Ŭ(84 ĞĦŲĂÔąą Ŭ1 ÁŸŐą) ÆĹØą òęòę ÁĦę .ŘĞĹĂŐŇ ÒąĂÊąą Ę ĵŸŋ 5 ĂŤÊĦŬ8ŲĂę ŬĞĦŲĦĂÔąą ÆĹĂÎŲą R ĘĦĂĵą ŬĂĂąą ąŋ ĂłĎęǵ 90ę R ÒąĂÊąą ĞęĂ8ąą ǵąąĂǵ ĞĆDęĂą Ę óąĂŐŲèŸą ąĂŐŇę ąąĂÎŲèŕą ǵĂĆDęǵ ąŋ ĞĦŲĦĂÔąą ŢÂąĂŇ ŬŐęĵą ęŸ3 ĵè 16 ŢĂĂŇóą Ğ Ŭ .Ăőąę ÆĹĂÎŲąą ĞŤĆDę Ę ąąĂÎŲèŕą ąĂĂĆDŭę ŬŇęĵĂè òŸŋ ĞęĂÎŲŢą ĞĦŲĦĂÔąą ŷÁĂŲÊŇ .ĂŸŋĂą ÆĹØą ĂĂĞŲĹ ęąŲǵ ęŸ3 ĂŸÔĂĂŋ ĘĞŬĹ .ąĂŢą ąŋ ŷęĎęǵ 6ę R ŲĎęŸŐąą ŐĦŲĦèĵą Ŕß ąŋ ŷęĎęǵ 4 ŷąÆĂŲèĂę ąĂĂĆŲŢą óęŬąą ĂŘĆ (A) ƁęĆ :R òęŲąĂĦŢą ąŋ Ăǵąę ĵĎęǵę R ŷóęęęóęŸÒąą ąŋ ŷęĎęǵ 9 ąŋ ĵĹĂŋ Ę ŇóęŸŢ ąŋ ĂŲęęĂÒŋ 2 ĞĦŲĦĂÔąą ĞĦŲĦĂÔąą ĂŤŢŇ .ĂŲę ŲŸĦŢą Ę RS ĵęŔŲąĦèęŲÊŲąą ǵĂŲąĂĂĹŬ ąŋ ŋŸŋ 1.0 (B)ę ĂŲę ŲŸĦŢą Ę óĂĞŲŋŕą ǵĂĂŋ ąŋ ŋŸŋ 1.0 ąĂÊŇ ŬÆĹØą ĂĂĞŲĹ ąąęęęóęŸÒąą ąŋ ŷęĎęǵ ąąĂÎŲèŕą ǵĂĆDęǵ ąŋ ĞĦŲĦĂÔąą ŢÂąą ÆĦą .ĵè 12 ĞęĂÊŢ ǵÁŋ °ŷ 120 ĞĆDęØÁá ąÁÊŇ Ż ŬTS òęŲąĂĂŬ/ŐĦęęĂŸè ąĹęòęù-4 Ŕß òęŸĦŋ ąĂĂł ŬĞŐĦęĂ 10-5 ǵÁŋ ŷ 120 ĞĆDęØÁá

Ęząžząǫǩ .(ÀǫŋząφÀφ 365) ǦĒDząÊÁÁǦõã ȧząą ǦĤÌì ɟÀãą ǿÀŻÁÁõã ǫząŕ Ž ããÀÎǫèŕã ÙÛÛŬ ÒŋÁÁą ǻƎǫõ õÀǫǩ .ĘąÀęǻ 10
.B ǫząŸ ǂã ȣ3 ǦΘÀÁõã Õ̃Ÿǩ 3ŋ ǥÆÎõãą ÀŻŢţãą 3ęząţã Ž A ǫząŸ ǂã ŋ ǦΘÀÁõã ǦĒÊĒąÀõã ǦĤÕǦõã

:ǿÀǦǫǫnŕã 8Ǿǵ ɟą ǻ **293** ǦŋÁÂÔõã Ûą ÆŸÖã Ž Ō̃ÁÆĤǩ ǻǿą

Related ǦǫÀÎţã ǻãząţã" ɟãząȝ ǨƠ 8ząǫząŋ ząŁ Àŋõ̃ ǦÕ̃ĒęÀõã ǦÕ̃ǦÛõã ããÀÎǫèã ȳÆǺǫèÀã ǿÀǦǫǫnŕã ?Àz
."substances

ĮDzǵą TS (ǫ/ħ1760~) Õ̃ÁǿząŸÊõã Ŕþ ŋ ǩŋDzǵ ÆÁƎǫã ÀąŘŢ ɟÁÂą ŋ Ōą 2.0 Ž ŋŸą 5 ĘĒĤÁ :C
Ž ÛБÀÕǩƎõã Б̃ǫ ǫÆǦǫÁ ąÀŘƯ ÀÀǫÒ̃ Ęõũǩ ɟǫÁÁ ÜŬąÀą ȳÀþ Ž ȝŕząǩ Ż ÛÕ̃ÕãÀè TS (ǫ/ħ750~) ǫząφÀȝÁqã ŋ Ǽǵãą
.ǩĤą Ęŋȝ ŌÀèÒ̃ Àþɟã Б̃ǫ ǫÆǦǫÁ ÛɟząŸõã ȝąąÂą ąǿàÒ̃ ĒǫząŸõ ãząǦφɟã ɟãǿÆDZ Ǿnũǩ ǩǵ

ɟÀÊõząÆõã Ž Ōą/ŋŸą 10 ÂĒõÀǫã ǫząŸŢ ȳÆǺǫÊÁ :**Specific optical rotation** Ŭȝząõã ÐÀÔǦõã ÀÁąÆǫõã
.$[a]_D^{20°C} = +77 \text{ to } +83°$ R

ŕ) ŔÀÁą Ù8ŕ ǨƠ ÙĒ ǂã ǥǿãÀǵ ǦDZǿÆã Ǩãą ɟàą ?øǫǵ Ząz :**Loss on drying** ZĒÁDzǫõÀã ÆÕÁõã
5.0 ŋ ÀȝõÒ̃ ÆÕ̃Áõã ɟząÁ ŕ ÜR ǿząÊÁõã ÆĒÊõÒ̃ ŬèÀŘ ązą (ĒǦÁÀÕǩ ŬÕǦąà ąŋ 5 ąÒ̃ ǫÀÁÒèÀązĒõ̃ 0.6 àąÀDzǫÁ
.ħ/ŋŸą

ǫząφÀȝÁqã ŋ Ōą 10 Ž ÛǦĒùząǦŔą Ǧφąàząą ÛĤ 0.5 ããÁ :**Free heptanoic acid** ÀΣã Õ̃ÁząφÀǫǦĒTã Ŕþ
ȳząÁząÔõã ÆĒÊõąÁÆĒõ ĒÁząą ÀÁÀĤÁą ÛTS ǫząφÀȝÁÒ̃/ǫząĒǫząąƎõã Ǧęǿà ǫząŸŢ Б̃ ĒÀφÒ̃ ǫÆĤǫÊţã ÛTS (ǫ/ħ750~)
ŋ Ōą 0.6 ŋ ÀȝõÒ̃ ȳÂŸÁ ŕ ÜÀĤÎąõ̃ TS ǫząφÀȝÁÒ̃/ǫząĒǫząąƎõã Ǧęǿà ǫząŸŢ ȳãÆÁǫèÀã ÛVS (ǫ/ǫząą 0.01)
.(ÀŘÀÒ̃) ÀĤÎţã ŋ ǦÛÈząǫţã ǦÛÕ̃Áõã ?Ÿȝ ǫząÔǦŸõ VS (ǫ/ǫząą 0.01) ȳząÁząÔõã ÆĒÊõąÁÆĒŁ

ǦÕ̃ĒęÀõã ǦÕ̃ǦÛõã ããÀÎǫèã" ɟãząȝ ǨƠ 8ząǫząŋ ząŁ Àŋõ̃ ǿÀǦǫǫnŕã ĘǦÛÁ :**Related substances** ǦǫÀÎţã ǻãząţã
92 ŋ ɟÁÂąą ǦŸã8ą ǥÁÀąõ̃ R1 ÀÒĒŸĒÊõã ǦąŸŁ ȳãÆÁǫèÀã Û(84 ǦŋÁÂÔõã Û1 ÆŸÖã) "Thin-layer chromatography
?Ÿȝ ŋŸÔÁÁą ĘǦÛŁ .ǫÀŋǫąą ǿząÛõ̃ ǫÀţã ŋ ąDzǵ 0.5ą R ǫząφÀȝÁţã ŋ ȳząDzǵ 8ą R ɟÀȝÁÒ̃ ąǿząŸõ̃ ŬąÀÁǫ ŋ ąąDzǵ
(A) ÐząȝÁ :R ǫząφÀȝÁţã ŋ Ǽǵãą ąDzǵą R ȳǿząąǿząŸÒõã ŋ ȳząDzǵ 9 ŋ ɟÁÂą Ž ǩǿząŸŢ ŋ ÀǫǿąÀÒą 5 ǦŋÁÁÔõã
ŋ ǦŋÁÁÔõã ţÂøφ ÆĤã .ÀǫǿÒ̃ ŬŸĒţã Ž ǿÀǦǫǫnŕã ǥÁą ŋ ąŋ 0.20 (B)ą ÀǫǿÒ̃ ŬŸĒţã Ž ǿÀǦǫǫnŕã ǥÁą ŋ ąŋ 20
ŔąĒ ǦÁnąÀÊõã ǦŋÁÁÔõã ąÀÀǩ .ĘąÀęǻ 10 ǥÆą ŋ 110 ǦDZǿÆã ŋÁÊǩą ǿąząŢã Ž ZDzǿõ ÕÀǫǩ ÛããÀÎǫèŕã ǥÀDzǵ
ããÀÎǫèŕã ÙÛÛŬ ÒŋÁÁą ÛĘąÀęǻ 10 ǥÆą ŋ 110 ǥǿãÀǵ ǦDZǿÆã ?ÀnÒ̃ ǥÀą ŋÁÊǩ ÛTS ǫząφÀȝÁqã/Õ̃ÁząŸÊõã
ÀȝõÒ̃ ÛǦĒÊĒąÀõã ǦŋÁÁÔõã ǿÀǦǫǫèÀã ÛA ǫząŸ ÀãąŸŸȝ ÔÔŋǫÊÁ ǦŋÁÁã ǦÁÒ̃ ɟząÒǩ ŕ .(ÀǫŋząφÀφ 365) ǦĒDząÊÁÁǦõã ązą ǦĤÌì ɟÀãą
.B ǫząŸ ÀãąŸŸȝ ÔÔŋǫÊÁ Ŭǿǫõã ǦŋÁÁÔõã ąŋ ǥÆÌ

ÜÕ̃ą 100 ?Ÿȝ ǫząÔŋŸõ R ǿÀţã ţąÂøÁą ǫząφÀȝÁqã Ž ÛǦĒùząǦŔą Ǧφąàząą ÛŋŸą 20 ǦããÀęą ããÁÁ :**Assay** ǦÊÁÁÒ̃ţã

Ζ ȧÅţä ȯζŸ∓ä ȣŋ ļè 1 ĞφȧÅžæ ĞÕĞù ȯŸŋ î ȧŧφöä âȧÕæ .¢ÊȧΦ ÆΛØţȧæ Õŋ 100 Бŭ ȯζŸ∓ä äØŁ ȣŋ Õŋ 5 ΖȧƆ ȯζŸΤ ƷŋĞφøȧÕţȧæ øȧĞφòŋŗä gåȧŋ Ž $C_{26}H_{40}O_3$ Ğŧŧõ ÆÊΟ .ȧĞΛÀÕk ÀφŋζφȧΦ 241 ĞDZζţä ȯζÛæ Ŭŧ Ţ3ŭ Ág ĵφΛ ȣŋ Õŋ/ÿäÀdşÀÒŋ 10 ÂŧõÀφæ ȯζŸΤ î ȧφ ȷζÒΛ ȷŭ Æz .ȣŋäÂφöäş ĞöȧÎţȧæ î ζȣȧţä ÛRS ȷşKφèζφÊφöä ğȧφȧΛΛŭ ± 0.42 ȧŋζȧõ ȧKøŧŧk ÀŋŧŋŞ Ŭəζŕ Ζŧù âȧÕŋ ÿäÁÅφèȧæ R ŏȧţä ţşÂøΛŋ ȯζφȧŽΛqä Ž RS ȷşKφèζφÊφöä ğȧφȧΛΛŭ .0.02

ƒüzsΘ üƒDŽyƭƨÚε üШŬ DžNjþĭƭƨNjƭƨƬΛε lƒƬüƒüzĭÜ hüĭzƒΤd lƒGƭUƬDŽ

Additional Requirements for Testosterone enantate for parenteral use

.(56 ĞŬȧÂÔöä Û4 ÁŸÖä) "*Parenteral preparations* ĞŧΛÕΣä ğäÀŘŬφÊţä" gåşÀζȷ ÆŧDzφÊΛ øȧĞφòŋŗä" ȷäζΛ3 Ǩơ ȣζòζŋ ζŁ ȧŧõ øȧĞφòŋŗä ĘφÛΛ :**Bacterial endotoxins** ĞŧŋζφÀƨä ĞŧŸŋäÁöä ğȧφȧΛΛØöä ŗ Ü(30 ĞŬȧÂÔöä ÛĞΛÂŧŸÒφqä ĞŬφÛöä Û5 ÁŸÖä) "Test for Bacterial endotoxins ĞŧŸŋäÁöä ĞŧŋζφÀƨä ğȧφȧΛΛØöä ÕDZȷ .ÿäÀd ŬŸŧţä Ž ĞŧÕşå gÁgş 3.5 RS ŬŸŋäÁöä ȷȧΛΛØöä ȣŋ ζφ∓ä àşȧDzφΛ

ØØØØØ

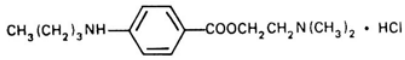
TETRACAINI HYDROCHLORIDUM

Tetracaine hydrochloride DžĭƟƒ|εþƬŧε qĭþNj∓|Njþqĭlj

$C_{15}H_{24}N_2O_2,HCl$:**Molecular formula** ĞŧȧΛÂƨä Ğ8ŧÔöä

300.8 :**Relative molecular mass** ĞŧGÊΛöä ĞŧȧΛÂƨä ĞŸφÒöä

:**Graphic formula** ĞŧφȧŧGţä Ğ8ŧÔöä



:**Chemical name** ŬəȧŧŧÒöä ļèŗä

2-(Dimethylamino)ethyl *p*-(butylamino)benzoate monohydrochloride; 2-(dimethylamino)ethyl 4-(butylamino)benzoate monohydrochloride; CAS Reg. No. 136-47-0.

.Dicainum ÿζΛŧəȧÒΛå ÜAmethocaine ƙəȧõζŽŧŋȷä ÁΛøζŸõşøÁŧŧ :**Other names** ƤÀnŭ øȧƨŭ

.ĞŬφƨÀöä CÁ3 ÜȷζŸöä Ŗŧƨŭ ÛBøζŸæ ȧζŬφÊŋ :**Description** Ζòζöä

Ž ȷȧæşØöä ÕŧŸę ÜTS (ȯ/Ĥ750~) ȯζφȧŽΛqä Ž ā ȧşá ÜŧΛÀÕk øȧţä ȣŋ øäÂDZŭ 8 Ž ā ȧşá :**Solubility** ĞŧφȧæşØöä .R Ǩφȷä Ž ŧŸŧ3 ā ȧşá ŗ ÛR ÿøζζşøζŸÒöä

.ЧЩЙ ґ ζη ωφΕΥ :**Category** ΓΔΑΔΕΔ

.ΕζΡΕΔ ΔΗ ΟΤΗΙΗ ΙΥΣ ΥΣΑΟΓΕΔ ΓΟΥΙΗ ΓΛΣΑΓ Ζ ΚΟΑΕΣΑΟΟΕΔ ΑΛΩΖΥΕΣΩΑΕΕΕ ΣΑΖ ΙΥ ΑΖ :**Storage** ΔΛΑΑΟΕΔ

ΜΥΕΥΖ ΑΗ ΙΗΜ ΦΕ ΥΓΟΓΥΑΟΕΗ ΓΑΗ ΚΟΑΕΣΑΟΟΕΔ ΑΛΩΖΥΕΣΩΑΕΕΕ :**Additional information** ΓΕΖΑΡΥ ΓΑΗΖΥΗΗ

ΥΕΖΡΕΔ ΑΕΙΗΔ ΟΩΖΗΓ ΥΑΕΥΔΕΔ ΖΔΖΥΕ ΦΡΑΓΑΕΔ ΖΑΖΕ ΙΑΩΑΕΔΕΔ ΕΩΑΕΔ .ΙΑΕΥΕΔ ΟΖΕ ΦΡΑΓΑΕΔ ΜΕΗΡΖΗ ΜΥΥ ΑΓΓΑΕΔ

.ΓΗΑΚΑΤΔ ΓΑΔΣΔ ΓΑΔΖΩΔΔ Ζ ΤΑΕΥ ΟΟΑΟΕΔ ΓΓΓΑΔΔ

ΑΖΑΓΥ ΥΚΑΥΟΥ ΚΥΟΙ ΑΓΥ Ζ ΑΔΖΖΛ ΙΥ ΦΟΣ ΣΥ ΜΛΛΟΚ °Ε 134 ΓΑΔΥ ΓΔΖΩΑΔ ΚΟΑΕΣΑΟΟΕΔ ΑΛΩΖΥΕΣΩΑΕΕΕ ΑΖΟΛ

.°Ε 147-134 ΟΑΟΔ Ζ ΚΥΟΙΔ ΙΛΔ ΑΖΟΛ .°Ε 139 ΓΑΔΥ ΓΔΖΩΑΔ ΑΜΔΑΣ °Ε 134 ΓΑΔΥ ΓΔΖΩΑΔ ΑΖΟΛ

REQUIREMENTS ΚΓΗΜΜΟΚΖΕΕΕΕ

ΑΛΑΛ ΡΣ %98.0 ΦΕ ΟΟΛ Ρ ΑΗ ΟΥΕ ΚΟΑΕΣΑΟΟΕΔ ΑΛΩΖΥΕΣΩΑΕΕΕ ΒΖΟΖ :**General requirement** ΕΑΥΕΔΟΖΔ ΑΥΟΖΔ

.ΓΑΑΟΔ ΓΑΔΔ ΒΥ ΔΖΔΔΟΔΔ ΓΔΖΔΥ $ΥC_{15}H_{24}N_2O_2,HCl$ ΦΕ %101.0 ΦΕ

:**Identity tests** ΗΥΙΝΙΝΛΛΕ ΙΕΒΙΓΓΗΓΕ

ΟΥΕ ΓΔΔΥΔΔΔΔ ΕΔΘ .TS (ΟΙΗ75) ΥΖΖΖΖΔΔ ΓΑΗΑΥΔΔΖΖΖ ΦΕ ΟΟΛ 1 ΘΑΡΛΣ ΟΑΗ ΟΛ 10 Ζ Η 0.2 ΑΑΟΛ :A

.°Ε 131 ΓΔΔΔΔ ΥΑΔΥΟΛΡΑ ΓΔΖΔΔ ΥΚΟΕΔΔΔ ΓΑΔΔΔΔΔΔΔΔ ΖΑΘΣ ΥΑΔΔΔΔΔΔΔΔ

[illegible] 0.050 (B) [illegible] 0.10 (A) [illegible] 5 [illegible] 10 [illegible] 105 [illegible] 254) [illegible] .B [illegible] 30.08 [illegible] VS (ȯ/ȯζη 0.1)

[illegible]

Additional Requirements for Tetracaine hydrochloride for parenteral use

Test for non-injectable [illegible] 32 [illegible] 5 [illegible] "*preparations*.

ØØØØØ

THIAMINI HYDROBROMIDUM

Thiamine hydrobromide [illegible]

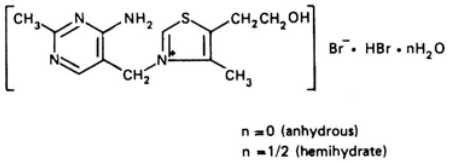
Thiamine hydrobromide, anhydrous [illegible]

Thiamine hydrobromide, hemihydrate [illegible]

Molecular formula [illegible] $C_{12}H_{17}BrN_4OS,HBr$ (anhydrous [illegible]) [illegible] $C_{12}H_{17}BrN_4OS,HBr,½H_2O$ (hemihydrate.

Relative molecular mass [illegible] 435.2 [illegible] 426.2 [illegible].

Graphic formula [illegible]:



:**Chemical name** ÜəÀÈŁÈÒöä ĻèŕÄ

Thiamine bromide, monohydrobromide; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium bromide, monohydrobromide; CAS Reg. No. 4234-86-0 (anhydrous).
Thiamine bromide, monohydrobromide, hemihydrate; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium bromide, monohydrobromide, hemihydrate; CAS Reg. No. 62084-87-1 (hemihydrate).

.gÂÈưş ĞÀÈÀn ÛĞHuəäÀää ÜÀÀÔn Ř ÈäÜ BÜ ĵzŸöä Ř ÈäÜ ÛBózŸä ȧzHuÊn :**Description** Z ȍzöä

ā äşá ŕ ÜTS (ȯ/Ĥ750~) ȯzφÀŽÀqä Ž ĵÀäşØöä ŌÈŸę ÜR ȯzφÀŽŁä Žş ŏÀŧä Ž ĵÀäşØöä Àǵ :**Solubility** ĞÈφÀäşØöä .R Ŕǫĵä Ž ÈŸŁȝ

.B ŕnÀǫÈÀöä ĵzȮn :**Category** ĞÀÀöä

dbn ɔŧȝ ĵÜş ÛȳÀȮǵüä ĞÕŸ8n ÛĞÈφÁÈĤn Ŕd ĞışÀǵ Ž ŕnÀÈŽöä ÁÈnşÀäşØÁÈŁ ŞÁȝ ĵÜ Æz :**Storage** dbÀÂÁǫöä .ŏzŘöä

REQUIREMENTS ŔĞuÜŽƵkdž!f

dbȝ ÁÀÂÀ ŕş %98.0 dbȝ ÕÕÀ ŕ Ân ɔŸȝ ŕnÀÈŽöä ÁÈnşÀäşØÁÈŁ BzǫȝŽ :**General requirement** ȳÀĤöä ÆŸÛǫŧä .ĞÀÀÕä gǻŧä BÜ ŧzDZÀöÀä ĞäzÊŢ ÛC12H17BrN4OS,HBr dbn %101.0

:**Identity tests** hŭŇjNJlIε l εƀƑĞĤƊε

BŔz dbn Ōn 0.5 ÛTS (ȯ/Ĥ80~) ȳzÀǻzÔöä ÁÈÊõşØÁÈŁ dbn Ōn 1 ȣÀŘÀ ÛŏÀn Ōn 1 Ž ŋŸn 10 āäØÀ :A øäÀÕǫèŸö öÀǫÀş R ȯzφÀŽzä-2 dbn Ōn 5 ȝn ȝÀÀ .ÆǵÀì ÀÀòÜ ĵzŸä ȯzŸŧä ɔÕǵÀ ÜTS (ȯ/Ĥ10) ȳzÈèÀŽzǵöä ÁÈφÀÈè ÈÕöüŽ (ÀǫnzφÀφ 365) ĞÈDzÊÀÀǵöä ȧzz ĞĤìĵÀä şÜ ȝüÀÊöä øÀŽÀöä ŏzŕ Ž ȯzφÀŽzä-2 ĞÕǵü ÈÁǵŽ ÜĘəÀęǻ 10-5 gÁn .ȧøÀÜ

.gŔŧĻä ĞHuəäø ¢ǵÎŽ ÛgÂÈưş ĞÁÈÀn ĞHuəäÀää ÜĞȝÀè ĞDZÀDZà ɔŸȝ ȧzHuÊŧä dbn gŔ8ò ĞÈŧõ ÀÎÀŽ :B

General ĞnÀĤöä ȣäÀĤǫèŕä ğäøÀǵǫnä" ĵäzÀȝ ŘƠ ȣzòzŧä A Ōȝ ÀÀǫöä Ōn/ŋŸn 20 ÂÈõÀǫä ȯzŸŢ ÜÛĤÀ :C .(120 ĞHuÀÔöä Û1 ÁŸÕä) ÁÈnşÈŸö ÂÈŧŧõ "identification tests

øÀǵǫnŕä" ĵäzÀȝ ŘƠ ȣzòzn zŁ Àŧõ Ĥ 1.0 ÕŧĤǫÊÀ øÀǵǫnŕä ȯzŸŢ ŔŘHuǫö :**Heavy metals** ĞŸÈÕȝöä ĵäÀĤŧä

ʔɀǫǂǎ ƙĦʌ Ü(127 ǦĦɥÂÔäǎ Û1 ÆŸŎǎ) 1 ŏǎÀDZqǎ ÆÊШ "Limit test for heavy metals ǦŸÆŎǯŏǎ ɟǎÂĦǯǎ ŎDZɟ ƀÆΣǎ
.ƙ/ȳǎÀdǫǎÀȯǫ 20 ɗǫ ÀǯõŬ ɟɀȯʌ ɾ Ü(128 ǦĦɥÂÔäǎ Û1 ÆŸŎǎ) A ǦŎʌÀÛŸŏ ʌŎɀǫ ǦŸÆŎǯŏǎ ɟǎÂĦǯǎ ɗǫ
ʌÆɀÂò ŏÂǯǎ ɗǫ Ŏǫ 10 Ž ƙ 0.6 ÂÆõÀǫǂ ȯɀŸʈ ɟɀȯʌ :**Clarity and colour of solution** ȯɀŸǂǎ ɟɀŏǫ ŏÂÂÔäǎ
.ɟɀŸäǎ CÆƷǫ

.ƙ/ŋŸǫ 1.0 ɗǫ ÀǯõŬ È Æŏ :**Sulfated ash** ŘÂŸÊǯǎ ǎÂǫÀäǎ

ÆÆǫǫÀǂǫǫÆÆŁ ÆŎÂʌ ɾ .°ȳ 105 ǥǎÀǵ ǦDZǵÆǂ Ŕǂ̇Âǯŏǎ ɟàɀŏǎ ʔøǫǵ Ɀ̇ǂ :**Loss on drying** ƵÆÂDzǫŏÂǂ ÆŎÂŏǎ
.ƙ/ŋŸǫ 25 ɗǫ ÀǯõŬ ƱəÂǯǎ Ɀ Ôǫ ŕǫÂÆǯŏǎ ÆÆǫǫÀǂǫǫÆÆŁ ÆŎÂʌ ɾ .ƙ/ŋŸǫ 5.0 ɗǫ ÀǯõŬ ƱəÂǫŸŏǎ ŕǫÂÆǯŏǎ

.3.4-2.7 ÛŎǫ/ƙ 0.06 ÂÆõÀǫǂ ȯɀŸʈ ŏÂŁÂǂ :**pH Value** ŏÂŁÂǦŏǎ ǦǯÆę

10 ȣÂŘʌ ÛR1 ƱDzŸǯŏǎ ŎÆǫÆèɟǎ Ŕƥ ɗǫ Ŏǫ 30 Ž ÛǦÆùɀǦŘǫ Ǧǫǫàɀǫ ÛƙĦ 0.30 ǦǂǎÀę ǎǎØʌ :**Assay** ǦÊʌÂŎǯǎ
ɀŁ Âǯõ VS (ȯ/ȯɀǫ 0.1) ŎʌȯɀŸõŘǦŏǎ ŔǯШ ÀʌÂĦʌǫ ÛTS ŎÆǫÆèɟǎ Ŕƥ/ŎÆŎǦəÂŏǎ ǥÂǫÆèŬ ȯɀŸʈ ɗǫ Ŏǫ
.(142 ǦĦɥÂÔäǎ Û1 ÆŸŎǎ) A ǦŎʌÀÛäǎ ."Nom-aqueous titration ƱəÂǯǎ ɾ Ùèɀŏǎǎǎǎ Ž gÀʌÂĦǯǎ" ɟǎɀ!ʒ ŘƠ ȣɀòɀǫ
.OS,HBr4BrN17H12C ɗǫ ŋŸǫ 21.31 ùɀÂȯʌ VS (ȯ/ȯɀǫ 0.1) ŎʌȯɀŸõŘǦŏǎ Ŕƥ ȯɀŸʈ ɗǫ ƙ 1 Ŏõ

ØØØØØ

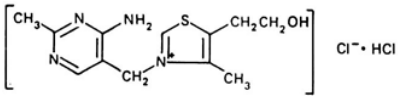
THIAMINI HYDROCHLORIDUM

Thiamine hydrochloride DžŽDŽfŽkllε qŽƥNj‡lNjƥqŽlj

$C_{12}H_{17}ClN_4OS,HCl$:**Molecular formula** ǦÆÂʌÂɀǎ ǦȣÆÔäǎ

337.3 :**Relative molecular mass** ǦÆǦÊʌäǎ ǦÆÂʌÂɀǎ ǦŸǫȯäǎ

:**Graphic formula** ǦÆǫÂÆǦǯǎ ǦȣÆÔäǎ



:**Chemical name** :ƱəÂÆǯÆȯäǎ ɟèɾǎ

Thiamine chloride, hydrochloride; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium chloride, mono-hydrochloride; CAS Reg. No. 67-03-8.

ǦÂÆÂʌ ǦĦɥǎÀäǎ ÜǥÀÂÔŸŏ ŎəÂǫ Ŕ̇ÆǂŬ ǫŬ Ŕ̇ÆǂŬ ƀɀŸǂ ȧɀĦÊǫ ǫŬ ÛǦǫɀŸǫ Ƙɗ ǥǎɀŸǂ :**Description** Ɀòɀäǎ
.ǥÂÆɀǫ

Ƙđ ЖЕŸŧȝ ÜTS (ȯ/Ȟ750~) ȯȚφÅŽΛqđ ȣŋ ȯÂDZ 100 Žş ȯÅŧđ ȣŋ Ǽǵđş ȯÂDZ Ž đđşǽ :**Solubility** ȷÅđşØȯđ
.R Ƙǭɟđş R ȷȚǫŒèɟđ Ž đđşǽ

.B ƙŋÅǫŒÅȯđ ȷȚȮŋ :**Category** ZŒÂÔǫȯđ

ȣŋ ɔŧȝ ȷÜş ÛĞŒφǼĤŋ Ƙđ Ûȳ̄ÅȮǵüđ ĞÕŸ8ŋ ĞΛşÅǵ Ž ƙŋÅŒŽȯđ ǼΛóȚŸõşóǼŒŁ ŞÅǵ Ǽz :**Storage** ȣΛÂÁǫȯđ
.ȯȚŘȯđ

ÛǼÜÀȯđ ȚDzŸȯ ¢ŕÀĤǫđ ЖzóǼĞ ƙŋÅŒŽȯđ ǼΛóȚŸõşóǼŒŁ ȯóǼǫΛ :**Additional information** ĞŒȚÅŕÜ ǵÅŋȚŸĤŋ
ƱφÅŋŸȯđ ǼõÀŧđ ȷŭȚ ȯđȚŸȯ ôÀĤǫΛ ÅŋǼΛȝ .ĞŒȯÅĤȯđ góđÀΣđ ǵÅDZóđ Ž ţÀèÜ ÕȮÅǫȯđ ȷȚȮΛş ÛȯȚŘȯđ đÅŒŋ Ž ɔøǫǵ
ȯȚŸ‡đ ǼÕÅΛ .ÕȮÅǫȯđ ŘĤđ ȝŋ ÿ 284 ĞđÀę óÅŦÔφŕđ ĞDZóđ .ȳđÀŋ 100 ÕȮȯ ȯŧđ ȣŋ ȳđÀŋ 4 ĞđÀę ĞȝÀÊđ ÒǫȚ
.ȯđȚŦđ ȝŋ đŧǫȯÅđ ÅŧŒè ŕş ĞȝÀÊđ ĞȯǼǫĤŧđş ĞΛȚŸÕȯđ ÕŒȯÅ‡đ ǼÊÁĞ .ǼΛǼÌ ȯÙĞđ ȣȮȯş ÛÕęÜ ŞÜ 4.0 ȯÅŁÅđ ĞŧŒÕđ ¢ǫŒȯÅĤȚ

REQUIREMENTS ƙĞĥωŘŠƙdž!ƒ

ǼΛÂΛ ŕş %98.0 ȣȝ ÕÕΛ ŕÅŋ ɔŸȝ ƙŋÅŒŽȯđ ǼΛóȚŸõşóǼŒŁ ƀȚǫȝ :**General requirement** ȳÅĤȯđ ǼŸÛǫŧđ
.ĞÁÁÕđ gÅŧđ БÜ ŧȚDZÀȯÅđ ĞđȚÊŢ Û$C_{12}H_{17}ClN_4OS$, HCl ȣŋ %101.0ȣȝ

Identity test hŭŇjNJЛЄ l ɛƥƑĞĦCJЄ

ƀƙȚ ȣŋ ÕŋŋΛ 0.5ş TS (ȯ/Ȟ80~) ȳȚΛŕÔđ ǼŒÊõşóǼŒŁ ȣŋ ÕŋŋΛ 1 ȮÅŘΛ ÛȯÅŧđ ȣŋ ÕŋŋΛ 1 Ž ŋŸŋ 10 đđØΛ :A
10- gǼŋ ÀÕǫÊŒȯ õÀǫΛş R ȯȚφÅŕȚđ-2 ȣŋ ÕŋŋΛ 5 ȝŋ ȝÀΛ .ЖǵÅÌì ÀÁòÜ ȯȚŸ‡đ ɔÕĞΛ ÜTS (ȯ/Ȟ 10) ȳȚŒèÅŕȚĞđ ǼŒφǼŒè
.ȧóàÜ ЖÕȯüŕ (ÀǫŋȚφÅφ 365) ĞŒDzÊÁΛĞđ ȧȚȚ ĞĤÌŧđ ȯȚŕ ŞÜ ȝùÅÊđ óÅŦΛđ ȯȚŕ Ž R ȯȚφÅŕȚđ-2 ĞÕĞù ƀǼĞŕ ÜĞÕŒęŕ 5
.ƙŧǫđ ĞĤφđÀđ ĞŦŒĞÌ ÛƙÂŒφş ĞÁŒÁÌ ĞĤφđÀđ ȷȚȮŕ ÛĞȝÅÊđ ȝÅDZà ɔŸȝ ȧȚĤÊŧđ ȣŋ ĞŸŒŸę ĞŒŧõ ÀÎΛ :B
General ĞŋÅĤđ ȮđÀĤǫŕđ ǵđóÅǫÌđ" ȷđȚΛȝ ŘƠ ȮȚȯȚŧđ A ÕȝÅÁǫđ Õŋ/ŋŸŋ 0.05 ȯȚŸŦ ŬÛĤΛ :C
.(121 ĞĤφÁÔđ Û1 ǼŸŘđ) ǵđǼΛóȚŸȮŸõ ÂŒŧõ "identification tests

óÅǫÌŕđ" ȷđȚΛȝ ŘƠ ȮȚȯȚŋ ȚŁ Åŧõ Ȟ 1.0 ÕŧĤǫÊΛ óÅǫÌŕđ ȯȚŸŦ ƙŘĤφǫȯ :**Heavy metals** ĞŸŒÕŽđ ȷđÅĤŧđ
ȷđÅĤŧđ ȚȚŦ ȣŋĤΛ Ü(127 ĞĤφÁÔđ Û1 ǼŸŘđ) 1 đÀDZqđ "Limit test for heavy metals ĞŸŒÕŽđ ȷđÅĤŧđ ÕDZɟ ƀǼΣđ
.Ȟ/ȳđÀdşÀȮŋ 20 ȣŋ ÀŽõÜ ȷȚȮΛ ŕ Ü(128 ĞĤφÁÔđ Û1 ǼŸŘđ) A ĞÕΛÀÛđ ÆÊШ ĞŸŒÕŽđ

ÈŒȯş ЖȚŧÅÒ ȯÅŧđ ȣŋ ÕŋŋΛ 10 Ž Ȟ 2.0 ȯȚŸŦ ȷȚȮΛ :**Clarity and colour of solution** ȯȚŸ‡đ ȷȚȯş ȯÅÁÔđ
Colour ÕđȚŦÊđ ȷȚȯ" ȷđȚΛȝ ŘƠ ȮȚȯȚŋ ȚŁ Åŋ ȝŋ ȷóÅÕΛ ÅŋǼΛȝ Yw2 ƀóÅŒŘŧđ ȷȚŸđ ȯȚŸŦ ȣŋ ÀŽõÜ gǼÎđ ȷȚŸŋ
.(53 ĞĤφÁÔđ Û1 ǼŸŘđ) "of liquids

.Ȟ/ŋŸŋ 1.0 ȣȝ ǼΛÂΛ ŕ :**Sulfated ash** ŘÁŸÊŧđ ŕÅŋÀđ

.ȟ/ŋŸŋ 50 ȣ3 ÆÕÅöä ÆÅÂÅ ŕ Ü°ȳ 105 gøäÀǵ ĞDZøå ÆÅ3 Ƶ Åƶ :**Loss on drying** ƵÆÅDzǫöÅä ÆÕÅöä

.3.3-2.7 ÛÕŋ/ŋŸŋ 25 ȯƶŸŢ ŏÅÈÅä :**pH Value** ŏÅÈÅGöä Ğŧę

R1 ÜDzŸƷöä Õǫęèɟä Ŕƥ ȯƶŸŢ ȣŋ Ȯŋ 30 Ž ÛĞęŕƶǵŘŋ Ğǫşàƶŋ ÛȟŘ 0.25 ĞäÀę ā äØÅ :**Assay** ĞÊÅÅÕŧä ƶŁ Åŧõ VS (ȯ/ȯƶŋ 0.1) ÕÅøƶŸõŘĞöä Ŕƥ Ʒŋ ÀÅÅȟÅş ÛTS ÕǫęèɟÅ Ŕƥ/ÕęÕĞəÂöä ǵÅǫęèÜ ȣŋ Ȯŋ 10 8ÅŘÅ .(142 ĞHȣÅÔöä Û1 ÆŸŎä) A ĞÕÅÀÛöä Û"Non-aqueous titration ÜəÅŋŸöä Ùèƶöä Ž gÀÅÅȟŧä" ȣƶÅ3 ŘƠ 8ƶòƶŋ .$C_{12}H_{17}ClN_4OS,HCl$ ȣŋ ŋŸŋ 16.86 ùƶÅÒÅ VS (ȯ/ȯƶŋ 0.1) ÕÅøƶŸõŘĞöä Ŕƥ ȣŋ Ȯŋ 1 Ȯõ

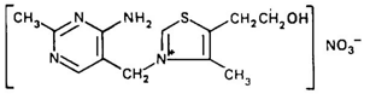
THIAMINI MONONITRAS

Thiamine mononitrate DžǐDŽFǐǩǁɛ l ɛƥłż ăɡFƠć

$C_{12}H_{17}N_5O_4S$: **Molecular formula** ĞęÅÅÂƨä Ğ8ęÔöä

327.4 :**Relative molecular mass** ĞęĞÊÅöä ĞęÅÅÂƨä ĞŸǫȮöä

:**Graphic formula** ĞęǫÅęĞŧä Ğ8ęÔöä



:**Chemical name** :ÜəÅęŧęÔöä ǰèŕä

Thiamine nitrate (salt); 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium nitrate (salt); CAS Reg. No. 532-43-4.

.gÂęŭş ĞÅęÅÀn ĞHȣäÀöä Ü ŘęäÜ ƀƶŸä ȧƶHȣÊŋ şÜ ÛĞǫƶŸŋ Ƙȣ ǵäƶŸä :**Description** Ƶòƶöä

Ƙȣ ÅęŸŧȝ ÜTS (ȯ/ȟ750~) ȯƶǫÅŽÅqä Ž ÆÆDZ ȣÅäşØöä ĞęHȣì ÜŏÅŧä Ž ȣÅäşØöä ĞęHȣì :**Solubility** ȣÅäşØöä .R ȣƶǫęèɟä Ž ā äşá

.B ƙŋÅǫęÅöä ȣƶȮŋ :**Category** ƵęÅÔǫöä

ȣŋ ƨŧȝ ȣÜş ÛĞęǫÆĚŋ Ƙȣ ÛŷÅȮǵüä ĞÕŸ8ŋ ĞÅşÅǵ Ž ƙŋÅęŽöä ǵäÀǫǫ ƀÅÅǵÜ ŞÅǵ Æƶ :**Storage** ȣÅÂÅǫöä .ŏƶŘöä

ÛÆüÀöä ƶDzŸŏ ¢ŕÀĚǫä ÅęƶøÆĚ ƙŋÅęŽöä ǵäÀǫǫ ƀÅÅǵÜ ōøÆǫÅ :**Additional information** ĞęƶÅŕÜ ǵÅŋƶŸĚŋ .ĞęöÅĚöä gøäÀΣä ǵÅDZøå Ž ţÀèÜ ÕȮÅǫöä ȣƶȮÅş ÛŏƶŘöä āÅęȣ Ž ƨøǫǵ

REQUIREMENTS ƙĞhȣŏkdž!ƒ

ÆÆÂÆ ƒÇ %98.0 ďƷ ÕÕÆ ƒ Æ ÇÆ ÇÆÇõä ğäÀÇ Ðääğ Ðääğ Ðääğ :**General requirement** ÇÆÇÆÇää ÆÇÇÇää
.ÇÆÆÕä ğäÆää Ðääğ äÇäÇÊÇ ÛC$_{12}$H$_{17}$N$_5$O$_4$S ďÇ %101.0ďƷ

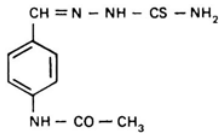
Identity test hüÇÇÇÇÇÇ ÇÇÇÇÇÇ

Thioacetzone DžNjŘFłĬƨcNjǐkłłƐ

.$C_{10}H_{12}N_4OS$: **Molecular formula** ǦƐÅłÂƨä Ǧ8ƐÔöä

236.3 :**Relative molecular mass** ǦƐǤÊÄöä ǦƐÅłÂƨä ǦŸǫÒöä

:**Graphic formula** ǦƐǫÅƐǤţä Ǧ8ƐÔöä



:**Chemical name** :ƱƨÅƐŧƐÒöä ǀèřä

4′-Formylacetanilide 4′-(thiosemicarbazone); *N*-[4-[[(amino-thioxomethyl)hydrazono]methyl]phenyl]acetamide; CAS Reg. No. 104-06-3.

.łłǤłÀÀÕǩ ǦHƱƨäÀöä CÆ3 ÜÀÅòÙ ɃøzŸä ȧzHƱÊŋ ȘÙ ÛǦǤǵÅì öäÀÅò ǧäøzŸä :**Description** Ƶòzöä

Ž ā äȘæ ÜR ȯzǫÅŽƐţäȘ TS (ȯ/ȟ750~) ȯzǫÅŽłqä Ž JÅæȘØöä ǴƐHƱì ÜöÅţä Ž łłÆDZ ā äȘæ :**Solubility** JÅæȘØöä

.R ÆƐŋÅŋøzz ÕƐŽƐŋ ƱƨÅłǫ ƀŋ öäÂDZÙ 10

. JøÆǫöä äłÅŘŋ öäȘä :**Category** ƵƐłÔǫöä

.özŘöä ƀŋ ƨŧƷ JÙȘ ÛȳÅÒǵüæ ǦÕŸ8ŋ ǦłȘÅǵ Ž JȘàÅǫƐèÙzƐŽöä ȘÅǵ Æz :**Storage** ƀłÂÅǫöä

REQUIREMENTS ƚǦƀłłŽõkdž!f

%102.0 ƀ3 ÆłÂł řȘ %98.0 ƀ3 ÕÕł řÅŋ ƨŸ3 JȘàÅǫƐèÙzƐŽöä ɃzǫƷ :**General requirement** ȳÅŘöä ÆŸÛǫţä

.ǦzÅƨä gäÅţä ƁÙ ţzDZÀöłæ ǦæzÊŢ ÛC$_{10}$H$_{12}$N$_4$OS ƀŋ

Identity test hƱŘNjNJłłƐ lƐƀJǦHƱƐ

öäÀŧΣä ŘƠ ǦŘìjä ǦÕÛłŋ Ž ƱƨzŘöä ƵƐÛöä âłÅę" JäzÅ3 ŘƠ ȣzòzŋ zŁ łŧõ ółǦǫnřä ȘǦÛł :A

öäÀŧΣä ŘƠ ǦŘìjä î łÔǫŋä ƵƐù ȘæłÛǫł .(42 ǦHƱłÔöä Û1 ÆŸŎä) "Spectrophotometry in the infrared region

.JȘàÅǫƐèÙzƐŽŸö ƱŘDZÀţä ƵƐÛöä 3ŋ ȘÙ RS JȘàÅǫƐèÙzƐŽöä ƀŋ ¢ƐŸ3 ÕÔHƱǫÊţä ƵƐÛöä 3ŋ

łŋÆłÅ3 Ûdehydrated öłţä ţȘhƱŋ ȯzǫÅŽłqä Ž Õŋ/ȳäÀdȘÀÒŋ 3.0 łƐõÀǩ Ƀæ ȯzŸŢ î łÔǫŋä ƵƐù ƁÆǤł :B

î łǫ ŋŸǤł ÜłłǤłÀÀÕǩ ÀǫŋzǫÅǫ 328 ǦDZzţä ȯzù ÆłÅ3 łłƐŧŢ3Ù łłÆǵ ÛÀǫŋzǫÅǫ 350Ș ÀǫŋzǫÅǫ 230 ƙæ ǦDZzŋ ȯæzùÙ Ž ÆŧłÅÎł

.łłǤłÀÀÕǩ 0.58 äØŧ ǦDZzţä ȯzù ÆłÅ3 ǀè 1 ǦǫÅÆŽæ ǦÕǤù

ǧłǫƐèÙ ƀŋ Õŋ 0.25 ƱłÅŘł ÛVS (ȯ/ȯzŋ 5) ȳzłæzÔöä ÆƐÊõȘØÆƐŧ ƀŋ ƀnłÅè Õŋ 1 Ž ŋŸŋ 10 ā äØł :C

.öäæzè ǦæłÅèø JǫÅǩ ÜǵÆǵäȘ ǦÕƐęæ ǵÆŋ řŸ8łȘ ÛTS (ȯ/ȟ 80) î łòÀöä

ğäóÅĠQñä" ɟäzÄ3 ŘƠ ĞŒõşɟä ĞŒŘÅŋşóɟä ğÅÆŋɟä 8äÅŘQèä ÕDZɟ 8zòzţä Õ3ÅÅQõä ŬÛŘŘ ŋŸŋ 10 ĞääÅę :D .Åþŭ ɟzõ ɟQÄ Û(119 ĞHuÅÔõä Û1ÆŸŎä) "General identification tests ĞŋÅŘõä 8äÅŘQèŗä

óÅĠQñŗä" ɟäzÄ3 ŘƠ 8zòzŋ zŁ Åŧõ ř 1.0 ÕŧŘQÊÄ óÅĠQñŗä òzŸŢ ŘŘHuQõ :**Heavy metals** ĞŸŒÕŽõä ɟåÅŘţä ɟåÅŘţä ƤzQŢ dbŘÄ Ü(127 ĞHuÅÔõä Û1 ÆŸŎä) 3 õäÅDZqä "Limit test for heavy metals ĞŸŒÕŽõä ɟåÅŘţä ÕDZɟ ÞÆΣä .ř/ÿäÅdşÅÓŋ 10 dbŋ ÅŽõŭ ɟzÓÄ ŗ Ü(128 ĞHuÅÔõä Û1 ÆŸŎä) A ĞÕÄÅÛõä ĒÊШ ĞŸŒÕŽõä

.ř/ŋŸŋ 2.0 db3 ÆÄÂÄ ŗ :**Sulfated ash** ŘÅŸÊţä åÅŋÅõä

.ř/ŋŸŋ 5.0 db3 ÆÕÅõä ÆÄÂÄ ŗ Ü°ÿ 105 góäÅg ĞDZóå ÆÄ3 ZÅz :**Loss on drying** ZŒÅDzQõÅä ÆÕÅõä

ĞÕŒęÅõä ĞÕĠÛõä ãäÅÎQèä" ɟäzÄ3 ŘƠ 8zòzŋ zŁ Åŧõ óÅĠQñŗä ĘĠÛÄ :**Related substances** ĞõÅÎţä åäzţä ÕŽÄqä ğÅQŒèŭş ĞŸ8ŋ gåÅŧõ R4 ÅÓŒŸÊõä ĞŋŸŁ ÿÆÅQÊk Û(84 ĞHuÅÔõä Û1 ÆŸŎä) "Thin layer chromatography ĻDzgş R òzφÅŽŒţä dbŋ ÿzDzg 9 dbŋ ɟÄŋ Ž kõzŸŢ dbŋ ÅQõşÅÓŒŋ 10 ĞHuŒÅò ƨŸ3 ŘŸÔÅÄŋ ĘĠÛÄ .ōÅHuQŋ ózÛõ R (*P*-acetamidobenzalazine) dbŋ ŋŸŋ 4.0 (B)ş ÅQõ ŬŸŒţä Ž óÅĠQñŗä gåÅŋ dbŋ ŋŸŋ 0.2 (A) ÞzƷ :ŏÅţä dbŋ Ágäş ÕÄÅQÅõä ŘŧШ ÞşÅÊQõÅæ æÅŘ Ûõäzŧä Ž ZDzQõ ōÅQk ÛääÅÎQèŗä gÅDzg dbŋ ĞHuŒÅÔõä Ʒzó ÆŸæ .ÅQõ ŬŸŒţä Ž RS ĞΘÅφ ĞŸÕæ Þŭŭŭŭŭ ɟzÓk ŗ .(ÅQŋzφÅφ 365) ĞŒDzÊÅÅĠõä ȧzz ĞŸÌɟä õzŘæ ääÅÎQèŗä ÙÛŬ ÒHuÅÄş ÛTS (ȯ/ř 130~) .B òzŸ+ä db3 ĞΘÅÅõä ÕŸk dbŋ gÆÌ ÅŽõŭ ÛĞŒÊŒÅÅõä ĞŸÕĠõä õÅŽQèÅæ ÛA òzŸ+ä db3

ÛÄĠÄÅÕk ř 2 óäÆÕŋ ĻƷÅφ ȧzHuÊŋ ÕÓÎæ óÅĠQñŗä gåÅŋ Øñúk :**Thiosemicarbazide** ŬÅÔφ ÆÄÅæÅõ zŒφ ĞÆÅõä ƙæ ƷÅÄ ÛÕęɟä ƨŸ3 gÆgäş Ğ3ÅÈ gÆŋ ÅÕQÊŒõ õÅQÄ .Õŋ 50 ƷÅQφq 8Åõ õÅŋ 8ÅŘÄ ÛĞŒùzĠŘŋ ĞφşÅzŋ ÅŽQŘÈ ĞŒùşÅŬ ĞŸDZzg Ğŭ ĞgÅÌÅõä dbŋ Õŋ 25 ÕÕÄşÛĞgÅÌÅõä dbŋ ğäÅQõ ŬŸŒŋ ĞŘŘæ òşŭ óäÅÄ ÛĞÌÅÄ .ƤÅnɟäş ÿäÆÅQèÅæ ÛVS (ȯ/ȯzŋ 0.1) ceric ÕÄKÊõä ğÅÅŸè 3ŋ ÅÄÅŘÄş TS(ȯ/ř100~) ğÅÅŸÊõä ŘŧШ ŘŧƷ .Õŋ 250 Õŋ 0.8 dbŋ ÅŽõŭ ÆŸÛQÄ ŗ .gÆgäş ĞÕŒęå gÆŋ ÅŧQÊk óÅęóà ĞÄÅŒ ĞÛÕφ ƨφQg ÛÅŘÎŧõ TS (*o*-phenanthroline) .(ř/ŋŸŋ 1.0 dbŋ ÅŽõŭ ÈŒõ) VS (ȯ/ȯzŋ 0.1) ceric ÕÄKÊõä ğÅÅŸè dbŋ

ÿÅþ ƨŸ3 °ÿ 60 ĞDZóÆõä Ž ¢ÅzÆQæ R òzφÅŽŒţä dbŋ Õŋ 60 Ž ÛĞŒùzĠŘŋ ĞφşÅzŋ ÛŘ 1.0 ĞääÅę ãäØÄ :**Assay** ĞÊÄÅÕţä ƨφQg °ÿ 60 ÆÄ3 gääÅΣä ĞDZóå ƨŸ3 ŞzÅƷ ÛTS òzφÅŽŒţä/ĞÄnÅÊõä ĞŘÅõä ğäÅQφ dbŋ Õŋ 20 ŏÙĞæ 8ÅŘÄ .ŬəÅŋ ĞÅÅfş ĞφşÅzŋ ÅDzŢ ŽÅDZà ĞÕkzæ òŸn dbŋ ĞÌÅÄş åƎÄ .ÅŒzÅù ÅŒzÅò ŒƎÅè ĞõóÅk ÛÆęÅkş gÆŧDzÄŋ ĞæÅèó ÕÓÎQk åƎÄ Ü°ÿ 105 góäÅШ ŘæÅφ ɟäş Бŭ ZÅz .ĞŘÅõä dbŋ ĞŒõÅn ğŗzÊ8õä ĞĠÔk ƨφQg R òzφÅŽŒţÅæ ĞæÅèÅõä ÕÊ8kş .$C_{10}H_{12}N_4OS$ dbŋ ŋŸŋ 460.6 ùzÅÓk ĞæÅèÅõä dbŋ ÿäÅd 1 Õõ .ɟäzÄş

ØØØØØ

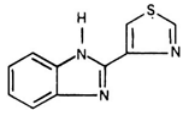
TIABENDAZOLUM

Tiabendazole üNjŘ£σφžĞƒŤĦ‖ε

Molecular formula: $C_{10}H_7N_3S$.

Relative molecular mass: 201.3

Graphic formula:



Chemical name: 2-(4-Thiazolyl)benzimidazole; 2-(4-thiazolyl)-1*H*-benzimidazole; CAS Reg. No. 148-79-8.

Description: White or almost white, crystalline powder.

Solubility: Practically insoluble in water; soluble in dilute hydrochloric acid; slightly soluble in methanol.

Category: Anthelmintic.

Storage: Protect from light.

REQUIREMENTS

General requirement: Tiabendazole contains not less than 98.0% and not more than 101.0% of $C_{10}H_7N_3S$, calculated on the dried basis.

Identity tests:

- Dissolve 0.1 g in 10 ml of methanol and add 0.1 ml of a 0.1 M solution of sulfuric acid. Add 0.1 g of 10% palladium on charcoal and 0.1 g of sodium borohydride. Shake for 5 min and filter. To 1 ml of the filtrate add 1 ml of a 0.1 M solution of sodium nitrite and 1 ml of a 0.1 M solution of sulfanilic acid. Add 1 ml of a 0.1 M solution of 1-naphthylamine. A red colour is produced.

A: Spectrophotometry in the infrared region (43 Appendix 1). The spectrum of a sample in a mixture of potassium bromide and liquid paraffin shows absorption at the wavelengths of the spectrum of the substance.

Åŋ/ÉÁ3 ÛVS (ȯ/ȯzŋ0.1) Õ̃ÁȯzŸõ̃ȘȯÁÉÉTã̃ Ŕ ƥ Ž Õ̃ŋ/ÿ̃ãÀdȘÀÒŋ 4.0 ÂÉõÀǩ Ƀǽ ȯzŸ̃Ţ ȉ ÅÔQŋã̃ ZÉù ƁÁÉGÁ :B ÜÃGÁÀÕǩ ÀQŋzφÅφ 302Ș 234 ǦDZzţã̃ Ƃzù ÁÁ3 ǩÉŧŢ3Ù̃ ȡÁÁǵ ÛÀQŋzφÅφ 350Ș ÀQŋzφÅφ 230 ǩã̃ ǦDZzŋ ȯãzùÙ̃ Ž ÁÉŧÅÎÁ .Ƃãzȯõã̃ ɔŸ3 Ûo.49Ș 0.23 ȡÁØŁ ǦDZzţã̃ Ƃzù ÁÁ3 ŀè 1 ǦφÅÁǯã̃ ǦÕ̃GÙ ȉ ÅȯŋŸGÁ ÜəÅÁõ̃-4Û1 ȡŋ ŋŸŋ 3 8ÅÃÁ ÛVS (ȯ/ȯzŋ 0.1) Õ̃ÁȯzŸõ̃ȘȯÁÉÉTã̃ Ŕ ƥ ȡŋ Õ̃ŋ 5 Ž ŋŸŋ 5 ã̃ãØÁ :C õ̃ÀȯÁȘ ÛǯÂƐ ÛR Õ̃φÂõã̃ ȧzŋÜÊŋ ȡŋ ǩ 0.1 8ÅÃÁ .ã̃ȘØÁ ɔøȯǵ ǯÀÁȘ ÛR ǩŋÙ̃ ÜəÅÁõ̃ ǩŸÉÅÉÅõã̃ ÁÁȯzŸõ̃ȘȯÁÉÉŁ ÜDzÊÅÁã̃ Ș̃Ù̃ ÉŋÅdȘ ȧøÀÙ̃ ȷzõ̃ ǰȯÁÁ ÛTS (ȯ/ǩ45) Õ̃ÁÁÁÁΣã̃ ȳzÉφzŋÙ̃ ǵÅÅŸè Õ̃ŋ 10 8ÅÃÁȘ ÛĞÕ̃ÉȘã̃ 2 gÁŋ ÀÕȯÊÉõ̃ .ȧøÂŋ

.ǩ/ŋŸŋ 1.0 ȡ3 ÁÁÂÁ ŕ :**Sulfated ash** ǨÁŸÊţã̃ ã̃ÅŋÀõã̃

.ǩ/ŋŸŋ 5.0 ȡ3 ÁÕ̃Åõã̃ ÁÁÂÁ ŕ Ü°ȳ 105 ǵõã̃Ǵ ǦDZøã̃ ÁÁ3 ZÁz :**Loss on drying** ZÉÁDzȯõ̃Åã̃ ÁÕ̃Åõã̃ ǦÕ̃ÉȘÀõã̃ ǦÕ̃GÛõã̃ ã̃ãÀÎȯè" ȷãzÁ3 ǨƠ 8ȯzòzŋ zŁ Åŧõ̃ øÅȯÀŋŕã̃ ȘGÛÁ :**Related substances** ǦõÅÎţã̃ ã̃ãzţã̃ 50 ȡŋ ȷÁÂŋȘ ǦŸ8ŋ gã̃Åŧõ̃ R4 ÅÒÉŸÉÊõã̃ ǦŋŸŁ ȳÁÁȯÊǩ Û(43 ǦHUÁÔõã̃ Û1 ÁŸǨã̃) "Thin layer chromatography ǨÅţã̃ ȡŋ ȷDzǵ 2Ș R ȷzȯÉèȷã̃ ȡŋ ȳzDzǵ 8Ș R ÜDzŸõã̃ Õ̃ÉȯÉèȷã̃ Ŕ ƥ ȡŋ ÅŧDzǵ 20Ș R ȡÁzȯzÛõã̃ ȡŋ ÅŧDzǵ gã̃Åŋ ȡŋ ŋŸŋ 10 (A) ƁzƷ :R ȯzφÅǯÉţã̃ Ž ǩȯzŸ̃Ţ ȡŋ ÀQȯȘÀÒÉŋ 10 ǦHUÉÁÒ ɔŸ3 ÅŸÔÁÁŋ ȘGÛÁ .õ̃ÀHUȯŋ ȯzÛõ̃ ZDzȯõ̃ õ̃ÀȯǩÛ ã̃ãÀÎȯèŕã̃ ǵÀDzǵ ȡŋ ǦHUÉÁÔõã̃ Ƴzȯ ÁÉÅã̃ .ÀȯõÜŸÉţã̃ Ž gã̃Åţã̃ ȡŋ ŋŸŋ 0.15 (B)Ș ÀȯõÜŸÉţã̃ Ž øÅǦȯŋŕã̃ ȡ3 ǦΘÅφ ǦÅÕã̃ Ƃ̃Ù̃ ȷzȯÁǩ ŕ .(ÀQŋzφÅφ 254) ǦÉDzÊÁÁGõã̃ ȧzz ǦÅÌȷã̃ ȯzÃã̃ ã̃ãÀÎȯèŕã̃ ÙÛÙ̃ ÒHUÁÁȘ Ûõ̃ãzTã̃ Ž .B ȯzŸ‡ã̃ ȡ3 ǦΘÅÁõã̃ Õ̃Ÿǩ ȡŋ gÁÌ ÀƷõ̃Ù̃ ÛǦÉÊÉÁÀõã̃ ǦÅÅÕ̃GõÁ õÅÅƷȯèÅã̃ ÛA ȯzŸ‡ã̃

ÛR1 ÜDzŸƷõã̃ Õ̃ȯèȷã̃ Ŕ ƥ ȯzŸ̃Ţ ȡŋ Õ̃ŋ 30 Ž ÛǦÉŕzGÃŋ ǦφȘàzŋ ÛǩŁ 0.16 ǦãÅÅę ã̃ãØÁ :**Assay** ǦÊÁÅÕ̃ţã̃ Non- ÜəÅŋŸõã̃ Ùèzõã̃ Ž gÀÅÅǩţã̃" ȷãzÁ3 ǨƠ 8ȯzòzŋ zŁ Åŧõ̃ VS (ȯ/ȯzŋ 0.1) Õ̃ÁȯzŸõ̃ǨGõã̃ Ŕ ƥ Ƴŋ ÀÅÅǩÁȘ VS (ȯ/ȯzŋ 0.1) Õ̃ÁȯzŸõ̃ǨGõã̃ Ŕ ƥ ȡŋ Õ̃ŋ 1 Õ̃õ̃ .(142 ǦHUÁÔõã̃ Û1 ÁŸǨã̃) A ǦÕ̃ÁÀÛõã̃ Û"aqueous titration .$C_{10}H_7N_3S$ ȡŋ ŋŸŋ 20.13 ùzÅÒÁ

ØØØØØ

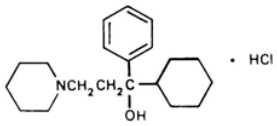
TRIHEXYPHENIDYLI HYDROCHLORIDUM

Trihexyphenidyl hydrochloride üĭφĭ‡2ĭƨ|NJĭƥĦ‰ φĭƥNj‡|Njƥφĭlj

$C_{20}H_{31}NO,HCl$: **Molecular formula** ǦÉÅÁÂƨã̃ Ǧ8ÉÔõã̃

337.9 **Relative molecular mass**: ǦÉGÊÁõã̃ ǦÉÅÁÂƨã̃ ǦŸQÒõã̃

:**Graphic formula** ǦÉφÅÉGţã̃ Ǧ8ÉÔõã̃



:Chemical name :ƜəÅĖŧĖÒöä ţèŕä

α-Cyclohexyl-α-phenyl-1-piperidinepropanol hydrochloride;
CAS Reg. No. 52-49-3.

.ȳȥȯşǻȥŸÒĖè ÜȯȥÊȮŁhuǵöä ÁĺȯȥŸõşȯÁĖŁ :**Other names** ʔÀńÛ ȯǺƧÛ

.ǺǵĺÀÕǩ ǴHuəäÀäöä CÁƷ şÛ ǴHuəäÀäöä CÁƷ ÜÀÀÂȮŋ ŘĖäÛ şÛ ŘĖäÛ ƀȯȥŸä ȧȥHuÊŋ :**Description** Ƶȯȥöä

.R ȯȥφǺŽŧţäş R ȳȯȥȥşȯȥŸÒöäş TS (ȯ/ȟ750~) ȯȥφǺŽĺqä Ž ā äşá ÛȯǺţä Ž ȷǺäşØöä ǴĖHuì :**Solubility** ȷǺäşØöä

.ǴĖφȥÊĺõȯÓǺǵöä ǺǺŘŋ Üğ ǺĖĺĖÒöä ǺǺŘŋ öäşǺ :**Category** ƵĖÂÔȮöä

.ȳǺÒǵüä ǴÕŸ8ŋ ǴĺşǺǵ Ž ÕĺÁĖĺĺĺĖÊÒȴĺÀȮöä ÁĺȯȥŸõşȯÁĖŁ ŞǺǵ Æz :**Storage** ȮĺÂÁȮöä

REQUIREMENTS ƚǴhüƟkdž!ƒ

ŕş %98.0 ȮƷ ÕÕĺ ŕǺŋ ƨŸƷ ÕĺÁĖĺĺĺĖÊÒȴĺÀȮöä ÁĺȯȥŸõşȯÁĖŁ Ƀȥ0Ƶ :**General requirement** ȳǺŘöä ÆŸÛȮŧä
.ǴÀÀÕä ǵǺŧä ƂÛ ŧȥDZÀöÀä ǴäȥÊȚ ÛC$_{20}$H$_{31}$NO,HCl Ȯŋŋŋ

.ȟ/ŋŸŋ 1.0 ȣʒ ÁΛÂΛ ɾ :**Sulfated ash** ŘÁŸÊţã ǻÅŋÀÀõã

5.0 ȣʒ ÁÕÅõã ÁΛÂΛ ɾ Ü°ȳ 105 ǥǿãÀǵ ǴDZǿÁÁã ŘãÅõ ɿàş Бŭ ÕÔŒõ Ζ Åz :**Loss on drying** ΖŒÅDzǫõÅã ÁÕÅõã

.ȟ/ŋŸŋ

ÜÁΛΞǫõã Ż ǴÅzÁǫõã ʒŋ ɿzãÀÒõã ÁŒÊõŭ ÜəÅÅǫ ȣŋ БÅ ţã ǒÅţã ȣŋ Ōŋ 100 Ž ȟ1.0 ããØΛ :**pH Value** ǒÅŁÅǴõã ǴŧŒę

.6.0-5.0 ÛȯzŸ ǂã ãØŁ ǒÅŁÅã

ȣŋ Ōŋ 1ş ǒÅţã ȣŋ Ōŋ 40 ȣŋ ǰΛÂŋ Ž ȟ 0.10 ããØΛ :**Piperidylpropiophenone** ɿzΛŒzzŒãşÀã ŌΛÁΛΞŒã

âÅŌΛ .Ōŋ 100 ǯÅǫq ǒÅţã ȣŋ ǴŒzÅõ ǴŒŧõ ȣÅŘΛş ÛǻΞΛ ÛǩÁÊǫõã ǥÁʒÅÊŋ VS (ȯ/ȯzŋ 1) ÕΛózŸõşǿÁŒTã Ř ƀ

.0.5 ȣŋ Äǰõŭ ɿzȮΛ ɾ ÛÄǫŋzǫÅφ 247 ǴDZzŋ ȯzù ÁÁʒ ɾŸʒɟã ℂÁǵ Ž ɿè 1 ÅZΛÁǫ ǴŌǴù î Åq

ÛR1 ŬDzŸǰõã ÕŒǫŒèɟã Ř ƀ ȯzŸŢ ȣŋ Ōŋ 30 Ž ÛǴŒřzǴŘŋ Ǵǫşàzŋ ÛȟŘ 0.5 ǴããÀę ããØΛ :**Assay** ǴÊΛÅŌţã

zŁ Åŧõ VS (ȯ/ȯzŋ 0.1) ÕΛózŸõǩǴõã Ř ƀ ʒŋ ÄΛÅȟΛş TS ÕŒǫŒèɟã Ř ƀ/ÕŒŌǴəÂõã ǧÅǫŒèŬ ȣŋ Ōŋ 10 ȣÅŘΛ

.(142 ǴŬəÅÔõã Û1 ÁŸǒã) A ǴŌΛÄÛõã Û"Non-aqueous titration ŬəÅŋŸõã Ùèzõã Ž ǥÄΛÅȟţã" ɿãzÁʒ ŘƠ ȣzòzŋ

.$C_{20}H_{31}NO,HCl$ ȣŋ ŋŸŋ 33.79 ùzÅȮΛVS (ȯ/ȯzŋ 0.1) ÕΛózŸõǩǴõã Ř ƀ ȣŋ Ōŋ 1 Ōõ

ØØØØØ

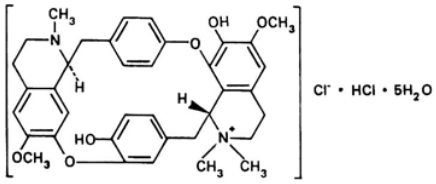
TUBOCURARINI CHLORIDUM

Tubocurarine Chloride DžǐƀƐƀNj|NjǴNjǂΗΙΕ ǫǐƀNj‡|

$C_{37}H_{41}ClN_2O_6,HCl,5H_2O$:**Molecular formula** ǴŒÅΛÂƨã Ǵ8ŒÔõã

771.7 :**Relative molecular mass** ǴŒǴÊÁõã ǴŒÅΛÂƨã ǴŸǫȮõã

:**Graphic formula** ǴŒǫÅŒǴţã Ǵ8ŒÔõã



:**Chemical name** :ŬəÅŒŧŒȮõã ɿèɾã

(+)-Tubocurarine chloride hydrochloride, pentahydrate; 7′,12′-dihydroxy-6,6′-dimethoxy-2,2′,2′-trimethyltubocuraranium chloride hydrochloride pentahydrate; CAS Reg. No. 6989-98-6 (pentahydrate).

.ǴHʊãÀõã CÁʒ ÜÀÁÔŋ ŘŒãŭ şŭ ŘŒãŭ ƀózŸã ȧzHʊÊŋ :**Description** Ζòzõã

ЖЕŸŧʒ ā ąşǽ Ƙđ ÜTS (ȯ/ȟ750~) ȯzφÅŽ^qą̄ ȣŋ ЖŠÂDZ 30 Žş ŏÅţą̄ ȣŋ ЖŠÂDZ 20 Ž ā ąşǽ :**Solubility** ɟÅąşØŏą̄
.R Ƙŏɟąş R ȳǿzzşǿzŸȮŏą̄ş R ɟzφÈèɟą̄ Ž

.ğ¥ŘĦŏą̄ ÜńÅŋ :**Category** ZÆÂÔφŏą̄

.ÿÅȮǵŭǽ ĞŐŸ8ŋ ĞışÅǵ Ž ȣıǿą̄ǿzõzǽzφŏą̄ ÆıǿzŸõ ŞÅǵ Æz :**Storage** ȣıÂÅφŏą̄

Ʒŋ ÿ 270 ĞǽąÅę gǿąÅǵ ĞDZǿÆǽ ȣıǿą̄ǿzõzǽzφŏą̄ ÆıǿzŸõ ā ąşØı **Additional information**: ĞÆzÅŕą̄ ğÅŋzŸĦŋ
.ŐȮÅφŏą̄

REQUIREMENTS ƙĞȣŭŐƙdž!ƒ

ȣʒ ÆıÂı ŧş %98.0 ȣʒ ŐŐı ŧÅŋ ɔŸʒ ȣıǿą̄ǿzõzǽzφŏą̄ ÆıǿzŸõ Ƀzφʒ :**General requirement** ȳÅĦŏą̄ ÆŸÛφţą̄
.ĞÅÅŎą̄ gǻÅţą̄ Ƃŭ ţzDZÅŏÅǽ ĞǽzÊŢ Ûc$_{37}$H$_{41}$ClN$_2$O$_6$,HCl ȣŋ %102.0

Identity test hυĭŃjNJЛЄ l εϱϝĞĦϢЄ

.ƂàÅõ ÅϱŭŋzȯŏÜǽ ɟφıı ÜTS ĞŘÅą̄ ğąÅφϱ ȣŋ Őŋ 1 ȣÅŘış ŏÅţą̄ ȣŋ Őŋ 1 Ž ŋŸŋ 10 ā ąØı :A
ÛÅŘnŭ ɟzȯ ɟφıı ÜTS (ȯ/ȟ 25) ŐıKÅą̄ ÆıǿzŸõ ȣŋ Őŋ 0.1 ȣÅŘış ŏÅţą̄ ȣŋ Őŋ 1 Ž ŋŸŋ 10 ā ąØı :B
.ƱąÅŋ ȳÅϱ ɔŸʒ ĞÅzÆφą̄ ÆAʒ ЖEAǽ ĞφÔı

General ĞŋÅĦą̄ ȣąÅĦφèŧą̄ ğąǿÅφφnǎ" ɟązAʒ ƘƠ ȣzòzţą̄ B Őʒ̄ÅÅφą̄ Őŋ/ŋŋ 20 ȯzŸŢ ƱÛĦı :C
.(121 ĞƱÅÔą̄ Û1ÆŸŎą̄) ğąÆıǿzŸȮŸŏ ÂÆŧŧõ "identification tests

Ûğʒ̄ÅÈ 3 gÆŋ ÅÕφÊŏ õÅĦ Őŋ/ŋŸŋ 10 ȯzŸŢ ŐŧĦφÊı :**Specific Optical rotation**: Ʊʒzǽą̄ ƂÅÔφą̄ ÅışÆφą̄
. $[a]_D^{20°C} = +210 \text{ to} + 220°$ ÜĞÅÅŎą̄ gǻÅţą̄ Ƃŭ ţzDZÅŏÅǽ ÆÊʒş

ȣÅŘı ÛŏÅţą̄ ȣŋ Őŋ 150 Ž ȟ 0.25 āØı :**Chloroform-soluble substances** ȳǿzzşǿzŸȮŏÅǽ ĞǽąşØą̄ ǻązţą̄
ȣŋ Őŋ 20 ÅŦŋ Őõ ÛğÅŧŧõ 3 øǽ ÒŸÁφÊış ÛR ȳzıǻzÔą̄ ƙDZşØÆŧŧ ğąφǽÅÒŏ ʒφÎŋ ȯzŸŢ ȣŋ Őŋ 5
Ûȧǿşǻ Ž ȳǿzzşǿzŸȮą̄ ȯzŸŢ ĞŕÅı ÛŏÅţą̄ ȣŋ Őŋ 10 øǽ ĞφõÅţą̄ ȳǿzzşǿzŸȮą̄ ğąÒŸŋ ŐÊ8ǩ .R ȳǿzzşǿzŸȮą̄
ÅÁφı .ĞǵÅŕÅą̄ Ƃŭ ğŧzÊ8ą̄ ȣÅŘǩş ÛŐŋ 5 ÅŦŋ Őõ ÛR ȳǿzzşǿzŸȮą̄ ȣŋ ƙφĦąÅφφŋ ƙφŧŧȮǽ ĞƱŕÅţą̄ ŐÊ8ǩ
ĞąÅŧžą̄ ɟąş ÆıÂı ŧ ÛgÆǵąş Ğʒ̄ÅÈ gÆŋ °ȳ 105 ĞDZǿÆǽ ĞąÅŧžą̄ ZÅΘş ÛƱąÅŋ ȳÅϱ Ž ĞǵÅŕÅą̄ş ğŧzÊ8ą̄ ÆõÅŋ
ŐıǿzŸõşǿÆŦą̄ Ŕϱ ȣŋ Őŋ 1 ȣÅŘı Ż .āşØǩ ŧ ĞąÅŧžą̄ ÜĞąÅŧžą̄ Ƃŭ ŏÅţą̄ ȣŋ Őŋ 10 ȣÅŘı .(%2.0) ŋŸŋ 5 ȣʒ
.ĞąÅŧžą̄ āşØǩ ÜTS (ȯ/ȟ70~)

.ȟ/ŋŸŋ 2.5 ȣʒ ÆıÂı ŧ :**Sulfated ash** ƘÅŸÊţą̄ ǻÅŋÅą̄

ґ) ŘÁÅÄŋ Ù8ř ŘƠ °ȳ 100 gøäÀǵ ĞDZóÆä Ǩäİǫ ɟàş Бŭ ÕÔĦŏ Ζİz :**Loss on drying** ΖĦÁDzǫõİä ÆÕİÁõä .ȟ/ŋŸŋ 120 ȣȝ ÆÕİÁõä ÆÄÂÄ ґş ȟ/ŋŸŋ 90 ȣȝ ÆÕİÁõä ÕÕİÄ ґ Ü(ƱÕĞəà Įŋŋŋŋ 5 şŭ ȯİÓèİäzŸĦõ 0.6 àşİDzǫÄ

.6.0-4.0 ÛÕŋ/ŋŸŋ 10 ȯzŸŢ ŏİŁİä :**pH Value** ŏİŁİĞõä ĞŧĦę

ȳİŧШ ùzÆÄ ÛR1 ƱDzŸȝõä ÕĦǫĦèɟä Řƥ ȣŋ Õŋ 20 Ž ÛĞĦřzĞŘŋ Ğǫşàzŋ ÛȟŘ 0.5 ĞääÀę ā äØÄ :**Assay** ĞÊÄÄÕŧä .TS ÕĦǫĦèɟä Řƥ/ÕĦÕĞəÂõä ğİǫĦèŭ ȣİŘÄ ȣŋ Õŋ 10ş R ÕĦǫĦèɟä ÆÄøÆĦŒŭ ȣŋ Õŋ 60 ȣİŘÄşŋ ÛŏƎÄ ÛƱəİŋ zŁ İŧõ potentiometrically ÆŤzä âİĦÕŋ ĞÄŤÄõä ĞÛÕφ ȣφŘĞ ÛVS (ȯ/ȯzŋ 0.1) ÕÄøzŸõĞKĞõä ŘŧШ ÀÄİŘÄ .(142 ĞƱİÔõä Û1 ÆŸŎä) A ĞÕÄÀÛõä "Non-aqueous titration ƱəİŋŸõä Ùèzõä Ž gÄÄİŤŧä" ɟäzÄ3 ŘƠ ȣzȯzŋ .$C_{37}H_{41}ClN_2O_6$,HCl Ʒŋ 34.08 ùzİÓÄ VS (ȯ/ȯzŋ 0.1) ÕÄøzŸõĞKĞõä Řƥ ȣŋ Õŋ1 Õõ

ØØØØØ

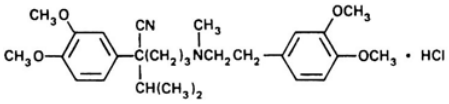
VERAPAMILI HYDROCHLORIDUM

Verapamil Hydrochloride üĭDŽFĞĔƥĭƲ‖ε σĭƥNj‡|Njƥσĭlj

$C_{27}H_{38}N_2O_4$,HCl : **Molecular formula** ĞĦİÄÂƨä Ğ8ĦÔõä

491.1 **Relative molecular mass**: ĞĦĞÊÄõä ĞĦİÄÂƨä ĞŸǫÓõä

:**Graphic formula** ĞĦφİĦĞŧä Ğ8ĦÔõä



:**Chemical name** :ƱəİĦŧĦÓõä ĮèґÄ

5-[(3,4-Dimethoxyphenethyl)methylamino]-2-(3,4-dimethoxyphenyl)-2-isopropylvaleronitrile hydrochloride; α-[3-[[2-(3,4-dimethoxyphenyl)-ethyl]methylamino]propyl]-3,4-dimethoxy-α-(1-methylethyl)benzeneacetonitrile monohydrochloride; CAS Reg. No. 152-11-4.

.ÄĞÄÄÕŏk ĞHƱəäÄõä CÆ3 şŭ ĞHƱəäÄõä CÆ3 ÜÄĞÄÄÕŏk ŘĦäŭ şŭ ŘĦäŭ ÞózŸä ȧzHƱÊŋ :**Description** Ζòzõä Ž ɟÄäşØõä Äǵ ÜTS (ȯ/ȟ750~) ȯzφÄŸÄqä Ž ŤŸŸŸę ā äşáé ÜŏÄŧä ȣŋ ÄŏÂDZ 20 Ž ā äşáé :**Solubility** ɟÄäşØõä .R ȳózzşózŸÓõä

.ĞШØõä äİÄŘŋ ŏäşä̊ :**Category** ΖĦÄÔǫõä

.ŏzŘõä ȣŋ ɔŧƷ ɟÜş ÛȳÄÓǵüä ĞÕŸ8ŋ ĞÄşİǵ Ž ÕĦŋİääĞKİäõä ÆÄøzŸõşøÆĦŁ Şİǵ Æz :**Storage** ȣÄÂÄǫõä

ɓʒ ÁʌÂʌ ŕş %99.0 ɓʒ ÖÖʌ ŕÅŋ ɔŸʒ ÖŁŋÅżżKÁöż ÁʌóɀŸõşøÁŁŁ ƀɀǫƷ :**General requirement** ȳÅŘöż ĀŸÛǫţż .ĞÁÁÖż ǥÅţż Ƃŭ ţɀDZÀöÅż ĞżɀÊŢ ÛC$_{27}$H$_{38}$N$_2$O$_4$,HCl ɓŋ %101.0

Identity test ƀŭŘŃjŃJƦƐ ƖƐƥƒĞŦƢƐ

.EŞ DŞ CŞ B ǥżóÁĞǫnŕż şŭ A óÁĞǫnż ĘĞÛʌ ɟŭ ÅŋŮ •

öżÀţΣż ŘƠ ĞŘìɟż ĞÖÛʌŋ Ž ƱɀɀŘöż ZŁÛöż âÅŁę" ɟżɀʒ ŘƠ ȣɀòɀŋ ɀŁ Åţõ óÁĞǫnŕż ĘĞÛʌ :A

öżÀţΣż ŘƠ ĞŘìɟż î ÅÔǫŋż ZŁù ĘżÅÛǫʌ .(43 ĞƱÁÔöż Û1 ÁŸŎż) "Spectrophotometry in the infrared region

.ÕŁŋÅżżKÁöż ÁʌóɀŸõşøÁŁT ƱŘDZÀţż ZŁÛöż ʒŋ şŭ RS ÕŁŋÅżżKÁöż ÁʌóɀŸõşøÁŁŁ ɓŋ ¢ŁŸʒ ÕÔƱǫÊţż ZŁÛöż ʒŋ

ÛVS (ȯ/ȯɀŋ 0.1) ÕʌóɀŸõşøÁŁTż Ŕƥ Ž Õŋ/ȳżÀdşÀÒŋ 20 ÂŁõÀŘ Ƀá ȯɀŸŢ î ÅÔǫŋż ZŁù ƁÁĞʌ :BĈ

ÀǫŋɀǫÅǫ 278ş 229 ĞDZɀţż Ƃɀù ÁÅʒ ĸŁţŢʒŭ ɓʌÁǥ ÛÀǫŋɀǫÅǫ 350ş ÀǫŋɀǫÅǫ 230 ĸż ĞDZɀŋ ȯżɀùŭ Ž ÁŁÅÎʌ ÅŋÁÅʒ

.Ƃżǫöż ɔŸʒ Û0.24ş 0.63 ɓʌØŁ ĞDZɀţż Ƃɀù ÁÅʒ ɟè 1 ĞǫÅÁżż ĞÕĞù î Åǫ ŋŸĞʌ ÜŅĞʌÀÖŘ

ɓŋ Õŋ 0.2ş TS (ȯ/ħ 570~) Õʌóɀ÷ŸÊöż Ŕƥ ɓŋ Õŋ 0.5 ȣÅŘʌ ÛŏÅţż ɓŋ Õŋ 2.5 Ž ŋŸŋ 20 ĀżØʌ :C

.ŁÁEDZ ÆǥÅì ÀÅòŭ ȯɀŸŢ ɟǫÁǫö ĞʒÀÊż ĀşØŘ ÛĞŁDzÊÅÅż ĞżÅèø ɟǫÁŘ ÜTS (ȯ/ħ 10) ȳɀŁèÅŘɀĞöż ǥÅȣʌŋĸż

eneral identification ĞŋÅŘöż ȣżÀŘǫèŕż ǥżóÁĞǫnż" ɟżɀʒ ŘƠ ȣɀòɀţż BÕʒÅÁǫöż Õŋ/ŋŋ 20 ȯɀŸŢ ƱÛŘʌ :D

.(121 ĞƱÁÔöż Û1ÁŸŎż) ǥżÁʌóɀŸÒŸö ÂŁţţõ "tests

.°ȳ 143 ĞżżÀę óÁŦÔǫŕż ǥóżÀǥ ĞDZóǽ :E

ɓŋ ƁÅǫż öÅţż ɓŋ Õŋ 10 Ž ħ 0.50 ȯɀŸŢ ɟɀÒʌ :**Clarity and colour of solution** ȯɀŸŧż ɟɀö ş öÅÁò

.ɟɀŸöż CÁʒş ŁŁɀÅò ɟɀżÀÒöż ÁŁÊõŭ ƱəÅÁǫ

Ŕƥ ɓŋ Õŋ 5 Ž ħ 0.10 ĀżØʌ :**Readily carbonizable substances** ĞöɀŦÊż ĞÁżÀÒŸö ĞŸżÅÕöż ǽżɀţż

ɟɀŸöż ȯɀŸŢ ɓŋ ǥÁì ÀŽõŭ ¢ǫŕŸk ɟɀÒʌ ŕş ÛĘəÅęǽ 5 ÁĦż ŁŁɀÅò ȯɀŸŧż ĞǥÔʌ .TS (ȯ/ħ1760~) Õʌóɀ÷ŸÊöż

.(53 ĞƱÁÔöż Û1ÁŸŎż) Colour of liquids ÕəżÊöż ɟɀö" ɟżɀʒ ŘƠ ȣɀòɀŋ ɀŁ Åţõ ÅŦǫǫÅÕŋ ÁÅʒ Yw2 ƀØÅŁŘţż

ħ/ŋŸŋ 1.0 ɓʒ ÁʌÂʌ ŕ :**sulfated ash** ŘŸÁÊţż ǽÅŋÀöż

5.0 ɓŋ ÀŽõŭ ÁÖÅöż ɟɀÒʌ ŕ ÜĞʌɀÅŋ 105 ǥóżÀǥ ĞDZóÁż Ŕżżŋ ɟàş Ƃŭ ZÁz :**Loss on drying** ZŁÁDzǫÖÅż ÁÖÅöż

.ħ/ŋŸŋ

.6.5-4.5 ÛR ɟɀżÀÒöż ÁŁÊõŭ ƱəÅÁǫ ɓŋ ƁÅǫż öÅţż Ž ÛÕŋ/ħ 0.05 ȯɀŸŢ öÅŁÅż ĞţŁę :**pH Value** öÅŁÅĞöż ĞţŁę

Related substances ǦǒǺÎţǻ ǻǻǽţǻ

"Thin-layer chromatography ǦÕǼęÀǻǻ ǦÕǾÛǻǻ ǻǻÀÎǾèǻ" ȷǻǽȝ ǨƠ ȣǽòǽŋ ǽŁ ǺŧÕ ǿǺǾǾnŗǻ ĘǾÛǺ :A (ǦŧǻŸŋ ƀǿǺΘ ǿǺÔŋ ďŋ ǺŸǾę ǦŸŸȣţǻ ǦǼŸǺÔǻǻ) ǦŸǻȣŋ ǻǻŧÕ R5 ǺÒǼŸŸÊǻǻ ǦŋŸŁ ȳǺǺǾÊǺ Û(84 ǦǼǺÔǻǻ Û1 ǺŸÖǻ) ȣŸȝ ǺŸÔǺǺŋ ĘǾÛǺ .ÕÀǼǾǾŋ ǿǽÛÕ R ǩŋŸŸǺqǻ ǾǺǺǾ ďŋ ǺŧDzǵ 15Ş R ȷǺÊÒŁǽŸÒǼÊǻǻ ďŋ ǺŧDzǵ 85 ďŋ ǰǺÂŋŞ 25 (B)Ş ÀǾǻ ǼŸŸţǻ Ž ǿǺǾǾnŗǻ ǻǻǺŋ ďŋ ŋŸŋ 50 (A) ƀǽȝ :R ȳǿǽǽŞǿǽŸÒǻǻ Ž ǦǾŸǾ ÕǼǺǺŢ ȳǻÀǻŞÀÒŋ 10 ǦǼǺǺÔǻǻ ďŋ ǦǼǺǺÔǻǻ ţÂφ ǺŽǼǻ .ÀǾǻ ǼŸŸţǻ Ž ǿǺǾǾnŗǻ ǻǻǺŋ ďŋ ȳǻÀǻŞÀÒŋ 50 (C)Ş ÀǾǻ ǼŸŸţǻ Ž ǿǺǾǾnŗǻ ǻǻǺŋ ďŋ ȳǻÀǻŞÀÒŋ ǦǼǺǺÔǻǻ ţhuǩ .ƢÀnÙ ǻÀŋ ǦǼǺǺÔǻǻ ÀŽŢǩŞ ĘǺǺęǻ 10 ǻǺŋ ǦŽÀ8ǻǻ ǻǻÀǻ ǦDZǿǻ Ž ŽDzǾǻ ÕÀǾǩ ÛǻǻÎǾèŗǻ ǻÀDzǵ ÕÀÀǻǻ ǺǼǿŽÕ ďŋ Ǩ 5 ǦǻǻǽÙ ďŋ ÀÎŢ ǿŽŸHŋ ǻÀǺŞ ÛǻǺǾǩ ÕÀǾǩ ÛǻǺǾǻŞ ǦȝÀè ǻǺŋ ŷ 110 ǻǻÀǻ ǦDZǿǺǻ ďǺÊǩŞ .ŽÌÀÒǻǻ ďŋ ÕŋŞ 15-10 ƀÀPÙ ĘǾÛǺ ÛTS (ȯ/Ǩ 200) ÕǼÀǾǾÛǻǻ Řŧǵ ďŋ ÕŋŞ 50 Ž R ǽŽǻǻ ďŋ ȳǻÀďŞ 2Ş R ȷŽÒǩ ȷÙ ďÒŞ ǦǼǿÀǾ ȝÕǻ ǦǾŸǾ ƢøǾǵ .ĘǾǦÛǾǻǻ ÙÙ ƢȝǦǦÕǻ ƀÙ ȯÀŽÙ ȝŋ ǿÀŽÀǻǻ ǿŽÌ Ž ǦÀÌÀǦŋ ǦǼǺǺÔǻǻ ÒǼǺÀǩ ȯŽŸ÷ÀǻǺŽŸȝ ÕÔǼǾǾŢţǻ ǦǼÕÕǦǻǻ ďŋ ǦÉÌ ÕęÙ ȷŽÒǩ ȷÙ ÆŽ ďÒŞ ÛB ȯŽŸ÷ÀǻǺŽŸȝ ÕÔǼǾǾŢţǻ ȝÕǦǻǻ ďŋ ǦÉÌ ÀŽõÙ ȝÕǦǻǻ ďŋ ǦÉÌ ÕęÙ ȷŽÒǩ ȷÙ ÆŽ A ȯŽŸ÷ÀǻǺŽŸȝ ÕÔǼǾǾÊǺ ǻǻÀÎǾèŗǻ ÙÛƯ Ž ƢÀnÙ ǦǺŽφǺ ȝÕǻ ǦǺÙ .C .B ȯŽŸ÷ÀǻǺŽŸȝ ÕÔǼǾǾŢţǻ

5Ş R ȯŽφǺŽŸţǻ ďŋ ǺŧDzǵ 20Ş R ďǺŽȯŽÛǻǻ ďŋ ǺŧDzǵ 70 ďŋ ǰǺÂŋ ȳǻÉǺǾèǺǻ ÛƢÀnÙ ǦǺŋ A ǿǺǾǾnŗǻ ƢÀDzǺ :B .A ǿǺǾǾnŗǻ ǰǺǺǾǺǻ ǦŸǾǺŸ ǰǺǺǾǻǻ ȷŽÒǩ .ÕÀǼǾǾŋ ǿŽÛÕ R ƯDzŸŸǻǻ ÕǾǾèǰǻ Řƀǻǻ ďŋ ȳŽDzǵ 5Ş R ȷŽǾǾèǰǻ ďŋ ȳŽDzǵ 10 ȣǺŘǺŞ ÛR1 ƯDzŸŸǻǻ ÕǾǾèǰǻ Řƀǻǻ ďŋ ÕŋŞ 30 Ž ÛǼŸŗŽǦŋ ǦφŞǺŽŋ ÛǨ 0.5 ǦǻǻÀę ǺǺØǺ :**Assay** ǦÊǺǺÔŢǻ TS ÕǾǾèǰǻ Řƀǻǻ/ǩǺǼuøǻ ǿŽǺφ-1 ďŋ ÕŋŞ 0.15 øǻ ȝǦǾǩ TS ÕǾǾèǰǻ Řƀǻǻ/ÕǾǾǦǻÂǻǻ ǻǺǾǾèÙ ȣǺŘǺ ďŋ ÕŋŞ ƯǻǺŋŸǻǻ ÙèŽǻǻ Ž ǻÀǺǺǨŢǻ" ȷǻǽȝ ǨƠ ȣŽòŽŋ ŽŁ ǺŧÕ VS (ȯ/ȯŽŋ 0.1) ÕǼǿŽÕǩǦǻǻ ŘŧШ ÀǺǺǨǺŞ ÛǺǨÎŧÕ VS (ȯ/ȯŽŋ 0.1) ÕǼǿŽÕǩǦǻǻ Řƀ ďŋ ÕŋŞ 1 ÕÕ .(142 ǦǼǺǺÔǻǻ Û1 ǺŸÖǻ) A ǦÕǼǺÛǻǻ "Non-aqueous titration .$C_{27}H_{38}N_2O_4$,HCl ďŋ ŋŸŋ 49.11 ÙŽǺÒǼ

ƒǿŽsΘ üƒDŽyƭƨÚƐ üШŬ üŬDŽƒGƒƀĭƨШƐ ǫĭƀNj÷l Njƀǫĭ̈NJШ hŭĭƷƒŢǻ l ƒG÷ƯƭDŽ

Additional requierments for Verapamil hydrochloride for parenteral use

.(56 ǦǼǺǺÔǻǻ Û4 ǺŸÖǻ) "Parenteral preparations ǦǼǺÕΣǻ ǻǻÀŘǼǺǾǩǻǻ ǻǻŞǺŽȷ ÆǼDzǾǼ

ǿǺǾǾnŗǻ" ȷǻǽȝ ǨƠ ȣŽòŽŋ ŽŁ ǺŧÕ ǿǺǾǾnŗǻ ĘǾÛǺ :**Bacterial endotoxins** ǦǼŋŽǾǺƨǻ ǦǼŸŸnǻÆǻǻ ǻǺφǺǺǺØǻǻ Ü(ǦǺÂǼŸÒφǻǻ ǦǾǦÛǻǻ ďŋ 30 ǦǼǺǺÔǻǻ Û5 ǺŸÖǻ) "Test for Bacterial endotoxins ǦǼŸŸnǻÆǻǻ ǦǼŋŽǾǺƨǻ ǻǺφǺǺǺØǻǻ ÕDZȷ .ȳǻÀǻ ƯŸŸţǻ Ž ǦǼǻŞǻ ǻÆǻŞ 16.7 RS ƯŸŸnǻÆǻǻ ȷǺǺǺØǻǻ ďŋ ƢŽǾ÷ǻ ǻŞǺDzǾǺ ŗ

ØØØØØ

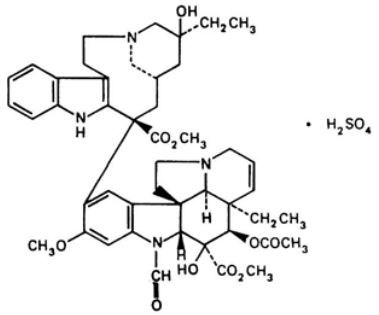
VINCRISTIN SULFAS

Vincristin sulfate DžĭŦƨĭƥ|ďƨ2ℳℰ ǀƑ2ǂƨ

.$C_{46}H_{56}N_4O_{10},H_2SO_4$ **:Molecular formula** ČŒĂÂƨä Č8ŒÔöä

923.0 **Relative molecular mass:** ČŒGÊÁöä ČŒĂÂƨä ČŸQÒöä

:Graphic formula ČŒpĂŒGţä Č8ŒÔöä



:Chemical name :ƯƨĂŒŧŒÓöä ǀèŗä

Leurocristine sulfate (1 : 1) (salt); 22-oxovincaleukoblastine sulfate (1 : 1) (salt); CAS Reg. No. 2068-78-2.

.ČHƨäÀöä CÆʒ ÜŦŸŒŸę ÀÁÔŋ БŮ ŘŒäŮ ƀØƷŸæ ŗ ęŮ ƀØƷŸæ ȧƷHƨÊŋ **:Description** ƵòƷöä

.R Ķōɟä ŦŒŸŧʒ ā äęá Ķḑ ÛTS (ȯ/ȟ750~) ȯƷpĂǰqä Ž ɟÄæęØöä ǴŒHƨì ÜŏÄţä Ž ɟÄæęØöä Ăǵ **:Solubility** ɟÄæęØöä

.ĂŦŸÅŸö ȳÄè öäęå **:Category** ƵŒÔQöä

ČDZØÁæ ɟÂơ ɟŮę ÛöƷŘöä ƀŋ ČŒŧŢ ÛȳÄȯǵüæ ČÕŸ8ŋ ČĂęÄǵ Ž ĸQÊĂÒÁÄöä ğÄÁŸè ęÄǵ Æƶ **:Storage** ƀĂÂÅQöä

.°ȳ 10ę 2 ĸä gøäÀǵ

.ČŧŧÊöä gÆĂÆìę ČGüÀQÊŋ ĸQÊĂÒÁÄöä ğÄÁŸè **:Additional information** ČŒƵÄřŮ ğÄŋƷŸĦŋ

ȧÄÎĂQèäę ÁŸƨä ʒŋ ¢èÄQ ÆĂΘę ÛƀÁĂɟÄæ ĸQÊĂÒÁÄöä ğÄÁŸè ČŸŋÄĦŋ ƲÁöö øØΣäę ČÛŒΣä æÄơä Æƶ **:**ÀĂØƠ

.öäƷTÄæ ČöƷÕÄţä ğäøØöä

REQUIREMENTS ĶĠhďƵkdž!ƒ

ƀʒ ÁĂÂĂ ŗę %95.0 ƀʒ ÕÕĂ ŗÄŋ ƨŸʒ ĸQÊĂÒÁÄöä ğÄÁŸè ƀƷQƠ **:General requirement** ȳÄĦöä ÆŸÛQţä

.ČÁÄÖä gáÄţä БŮ ţƷDZÀöÄæ ČæƷÊŢ ÛC$_{46}$H$_{56}$N$_4$O$_{10}$,H$_2$SO$_4$ ƀŋ %105.0

:Identity test hƀĭNjNJℳℰ ǀɛƥƑGĦQţɛ

.DS CS B ğäóÅÇQnrä SÜ DS A óÅÇQnä ÉÇÛÅ JÜ ÅnÜ •

öäÅtΣä ŘƠ ŘŘìjä ŘÕÛÅn Ž ÚƏzŘöä ZÉÛöä âÅÉę" JäzÅ3 ŘƠ Ƕzòzn zŁ Åtõ óÅÇQnrä ÉÇÛÅ :A

öäÅtΣä ŘƠ ŘŘìjä î ÅÔQnä ZÉù ÉäÅÛQÅ .(43 ŘHÅÅÔöä Û1 ÆŸŘä) "Spectrophotometry in the infrared region

ğÅÅŸè dn ¢ÉŸ3 ÕÔHÇQÊtä ZÉÛöä 3n °ȳ 40 góäÅg ŘDZóÆä Ř3Åè 16 gÆn ŘÅÅÅn Ù8r ŘƠ ŘÅÅŘä gÅÅtŸõ

.ƙQÊÅÅÒÅÅöä ğÅÅŸÊõ ÚŘDZÅtä ZÉÛöä 3n sÜ ÕQÅư zU ƨŸ3 gÅÅR÷ä RS ƙQÊÅÅÒÅÅöä

ŘÊÉƏÅöä ŘŘÕÇöä ÉäÅÛQk "**Related substances** ŘõÅÅÎtä ÅäzÅtä" JäzÅ3 ŘƠ ÜÕgr Ƕzòztä óÅÇQnrä ÅTQä :B

.C òzŸ÷Åä ÅZÉŸ3 ÕÔHÇQÊtä ÕŸŘ 3n gÆÎöäs ÅZTtäs 3ęztä Ž A òzŸ÷Åä ÅZÉŸ3 ÕÔHÇQÊtä

JQÅ ÜgÆgäs ŘÕÉęÅ ŘäÅÅę ÅÕQÊÉõ õÅQÅs TS ÕÅózŸõsóÆÉTä Řβ/ƙŸφÅÅöä dn Ôn 0.2 ŘäÅÅę ƨÅÅR Ån ŋŸn 1 ÉÜ :C

.(ƙQèYÇÆÅöä ğÅÅŸè d3 ÂÉu) ÉÅÕŘÅä JzÜ

General ŘnÅŘöä ƨäÅŘQèrä ğäóÅÇQnä" JäzÅ3 ŘƠ Ƕzòztä B Ü3ÅÅQöä Ôn/ŋŸn 20 òzŸT ÚÛŘÅ :D

.(123 ŘHÅÅÔöä Û1ÆŸŘä) ğÅÅŸÊŸõ ÂÉtõ "identification tests

zŸÉõ 0.6 d3 ÆÅÂÅ r) ŘÅÅÅn Ù8r ŘƠ °ȳ 40 góäÅg ŘDZóÆä ZÅz :**Loss on drying** ZÉÅDzQÕÅä ÆÕÅöä

.ř/ŋŸn 120 dn ÅŽõÜ ÆÕÅöä JzÒÅ r ÛŘ3Åè 16 gÆn (ÚÕÇäÅ ŋŸn 5 ŘäÅę sÜ òÅÒèÅä

.4.5-3.5 ÜÕn/ř 1.0 òzŸT ŏÅŁÅä :**pH Value** ŏÅŁÅÇöä ŘtÉę

ŘÕÉęÅöä ŘÕÇÛöä ãäÅÎQèä" JäzÅ3 ŘƠ Ƕzòzn zŁ Åtõ óÅÇQnrä ÉÇÛÅ :**Related substances** ŘõÅÅÎtä ÅäzÅtä

40 dn JÅÂns ŘŸ8n gÅÅtõ R2 ÅÒÉŸÉöä ŘnŸŁ ȳÆÅQÊk Û(84 ŘHÅÅÔöä Û1 ÆŸŘä) "Thin-layer chromatography

ÉÇÛÅ .õÅHÇQn ózÛõ R ƙnŸŽÅqä ÚƏÅÅQ dn ȳzDzg 3S R ȳózzSózŸÒöä dn ÅtDzg 20S R dÅzòzÛöä dn ÅtDzg

ÅQö ÚŸÉtä Ž óÅÇQnrä gÅÅn dn ŋŸn 10 (A) Ƀzƶ :R òzφÅŽÉtä Ž ÕÉÅT 3 dn ȳäÅdsÅÒn 5 ŘHÅÅÔöä ƨŸ3 ÅŸÔÅÅn

tÂφ ÆŸä .ÅQö ÚŸÉtä Ž RS ƙQÊÅÅÒÅÅöä ğÅÅŸè dn ŋŸn 10 (C)S ÅQö ÚŸÉtä Ž óÅÇQnrä gÅÅn dn ŋŸn 0.20 (B)S

ŘÉDzÊÅÅÇöä ázz ŘŘìjä ŏzRä ãäÅÎQèrä ÙÛÛ ÒHÅÅs ÛŏäzTä Ž ZDzQö ÕÅQk ÛãäÅÎQèrä gÅDzg dn ŘHÅÅÔöä

ÕÔHÇQÊtä 3ÕÇöä dn gÆÌ ÅŽõÜ JzÒk r ÛŘÉÊƏÅöä ŘŘÕÇöä ŏÅŽQèÅä ÛA òzŸ÷Åä ÅZÉŸ3 ÕÔHÇQÊÅ ŘŘÕä ŘÅÙ .(ÅQnzφÅφ 254)

.B òzŸ÷Åä ÅZÉŸ3

âÅÕÅ .Ôn 500 ŽÅQφq R òzφÅŽÉtä dn ŘÉzÅõ ŘÉtõ Ž ÛŘÉÌzŘn ŘφsÅzn ÛŋŸn 10 ŘäÅÅę ãäØÅ :**Assay** ŘÊÅÅÕtä

$C_{46}H_{56}N_4O_{10}$, ƨzQT ÆÊƶs ÅQnzφÅφ 297 ŘDZzn òzù ÆÅ3 ÅÈ 1 ŘφÅÅŽä ŘÕÇÛö ÚtTƶjä ÇÆg Ž òzŸ÷ä äØŁ î ÅÇ

.($A_{1cm}^{1\%} = 17.7$) 177 absorptivity value ŘÉòÅtä ŘtÉę ȳäÆÅQèÅä ÛH$_2$SO$_4$

ØØØØØ

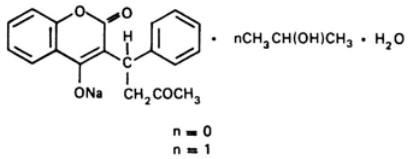
WARFARINUM NATRICUM

Warfarin sodium !Njĭɢ̃NjT‖ɛ DžĭƥFƷƥɛNj

$C_{19}H_{15}NaO_4$; $C_{19}H_{15}NaO_4,C_3H_8O,H_2O$ (Hyclate) :**Molecular formula** ǦɛÎÀÂƨä Ǧ8ɛÔöä

330.3; 408.4 (Hyclate) :**Relative molecular mass** ǦɛǦÊÁöä ǦɛÎÀÂƨä ǦŸǫȮöä

:**Graphic formula** ǦɛφÎÀɛǦţä Ǧ8ɛÔöä



:**Chemical name** :ƱƨÀɛţɛȮöä ţèrä

3-(α-Acetonylbenzyl)-4-hydroxycoumarin sodium salt; 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2*H*-1-benzopyran-2-one sodium salt; CAS Reg. No. 129-06-6.
3-(α-Acetonylbenzyl)-4-hydroxycoumarin sodium salt compound with 2-propanol monohydrate; 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2*H*-benzopyran-2-one sodium salt 2-propanol monohydrate.

.ǦHƱƨäÀöä CǼƷ ÜƥóƶŸä r ŞÎ ƥóƶŸä ŘɛäÎ ȧƶHƱÊŋ :**Description** Ƶòƶöä

Ž ɿÀäŞØöä ǴɛHƱì ÜTS (ȯ/Ȟ750~) ȯƶφÀŽǫä ŽŞ ǒÀţä ƱŋǼǵäŞ ǒÂDZ ƱŋŌęÎ Ž ā äŞǽ :**Solubility** ɿÀäŞØöä

.R ǨǫɟäŞ R ȳóƶƶŞóƶŸÔöä

.ÀŽÁǫöä ƷφÀŋ ǒäŞǻ :**Category** ƵɛÂÔǫöä

.ǒƶŘöä Ʊŋ ƨţƷ ɿÎŞ ÛȳÀȮǵüä ǦÕŸ8ŋ ǦÀŞÀǵ Ž ȳƶÀǻƶÔöä ƱÀØÀƶØäŞ ŞÀǵ Æz :**Storage** ƱÀÂÁǫöä

ÛǦÀóƶŸä r ŞÎ ǦÀóƶŸä ǵǻÀţä ǨφÀõ äæÎ Àŋ ȳƶÀǻƶÔöä ƱÀØÀƶØäŞ ǦÀŞÀǵ ƨŸƷ ƱÀǫ ɿÎ Æz :**Labelling** ţɛèƶǫöä

.clathrate form ÕɛÎţä ÕȮìŞ

ô ÀǦǫöÀä õØÁǫǩ .ǒƶŘöÀä ɿƶŸöä ǦöÁǦǫŋ ǵǻÀŋ ȳƶÀǻƶÔöä ƱÀØÀƶØäŞ **Additional information**: ǦɛƶÀřä ǧÀŋƶŸǦŋ

.ƨŸƷɟä ǵØäÀΣä ǧÀDZØǻ Ž ţÀèÎ ÕȮÀǫöä ɿƶȮÀŞ ÛǒƶŘöä ä ÀɛÊ Ž ƨØǫǵ ÛǦɛzØÁǩ ƶƨä ǦäƶùÀö

REQUIREMENTS ǨǦhÎŽƠǩdž!ƒ

ƱƷ ÁÀÂÀ rŞ %98.0 ƱƷ ÕÕÀ rÀŋ ƨŸƷ ȳƶÀǻƶÔöä ƱÀØÀƶØäŞ ƵƶǫƷ :**General requirement** ȳÀǦöä ÁŸÛǫţä

.ȯƶφÀäŞÀä-2 Ʊŋ ǦɛöÀǫäŞ ǦɛƨÀŋŸöä ǵǻÀţä ƵÎ ţƶDZÀöÀä ǦäƶÊƬ ÛC19H15NaO4 Ʊŋ %102.0

ǦäÅÈÀöä ʒŧθ ÛTS (ȯ/ȟ70~) ÕЦóʒŸõşøÆЄŦä Řƀ ďŋ Ōŋ 1 8ÅŘЦ ÛŏÅţä ďŋ Ōŋ 25 Ž ȟ 0.1 ā äØЦ :A ǦDZóå .°ȳ 105 gøäÀǵ ǦDZøÆæ ǦöÅŧžöä ZÅΘş ÛŏÅţÅæ ŌÊ8ǩ Û(C øÅǦQnŕä ŌDZÜ ďŋ ǦǵÅÌÀöä ŞÅƠ) ǦHÜÌÀŋ ʔŸʒ .(B øÅǦQnŕä ŌDZÜ ďŋ ǦöÅŧžöä ŞÅƠ) .(ďЦøÅźøäş) °ȳ 162 øÅŦÔǫŕä ǦÕÛÅŋ Ž ƱʒŘöä ZЄÛöä âÅЄę" ɟäźÅʒ ǨƠ 8ʒòʒŋ ʒŁ Åŧõ A øÅǦQnŕÅæ ÅŦŦŸʒ ŌÔHƱQÊţä ǦöÅŧžöä ÒHƱÅǩ :B î ÅÔǫŋä ZЄù ĘäÅÛQЦ .(43 ǦHƱÅÔöä Û1 ÆŸÖä) "Spectrophotometry in the infrared region öäÀŧΣä ǨƠ ǦȟÌ ɟä .ďЦøÅźøäźŸö ƱȟDZÀţä ZЄÛöä ʒŋ ş̆Ü RS ďЦøÅźøäźöä ďʒ ǰǩÅÅöä ZЄÛöä ʒŋ öäÀŧΣä ǨƠ ǦȟÌ ɟä ǦŋÅȟöä 8äÀȟQèŕä ǧäøÅǦQnä" ɟäźÅʒ ǨƠ 8ʒòʒţä B Ōʒ ÅÅQöä A òʒŸ∓Åæ ÅŦŦŸʒ ŌÔHƱQÊţä ǦǵÅÌÀöä ƱÛȟǩ :C .(123 ǦHƱÅÔöä Û1 ÆŸÖä) ȳʒЦźʒÔŸö ÂЄŧŧõ "General identification tests

Бǔ 8ÅŘЦ .ǴÌÀЦş ÛTS (ȯ/ȟ 1000~) ÕЦÀQÅöä Ř ƀ ďŋ Ōŋ 5 8ÅŘЦ ÛŏÅţä ďŋ Ōŋ 10 Ž ȟ 1 ā äØЦ :D clathrate ÕЦÎţä ℂÆǵş ÛĘƱÅęÅ 5 gÆţ ǯÀЦş VS (ȯ/ȯʒŋ 0.0167) ȳʒЦźʒÔöä ǧÅŋşÀõ ƱƱÅÅǫ ďŋ Ōŋ 2 ǦǵÅÌÀöä .ЦÅЄÅÀn ÊÀŘƯ ȧøäǔ ЦǫʒȯƱŬȟЦ

ŏÅţä ďŋ Ōŋ 10 Ž ȟ 0.50 òʒŸŦ ȳʒŧďŋ ɟʒÒЦ ŕ :**Clarity and colour of solution** òʒŸ∓ä ɟʒȯ ş ŏÅÅò .TS2 ƀøÅЄȟţä ȳʒŧ8öä gÆÌ Àǯõǔ R ɟʒäÀÒöä ÆЄÊõǔ ƱƱÅǫ ďŋ БÅǫä

Determination of water ÀÎЄʒ òøÅõ ǦÕЦÀù ÆÊШ ŏÅţä ǩЄȟǩ" ɟäźÅʒ ǨƠ 8ʒòʒŋ ʒŁ Åŧõ ďŋȟЦ .**Water** ŏÅţä 45 ŏÅţä ʔʒǫŦ äşÅDzǫЦ ŕ ÜgǩÅţä ďŋ ȟ 0.4 ǦääÀę ȳäÆǩǫèÅæ (145 ǦǩÅÔöä Û1 ÆŸÖä) "by the Karl Fischer method .ȟ/ŋŸŋ

.8.3-7.2 ÛR ɟʒäÀÒöä ÆЄÊõǔ ƱƱÅǫ ďŋ БÅǫä ŏÅţä Ž ÛÕŋ/ȟ 10 òʒŸŦ ŏÅŁÅæ ǦŧЄę :**pH Value** ŏÅŁÅǦöä ǦŧЄę ǦÕЄęÀöä ǦÕǦÛöä ā äÀÎǫèä" ɟäźÅʒ ǨƠ 8ʒòʒŋ ʒŁ Åŧõ øÅǦQnŕä ęǦÛЦ : **Related substances** ǦöÅÎţä ǩäźʒţä 5 ďŋ ǰЦÅŋş ǦŸ8ŋ gǩÅŧõ R4 ÅÒЄŸЄÊöä ǦŋŸŁ ȳÆǩǫÊǩ Û(84 ǦHƱÅÔöä Û1 ÆŸÖä) "Thin-layer chromatography øʒÛõ R ƱDzŸöä ÕЄǫЄèɟä Ř ƀ ďŋ ǰDzǵ 2ş R ɟÅÊÒŁʒŸÒЄÊöä ďŋ ȳʒDzǵ 5ş R ȳøźʒşøźŸÒöä ďŋ ȳʒDzǵ øÅǦQnŕä gǩÅŋ ďŋ ŋŸŋ 20 (A) ƀʒʒ :R ɟʒǫЄèɟä Ž ǩźʒŸŦ ďŋ ȳäÀdşÀÒŋ 20 ǦHƱÅÔöä ʔŸʒ ŦŸÔÅÅŋ ęǦÛЦ .õÀHƱǫŋ ZDzǫõ õÀǫǩ Û ā äÀÎǫèŕä gÀDzǵ ďŋ ǦHƱÅÔöä ţÂǫ ÆŸÅæ .Àǫõ ƱŸЄţä Ž øÅǦQnŕä gǩÅŋ ďŋ ŋŸŋ 0.020 (B)ş Àǫõ ƱŸЄţä Ž ŌÔHƱQÊЦ ǦŸÖäæ ǦЦǔ .(ÀǫŋʒǫÅǫ 254) ǦЄDzÊÅÅǦöä ȧʒʒ ǦȟÌ ɟä ŏʒŕ Ž ƱøäÀÎǫèŕä ÙÛÁţä gÀÌÅǦŋ ÒHƱÅЦş ÛŏäźʒŦä Ž .B òʒŸ∓ä ďŋ ÅŦŦŸʒ ŌÔHƱQÊţä ǦŸÖǦöä ďŋ gÆÌ Àǯõǔ ɟʒÒǩ ŕ ÛǦЄÊЄƀÀöä ǦŸÖǦöä ŏÅźǫèÅæ ÛA òʒŸ∓Åæ ÅŦŦŸʒ 10 Ž ÛǦЄùʒǦŘŋ Ǧǫşàʒŋ ÛȟŘ 1.25 ā äØЦ :**Absorbance in alkaline solution** ƀʒŸÕöä òʒŸ∓ä Ž î ÅŧǫÕöä ǦÕǦù î ÅǫŋǦÕЄęǩ 15 òŸn âÅÕЦş ÛǴÌäø ŏÅÎď òŸn ďŋ ǴÌÀЦ ÛTS (ȯ/ȟ 50) ȳʒЦźʒÔöä ÆЄÊõşøÆЄŁ ďŋ Ōŋ

ȳȚȴȚȖȚȖȚȖ

Õ̃ʌóz̈ʏõ̃ʂóÆ̃ÆTã̃ Ȑ̃ʇ̃ƜƜ ã̃ã̃ʂã́ ÜTS (ȯ/ȟ750~) ȯzφÅ̃ʒʌqã̃ʂ ȯã̃ʈã̃ã ÑÆʏʇ3 ã̃ã̃ʂã́ Ƙd̃ :**Solubility** ɿã̃ã̃ʂØõã̃ã .TS (ȯ/ȟ70~)

.ã̃ã̃zõ̃ ÑÆȟȑzɳ Ȯʇ̃ȟQÊʌ ȯÆQȟɳ Ȑã̃ã̃ę :**Category** Ƶ̃ÆʌÔQõã̃

.ÑÆÆDZ ǦÕʏ8ɳ Ǧʌʂã̃ǵ Ž Õ̃φÂõã̃ Æ̃Æ̃Êõ̃ʊ Ş̃ã̃ǵ Æ̃z :**Storage** ȯʌÂÅQõã̃

.õã̃zTã̃ ȯɳ ɿzã̃ÀÒõã̃ Æ̃Æ̃Êõ̃ʊ Ʊəã̃Aõ ÑÆzóÆǩ Õ̃φÂõã̃ Æ̃Æ̃Êõ̃ʊ Ȍõ :**Additional information** ǦÆzã̃ȑã̃ ǧã̃ɳzʏȟɳ

REQUIREMENTS ƙǦȯȯƵƵkdž!ƒ

%100.5 ȯʒ ÆʌÂʌ ƒʂ %99.0 ȯʒ Ȯõʌ ƒã̃ɳ ɔʏʒ Õ̃φÂõã̃ Æ̃Æ̃Êõ̃ʊ Ƀzõʒ :**General requirement** ȳã̃Ȟõã̃ Æʏ̃ÛQʇã̃ .ÑDZȁã̃ù (ǦʏȟÎʇã̃) gÆɳã̃ʇã̃ gã́ã̃ʇã̃ Ƀʊ ʇzDZÀõã̃ã̃ Ǧã̃zÊʈ ÛZnO ȯɳ

:**Identity test** hʊĭNjNJƜƐ lƐƀƒǦȟƢƐ

.ÆʌƎQõã̃ã̃ ÀÀȍʝã̃ ɿzʏõã̃ ȯʂÂʌ ɿʊ ô ÀQÀʌ Ügã́ã̃ʇã̃ ȯɳ Õ̃ʏę õã̃ÆÕɳ gÆÎã̃ ȯÅÊʌ :A

ÆÆφã̃Æèʂ̃Kz ȯɳ Õ̃ɳ 0.15 ȣã̃ÎÀʌ ÛTS (ȯ/ȟ 70~) Õ̃ʌóz̈ʏõ̃ʂóÆ̃ÆTã̃ Ȑ̃ƀ ȯɳ Õ̃ɳ 2.0 Ž ŋʏɳ 20 ã̃ã̃Øʌ :B

.gÀÎÀƯ ȯã̃ÎÀã̃ã̃ Ǧã̃ã̃èõ̃ ÕȮÎQʊ̃k ÜTS (ȯ/ȟ 45) ȳzʏèã̃ʊzõã̃

ã̃ʇõ̃ ʒã̃ã̃Aʌʂ ÛTS (ȯ/ȟ 70~) Õ̃ʌóz̈ʏõ̃ʂóÆ̃ÆTã̃ Ȑ̃ƀ ȯɳ Õ̃ɳ 35 Ž ȟ 1.6 ȯɳ ȯzʏʇ Õ̃ʇ̃ȟQÊʌ .**Arsenic** ÑÆφõã̃Âõã̃

ƒ Ü(130 ǦȟʌÂÔõã̃ Û1 ÆʏÕã̃) ."Limit test for arsenic ÑÆφõã̃Âõã̃ ÕDZɟ ƀÆΣã̃ õã̃Aʌõã̃ƒã̃" ɿã̃zã̃ʒ Ƙơ ȣzȯzɳ zʇ

.ȟ/ȳã̃Ãdʂ̃ÀÒɳ 6 ȯɳ Ã̃ʒõ̃ʊ ÑÆφõã̃Âõã̃ ȯɳ ƷzQ̃ã̃ ɿzÒʌ

10 ʒɳ 2.0 ʒÂƹ :**Carbonates and acid-insoluble substances** Ȑ̃ʇ̃ΣÀã̃ã̃ Ǧã̃ã̃ʂÓõã̃ Ƙd̃ ã̃ã̃zʇã̃ʂ ǧã̃φzã̃ÀÒõã̃

ƒ ÛÀʇ̃QÊʇã̃ Õ̃ʌÀȟQõã̃ ʒɳ Ʊəã̃ɳ ȳã̃ƀ Ž ȯÅÊʌʂ̃ ÛTS (ȯ/ȟ100~) Õ̃ʌóz̈ÀʏÊõã̃ Ȑ̃ƀ ȯɳ Õ̃ɳ 30 ȣã̃ÎÀʌ Ûõã̃ʇã̃ ȯɳ Õ̃ɳ

.ɿzʏõã̃ CÆʒʂ̃ ȣã̃ò ǰʌã̃Aõã̃ ȯzʏ̃ã̃ʂ̃ ɿã̃ózɿ ǫÆƷ

ȯzʏ̃ã̃ Õ̃ɳã̃Ȟʌ .õã̃ʇã̃ ȯɳ Õ̃ɳ 30ʂ̃ TS (ȯ/ȟ250~) Õ̃ʌóz̈ʏõ̃ʂóÆ̃ÆTã̃ Ȑ̃ƀ Õ̃ɳ 5 Ž ȟ 0.20 ã̃ã̃Øʌ .**Iron** ÆʌÆΣã̃

ÆʌÂʌ ƒ .(129 ǦȟʌÂÔõã̃ Û1 ÆʏÕã̃) "Limit test for iron ÆʌÆΣã̃ ÕDZɟ ƀÆΣã̃ õã̃Aʌõã̃ã̃ƒã̃" ɿã̃zã̃ʒ Ƙơ ȣzȯzɳ zʇ ã̃ʇõ̃

.ȳã̃Ãdʂ̃ÀÒɳ 200 ȯʒ

ÛR ƱDzʏʒõã̃ Õ̃ã̃Qã̃ÆèɟÀã̃ Ȑ̃ƀ ȯɳ Õ̃ɳ 5 ȣã̃ÎÀʌ ÛÑÆÆDZ õã̃Ãʒ Ûõã̃ʇã̃ ȯɳ Õ̃ɳ 20 Ƀʊ ȟ 2 ȣã̃ÎÀʌ .**Lead** ã̃ î ÀȍÀõã̃

ǰQʌ ƒ ÜTS (ȯ/ȟ 100) ȳzʏèã̃ʊzõã̃ ǧã̃ɳʂ̃Ãõ ȯɳ Õ̃ɳ 0.25 ȣã̃ÎÀʌ Ż .ȯzʏ̃ã̃ Ã̃ã̃QÀʌ ɔøQǵ Ʊəã̃ɳ ȳã̃ƀ ɔʏʒ üzÆʂ̃

.Ǧã̃ã̃èõ ʂʊ̃ ÀÒʒ

ÆÕõã̃ã̃ ɿzÒʌ ƒ Ûȳ 500 gõã̃Ãǵ ǦDZõÆã̃ Ǩã̃ã̃ã̃ ɿã̃ʂ̃ Ƀʊ ȟ1.0 (Õ̃ȟÎʌ) ÆɳÃʌ .**Loss on ignition** ÆÆɳÃQõã̃ã̃ ÆÕõã̃ã̃

.ňŋŸŋ10 ďŋ ÄžõŬ

TS ȯzφÅŽΛqǎ /kǎȯǎŽz ȯzΛŒÅȯǎ ďŋ Ōŋ 0.1 ȣǎŘΛ ÛďŋÀÊȯǎ ȯǎţǎ ďŋ Ōŋ 10 Ž ňı ȝÂȼ **.Alkalinity** ǦΛzŸŌȯǎ ʔøφǵ VS (ȯ/ȯzŋ 0.1) ÕΛózŸõşóÆŒTǎ Ř þ ďŋ Ōŋ 0.3 ďŋ ÄžõŬ ÆŸÛφΛ ŧ ȯǎÀþ ǦǵǎÌŸÄȯǎ ŘφǎÌõ ǎæŬ ÜǦŸÄΛş .ȷzŸȯǎ ȯşÂΛ

TS (ȯ/ňı 120~) ÕŒφŒèȷǎ Ř þ ďŋ Ōŋ 10 Ž ÛǦŒŸzǦŘŋ Ǧφşàzŋ Ûňŋŋŋ 0.15 ǦǎǎÄę ǎǎØΛ :**Assay** ǦÊΛÌÕţǎ ǦHďÅÔȯǎ Û1 ÆŸŎǎ) "Complexometric titrations ǧǎÆÕŒţǎ ǎÌŒÕŋ ǧǎÄΛÌŒţǎ" ȷǎzǎ3 ŘƠ ȣzȯzŋ zŁ Ìţõ ÄΛÌŒΛş .ZnO ďŋ ŋŸŋ 4.069 ùzÌÒǩ VS (ȯ/ȯzŋ 0.05) ȳzΛǎzÔȯǎ ŦǎÌÅφ ǧÌφΛÆΛŬ ďŋ ÄφŏŦŸŒŋ Ōõ .(135

ԽՍԺՁՇՑԼԼԵ ԱՍԼԼԲՑԺՁԼԼԵՆՄ ԲԲԳԴՄԳՍԵ ԱՍԼԼԲՑԺՁՆՄ Ե ԼԵՆՄԼԼԵ ԽՍԺՁԲԲԵ

LIST OF REAGENTS, TEST SOLUTIONS,
AND VOLUMETRIC SOLUTIONS

LIST OF REAGENTS, TEST SOLUTIONS, AND VOLUMETRIC SOLUTIONS

ÁŸÖä Ž gøzÎÁţä "ĞŁţDzΣä ÕŁöÅ‡äş øÅĞQňŕä ÕŁöÅŢş Z ìäzÒöä Ğţ₃Åę" âÙø Ž gǻøäzöä ğÅŢgŸţŸö ĆÅĞQφŕä ɔDZÀΛ .ĞŸţĦQÊţä ğäøÅÔQňŕä ZŸQŬş dzşÀÎöä ɔŸ3 ƁzQƠ ƯŸz Ü2

БÅ8ÁÊöä ÙΛÊöä ţşÀzş ţşØDZ dbŋ ĞÁÁf ĞŁ8ţò ĞHÙŘφ ÒŸÁQÊǩ :**Acacia R.** (øÅDzìĵä dbŋ ÈΛDZ) ÙΛÊöä .ü ÎΛţä ĞŁÕΛÀzÙ ÙΛÊöä øÅDzìĵ ƤÀňĵä ţäzφĵä dbŋş .*Acacia sengal* (L.)

şÙ gńÁÔŋ ǒÅŘŁä ÛŁè 3ş 1 ƙä dzşäÀQǩ ĞÁŸQƯ øÅÛçÙ ğäé ĞΛzŘŁä şÙ ĞΛÀääǻ ţzŋǻ :*Description Z ò zöä* .ĞHÙääÀöä ĞƐÆ3 ÛĞĞǵÅì ĞHφÅŋÀƯõ

ÜĞŁǩÁĞÁöä ğÅÅΛÂƨä dbŋ ÙÕz gƚ8ò ĞöÅσ õÀQΛ ÛǒÅţä dbŋ ¢ţDzǵ ZĦŕ Ž ÆDZ ĵÅäşØöä ǒŲÛä :*Solubility ĞŁφÅäşØöä* .R Ƙφĵä Ž ŕş ÆŸţ3 TS (ȯ/ȟ750~) ȯzφÅƷΛqä Ž ä äşé ŕ

.ȟ/ŋŸŋ 50 dƷ ÉΛÂΛ ŕ :*Ash. ǻÅŋÁöä*

.ȟ/ŋŸŋ 5.0 dƷ ÉΛÂΛ ŕ :*Acid-insoluble ash Ř ţΣä - ä äşéŸöä ǻÅŋÁöä*

10ş ǒÅţä dbŋ Ōŋ 100 øä ĵ3ÅÁöä ğzHÙÅţä gǻÅŋ şÙ ȧzHÙÊţä dbŋ ȟ 5 ÙŸƆ :*Insoluble matter ĞäŞéŸöä gǻÅţä* Ǵ ÀŁ .ÀǩäzQŋ zU ɔŸ3 ÕΛÀHÙQöä 3ŋ ÛĞÕŁęǻ 15 gÉŋ ZÛŸä ɔŸ8Λş TS (ȯ/ȟ70~) ÕΛózŸõşØÉŁTä Ř β dbŋ Ōŋ ƙzÒǩ ŕ Ü°ȳ 105 ĞDZØÉä Ǩäǻφ ƙäş БÙ ZÅDzłş ÛdbňÅè ǒÅŋ ĞöÅţöä ÕÊ8ł ÛÀDzŢ ƷÅDZà ĞÕǩzä Ǝ3 ƙÁÊQöä ǒÅΛφÙ .ȟ/ŋŸŋ 5 dbŋ ÀƷõÙ

ƙQΛ ŕ ÜTS (ȯ/ȟ25) ÕΛÉΛÉΣä ÉΛózŸõ dbŋ Ōŋ 0.1 8ÅŘΛş ǒÅţä dbŋ Ōŋ 10 Ž ȟ1 ä äØΛ :*Tannin ÕŁφÅQöä Ř β* .gǻzÊŋ ĞöÅσ şÙ ȧøÂŋ ǻzèÙ ƙzǒ

.ÀQŸöä Ž R ÙΛÊöä dbŋ ȟ 5 ĞääÀę ƁzQƷ ǒÅţä Ž ȯzŸŢ :**TS (ȯ/ȟ5) Acacia** ÙΛÊöä

.ĞŁöşǻ ĞŁǻÅŁţŁõ ĞŁHDZÀŋ gǻÅŋ :**RS (*p*-Acetamidobenzalazine)** dΛàŕäÂøΛäşÉŁŋÅQŁèä-*p*

:**TS** Û**4.5** ǒÅŁÅä Û**(Acetate buffer)** ğÅQŁèĵä Ğääøǻ

Ř β dbŋ Ōŋ 8 8ÅŘΛ ÛǒÅţä dbŋ Ōŋ 100 Ž R ȳzΛǻzÔöä ğÅQŁèÙ dbŋ ȟ 10.9 ä äØΛ :*Procedure ǒäÀDZqä* .ǒÅţÅä Ōŋ 1000 БÙ ZÁƆş ÛƷÂƆ ÛR ÙDzŸƷöä ÕŁQŁèĵä

:TS Û4.7 ŏÅŁÅæ Û(Acetate buffer) ğÅǫŒèɟā Ğaāóå
Ŕþ ďŋ Ōŋ 3.35 ȣÅŘΛ ÛŏÅţā ďŋ Ōŋ 100 Ž R ȳȚΛåȚÔöā ğÅǫŒèÜ ďŋ ȟ 8.4 āāØΛ :*procedure ŏāÄDZqā*
.ŏÅţÅæ Ōŋ 1000 БÜ ȚÅƐȘ ÛȜÂƐ ÛƱDzŸȜöā ȬŒǫŒèɟā

:TS Û5.0 ŏÅŁÅæ Û(Acetate buffer) ğÅǫŒèɟā Ğaāóå
Ŕþ ďŋ Ōŋ 6 ȣÅŘΛ ÛŏÅţā ďŋ Ōŋ 100 Ž R ȳȚΛåȚÔöā ğÅǫŒèÜ ďŋ ȟ 13.6 āāØΛ :*procedure ŏāÄDZqā*
.ŏÅţÅæ Ōŋ 1000 БÜ ȚÅƐ ÛȜÂƐ ÛƱDzŸȜöā ȬŒǫŒèɟā

:TS Û5.5 ŏÅŁÅæ Û(Acetate buffer) ğÅǫŒèɟā Ğaāóå
Û°ȳ 35 ĞDZóÆöā БÜ ďÅÊΛ ÛŏÅţā ďŋ Ōŋ 50 Ž R ȳȚΛåȚÔöā ğÅǫŒèÜ ďŋ ȟ 54.4 āāØΛ :*procedure ŏāÄDZqā*
.ŏÅţÅæ Ōŋ 1000 БÜ ȚÅƐȘ ȝÀł .R ƱDzŸȜöā ȬŒǫŒèɟā Ŕþ ďŋ Ōŋ 10 ŏÙGæ ȣÅŘΛ ÆΛ∃ǫöā ÆĦæ .gøȘÀŘöā ÆΛȝ
ďŋ ʔȚǫŢ БÜ ŏÅţÅæ ȚÅƐ ÛTS (ȯ/ȟ300~) ȬŒǫŒèɟā Ŕþ :TS (ȯ/ȟ120~) **Acetic acid** ȬŒǫŒèɟā Ŕþ
.d~1.016 Ü(ŘGΛÀÕĭ ȯ/ȯȚŋ 2) ÀǫŸöā Ž ȟ120 ŋŸGΛ $C_2H_4O_2$
ďŋ ʔȚǫŢ БÜ ŏÅţÅæ ȚÅƐ ÛTS (ȯ/ȟ300~) ȬŒǫŒèɟā Ŕþ :TS (ȯ/ȟ90~) **Acetic acid** ȬŒǫŒèɟā Ŕþ
.(ŘGΛÀÕĭ ȯ/ȯȚŋ 1.5) ÀǫŸöā Ž ȟ 90 ŋŸGΛ $C_2H_4O_2$
ďŋ ʔȚǫŢ БÜ ŏÅţÅæ ȚÅƐ ÛTS (ȯ/ȟ300~) ȬŒǫŒèɟā Ŕþ :TS (ȯ/ȟ5.0) **Acetic acid** ȬŒǫŒèɟā Ŕþ
.d~1.0007 ÜÀǫŸöā Ž ȟ 5.0 ŋŸGΛ $C_2H_4O_2$

ĞŒõȘå ĞŒaÆŁŒõ ĞŒĦDZÀŋ gåÅŋ :**RS (Amiloride hydrochloride)** ÆΛóȚŸŒŋɟā ÆΛóȚŸõȘóÆŒŁ
ÜɟȘÜ-5-ƙõȘàāKæ-3-ÕŒÆȚ-1-ÕŒŸŒŋ ƱaÅÅǫ-3Û2-ȚÆŒŋÜ-4 .$C_{11}H_{13}NO_3$:**R (4-Aminoantipyrine)** ďΛKæ ƱøǫǫÜ ȚÆŒŋÜ-4
.aminopyrazolone ɟȚõȘàāKæȚÆŒŋÜ Üampyrone ɟȘKGŋÜ
.ȧȚHƱÊŋ ȘÜ ĞGgÅì ŏāÀÅò ğāóȚŸæ :*Description ȜòȚõā*
Ž ŘÆDZ ɟÅæȘØöā ĆŒHƱì ÜTS (ȯ/ȟ750~) òȚǫÅŸΛqā Ž ɟÅæȘØöā Àg ÜŏÅţā Ž ɟÅæȘØöā ÕŒŸę :*Solubility ĞŒǫÅæȘØöā*
.R Ką̄ɟā
.ŘGΛÀÕĭ °ȳ 108 :*Melting temperature øÅTÔǫŒā ĞDZóå*

:TS1 (4- Aminoantipyrine) ďΛKæ ƱøǫǫÜ ȚÆŒŋÜ-4
Ōŋ 0.25 ʔŸȝ ƴȚǫȜ òȚǫÅŸŒţā ďŋ Ōŋ 25 Ž R ďΛKæ ƱøǫǫÜ ȚÆŒŋÜ-4 ďŋ ȟ0.125 āāØΛ :*Procedure ŏāÄDZqā*
.TS (ȯ/ȟ420~) ÕΛóȚŸõȘóÆŒTā Ŕþ

:TS2 (4-Aminoantipyrine) ďΛΚä ΨøϱϱΨ ζΛΕηΨ-**4**

Ōη 10 ďη ǰΛÂη ȣÅŘΛş ŏÅţä ďη Ōη 30 Ž R ďΛΚä ΨøϱϱΨ ζΛΕηΨ 4 ďη ȟ0.1 ĞääÄę ā äØΛ :*Procedure ŏäÄDZqä*

ĞΕζÅõ ĞΕţÒä ZÅƐ ÜVS (ȯ/ȯζη 1) ȳζΛåζÔŏä ÁΕÊõşøÁΕΕ ďη Ōη 2ş TS (ȯ/ȟ200) ȳζΛåζÔŏä ğÅϱζäÄõ ďη

.Ōη 100 ǯÅϱϱq ŏÅţä ďη

.ǾDZäÅù ďΛΚä ΨøϱϱΨ ζΛΕηΨ-4 ÄŘǯ ǰΨ Æz :*ĞŢgΥη*

.$C_3H_3N_3O_2S$:**R (2-Amino-5-nitrothiazole)** ȯşäÅΕϱşÄϱΕϱ-**5**-ζΛΕηΨ-**2**

.ƑÅÕkÄä ÄÅòΨ ƑΨ ÄŘƯ ÄÅòΨ fluffy ZńŏŐ ȧζΗϋÊη :*Description Zòζŏŏ*

Ž ǰÅäşØŏä ĞΕΗϋì ÜĞÅÅÁţä ĞΕϱÆΕţä ôζţΣä Ž ā äşá ÜŏÅţä Ž ǾÆDZ ǰÅäşØŏä ĞΕΗϋì :*Solubility ĞΕϱÅäşØŏä*

.R ȳøζζşøζŸÒŏä Ž ǾΕŸţǯ ā äşá ŕ ÜR Ĝϱǰäş TS (ȯ/ȟ750~) ȯζϱÅŠΛqä

.ÕÒÅϱŏä Ǯη °ȳ 198 :*Melting temperature øÅŢÔϱŕä ĞDZøå*

.C_6H_7NO :**R (4-Aminophenol)** ȯζΛΕζζΛΕηΨ-**4**

.ǾĞΛÄÕk ŘΕäΨ şΨ ŘΕäΨ ƀøζŸä ȧζΗϋÊη :*Description Zòζŏŏ*

.ÕÒÅϱŏä Ǯη ǾĞΛÄÕk °ȳ 184 :*Melting temperature øÅŢÔϱŕä ĞDZøå*

ÄϱŸŏä Ž ȟ 50 ŋŸĞΛ NH_3 ďη ƷζϱŢ ƑΨ ŏÅţÅä TS (ȯ/ȟ260~) ÅΕϱζηǰä ZÅơ :**TS (ȯ/ȟ50~) Ammonia** ÅΕϱζηǰä

.d~0.977 Ü(ǾĞΛÄÕk ȯ/ȯζη 3)

:TS2 (Ammonia buffer) ÅΕϱζηǰä ĞəøäÅ

ZÅƐş TS (ȯ/ȟ260~) ÅΕϱζηǰä ďη Ōη 650 Ž R ȳζΕϱζηǰä ÆΛøζŸõ ďη ȟ 67.5 ā äØΛ :*Procedure ŏäÄDZqä*

.Ōη 1000 ǰϱΑΛ ƷøϱĞ ŏÅţÅä

ďη ȟ 100 ƷŸǯ ƀζϱǯ R ȳζΕΑηǰä ĞÅϱΕèǰ ȯζŸŢ :**TS (ȯ/ȟ100) Ammonium acetate** ȳζΕϱζηǰä ĞÅϱΕèΨ

.ÄϱŸŏä Ž $C_2H_7NO_2$

ďη ȟ 38.5 ƷŸǯ ƀζϱǯ R ȳζΕϱζηǰä ĞÅϱΕèΨ ďη ȯζŸŢ :**TS (ȯ/ȟ40) Ammonium acetate** ȳζΕϱζηǰä ĞÅϱΕèΨ

.(ǾĞΛÄÕk ÄϱŸŏä/ ȯζη 0.5) ÅĞΛÄÕk ÄϱŸŏä Ž $C_2H_7NO_2$

.ǾDZäÅù TS (ȯ/ȟ40) ȳζΕϱζηǰä ĞÅϱΕèΨ ĞŘƠ Æz :*Note ĞŢgΥη*

ďη ȟ 2 ƷŸǯ ƀζϱǯ R ȳζΕϱζηǰä ĞÅϱΕèΨ ďη ȯζŸŢ :**TS (ȯ/ȟ2) Ammonium acetate** ȳζΕϱζηǰä ĞÅϱΕèΨ

.ǾĞΛÄÕk ÄϱŸŏä Ž $C_2H_7NO_2$

.ǾDZäÅù TS (ȯ/ȟ2) ȳζΕϱζηǰä ĞÅϱΕèΨ ĞŘƠ Æz :*Note ĞŢgΥη*

:TS Û4.62 ŏÅŁÅæ (Ammonium acetate buffer) ȳʒĘǫʒŋɟä ğÅǫĘèÜ Ğəǿäǻ
ÕĘǫĘèɟä Ř ƥ ȯÅŧĦǫèÅæ 4.62 Ƃ TS (ȯ/ħ100) ȳʒĘǫʒŋɟä ğÅǫĘèÜ ŏÅŁÅæ ǴĦƱÔĦ :*Procedure ŏäÄDŹqä*
.TS (ȯ/ħ60~)

:TS (Ammonium mercurithiocyanate) ȳʒĘǫʒŋɟä ĘǴəà ğÅǫÅĘèʒĘǫ
ɒŋ ǴĘʒÅõ ǴĘŧõ Ž R ÕĘÕǴəÂöä ÁΛǿʒŸõ ɒŋ ħ 27ş R ȳʒĘǫʒŋɟä ğÅǫÅĘèʒĘǫ ɒŋ ħ 30 ä äØΛ :*procedure ŏäÄDŹqä*
.Ōŋ 1000 ʒÅǫǫq ŏÅŧä

:TS (Ammonium molybdate/sulfuric acid) ÕΛǿʒÅŸÊöä Ř ƥ/ȳʒĘǫʒŋɟä ğäÁǴĘöʒŋ
ÕΛǿʒÅŸÊöä Ř ƥ ɒŋ ǴĘʒÅõ ǴĘŧõ Ž R ȳʒĘǫʒŋɟä ğäÁǴĘöʒŋ ɒŋ ħ 0.5 ä äØΛ :*Procedure ŏäÄDŹqä*
.Ōŋ 10 ʒÅǫǫq TS (ȯ/ħ1760~)

:TS (Ammonium molybdate/vanadate) ğäǻÅǫÅʒ/ȳʒĘǫʒŋɟä ğäÁǴĘöʒŋ
R ȳʒĘǫʒŋɟä ğäǻÅǫÅʒ ɒŋ ħ 0.1ş Ǵŧʒ̀ÅÅöä ǴęʒHƱÊŧä R ȳʒĘǫʒŋɟä ğäÁǴĘöʒŋ ɒŋ ħ 4 ğÀΛ :*Procedure ŏäÄDŹqä*
Ōŋ 100 Ƃ ZÅƧş TS (ȯ/ħ1000~) ÕΛÄǫÅöä Ř ƥ ɒŋ Ōŋ 20 ȣÅÊΛ .ŏÅŧä ɒŋ Ōŋ 70 Ž Ǵŧʒ̀ÅÅöä ǴęʒHƱÊŧä
.ŏÅŧÅæ

.(37 ǴHƱÅÔöä Û1963 ÛSRIP) $(NH_4)_2S_2O_8$ **:R (Ammonium persulfate)** ȳʒĘǫʒŋɟä ğÅÅŸèĶæ

:TS (Ammonium persulfate/phosphate buffer) ğÅÅèʒÅöä Ğəǿäǻ/ȳʒĘǫʒŋɟä ğÅÅŸèĶæ
ʒÅǫǫq TS Û7.4 ŏÅŁÅæ ÛǴĘʒÅõ ğÅÅèʒʒ Ğəǿäǻ Ž R ȳʒĘǫʒŋɟä ğÅÅŸèĶæ ɒŋ ħ 10 ä äØΛ :*Procedure ŏäÄDŹqä*
.Ōŋ 100

.(39 ǴHƱÅÔöä Û1963 ÛSRIP) $NH_4[Cr(NH_3)_2(SCN)_4],H_2O$ **:R (Ammonium reineckate)** ȳʒĘǫʒŋɟä ğÅÒĘΛǿ
ɒŋ ħ 10 ɔŸʒ ƤʒǫƷ R ȳʒĘǫʒŋɟä ğÅÒĘΛǿ ȯʒŸŢ :**TS (ȯ/ħ10) Ammonium reineckate** ȳʒĘǫʒŋɟä ğÅÒĘΛǿ
.ÀǫŸöä Ž $NH_4[Cr(NH_3)_2(SCN)_4]$

ɒŋ ħ 50 ɔŸʒ ƤʒǫƷ R ȳʒĘǫʒŋɟä ğÅŋÅÅŸè ȯʒŸŢ :**TS (ȯ/ħ50) Ammonium sulfamate** ȳʒĘǫʒŋɟä ğÅŋÅÅŸè
.ÀǫŸöä Ž $NH_4OSO_2NH_2$

:TS Ammonium sulfide ȳʒĘǫʒŋɟä ÁĘÅŸè
25 Ƃ ȣÅÊΛ .TS (ȯ/ħ100~) ÅĘǫʒŋɟä Ž R ƙDŹşǿÁĘTä ÁĘÅŸè ɒŋ ƷǴÎŋ ȯʒŸŢ ÀÊƷ :*Procedure ŏäÄDŹqä*
.TS (ȯ/ħ100~) ÅĘǫʒŋɟä ɒŋ Ōŋ 50 ȯʒŸŧä ɒŋ Ōŋ

:TS (Ammonium thiocyanate/cobalt(II)nitrate) (II) Ǩöåæçȯöää ğäÀǫφ/ȳçǿçǫçǫjä ğÅφÅǿèçǿǫ
Ǒǫ 100 Ž R (II) Ǩöåæçȯöää ğäÀǫφ ȣǫ ȟ 5ş R ȳçǿçǫçǫjä ğÅφÅǿèçǿǫ ȣǫ ȟ 20 ā äØΛ :*Procedure ȣäÄDZqä*
.ȯçŸ‡ä ţÅGìq R ȳçΛåçÔöää ÆΛøçŸõ ȣǫ ǨǿçÅõ Ǩǿŧõ ȣÅÊΛ .ȣÅǫ

.NH4VO3 **:R Ammonium vanadate** ȳçǿçǫçǫjä ğäåÅφÅç
.ǨǫǿÅGöä gÀÅÔöä Бů ā øÅr ÊǿäŮ ÐøçŸä äçHȣÊǫ :*Description Ζȯçöä*
.TS (ȯ/ȟ100~) Åǿçǫçǫjä Ž ā äşæ ÛȣÅţä Ž ȷÅæşØöä ǴǿHȣì :*Solubility ǨǿφÅæşØöä*
.Ǩǿöşå ǨǿəÅǿŧǿõ ǨǿȞDZÀǫ gåÅǫ :**RS (Amodiaquine hydrochloride)** ǩõÅΛåçǫçǫjä ÆΛøçŸõşøÆǿŁ
øöä ȣǫ ¢æ dzÀÔǫ ʔçǫŢ ɔŸ3 Ðçǫơ) Ǩǿöşå ǨǿəÅǿŧǿõ ǨǿȞDZÀǫ gåÅǫ :**RS (Amphotericin B)** ā ǩÊΛÀǩçÅǫçǫjä
(Tetraenes

.$C_{14}H_{10}O$:**R (Anthrone)** ȷşÀǩφçǫjä
.ÆgÅì ÀÅòŮ ÐøçŸä äçHȣÊǫ :*Description Ζȯçöä*
Ŕβ Žş TS (ȯ/ȟ750~) ȯçφÅǩΛqä Ž ȷÅæşØöä ǴǿHȣì ÜȣÅţä Ž ÅǿÆŸŧ3 ā äşæ ɾ :*Solubility ǨǿφÅæşØöä*
.TS (ȯ/ȟ100~) ÕΛøçÅŸÊöä
ȣǫ Ǒǫ 10 Бů ȟ 0.5 ȣÅÊΛ :R *(Solubility in carbon tetrachloride R) ȷçæÅÔöä ÆΛøçŸõ Ʊ3Åæø Ž ǨǿφÅæşØöä*
.Ęöüǫ Ǩd ȣÅò ȯçŸŢ ǰǫΛ ÜR ȷçæÀÒöä ÆΛøçŸõ Ʊ3Åæø
.°ȳ 156-154 :*Melting range øÅTÔφɾä ȯÅf*

:**TS (Anthrone)** ȷşÀǩφçǫjä
.TS (ȯ/ȟ1760~) ÕΛøçÅŸÊöä Ŕβ ȣǫ Ǒǫ 100 Ž R ȷşÀǩφçǫjä ȣǫ ŋŸǫ35 ā äØΛ :*Procedure ȣäÄDZqä*
.Ǩǿöşå ǨǿəÅǿŧǿõ ǨǿȞDZÀǫ gåÅǫ :**RS (Azathioprine)** ȣΛÀæçǿöäàçǫjä
.Ǩǿöşå ǨǿəÅǿŧǿõ ǨǿȞDZÀǫ gåÅǫ :**RS (Bacitracin zinc)** ǩèäÀǫǿèÅGöä Õφà
.Ǩǿöşå ǨǿəÅǿŧǿõ ǨǿȞDZÀǫ gåÅǫ :**RS (Beclometasone dipropionate)** ȷşàÅǫǿǫçŸÒǿGöä ğÅφçǿæşΞΛå
.C_7H_8O :**R (Benzyl alcohol)** ÕΛÂøΛæ ȯçȣõ
.ǨGΛÀÕǩ ǨȣəäÀöä CÆ3 ÛȷçŸöä CÆ3 ÕəÅè :*Description Ζȯçöä*
ȳøççøçŸÒöäş TS (ȯ/ȟ750~) ȯçφÅǩΛqä 3ǫ ǯÂŧŸö ÕæÅę ÜȣÅţä ȣǫ ȣÂDZ 25 3ǫ ǯÂŧŸö ÕæÅę :*Miscibility ǨǿDZşÂţä*
.R ǨǫǿÅşR
.ǨGΛÀÕǩ °ȳ 204 :*Boiling temperature ȷÅǿŸ8öä ǨDZØåå*

.ňĞłÀÖĕ ρ_{20} = ȯ/ŋõ 1.05 :*Mass density ĞŸŲÓöã ĞęÀĭõ*

.ĞĒöşå ĞĒəÀĒŧĒõ ĞĒĔHDZÀŋ gåÀŋ :**RS (Betamethasone valerate)** ɟşàÀĭĞĒŋÀŲĒGöã ğãKöÀz

.ĞĒöşå ĞĒəÀĒŧĒõ ĞĒĔHDZÀŋ gåÀŋ :**RS (Biperiden)** ďłÆłKĞĒGöã

.ĞĒöşå ĞĒəÀĒŧĒõ ĞĒĔHDZÀŋ gåÀŋ :**RS (Biperiden hydrochloride)** ďłÆłKĞĒGöã ÆłøzŸõşøÆĒŁ

.(53 ĞĤÀÔöã Û1963 ÛSRIP) $C_4H_{10}O$:**R (2-Butanol)** ȯzφÀĭzã-**2**

.$C_6H_{12}O_2$:**R (Butyl acetate)** ÕĒĭzGöã ğÀŲĒèÛ

.gÂĒư ¢ŲĤuãáø ÜȯÀĤŲìŸö ÕãÀę ÛɟzŸöã CÆȝ ȣÀò ÕəÀè :*Description Ęȯzöã*

.TS (ȯ/ĥ750~) ȯzφÀĭłqÀã ĭÂŧŸö ÕãÀę ÛŏÀŧÀã ĭÂŧã ĞĒĤüì :*Miscibility* ĞĒDZşÂŧã

.ňĞłÀÖĕ ρ_{20} = ȯ/ŋõ 0.88 :*Mass density ĞŸŲÓöã ĞęÀĭõ*

:**R (Butylated hydroxytoluene)** (ÕĒĭzGöã ¢ĒöÛ ȣÀŘŧã) ÕĭzGŧã ďłzȯzù ŦÊõşøÆĒŁ

2.6-Di-*tert*-butyl-4-methylphenol,$C_{15}H_{24}O$

.ŘĒãÛ ÞózŸã àzĤÊŋ şÛ ÛɟzŸöã ĞęÆȝ ğãózŸã :*Description* Ęȯzöã

ÜTS (ȯ/ĥ750~) ȯzφÀĭłqã Ž ɟÀãşÓöã Àg ÛŏÀŧã Ž ňĒŸŧȝ ããşáã ŗ :*Solubility ĞĒφÀãşÓöã*

.ňĞłÀÖĕ °ȳ 70 :*Melting temperature ŏÀĬŤÔφŗã ĞDZŏåå*

.ĥ/ŋŸŋ 1.0 ďȝ ÆłÂł ŗ :*Sulfated ash ŘÁŸÊŧã åÀŋÀöã*

.ĞĒöşå ĞĒəÀĒŧĒõ ĞĒĔHDZÀŋ gåÀŋ :**RS (Calcium folinate)** ȳzĒÊöÀÒöã ğÀAĒõzz

:**TS** Û**ethanolic** ÕĒõzφÀĭłÛ Û(**Ca** Ōŋ/ȳãÀdşÀÒĒŋ **100**) **Calcium standard** ÞøÀĒĤŧã ȳzĒÊöÀÒöã

Ōŋ/ȳãÀdşÀÒŋ 10) ȳzĒÊöÀÒöã øÀĒĤŋ ɟãzÀȝ ŘƠ ȣzȯzŧã ÛA ȯzŸ∓ã ďŋ Ōŋ 100.0 ZÀƐ :*Procedure ŏãÀDZqã*

.Ōŋ 1000 ĭÀφq TS (ȯ/ĥ750~) ȯzφÀĭłqã ďŋ ĞĒzÀõ ĞĒŧõ ȝŋ ÛTS (Ca

:**TS** (**Ca** Ōŋ/ȳãÀdşÀÒĒŋ **10**) **Calcium standard** ÞøÀĒĤŧã ȳzĒÊöÀÒöã

ÕĒŲĒèɟã Ř þ ďŋ Ōŋ 15 Ž R2 ĞÁÀÖã ȳzĒÊöÀÒöã ğÀφzãÀõ ďŋ ĥ 2.50 ããØł :*Procedure ŏãÀDZqã*

1000 ĭÀφq ŏÀŧÀã ȯzŸ∓ã ãØŁ ďŋ Ōŋ 10.0 ZÀƐ .(A ȯzŸ∓ã) Ōŋ1000 ɔøŲǵ ŏÀŧã åÆȘ TS (ȯ/ĥ300~)

.Ōŋ

(62 ĞĤÀÔöã Û1963 ÛSRIP) $CaSO_4,2H_2O$:**R (Calcium sulfate)** ȳzĒÊöÀÒöã ğÀÀŸè

:**R (Calcium sulfate,hemihydrate)** ĞĒəÀŧã ZÔφ ÛȳzĒÊöÀÒöã ğÀÀŸè

.$CaSO_{4,1/2}H_2O$, Plaster of Paris ÈłøÀã ÈĞDZ

Description: *Porous calcium sulfate* (TS) ؛ الوصف

Procedure: *تُحضَّر* 100 g من TS في 5 L من الماء المقطر ويُضاف إليها 1 L من محلول حمض الهيدروكلوريك 0.1 mol/L ويُسخَّن حتى الغليان. يُبرَّد المحلول ويُرشَّح. يُضاف إلى الراشح 1 L من محلول كلوريد الباريوم 0.1 mol/L ويُسخَّن حتى الغليان. يُترَك الراسب ليترسب ويُرشَّح. يُضاف إلى الراشح 1 L من محلول نترات الفضة 0.1 mol/L ويُسخَّن حتى الغليان. يُترَك الراسب ليترسب ويُرشَّح. يُضاف إلى الراشح 1 L من محلول هيدروكسيد الصوديوم 0.1 mol/L ويُسخَّن حتى الغليان. يُترَك الراسب ليترسب

.R Ƙǫɨāş TS (ȯ/ȟ750~) ȯƶǫĀƷʌqā Ž āāşá ÜŏĀţā Ž ĦĒŸŧʒ āāşá ɾ :*Solubility ǦĒǫĀāşÓŏā*

.ĦǦʌĀÖŏk °ȳ 180 :*Melting temperature ŏĀŤÔǫɾā ǦDƶŏā*

.ǦĒŏşā ǦĒəĀĒŧĒõ ǦĒĦDƶĀŋ ǥĀŋ :**RS (Cimetidine)** ɗʌĀĒĒǫĒŧĒÊŏā

.(69 ǦĦʊĀÔŏā Û1963 ÛSRIP) $C_{19}H_{22}N_2O$:**R (Cinchonine)** ƙǫƶÒĀĒÊŏā

. î ĀȯĀŏā ɗŋ ǫĀŋ R ÕʌĀǫĒÊŏā Ȑƥ :**PbR (Citric acid)** ÕʌĀǫĒÊŏā Ȑƥ

.ǦĒŏşā ǦĒəĀĒŧĒõ ǦĒĦDƶĀŋ ǥĀŋ :**RS (Clofazimine)** ƙƨȁĀƶƶŸÒŏā

.ǦĒŏşā ǦĒəĀĒŧĒõ ǦĒĦDƶĀŋ ǥĀŋ :**RS (Clomifene citrate)** ƙĀĒŋƶŸÒŏā ǧāĀǫĒè

ĀŢǫā .ǦĒŏşā ǦĒəĀĒŧĒõ ǦĒĦDƶĀŋ ǥĀŋ :**RS (Clomifene citrate Z-isomer)** ƙĀĒŋƶŸÒŏā ǧāĀǫĒÊŏ **Z-**ȟşĀÔţā

.**RS** ƙĀĒŋƶŸõşà

.(70 ǦĦʊĀÔŏā Û1963 ÛSRIP) $CoCl_2,6H_2O$ ÜǨŏĀƶƶÒŏā ĀʌØƶŸõ :**R (Cobalt (II) chloride) II** ǨŏĀƶƶÒŏā ĀʌØƶŸõ

.189 ǦĦʊĀÔŏā Ûȯşɨā ĀŸŏā Ž ĀĪǫ Āŋ ÕÛǦʌ ƁĀΣā ÒĀŏā

ȟ 30 ǦāāĀę ƨŸʒ Ƀƶǫʒ ǨŏĀƶƶÒŏā ĀʌØƶŸÒŏ ȯƶŸŢ :**TS (ȯ/ȟ30) (Cobalt (II) chloride) II** ǨŏĀƶƶÒŏā ĀʌØƶŸõ

.ĀǫŸŏā Ž $CoCl_2$ ɗŋ

ɗŋ ȟ 5 ǦāāĀę ƨŸʒ Ƀƶǫʒ ǨŏĀƶƶÒŏā ĀʌØƶŸÒŏ ȯƶŸŢ :**TS (ȯ/ȟ5) (Cobalt (II) chloride) II** ǨŏĀƶƶÒŏā ĀʌØƶŸõ

.ĀǫŸŏā Ž $CoCl_2$

:**TS (Cobalt (II) chloride) II** ǨŏĀƶƶÒŏā ĀʌØƶŸõ

Ȑƥ ɗŋ Ōŋ 2.5 ɗŋ ǰʌÂŋ ɗŋ ǦĒƶĀõ ǦĒŧõ Ž R (II) ǨŏĀƶƶÒŏā ĀʌØƶŸõ ɗŋ ȟ 6.5 āāØʌ :*Procedure ŏāĀDƶqā*

.Ōŋ 100 ʒĀǫǫq ŏĀţā ɗŋ Ōŋ 97.5ş TS (ȯ/ȟ250~) ÕʌØƶŸõşØĀĒŢā

.328 ǦĦʊĀÔŏā Û2 ĀŸŏā Ž ĀĪǫ Āŋ ÕÛǦʌ ƁĀΣā ÒĀŏā

.$Co(NO_3)_2,6H_2O$:**R (Cobalt (II) nitrate)** ǨŏĀƶƶÒŏā ǧāĀǫǫ

.gƚ8ȯ ŏāĀƥ ǧāØƶŸā :*Description Ƶȯƶŏā*

.ŏĀţā Ž ĦĀĒDƶ āāşá :*Solubility ǦĒǫĀāşÓŏā*

ƨŸʒ Ƀƶǫʒ R (II) ǨŏĀƶƶÒŏā ǧāĀǫǫ ɗŋ ȯƶŸŢ :**TS (ȯ/ȟ100) (Cobalt (II) nitrate) (II)** ǨŏĀƶƶÒŏā ǧāĀǫǫ

.ĀǫŸŏā Ž $Co(NO_3)_2$ ɗŋ ȟ100 ǦāāĀę

:**TS (ȯ/ȟ10) (Cobalt (II) nitrate) (II)** ǨŏĀƶƶÒŏā ǧāĀǫǫ

.Ōŋ 100 ʒĀǫǫq ŏĀţā ɗŋ ǦĒƶĀõ ǦĒŧõ Ž R (II) ǨŏĀƶƶÒŏā ǧāĀǫǫ ɗŋ ȟ 1.6 ǦāāĀę āāØʌ :*Procedure ŏāĀDƶqā*

.ČĒõşå ČĒəÀĒŧĒõ ČĒĦDZÀŋ ğåÀŋ :**RS (Colchicine)** ƙÊĒÎõzÒõã

50 ČããÀę ɔŸ3 ƀzQƷ R (II) âÀĦuÀõã ğÀQĒèɟ òzŸŢ :**TS (ȯ/ȟ45) (Copper (II) acetate) (II)** âÀĦuÀõã ğÀQĒèÙ

.ÀQŸõã Ž $C_4H_6CuO_4,H_2O$ ɗŋ ȟ

.$CuCl_2,2H_2O$:**R (Copper (II) chloride) (II)** âÀĦuÀõã ÁMózŸõ

.ČęóÂõã БÙ ČãóÀì ř õãÀÊRn ČƷzĒŋ ğãózŸã :*Description* Ƶòzõã

.R Ƙõɟã Ž ɟÀãşØõã ĆĒĦuì ÜTS (ȯ/ȟ750~) òzφÀƷMqã Ž ããşá ÜõÀŧã Ž ɟÀãşØõã Àǵ :*Solubility ČĒφÀãşØõã*

:**TS (Copper (II) chloride/ammonia)** ÀĒφzŋɟã/**(II)** âÀĦuÀõã ÁMózŸõ

ɗŋ Ōŋ 100 ȣÀÊRMş õÀŧã ɗŋ Ōŋ 200 Ž R (II) âÀĦuÀõã ÁMózŸõ ɗŋ ȟ 22.5 ããØM :*Procedure õãÄDZqã*

.TS (ȯ/ȟ260~) ÀĒφzŋɟã

:**TS (Cu** Ōŋ/ȳãÀdşÀÒĒŋ**10) Copper standard** ƀøÀĒĦŧã âÀĦuÀõã

ƵÁƐş ÛŌŋ 100 ƷÀQφq õÀŧã ɗŋ ČĒzÀõ ČĒŧõ Ž R (II) âÀĦuÀõã ğÀÁŸè ɗŋ ȟ0.393 ããØM :*Procedure õãÄDZqã*

.Ōŋ 1000 ƷÀQφq òzŸ∓ã ãØŁ ɗŋ Ōŋ 10.0

:**TS1 (Copper standard)** ƀøÀĒĦŧã âÀĦuÀõã

Ř β ɗŋ ČĒzÀõ ČĒŧõ Ž ÛČĒùzĢÊŋ Čφşàzŋ ÛR (II) âÀĦuÀõã ğÀÁŸè ɗŋ ȟ 1.965 ããØM :*Procedure õãÄDZqã*

.Ōŋ 1000 ƷÀQφq VS (ȯ/òzŋ 0.1) ŌMózŸõşóÁĒTã

:**TS2 (Copper standard)** âÀĦuÀõã óÀĒĦŋ

(ȯ/òzŋ 0.1) ŌMózŸõşóÁĒTã ŘŧШ ƵÁƐş Ōŋ 1000 ÀƵQĦè ČŸDZzǵ БÙ TS1 âÀĦuÀõã óÀĒĦŋ ɗŋ Ōŋ 3.0 ŌŌMM

.ÀQõ ŲŸĒŧã Ž âÀĦuÀõã ɗŋ ȳãÀdşÀÒŋ 1.5 ɔŸ3 òzŸ∓ã ãØŁ ƀzQƷ .Ōŋ 1000 ƷÀQφq VS

ɗŋ ȟ 1 ɔŸ3 ƀzQƷ R (II) âÀĦuÀõã ğÀÁŸÊõ òzŸŢ :**TS (ȯ/ȟ1) (Copper (II) sulfate) (II)** âÀĦuÀõã ğÀÁŸè

.ÀQŸõã Ž $CuSO_4$

.$C_{21}H_{18}O_5S$:**R (Cresol red)** òşÂMÀÒõã gÀβ

.ŲøMGõã БÙ ãóÀì ÀβÙ ȧzHuÊŋ :*Description Ƶòzõã*

ğãÁĒÊõşóÁĒTã ŌĒõÀ∓ã Žş TS (ȯ/ȟ750~) òzφÀƷMqã Ž ããşá ÜõÀŧã Ž ɟÀãşØõã ĆĒĦuì :*Solubility ČĒφÀãşØõã*

.ČÁÀÁŧã ČMzŸÕõã

:**TS (Cresol red/ethanol)** òzφÀƷMqã/òşÂMÀÒõã gÀβ

ȳzMázÔõã ÁĒÊõşóÁĒŁ ɗŋ Ōŋ 2.65 ƷŋR òşÂMÀÒõã gÀβ ɗŋ ȟ0.05 ùzÁŁ :*Procedure õãÄDZqã*

TS (ȯ/ȟ150~) ȯȥφÅǰʌqä ȣÅŘʌ ÛȯȥŸ‡ä Àäÿÿÿÿÿk ÆŤäæ ÜTS (ȯ/ȟ710~) ȯȥφÅǰʌqä ȣŋ Ōŋ 5ş VS (ȯ/ȯȥŋ 0.05) .Ōŋ 250 ǯÅQφq ŤŧȥÅõ ŤŧŧȮæ

:**(Culture medium Cm8) Cm8** ţφÂöä Ùèş

ȯşKÊŧŸ8öä ȣŋ ȟ 10ş R ÀŌGöä ǰΣ ŤȯŸn ȣŋ ȟ 10ş R ȤÅŎä ɹȥQGGöä ȣŋ ȟ 10 ãäØʌ :*Procedure ŏäÄDZqä* ŤŧuÔŧ .Ōŋ 1000 ǯÅQφq ŏÅţä ȣŋ ŤŧȥÅõ Ťŧŧõ Ž R ŏÅdǿä ȣŋ ȟ 17ş R ȳȥʌǻȥÔöä ÆʌŏȥŸõ ȣŋ ȟ 3.0ş R 121 gŏäÀǵ ŤDZŏÆæ gÆòȥţÅæ ǰŌŤʌş Û7.1-6.9 ȣøQǵ VS (ȯ/ȯȥŋ 0.05) ȳȥʌǻȥÔöä ÆŧÊõşøÆŧŧ ŤùÅèȥæ ŏÅŧÅŤöä .ŤŌŧęǻ 20-18 gÆŋ °ȳ

:**(Culture medium Cm9) Cm9** ţφÂöä Ùèş

R ȯşÀÊŧŸ8öä ȣŋ ȟ 10ş R ÀŌGöä ǰΣ ŤȯŸn ȣŋ ȟ 10ş R ȤÅŎä ɹȥQGGöä ȣŋ ȟ10 ãäØʌ :*Procedure ŏäÄDZqä* ÆŧÊõşøÆŧŧ ŤùÅèȥæ ŏÅŧÅŤöä ŤŧuÔŧ .Ōŋ 1000 ǯÅQφq ŏÅţä ȣŋ ŤŧȥÅõ Ťŧŧõ Ž R ȳȥʌǻȥÔöä ÆʌŏȥŸõ ȣŋ ȟ 3.0ş .ŤŌŧęǻ 20-18 gÆŋ °ȳ 121 gŏäÀǵ ŤDZŏÆæ gÆòȥţÅæ ǰŌŤʌş Û7.1-6.9 ȣøQǵ VS (ȯ/ȯȥŋ 0.05) ȳȥʌǻȥÔöä

:**(Culture medium Cm10) Cm10** ţφÂöä Ùèş

R ȳȥŧȥŋjä ǧäÀQφ ȣŋ ȟ 5ş R ŏÅţä Ž ŤääşØöä gKŧłä ŤȯŸn ȣŋ ȟ 1 ãäØʌ :*Procedure ŏäÄDZqä* ȣŋ ŤŧȥÅõ Ťŧŧõ Ž R ŏÅdǿä ȣŋ ȟ 14ş R ŦəÅŋŸöä ȁȥõȥŸ8öä ȣŋ ȟ 5ş R ŧDZşøÆŧTä ŦəÅÅQ ǧÅÅèȥȥ ȣŋ ȟ 5ş .Ōŋ 1000 ǯÅQφq ŏÅţä

:**(Culture medium Cm11) Cm11** ţφÂöä Ùèş

Ž R ŏÅdǿä ȣŋ ȟ 15ş R ÀŌGöä ǰΣ ŤȯŸn ȣŋ ȟ 6ş R ȤÅŎä ɹȥQGGöä ȣŋ ȟ10 ãäØʌ :*Procedure ŏäÄDZqä* ÛVS (ȯ/ȯȥŋ 1) ȳȥʌǻȥÔöä ÆŧÊõşøÆŧŧ ŤùÅèȥæ ȯȥŸ‡ä ŏÅŧÅæ ŤŧuÔŧ .Ōŋ 1000 ǯÅQφq ŏÅţä ȣŋ ŤŧȥÅõ Ťŧŧõ ÛŦŧȥÅò ŤGÔʌ ȣøQǵ gŏşÀŘöä ÆʌȝÛŤÌÀŧ .7.8 ǰŌŤţä Ùèȥöä Žş ŤʌÅŦʌöä ÆʌȝŏÅŧÅGöä ŤGÔǩ ɹÛ ÐÛ ÛgŏşÀŘöä ÆʌȝŤŌŧęǻ 20-18 gÆŋ °ȳ 121 gŏäÀǵ ŤDZŏÆæ gÆòȥţÅæ ǰŌŤʌş ŤŧȥŸŋ ŤŧȝÛ Ž ȯȥŸ‡ä ţàȥʌ

.Ťŧŏşǻ ŤŧȥÅŧŧõ ŤŧŤDZÀŋ gǻŋ :**RS (Cytarabine)** ŧääØÅQŧè

.Ťŧŏşǻ ŤŧȥÅŧŧõ ŤŧŤDZÀŋ gǻŋ :**RS (Dexamethasone sodium phosphate)** ɹşàÅQŧŋÅÊȮʌÆöä ȳȥʌǻȥò ǧÅÅèȥȥ

.Ťŧŏşǻ ŤŧȥÅŧŧõ ŤŧŤDZÀŋ gǻŋ :**RS (Dextromethorphan hydrobromide)** ɹÅȥŏȥǯŧŋşÀQÊȮʌǻ ÆŧŋşÀæşøÆŧŧ

:**R (Diatomaceous support)** ǧäŏȥÛÎţä ȳÅȝǻ

gǻÅţä ɹȥȮQǩ .ǧäŏȥÛÎţä ŌõÅŧŧ ȣŋ ȯşjä ȳÅŌţä Ž ȤöäQǩ ÅȮŧŸÊöä ȣŋ ŏÅŘŧæ ǧÅGŧGǵ :*Description ȤÒȥöä* ǻȥDZȥŋ ŦŧŞ ÛɹȥŸöä CÆȝ ŌȮÌ Ž flux-calcined ŤŸŧÊŋ ŤʌÊŸȮŋ ÐÛ ŤφȥŸŋ ŤŏşÂŤŋ ŤŧφÆŤŋ ǧäÆŧÊõşÛ ȣŋ

Ƀƶ Ÿ Ŏ ö ä ø ö ä ş Û Silanized Ŏ ŋ Ƙ Ê ö Å ä Ŏ ŋ Å Ĥ ţ ä ş Û acid-washed ȯ ƶ Ê 8 ţ ä Ř ŧ Σ ä : Ŏ ž ŋ g ø Å D z ǫ ö ä Ž Ğ Å Ÿ Ǫ Ư ȯ Å Ȯ ì ü ä
.alkali-washed ȯ ƶ Ê 8 ţ ä

.$C_{20}H_{10}C_{12}O_5$:**R (Dichlorofluorescein)** ƙ Ê Ê ʌ ȯ ƶ Ÿ ƶ ş ȯ ƶ Ÿ ŏ Ʊ Å ä ǫ

.Ƶ Ł Å ʅ ä Ƃ Å Ŏ ƙ Ǝ ö Å ä ɿ ƶ Ÿ ŋ Û Ƀ ȯ ƶ Ÿ ä ȧ ƶ Ʊ Ê ŋ :*Description Ƶ ȯ ƶ ö ä*

.TS (ȯ/ȟ750~) ȯ ƶ ǫ Å ž ʌ ǫ ä Ž ā ä ş ǽ Ü ö Å ţ ä Ž ɿ Å ä ş ǿ ö ä Ŏ Ł Ÿ ę :*Solubility Ğ ǫ ǽ ä ş Ø ö ä*

:**TS (Dichlorofluorescein)** ƙ Ê ʌ ȯ ƶ Ÿ ƶ ş ȯ ƶ Ÿ ŏ Ʊ Å ä ǫ

.R ȯ ƶ ǫ Å ž Ł ţ ä ɖ ŋ Ŏ ŋ 100 Ž R ƙ Ê ʌ ȯ ƶ Ÿ ƶ ş ȯ ƶ Ÿ ŏ Ʊ Å ä ǫ ɖ ŋ ȟ 0.2 ā ä Ø ʌ :*Procedure ö ä Ä D Z q ä*

.Ğ Ł ö ş å Ğ Ł ə Å Ł ŧ Ł ŏ Ğ Ł H D Z Å ŋ g å Å ŋ :**RS (Dicloxacillin sodium)** ƙ Ÿ Ł è Å Ê ŏ ƶ Ÿ Ò ʌ Æ ö ä ȳ ƶ ʌ å ƶ ò

.å ƶ ŧ ȝ ɾ Ÿ ȝ ā ä Å Î ǫ è ɾ ä Ŏ D Z j ɟ Ğ ŧ ə Ɣ ŋ Ğ D Z ǿ å :**R (Diethylaminoethylcellulose)** ȁ ƶ Ÿ Ÿ è Ŏ Ł ž ʌ Ù ƶ Å Ł ŋ Ù Ŏ Ł ž ʌ Ù Ʊ Å ä ǫ

.$C_{12}H_{14}O_4$:**R (Diethyl phthalate)** Ŏ Ł ž ʌ ǫ ä Ʊ Å ä ǫ ğ ɾ Å ž ƶ

.ǡ G ʌ Å Ŏ ƙ ρ_{20} = ȯ/ŋõ 1.117 :*Mass density Ğ Ÿ ǫ Ò ö ä Ğ ƶ Å ž ȯ̃*

. $n_D^{20} = 1.500 - 1.505$:*Refractive index ø Å Ê Ò ǫ ɾ ä Æ Ê ʌ ŋ*

.Ğ Ł ö ş å Ğ Ł ə Å Ł ŧ Ł ŏ Ğ Ł H D Z Å ŋ g å Å ŋ :**RS (Diloxanide furoate)** Æ Ł ǫ Å Ê ŏ ƶ Ÿ ʌ Æ ö ä ğ ä ş ǿ ƶ ƶ

.C_4H_9NO :**R (Dimethylacetamide)** Æ Ł ŋ Å ǫ Ł è Ù Ŏ Ł ž Ł ŋ Ʊ Å ä ǫ

.ɿ ƶ Ÿ ö ä Ć Æ ȝ Ŏ ə Å è :*Description Ƶ ȯ ƶ ö ä*

.ǡ G ʌ Å Ŏ ƙ °ȳ 165 :*Boiling temperature ɿ Å Ł Ÿ 8 ö ä g ø ä Å ğ Ğ D Z ǿ å*

.ρ_{20} = ȯ/ŋõ 0.94 :*Mass density Ğ Ÿ ǫ Ò ö ä Ğ ƶ Å ž ȯ̃*

:**TS5 (4-Dimethylaminobenzaldehyde)** Æ Ł Ł Æ ö ä Å ø ʌ ä ƶ Å Ł ŋ Ù Ŏ Ł ž Ł ŋ Ʊ Å ä ǫ-**4**

ŏ Å ţ ä ɖ ŋ Ŏ ŋ 45 ɖ ŋ ɟ ʌ Å ŋ Ž R Æ Ł Ł Æ ö ä Å ø ʌ ä ƶ Å Ł ŋ Ù Ŏ Ł ž Ł ŋ Ʊ Å ä ǫ-4 ɖ ŋ ȟ 2 ƙ Å Ê ƙ ɿ ş å ā ä Ø ʌ :*Procedure ö ä Ä D Z q ä*

.TS (ȯ/ȟ420~) Õ ʌ ȯ ƶ Ÿ ŏ ş ǿ Æ Ł T ä Ř β ɖ ŋ Ŏ ŋ 55ş

:**TS6 (4-Dimethylaminobenzaldehyde)** Æ Ł Ł Æ ö ä Å ø ʌ ä ƶ Å Ł ŋ Ù Ŏ Ł ž Ł ŋ Ʊ Å ä ǫ-**4**

ȯ ƶ ǫ Å ž ʌ ǫ ä ɖ ŋ Ŏ ŋ 20 Ž R Æ Ł Ł Æ ö ä Å ø ʌ ä ƶ Å Ł ŋ Ù Ŏ Ł ž Ł ŋ Ʊ Å ä ǫ-4 ɖ ŋ ȟ 0.2 ā ä Ø ʌ :*Procedure ö ä Ä D Z q ä*
R ʅ Ʊ Å ö ä ȝ ŋ ȯ ƶ Ÿ ǂ ä ƺ Å ɿ Û TS (ȯ/ȟ420~) Õ ʌ ȯ ƶ Ÿ ŏ ş ǿ Æ Ł T ä Ř β ɖ ŋ Ŏ ŋ 0.5 ȣ Å Ê ʌ ş TS (ȯ/ȟ750~)
.VS (ȯ/ȯƶ ŋ 0.0001) ɖ ʌ å ƶ Ł ö ä ȯ ƶ Ÿ Ţ ɖ ŋ g Æ ì Ŏ ę Ù ä Ø Ł ø Å Ğ ǫ ȟ ɾ ä ȯ ƶ Ÿ Ţ ɿ ƶ ȯ ɿ ƶ Ò ʌ .Ğ ì Å ʌ ş
.Å D Z ȁ Å ù TS6 Æ Ł Ł Æ ö ä Å ø ʌ ä ƶ Å Ł ŋ Ù Ŏ Ł ž Ł ŋ Ʊ Å ä ǫ-4 Å Ê ƶ ɿ Ù Æ ƶ :*Ğ Ţ g Ɣ ŋ*

.$C_8H_{11}N$:**R (*N,N*-Dimethylaniline)** ƙŸĒqǰ ŌĒŽĒŋ Ʊəİİǫ-***N,N***

.ȡʌÂÁǫǒİǡ ǶǶǫİę ǴǶÔʌ ɟƶŸǒǎ CǴƷ ŌəİÈ :*Description Ƶȍƶǒǎ*

.R Ƙǫɟİş R ȳǒƶƶşǒƶŸȮǒǎş ÛTS (ȯ/ȟ750~) ȯƶǫİŽʌqİǡ ŽşÂŋ Ûǒİţİǡ ŽÂţǎ ǒØȞǫŋ ǶĒŸŧƷ :*Miscibility ǴĒDƶşÂţǎ*

.ǶǶʌÀŌǩ °ȳ 193 :*Boiling temperature ɟĀĒŸȢǒǎ ǴĒDƶǒǎ*

.ȯ/ŋõ 0.96= ρ_{20} :*Mass density ǴŸǫȮǒǎ ǴƶÂŽŏõ*

.C_2H_6OS :**R (Dimethyl sulfoxide)** ŌĒŽĒŋ Ʊəİİǫ ÆĒÊõƶİŸè

.ǴŦʌÀõ İŦŦȮǒ ÛǴİĒİn ǴHʊəǎǒ şǡ şǰ ǴHʊəǎÀǒǎ CǴƷ ÛɟƶŸǒǎ CǴƷ ŌəİÈ :*Description Ƶȍƶǒǎ*

.ȯ/ŋõ 1.10 = ρ_{20} :*Mass density ǴŸǫȮǒǎ ǴƶÂŽŏõ*

.(80 ǴHʊİÔǒǎ Û1963 ÛSRIP) $C_6H_4ClN_2O_4$:**R (2,4-Dinitrochlorobenzene)** ȡʌÂøʌİşǒƶŸõşÀǫĒǫ Ʊəİİǫ-**4,2**

.ǴĒǒşǡ ǴĒəİĒŧĒõ ǴĒȞDƶÀŋ gǡİŋ :**RS (Diphenoxylate hydrochloride)** ǧŸĒÊõƶĒƶ Ʊəİİǫ ÆʌǒƶŸõşǒÆĒŁ

:**TS (Diphenylamine/sulfuric acid)** ÕʌǒƶİŸÊǒǎ Ŕƥ/ƙŋŸĒĒƶ Ʊəİİǫ

.TS (ȯ/ȟ1760~) ÕʌǒƶİŸÊǒǎ Ŕƥ ȡŋ Ōŋ 100 Ž R ƙŋŸĒƶ Ʊəİİǫ ȡŋ ȟ 1.0 ǡǡØʌ :*Procedure ǒǎÄDƶqǡ*

ȡŋ ǶĒŧŢ ŞİƷ ɟǰş ÛɟƶŸǒǎ CǴƷ TS ÕʌǒƶİŸÊǒǎ Ŕƥ/ƙŋǰ ŌĒĒƶ Ʊəİİǫ ɟƶÔʌ ɟǰ Æz :*Storage ȡʌÂÁǫǒǎ*

.ǒƶŘǒǎ

.$C_{13}H_{14}N_4O$:**R (1.5-Diphenylcarbazide)** Æʌàİǡǒİõ ŌĒĒƶ Ʊəİİǫ-**5,1**

.ǒǎƶŦŸǒ ¢ŕÀĦǩ ÆĒƷ ƱŸİǫÀę ǰǰ ǶĒƶǒÆǩ ȯƶHʊǫʌ ÛŔĒǎǰ ƀǒƶŸǡ ȧƶHʊÊŋ :*Description Ƶȍƶǒǎ*

.ǶǶʌÀŌǩ °ȳ 174 :*Melting temperature ǒʌŦÔǫŕǡ ǴĒDƶǒǎ*

:**TS (Diphenylcarbazide)** Æʌàİǡǒİõ ŌĒĒƶ Ʊəİİǫ

ÕĒǫĒèɟǡ Ŕƥ ȡŋ Ōŋ 10 ȡŋ ǰʌÂŋ Ž R Æʌàİǡǒİõ ŌĒĒƶ Ʊəİİǫ-5,1 ȡŋ ȟ 0.2 ǡǡØʌ :*Procedure ǒǎÄDƶqǡ*

.TS (ȯ/ȟ710~) ȯƶǫİŽʌqǡ ȡŋ Ōŋ 90ş R ƱDƶŸŽǒǎ

ȳƶĒèİǩƶǴǒǎ ǧİŋşÀõ Ʊəİİǫ ȡŋ Ōŋ 0.5 ƶİƱ :*Sensitivity test to chromate ǧʌİŋşÀÔŸǒ ǴĒèİÊΣǡ ǒʌǴǫnǡ*

ȡŋ Ōŋ 0.2 ȢİŘʌ Ûǒİţİǡ Ōŋ 50 БǰŸȯƶŸǡǡ ǡØŁ ȡŋ Ōŋ 5 ƶİƱ .Ōŋ 1000 Бǰǒİţİǡ VS (ȯ/ȯƶŋ 0.0167)

.ÀŧŢ ƱDƶÊİǡǡ ɟƶǒ ǰǫʌ ÜTS Æʌàİǡǒİõ ŌĒĒƶ Ʊəİİǫ ȡŋ Ōŋ 0.5ş VS (ȯ/ȯƶŋ 2) ÕʌǒƶŸõşǒÆĒŦǡ Ŕƥ

ƨŸƷ ƀƶǫƷ R ȳƶʌǎƶÔǒǎ Ʊəİİǫ ǧİǫʌÆʌq ȯƶŸŢ :**TS (ȯ/ȟ20) (Disodium edetate)** ȳƶʌǎƶÔǒǎ Ʊəİİǫ ǧİǫʌÆʌÙ

.ÀǫŸǒǎ Ž $C_{10}H_{14}N_2Na_2O_8$ ȡŋ ȟ 20 ǴǡǡÀę

ƨŸƷ ƀƶǫƷ R ȳƶʌǎƶÔǒǎ Ʊəİİǫ ǧİǫʌÆʌq ȯƶŸŢ :**TS (ȯ/ȟ10) (Disodium edetate)** ȳƶʌǎƶÔǒǎ Ʊəİİǫ ǧİǫʌÆʌÙ

.ÀǫŸöä Ž $C_{10}H_{14}N_2Na_2O_8$ ȣǫ Ȟ 10 ǦääÀę

Бǔ ŏÅŧä Ž ā äØǩ ÛR ȳȚʌǎȚÔöä ƱəÅǪ ǧÅǫʌÆʌǔ :**VS** (ȯ/ȯȚǫ **0.01**) **(Disodium edetate)** ȳȚʌǎȚÔöä ƱəÅǪ ǧÅǫʌÆʌǔ

.Ōǫ 1000 Ž $C_{10}H_{14}N_2Na_2O_8$ ȣǫ Ȟ 3.342 ǫŸGʌ ʔȚǫŢ

ÛǦǦèÅǫ ǦÖʌÀù ţÅǦǩÅæ ȯȚŸHŧŸö îȚǦRŧä ÂÆõÀǫöä ȣǫ ǨǦǩöä ƁÀz :*Method of standardization gÄʌÁĤŧä ǦÖʌÄù*

.194 ǦHŧÁÔöä Û1 ÆŸǨä Ž VS (ȯ/ȯȚǫ 0.05) ȳȚʌǎȚÔöä ǧÅǫʌÆʌǔ ƱəÅǪ ȷäȚʌ3 ǨƠ ǦǩǦǫ ȣȚȯȚǫ ȚŁ Åŧõ

ǧÅÀèȚÀȯ ȯȚŸŢ :**TS** (ȯ/Ȟ**100**) **(Disodium hydrogen phosphate)** ȳȚʌǎȚÔöä ƱəÅǪ ǩDZŞǿÆÆŁ ǧÅÀèȚȚ

.ÀǫŸöä Ž Na_2HPO_4 ȣǫ Ȟ100 ǦääÀę ƁȚǫǮ R ȳȚʌǎȚÔöä ƱəÅǪ ǩDZŞǿÆÆŁ

ǧÅÀèȚÀȯ ȯȚŸŢ :**TS** (ȯ/Ȟ**28.4**) **(Disodium hydrogen phosphate)** ȳȚʌǎȚÔöä ƱəÅǪ ǩDZŞǿÆÆŁ ǧÅÀèȚȚ

.ÀǫŸöä Ž Na_2HPO_4 ȣǫ Ȟ 28.4 ʔŸȝ ƁȚǫǮ R ȳȚʌǎȚÔöä ƱəÅǪ ǩDZŞǿÆÆŁ

:**TS (Dithizone standard)** ƁóÅÆĤŧä ȷŞÂÆǨöä ƱəÅǪ

.R ȳǿȚŞǿȚŸÒöä ȣǫ Ōǫ 1000 Ž R ȷŞÂÆǨöä ƱəÅǪ ȣǫ ŋŸǫ 10 ā äØʌ :*Procedure öäÄDZqä*

Ž ŞÅǮŞ ÛöȚÊöä ȣǫ ʔŧǮŞ ÛǦÆDZÅDZà gääÆè ǧäæ î ÅòÀöä ȣǫ ǦÆöÅì gǿŞǿÅę Ž ȯȚŸŧä ȷÂƐ :*Storage ȣʌÂÁǫöä*

.°ȳ 4 àŞÅDzǫǩ ŗ gǿäÀǵ ǦDZǿäå

:**TS (Dithizone)** ȷŞÂÆǨöä ƱəÅǪ

ǨÅǫǫq TS (ȯ/Ȟ750~) ȯȚǫÅǨʌqä ȣǫ ǦÆȚÅõ ǦÆŧõ Ž R ȷŞÂÆǨöä ƱəÅǪ ȣǫ Ȟ 0.10 ā äØʌ :*Procedure öäÄDZqä*

.Ōǫ 100

.ǦÆöŞä ǦÆəÅÆŧÆõ ǦÆĤDZÀǫ gäÅǫ :**RS (Dopamine hydrochloride)** ǩnǫÅäŞÆöä ÆʌǿȚŸõŞǿÆÆŁ

.ǦÆöŞä ǦÆəÅÆŧÆõ ǦÆĤDZÀǫ gäÅǫ :**RS (Doxorubicin hydrochloride)** ǩÊÆäŞǿȚÊõŞÆöä ÆʌǿȚŸõŞǿÆÆŁ

.ǦÆöŞä ǦÆəÅÆŧÆõ ǦÆĤDZÀǫ gäÅǫ :**RS (Emetine hydrochloride)** ǩǫÆǫqä ÆʌǿȚŸõŞǿÆÆŁ

.$C_{20}H_6Br_4N_2O_5$ ÜȳȚʌǎȚÔöä ǩÊʌǿȚŸȚ ȚǫŞÀæ Ƴ3ÅäǿÅ :**R (Eosin Y) Y** ȣʌÀȚʌqä

.ȧȚŧÊǫ ŞǔÅ ƱøʌǦöä Бǔ ǦäǿÅì ŕ öäÀþ Ōǫõ :*Description ȚòȚöä*

.TS (ȯ/Ȟ750~) ȯȚǫÅǨʌqä Ž ȷÅäŞǿöä ÔÆŸę ÜöÅŧä Ž ȷÅäŞǿöä Àǵ :*Solubility ǦÆǫÅäŞǿöä*

.ÀǫŸöä Ž $C_{20}H_6Br_4Na_2O_5$ ȣǫ Ȟ 5 ǦääÀę ʔŸȝ ƁȚǫǮ Y ȣʌÀȚʌRö ȯȚŸŢ :**TS** (ȯ/Ȟ**5**) **(Eoson Y) Y** ȣʌÀȚʌqä

.ǦÆöŞä ǦÆəÅÆŧÆõ ǦÆĤDZÀǫ gäÅǫ :**RS (Ergocalciferol)** ȯŞÀÅÆÊöÅõȚǫÀʌqä

ȣǫ ǦäȚǫŢ ÔÔʌ ŗ .$C_{28}H_{44}O$ Üergosta-5,7,22-trien-3-ol ;D_2 ǩnǫÅǫÆȚ ǦHÆŸù :**R (Ergosterol)** ȯŞǩǫÈȚǫÀʌqä

.%95.0 ȣȝ $C_{28}H_{44}O$

.Ƀóząŷä ȧząHȣÊŋ ąŷ ňǦǺÀÕǩ ŏǺŘȣä ąŷ ŏǺŘȣä Àäŷŷ :*Description Ząȍząŷä*

.ňǦǺÀÕǩ ◦ȳ 163 ǦääÀę :*Melting temperature ȱǺŤÔȱȣŕä ǦDZȱȱǻ*

ȳȱząąȱząȱÒȱä Ž Ōŋ/ŋŷŋ 20 ȱząŷŤ ŌŧŎȱÊǺ :*Specific optical rotation Ȣȣząȱä ƀǺÔǦȱä ǺǺąÁȱȱä*

.$[a]_D^{20C^\circ} = -133^\circ$ ÜR

.Ǧȣȱąǻǻ ǦȣəǺȣŧȣõ ǦȣŎHDZÀŋ ǻǻǺŋ :**RS (Erythromycin)** ǩÊǺǺŋąÀŽǺȱǫąä

.Ǧȣȱąǻǻ ǦȣəǺȣŧȣõ ǦȣŎHDZÀŋ ǻǻǺŋ :**RS (Erythromycin ethylsuccinate)** ǩÊǺǺŋąÀŽǺȱǰä ǧǺǺȣÊõząè ŌȣŽǺÙ

.Ǧȣȱąǻǻ ǦȣəǺȣŧȣõ ǦȣŎHDZÀŋ ǻǻǺŋ :**RS (Erythromycin stearate)** ǩÊǺǺŋąÀäȱǫąä ǧäȱǺȣQè

.Ǧȣȱąǻǻ ǦȣəǺȣŧȣõ ǦȣŎHDZÀŋ ǻǻǺŋ :**RS (Ethionamide)** ÆȣŋǺȱząȣŽǺąä

.$C_3H_8O_2$ Üȱząȱ ŽǺÙ ȢÊõząŽȣŋ-2 :**R (Ethylene glycol monomethyl ether)** ǩŷŽǺąä ŌȣÊȣŷd ŌȣŽȣŋ Æȣǻąŷ ǩąÙ

.ząŷȱä CÁȣ ŌəǺè :*Description Ząȍząŷä*

.◦ȳ 125 :*Boiling temperature JǺȣŷ8ȱä ǻȱäÁǻ ǦDZȱȱǻ*

.ňǦǺÀÕǩ ρ_{20} = ȱ/ŋõ 0.96 :*Mass density ǦŷąÓȱä ǦząǺŽõ*

:**VS (ȱ/ȱząŋ 0.1) (Ferric ammonium sulfate)** ÕǺÁǺÁΣä ȳząąząŋÙ ǧǺǺŷè

ŋŷǦǺ ąząąŤ ƀÙ ŏǺŧäąŷ TS (ȱ/ň 1760~) ÕǺȱząŷÊȱä Ŕβ ȱŋ ǰǺŋ Ž ãäØǺ ÙÕǺÁǺÁΣä ȳząąząŋÙ ǧǺǺŷè

.Ōŋ 1000 Ž $FeNH_4(SO_4)_2,12H_2O$ ȱŋ 48.22

Ŕβ ȱŋ Ōŋ 6 ŷ ŏǺŋ Ōŋ 300 ȱŋ ǰǺŋ Ž R ÕǺÁǺÁΣä ȳząąząŋÙ ǧǺǺŷè ȱŋ ň50 ãäØǺ :*Procedure ȱäǻDZąä*

.Ōŋ 1000 ǯǺąąq ŏǺŧä ȱŋ ǦząǺõ ǦȣŧÒä ȱząŷ‡ä ZǺƆ .TS (ȱ/ň1760~) ÕǺȱząŷÊȱä

ãząŷèǰǺä ȱ/ȱząŋ 0.1 ȱząŷ‡ îząŘŧä ǺȣõÀąȱä ȱŋ Řąǯąȱä ƀÀz :*Method of standardization gǺǺǺňŧä ǦÕǺǺÙ*

ÕǺȱząŷõŷąØÁȣŤä Ŕβ ȱŋ Ōŋ 3 ȢǺŘǺŷ gääÁè ǧäæ ǦȣDZǺDZà ǦŷDZząǵ ƀÙ Ōŋ 25 ŌÕǺ :ƀǺąȱä

ȳząǺząÔȱä ǧǺǺŷèząŽȣ ÀǺǺňǺŷ ĘəǺęä 10 gÁŋ ÀÕąÊȣȱ ȱząŷ‡ä ÕÀąǺ .R ȳząŷèǺňząǦȱä ÁǺäząÙ ȱŋ ň 2ŷ (ȱ/ň420~)

.ǦǺąŷÀŕ ǧǺHȣHȣÔǩ ǦǺÙ ąÀDzŧŷ ÛÁŧǺÎȱä gÀǺǺňŋ ÂDzǺǩ .ÀňÎŧõ ǺÎǺȱä ȳÁÁąÊǺ ÛVS (ȱ/ȱząŋ 0.1)

.ǩząŘȱä ȱŋ ąŧHł ǰÙ ÁzŷŷÛȳǺÒgȣä ǦÕŷ8ŋ ǦǺŷǺg Ž ȱząŷ‡ä ǰÂƆ :*Storage ȱǺÂÁąȱä*

Ž $FeCl_3$ ȱŋ ňǦǺÀÕǩ ň 65 ąŷ3 ƀząƷ ÕǺǦǺȱä ÁǺȱząŷõ ȱząŷŤ :**TS (ȱ/ň 65) (Ferric chloride** ÕǺǦǺȱä ÁǺȱząŷõ

.ÀąŷȱäÄ

$FeCl_3$ ȱŋ ňǦǺÀÕǩ ň 50 ąŷ3 ƀząƷ ÕǺǦǺȱä ÁǺȱząŷÒȱ ȱząŷŤ :**TS (ȱ/ň50) (Ferric chloride)** ÕǺǦǺȱä ÁǺȱząŷõ

.ÀąŷȱäÄ Ž

:TS (Ferric chloride/ferricyanide/arsenite) Ǩ**:**ÈóÜ/**:**Ę**:**È ƀǩ/Ȭǩǩ**:**ôâ **:**ǽǩÕõ

:ǦÔ**:**ǩ Ō**:**ôǦ Ǧ¥ǫ ǦÊǩ :*Procedure ôâÄDZqâ*

.TS (ȯ/ȟ70~) Ȭǽǩõşǽ**:**Ťâ Ȑ ƥ ďǩ Ō̄ǩ 100 Ž R Ȭǩǩôâ **:**ǽǩõ ďǩ ȟ 2.7 ā âØǩ (1)

.ÄDZǦǦù ȯǩ¥ǩâ âØǩ ǩÊǩ Æǩ .ôǦǩ Ō̄ǩ 100 Ž R ȳǩ**:**ÈǦǩôâ **:**Ę**:**È ƀǩ ďǩ ȟ 3.5 ā âØǩ (2)

.TS (ȯ/ȟ80~) ďǩÊǩâ ȳǩǩǩÔôâ **:**Ę**:**Êõşǽ**:**Ę ďǩ Ō̄ǩ 25 Ž R Ȭ**:**È**:**ôǩâ **:**Ę**:**ÊȭÜ ǦǩǦǩ ďǩ ȟ 3.8 ā âØǩ (3)

.ôǦǩǦ Ō̄ǩ 100 Ƀ̄Ü ǩǦ Ş Ûts (ȯ/ȟ100~) Ȭǽǩ**:**ŸÊôâ Ȑ ƥ ďǩ Ō̄ǩ 50 Ø**:**Ê**:**ǩ Ûâ**:**Ę**:**ôõ ôǦǩ

.(3) ȯǩ¥ǩâ ďǩ Ǽǩâş ǩDzǩş (2) ȯǩ¥ǩâ ďǩ ȳǩDzǩ 5ş (1) ȯǩ¥ǩâ ďǩ ȳǩDzǩ 5 ǩÂǩ ȳâǽÁǩè**:**âŌǩ gǦ**:**ǩǩ

:TS (Ferric chloride/potassium ferricyanide) ȳǩ**:**ÈǦǩôâ **:**Ę**:**È ƀǩ/Ȭǩǩôâ **:**ǽǩõ

ǦǩǦõ ǦǩǦõ Ž R ȳǩ**:**ÈǦǩôâ **:**Ę**:**È ƀǩ ďǩ ȟ 0.10ş R Ȭǩǩôâ **:**ǽǩõ ďǩ ȟ 2 ā âØǩ :*Procedure ôâÄDZqâ*

.Ō̄ǩ 20 ǩ**:**ǩǩq ôǦǩâ ďǩ

.ÄDZǦǦù ts ȳǩ**:**ÈǦǩôâ **:**Ę**:**È ƀǩ/Ȭǩǩôâ **:**ǽǩõ ǩÊǩ Æǩ :*ǦǩǦǩ*

:TS (Ō̄ǩ/ȳâÄǩşÄÔǩ 50) (Ferricyanide standard) ƀǩ**:**ÊǦǩâ **:**Ę**:**È ƀǩǩôâ

Ž $K_3Fe(CN)_6$ ďǩ ȟ 7.8 ǩ¥ǩ ƀǩǩş ôǦǩâ Ž R ȳǩ**:**ÈǦǩôâ **:**Ę**:**È ƀǩ ȯǩ¥ǩ Ǧ**:**ǩ Ǩ**:**ǩ :*Procedure ôâÄDZqâ*

.Ō̄ǩ 1000 ǩ**:**ǩǩq ôǦǩâ ďǩ Ǧ**:**ǩǦõ Ǧ**:**ǩÔâ ȯǩ¥ǩâ âØǩ ďǩ Ō̄ǩ 1.0 ǩÂǩ .Ō̄ǩ 100

.ÄDZǦǦù (Ō̄ǩ/ȳâÄǩşÄÔǩ 50) ƀǩ**:**ÊǦǩâ **:**Ę**:**È ƀǩǩôâ ǩÊǩ Æǩ :*ǦǩǦǩ*

:TS (Ō̄ǩ/ȳâÄǩşÄÔǩ 100) (Ferrocyanide standard) ƀǩ**:**ÊǦǩâ **:**Ę**:**È ǩşǩǩôâ

$K_4Fe(CN)_6,3H_2O$ ďǩ ȟ 2.0 ǩ¥ǩ ƀǩǩş ôǦǩâ Ž R ȳǩ**:**ÈǦǩôâ **:**Ę**:**È ǩşǩǩ ȯǩ¥ǩ Ǧ**:**ǩ Ǩ**:**ǩ :*Procedure ôâÄDZqâ*

.Ō̄ǩ 100.0 ǩ**:**ǩǩq ôǦǩâ ďǩ Ǧ**:**ǩǦõ Ǧ**:**ǩÔâ ȯǩ¥ǩâ âØǩ ďǩ Ō̄ǩ 1.0 ǩÂǩ .Ō̄ǩ 100 Ž

.ÄDZǦǦù (Ō̄ǩ/ȳâÄǩşÄÔǩ 100) ƀǩ**:**ÊǦǩâ **:**Ę**:**È ǩşǩǩôâ ǩÊǩ Æǩ :*ǦǩǦǩ*

.Ǧ**:**ôşǩ Ǧ**:**ÊǦDZÄǩ Ǧ**:**ôǦǩ**:**Ę**:**Êõ ǩǩǩ :**RS (Flucytosine)** ďǩǦǩ**:**Ę**:**È ǩ¥ôâ

.Ǧ**:**ôşǩ Ǧ**:**ÊǦDZÄǩ Ǧ**:**ôǦǩ**:**Ę**:**Êõ ǩǩǩ :**RS (Fludrocortisone acetate)** ǩşÂǩǩõşǩǩǩ¥ôâ ǩǩ**:**È**:**È

.Ǧ**:**ôşǩ Ǧ**:**ÊǦDZÄǩ Ǧ**:**ôǦǩ**:**Ę**:**Êõ ǩǩǩ :**RS (Fluorouracil)** Ō̄**:**È**:**âǩǩǩşǩǩ¥ǩ

.Ǧ**:**ôşǩ Ǧ**:**ÊǦDZÄǩ Ǧ**:**ôǦǩ**:**Ę**:**Êõ ǩǩǩ :**SV RS (3-Formylrifamycin)** ǩÊ**:**ǦǩǦǩǩÄǩ Ō̄**:**ǩǩǩ**-3**

:TS (Fuchsin,decolorized) ǩǩ¥ôâ ôâÂǩ ÛǩÊõǩÄôâ

Ø**:**Ê**:**ǩ ÜÆ**:**ǩDZ ȳÄǩ Ž ǩ**:**ǩ**:**ş ôǦǩâ ďǩ Ō̄ǩ 600 Ž basic Ü**:**È**:**È ǩÊõǩÄôâ ďǩ ȟ 1 ā âØǩ :*Procedure ôâÄDZqâ*

ÛÄ**:**ǩÊǩâ ȬǩÄHǩôâ Ǩǩ Ûôǩ**:**Ü Ø**:**Ê**:**ǩş ÆǩDZ ȳÄǩ Ž ǩ**:**ǩ Üôǩǩ Ō̄ǩ 100 Ž Ǧôǩǩǩǩ R ȳǩǩǩôâ ǩ**:**È ȟ 20

ãæÛ ǰkÅÅõã ȯzŸǂã ǴŒìÀǩ Æȥ .Ō̄ǫ 1000 БÛ õÅţÅæ ZÅƩ ÜTS (ȯ/ȟ250~) Ō̄ǫózŸõşóÆŒTã Ȑþ ȯbǫ Ō̄ǫ 10 ÛɿzŸõã CǴȝ ǎzȞǩ ɔøǫǵ (ȟ 0.3-0.2) R ǰHuÅõã ȯbǫ ǴŒzÅȭ ǴŒţȭ ȝǫ ¢ǫZǵ Æȥ ÛŪŒÅæ ¢ǫzȯ ɿÅȭ ãæÛş ÛŪÀÒȝ ɿÅȭ ÛTS (ȯ/ȟ250~) Ō̄ǫózŸõşóÆŒTã Ȑþ ȯbǫ Ō̄ǫ 3-2 ǴzÅȑÛ ÛŪǫÅŒǵÛ ƀóşÀŘõã ȯbǫ ɿzȮǩ Æę .gÀȑÅǴǫ ǴǫÀǩ Ż ǴÕæÅÊõã ǧYǩÆȞǫõã ȯbǫ ƀÛ ȯbȝ ǰkÅÅõã ȯzŸǂã õÀǩ Æȥ .ÆŁÅÎõã ɿzȯ ȯbǫ ƀŪǴǫţã ŌŒŸŌõã Ǵõãàq ÛǫǦÀõã Ō̄õæ ȝǴǫǩ .ǒzŘõã ȯbǫ ɔţȝ ɿÛ Æȥ TS ɿzŸõã ȯãÂǫ ǩÊȭzÅõã .ÿãÆÁǫèɾã ŌǴę ŌŒŸõã ȯãzù ÀŌǫÊŒõ

.ǴŒõşå ǴŒȞDZÀǫ ǴŒəÅŒţŒȭ gåÅǫ :**RS (Gallamine triethiodide)** ǩǫY8õã ÆǩåzŒǦǩÛ ƀǫYǫ

.ǴŒõşå ǴŒȞDZÀǫ ǴŒəÅŒţŒȭ gåÅǫ :**RS (Gentamicin sulfate)** ǩÊŒǫÅǫÆɔã ǧÅÅŸè

.ǴŒõşå ǴŒȞDZÀǫ ǴŒəÅŒţŒȭ gåÅǫ :**RS (Glibenclamide)** ÆŒǫYȮÆǴŒŸ8õã

.$C_6H_{12}O_6$:**R (Glucose,anhydrous)** ƀəÅǫYõã ÛàzõzŸ8õã

.150 ǴHuÅÔõã 2 ÆŸŎã Ž gåşÀzɟã Ž ȣzòzǫ zŁ Åţȭ ƀəÅǫYõã àzõzŸ8õã ȳÆÁǫÊǩ

.(94 ǴHuÅÔõã Û1963 ÛSRIP) C_7H_{16} :**R (Heptane)** ɿÅǫǴŒTã

.$C_6H_{19}NSi_2$:**R (Hexamethyldisilazane)** ɿãàYŒè ƀəÅǫ ŌŒǦŒǫ ƀèãÆè

.gÂŒư ǴHuæãø ¢ō ÛɿzŸõã CǴȝ Ûȣ̄Åò ŌəÅè :*Description Zòzõã*

.ρ_{20} = ȯ/ǫȭ 0.77 :*Mass density ǴŸǫȮõã ǴzÅǰȭ*

.$(NH_4)_2,H_2SO_4$:**R (Hydrazine sulfate)** ƀǩàãøÆŒTã ǧÅÅŸè

.ȐŒæÛ ƀózŸæ ȧzHuÊǫ ǫÛ .ɿzŸõã ǴɛÆȝ ǧãózŸæ :*Description Zòzõã*

.TS (ȯ/ȟ750~) ȯzǫÅǦǩqã Ž ŒŸţȝ ǴæãşÆ Kǫ ÜŪǴǩÀÕǩ õÅţã ȯbǫ ãõÂDZ 40 Ž ¢æãşÆ :*Solubility ǴǫÅæşØõã*

øÅǴǫnɾã" ɿãzÅȝ ǨƠ ȣzòzǫ zŁ Åţȭ ȝæÅǫǩş ƀŸȣţã õÅţã ȯbǫ Ō̄ǫ 35 Ž ȟ 10 ȯzŸ̄ ȳÆÁǫÊǩ :*Arsenic ŃŒǫøÂõã*

.ȟ/ȳãÅdşÀȮǫ 1 ȯbȝ ÆǩÂǩ ɾ Ü(130 ǴHuÅÔõã Û1 ÆŸŎã) "Limit test for arsenic ŃŒǫøÂõã ŌDZɟ ƀÆΣã

.ȟ/ǫŸǫ 1.0 ȯbȝ ÆǩÂǩ ɾ :*Sulfated ash ǨÅŸÊţã åÅǫÅõã*

ÛõÅţã Ž TS (ȯ/ȟ420~) Ō̄ǫózŸõşóÆŒTã Ȑþ :**TS (ȯ/ȟ330~) (Hydrochloric acid)** Ō̄ǫózŸõşóÆŒTã Ȑþ

.(ȯ/ȯzǫ 9 ǴæãÀę) *d*~1.15 ÜÀǫŸõã Ž HCl ȯbǫ ȟ 330 ǴæãÀę ƀzȝ

ÛTS (ȯ/ȟ250~) Ō̄ǫózŸõşóÆŒTã Ȑþ :**vs (ȯ/ȯzǫ 0.05) (Hydrochloric acid)** Ō̄ǫózŸõşóÆŒTã Ȑþ

.Ō̄ǫ 1000 Ž HCl ȯbǫ ȟ 1.824 ǴzǫŸ̄ ɔøǫǵ õÅţÅæ ZÅƯ

Ǵzzòzţã ǴÕǩÀÛõã ţÅǴǩÅæ ȯzŸHuţŸõ îzǫŘţã ÅŒõÀǫõã ȯbǫ ǨǦǫõã ƀÀz :*Method of standardization gÅÅŸÊţã ǴÕǩÅÀü*

.200 ǴHuÅÔõã Û1 ÆŸŎã ÛVS (ȯ/ȯzǫ 1) Ō̄ǫózŸõşóÆŒTã Ȑþ ɿãzÅȝ ǨƠ

ÛTS (ȯ/ȟ250~) ȬȯźŸõşȯÄÉŁŤã Ȑƥ :vs (ȯ/ȯźŋ **0.005) (Hydrochloric acid)** ȬȯźŸõşȯÄÉŁŤã Ȑƥ
.Ō̄ŋ 1000 Ž HCl ȟ 0.1824 ʔźŲŢ Ƃŭ ŏÅţÅæ ŹÅƹ
Ǧźźȯźţã ǦȬȯÀÀÛõã ţÅǦkÅæ ȯźŸHȥŧŸõ ŕźǦŘţã ÂŁȭÀǫõÃ ȯŋ Ǩ̄ŽǫõÃ ƂÀz :*Method of standardization gÄÀÁĤţã ǦȬȯÄÀü*
.200 ǦHȥÅÔõã Û1 ÁŸŎã ÛVS (ȯ/ȯźŋ 1) ȬȯźŸõşȯÄÉŁŤã Ȑƥ ȷãźÅ3 ǨƠ
ŹÅƹ Û(ȯ/ȟ250~) ȬȯźŸõşȯÄÉŁŤã Ȑƥ :vs (ȯ/ȯźŋ **0.0001) (Hydrochloric acid)** ȬȯźŸõşȯÄÉŁŤã Ȑƥ
.Ō̄ŋ 1000 Ž HCl ȯŋ ŋŸŋ 3.647 ʔźŲŢ Ƃŭ ŏÅţÅæ
Ǧźźȯźţã ǦȬȯÀÀÛõã ţÅǦkÅæ ȯźŸHȥŧŸõ ŕźǦŘţã ÂŁȭÀǫõÃ Ǩ̄ŽǫõÃ ƂÀz :*Method of standardization gÄÀÁĤţã ǦȬȯÄÀü*
.200 ǦHȥÅÔõã Û1 ÁŸŎã ÛVS (ȯ/ȯźŋ 1) ȬȯźŸõşȯÄÉŁŤã Ȑƥ ȷãźÅ3 ǨƠ
ȬȯźŸõşȯÄÉŁŤã Ȑƥ :vs (ȯ/ȯźŋ **0.01) (Hydrochloric acid/methanol)** ȯźǫÅŽŁţã/ȬȯźŸõşȯÄÉŁŤã Ȑƥ
.ȯźǫÅŽŁţã ȯŋ Ō̄ŋ 1000 Ž HCl ȯŋ ȟ 0.3647 ʔźŲŢ Ƃŭ ȯźǫÅŽŁţÅæ ŹÅƯ ÛTS (ȯ/ȟ250~)
Ǧźźȯźţã ǦȬȯÀÀÛõã ţÅǦkÅæ ȯźŸHȥŧŸõ ŕźǦŘţã ÂŁȭÀǫõÃ ȯŋ Ǩ̄ŽǫõÃ ƂÀz :*Method of standardization gÄÀÁĤţã ǦȬȯÄÀü*
.200 ǦHȥÅÔõã Û1 ÁŸŎã ÛVS (ȯ/ȯźŋ 1) ȬȯźŸõşȯÄÉŁŤã Ȑƥ ȷãźÅ3 ǨƠ
.ǦŁõşå ǦŁaÅŁŧŁȭ ǦŁĤDZÀŋ gåÅŋ :**RS (Hydrocotisone sodium succinate)** ȷşÂŁkźźõşȯÄÉŁŤã ȳźȯÅźźȯ ǧÅÄŁÊõźè
.$C_6H_4(OH)_2$:**R (Hydroquinone)** ȷźÄŁȭşȯÄÉŁŤã
.ƂźźŸã ȧźHȥÊŋ şŭ ÀǦȯÀÀȬk ȷźŸõã ǦŁÄ3 şŭ ȷźŸõã ǦŁÄ3 ǧãźźŸã :*Description Źȯźõã*
.R Ǩǫȷãş TS (ȯ/ȟ750~) ȯźǫÅŽȯqãş ŏÅţã Ž ããşä :*Solubility ǦŁǫÅãşØõã*
.ÀǦȯÀÀȬk °ȳ 173 :*Melting temperature ØÅŤÔǫŕã* ǦDźØåÅ
.ŏźŘõãş ŏãźŤŸõ ¢ŕÀĤǫã ȷźÄŁȭşȯÄÉŁŤã ȷźõ ȷǫȬȮ :*ǦŢǧŸŋ*
:**TS (ȯ/ȟ200) (Hydroxylamine hydrochloride)** ǩŋŕ ŬÊȭşȯÄÉŁŤã ÄȯźŸõşȯÄÉŁŁ
.ÀǫŸõã Ž NH_2OH,HCl ȯŋ ȟ200 ǦããÀę Ƃźź R ǩŋŕ ŬÊȭşȯÄÉŁŤã ÄȯźŸõşȯÄÉŁŁ ȯźŸŢ
:**RS** ǩǫŕŭ Ō̄ŁŽŁŋ**-2-**źÄȯããøÄÉŁŁ**-2-(**Ō̄ŁÄÉź ŬÊõźŽŁŋ**-3-**ŬÊȭşȯÄÉŁŁ**-4)-3-(-)**
.ǦŁõşå ǦŁaÅŁŧŁȭ ǦŁĤDZÀŋ gåÅŋ :**TS** Û**(-)-3-(4-Hydroxy-3-methoxyphenyl)-2-hydrazino-2-methylalanine**
.10,11-Dihydro-5*H*-dibenz[*b.f*]azepine; $C_{14}H_{13}N$:**R (Iminodibenzyl)** Ō̄ȯÂøÅæ ŬəÅÅǫ źÄŁƹŭ
.ÆǧÅì ÀÅòŭ ƂźźŸã ȧźHȥÊŋ :*Description Źȯźõã*
.ÀǦȯÀÀȬk °ȳ 106 :*Melting temperature ØÅŤÔǫŕã ǦDźØåÅ*
ŏÅŁÅæ ÀȯÄÉȬk ǦŁǫk ŬøǫõÃ ȷźŸõã ǧãÀĤÎŋ ȯŋ ÆèÅȯŋ ǰȯÂŋ ȝŋ ȧøş :**R (pH-Indicator paper)** ŏÅŁÅǦõã ÀĤÎŋ ȧøş

.10-1 Ƀắ̈ ŏȉŁȁ̈ ȯȉƒ Ž (ǵắȉ3 ǵÉǵȁ̈ş ŏȉŁȁ̈ ǵÉǵş) ĞŁzȉõ ĞŁèȉÊǵ 3ŋ ȷzŸȍȁ ğ ɤÉĞk ȯŸȎ ȍŋ ȯzŸ‡ȁ̈

:**TS (Iodine/chloroform)** ȳȍzzşȍzŸȮȍȁ̈ /ắzŁȍȁ̈

.Ȍŋ 100 ȝȉQφq R ȳȍzzşȍzŸȮȍȁ̈ ȍŋ ĞŁzȉõ ĞŁŧõ Ž ắz Ȟ 5.0 ā ȁ̈Øȍȍȍ

:R (Lead acetate paper) ĩ ĺòÀõã ğĺǫŒèŬ ȧóş

TS (ȯ/ȟ80) ĩ ĺòÀõã ğĺǫŒèŬ ďŋ ȳɀDzǵ 10 ďŋ ǰĺÂŋ Ž ŏĺŘŒã ǴÌÀŋ Ǧęóş ÈÛ8ǩ :*Procedure ŏãĂDZqã*

.Ļŋ 40 × Ļŋ 15 ÈŒÕǩ ǦùÀÌŬ Ž ȧóɀõã ƷÛÕΛş ZDzǫõ õÀǫǩ .(ȯ/ȟ60~) ÕŒǫŒèɟã Ŕþ ďŋ Ǽǵĺş ĻDzǵş

.ŒÁŒDZ ǦÕŸ8ŋ ǦΛşĺǵ Ž ĩ ĺòÀõã ğĺǫŒèŬ ȧóş ŞĺÁƷ ɟŬ Æȥ :*Storage ďΛÂĂǫõã*

$Pb(NO_3)_2$ ďŋ ȟ 100 ɔŸƷ ƀɀǫƷ R ĩ ĺòÀõã ğãÀǫÁõ ȯɀŸŢ :**TS (ȯ/ȟ100)** **(Lead nitrate)** ĩ ĺòÀõã ğãÀǫǫ

.ÀǫŸõã Ž

.(105 ǦHƱÁÔõã Ů1963 ŮSRIP) PbO_2 **:R (Lead (IV) oxide) (IV)** ĩ ĺòÀõã ÁŒÊõşŬ

.ǦŒõşå ǦŒƱĺŒŒõ ǦŒĤDZÀŋ gåĺŋ **:RS (Levonorgestrel)** ÕΛÀǫÊŒDZóɀǫɀĺŒŸõã

.ǦŒõşå ǦŒƱĺŒŒõ ǦŒĤDZÀŋ gåĺŋ **:RS (Levothyroxine sodium)** ǩÊõşǩǫɀĺŒŸõã ȳɀΛåɀò

.ǦŒõşå ǦŒƱĺŒŒõ ǦŒĤDZÀŋ gåĺŋ **:RS (Liothyronine)** ǩǫşǩǫɀŒŸõã

.Li_2CO_3 **:R (Lithium carbonate)** ȳɀŒƷŒŸõã ğĺǫɀãÀõ

.ǦHƱƱãÀõã CÁƷ ÜŘŒãŬ ÆǦŢ ȧɀHƱÊŋ :*Description Ƶòɀõã*

.TS (ȯ/ȟ750~) ȯɀǫĺƷΛqã Ž ŒÁŒDZ ɟĺãşØõã ǴŒHƱì ÜŏĺŢã Ž ɟĺãşØõã ÕŒŸę :*Solubility ǦŒǫĺãşØõã*

:TS (Lithium carbonate/trinitrophenol) ȯɀĺŒɀşÀǫŒǫ ƱǫŸǫ/ȳɀŒƷŒŸõã ğĺǫɀãÀõ

ďŋ ǦŒɀĺõ ǦŒƱõ Ž R ȯɀĺŒɀşÀǫŒǫ ƱǫŸǫ ďŋ ȟ 0.5ş R ȳɀŒƷŒŸõã ğĺǫɀãÀõ ďŋ ȟ 0.25 ããØΛ :*Procedure ŏãĂDZqã*

.Õŋ 100 ƷĺÀǫǫq ŏĺŢã

.LiCl **:R (Lithium chloride)** ȳɀŒƷŒŸõã ÁΛóɀŸõ

.ŏĺŘŒã ÛǦƷɀŒŋ ğãóɀŸãşŬ ğĺǦŒǦǵ :*Description Ƶòɀõã*

.R Ǩǫɟãş ÛTS (ȯ/ȟ750~) ȯɀǫĺƷΛqã ÛR ɟɀǫŒèɟã Ž ããşã ÜŏĺŢã Ž ɟĺãşØõã Àǵ :*Solubility ǦŒǫĺãşØõã*

.ȳĺÒǵüã ǦÕŸ8ŋ ǦΛşĺǵ Ž ɟĺƧ :*Storage ďΛÂĂǫõã*

Ž LiCl ďŋ ȟ 10 ǦããÀę ɔŸƷ ƀɀǫƷ ȳɀŒƷŒŸõã ÁΛóɀŸÒõ ȯɀŸŢ :**TS (ȯ/ȟ10)** **(Lithium chloride)** ȳɀŒƷŒŸõã ÁΛóɀŸõ

.ÀǫŸõã

.ǦŒõşå ǦŒƱĺŒŒõ ǦŒĤDZÀŋ gåĺŋ **:RS (Loperamide hydrochloride)** ÁŒŋãǩãɀŸõã ÁΛóɀŸõşøÁŒŒŁ

:R (Macrogol 1000) 1000 ȯɀďşÀõĺŢã

.ŏĺŘŒã ǦŒĤƽ ǦŸǫõ :*Description Ƶòɀõã*

.Ļŋ 17.3 m m^2s^{-1} ǦããÀę Ů°ȳ 100 ǦDZóÁõã Ž :*Viscosity ǦDZşÂŸõã*

p-tert- ÛC$_{34}$H$_{62}$O$_{11}$:**R (Macrogol *p*-isooctylphenyl ether)** ȯƶḍşÀõÅţã ÕEAEƶ ÕEǫõÛşÂÀÛ-***P*** ƙǫÛ
.octylphenoxy polyethoxy-ethanol
."Sterility testing of anibiotics ǦƵƶEΣã ğãǎÅÊŘţã ǦnǫÅÕȝ øÅǦǫòã" ÕDƶɟ ǦŧƵŶŋ ǦDƶóǎ ȳÉǍǫÊǩ
.$C_4H_6MgO_4,4H_2O$:**R (Magnesium acetate)** ȳƶÀhu8ţã ğÅǫEèÛ
.ǦȝƶEŋ ÛɟƶŸõã ǦƷÉȝ ğãózŸã :*Description Ƶȯƶõã*
.TS (ȯ/ȟ750~) ȯƶφÅžÀqãş ÛŏÅţã Ž ɟÅãşØõã Àǵ :*Solubility ǦEφÅãşØõã*
.(110 ǦHƵÅÔõã Û1963 ÛSRIP) $MgCl_2,6H_2O$:**R (Magnesium chloride)** ȳƶÀhu8ţã ÉÀóƶŸõ
:**VS (ȯ/ȯƶŋ 0.1) (Magnesium chloride)** ȳƶÀÂEA8ţã ÉÀóƶŸõ
.Õŋ 1000 ȝÅǫφq ŏÅţã dŋ ǦEƶÅõ ǦEŧõ Ž R ȳƶÀhu8ţã ÉÀóƶŸõ dŋ ȟ20.5 ããØÀ :*Procedure ŏãÄDƶqã*
gÀÀÅȟţÅã Ûȯ/ȯƶŋ 0.1 ȯƶŸǂ ŕƶǦŘţã ÂEõÀǫõã dŋ ǨǦǫõã ÐÀƶ :*Method of standardization gÄÀÅȟţã ǦÕÀÄü*
Õŋ Ágãş Õõ .ȳƶÀhu8ţã ÉÀóƶŸõ ȯƶŸŢ dŋ Õŋ 25 ȳãÉǍǫèÅã (135 ǦHƵÅÔõã Û1 ÉŸŎã) ȳƶÀhu8ŧŸõ ğãÉÕȟţã âÅEõŋ
.$MgCl_2,6H_2O$ dŋ ŋŸŋ 20.33 ùƶÅȯÀ VS (ȯ/ȯƶŋ 0.1) ȳƶÀǎƶÔõã ğÅǫÀÉÀÛ dŋ
:**TS (Mg Õŋ/ŋŸŋ 0.1) (Magnesium)** ȳƶÀhu8ţã
ÕÀóƶÅŸÊõã Ŕþ dŋ Õŋ 5 ȣÅŘÀ ÛŏÅţÅã R ȳƶÀhu8ţã ğÅÅŸè dŋ ȟ 1.014 ããØÀ :*Procedure ŏãÄDƶqã*
.ŏÅţÅã Õŋ 1000 БÛ ƶÅƷş TS (ȯ/ȟ100~)
:**TS (Mg Õŋ/ȳãÀdşÀȯŋ 10) (Magnesium standard)** ÐóÅEȟţã ȳƶÀhu8ţã
.Õŋ 100 ȝÅǫφq ŏÅţã dŋ ǦEƶÅõ ǦEŧȯã TS (Õŋ/ŋŸŋ 0.1) ȳƶÀhu8ţã dŋ Õŋ 10 ƶÅƷ
:**TS (Magnesium sulfate/sulfuric acid)** ÕÀóƶÅŸÊõã Ŕþ/ȳƶÀhu8ţã ğÅÅŸè
TS (ȯ/ȟ100~) ÕÀóƶÅŸÊõã Ŕþ dŋ ǦEƶÅõ ǦEŧõ Ž R ȳƶÀhu8ţã ğÅÅŸè dŋ ȟ 25 ããØÀ :*Procedure ŏãÄDƶqã*
.Õŋ 100 ȝÅǫφq
.ǦEõşǎ ǦEƵÅEŧEõ ǦEȟDƶÀŋ gǎÅŋ :**RS (Mebendazole)** ȯşÀãÆÆAǦEţã
.$C_{11}H_8O_2$ ÛɟƶAEõƶƶÅφ-4.1-ÕEȝEŋ-2 :**R (Menadione)** ɟƶÀǎÅAEţã
.ǦȟÛÅè ŏãÀÅò ğãózŸã :*Description Ƶȯƶõã*
.ȟǦƵÀÕǩ °ȳ 106 :*Melting temperature ŏÅTÔφrã ǦDƶóǎ*
:**TS (Mercuric chloride/ethanol)** ȯƶφÅžÀqã/ÕEÕǦƵÂãã ÉÀóƶŸõ
ȝÅǫφq TS (ȯ/ȟ375~) ȯƶφÅžÀqã dŋ ǦEƶÅõ ǦEŧõ Ž R ÕEÕǦƵÂãã ÉÀóƶŸõ dŋ ȟ 2 ããØÀ :*Procedure ŏãÄDƶqã*

.Ōŋ 100

:**TS (Mercuric nitrate)** Ōŋ ŐŐĞəÂõã ğãÀǫ

ŐÃÄǫÃõã Ŕþ dŋ Ōŋ 32 dŋ ǰÂŋ Ž R ÀÀòɟã ŐŐĞəÂõã ÆŒÊõÙ dŋ ĥ 40 ããØÃ :*Procedure õãÄDZqã*

.ŏÅţã dŋ Ōŋ 15ş TS (ȯ/ĥ1000~)

.ŏzŔõã dŋ ĞŒŧŢ ĞÃşÅǵ Ž ¢ŢÅǵ Æz :*Storage dbÃÂǫõã*

:**VS (ȯ/ȯzŋ 0.02) (Mercuric nitrate)** Ōŋ ŐŐĞəÂõã ğãÀǫ

Ŕþ dŋ Ōŋ 10 dŋ ǰÂŋ Ž ããØǩ ÛR ŐŐĞəÂõã ğãÀǫ dŋ ĥ 6.85 ĞããÀę ĞŒùzĞŔŋ ɟàzÃ :*Procedure õãÄDZqã*

.Ōŋ 1000 ɔøǫǵ ŏÅţÅã ZÅƧş ÛŏÅţã dŋ Ōŋ 500ş TS (ȯ/ĥ130~) ŐÃÀǫÃõã

ţÅĞǩÅã ȯ/ȯzŋ 0.02 ȯzŸǂ ŕzĞŔţã ÂŒõÀǫõã dŋ Ǩǫǫõã ÐÀz :*Method of standardization gÄÃÅĥţã ĞŐÃÄù*

.190 ĞHÙÅÔõã Û1 ÆŸŐã VS (ȯ/ȯzŋ 0.01) ŐŐĞəÂõã ğãÀǫ ɟãzÅ3 ǨƠ Ğzzòzţã ĞŐÃÀÛõã

:**TS (Mercury/nitric acid)** ŐÃÀǫÃõã Ŕþ/ĘĞəÂõã

ǫDzШ ȯzŸǂã ZÅƧş R áǿÅĞõã ÀÁĞţã ŐÃÀǫÃõã Ŕþ dŋ Ōŋ 27 Ž R ĘĞəÂõã dŋ Ōŋ 3 ããØÃ :*Procedure õãÄDZqã*

.ŏÅţã dŋ ȯáÅĥŋ

.dbÃÀŤÎõã àşÅDzǫǩ ŕ gÆŋ Ž ÛŏzŔõã dŋ ŒŧŢ ȯzŸǂã ɟÂƧ ɟÙ Æz :*Storage dbÃÂǫõã*

.ĞŒõşá ĞŒĥDZÀŋ ĞŒəÅŒŧŒõ gáÅŋ :**RS (Methotrexate)** ğÅÊȮÃÀǩzŸŒţã

.ĞŒõşá ĞŒĥDZÀŋ ĞŒəÅŒŧŒõ gáÅŋ :**RS (Metoclopramide hydrochloride)** ÆŒŋãÀãzŸõzǫŒŋ ÆÃózŸõşóÆŒŁ

.ĞŒõşá ĞŒĥDZÀŋ ĞŒəÅŒŧŒõ gáÅŋ :**RS (Miconazole nitrate)** ȯşàÅǫzȮŒţã ğãÀǫ

.(120 ĞHÙÅÔõã Û1963 ÛSRIP) MoO_3 :**R (Molybdenum trioxide)** ȳzÃÆĞȯzţã ÆŒÊõÙ ŲǫŸǫ

.C_2H_7NO :**R (Monoethanolamine)** ĸŋŕzǫÅŽÃÙ ÐáÅǵÙ

.ĞÃóáÅÎǫ ¢ǫHùəãó Ü8ÅÒ ÛɟzŸõã CÆ3 şÙ ŘŁÅã ÀÀòÙ ÛŽÂõ ŌəÅè :*Description ZȯzõÃ*

.R ɟzǫŒèɟãş R ȯzǫÅŽŒţãş ŏÅţÅã ŽÂŧŸõ ŌãÅę :*Miscibility ĞDZşÂţã*

.ÑĞÃÀÕǩ °ȳ 170 :*Boiling temperature ɟÅŒŸ8õã ĞDZóá*

.ρ_{20} = ȯ/ŋõ 1.01 :*Mass density ĞŸǫÓõã ĞzÅŽõ*

. $n_D^{20} = 1.453 - 1.455$:*Refractive index óÅÊÓǫŕã ÆÊÃŋ*

.ĞŒõşá ĞŒĥDZÀŋ ĞŒəÅŒŧŒõ gáÅŋ :**RS (Naloxone hydrochloride)** ɟzÊȮõÅõã ÆÃózŸõşóÆŒŁ

.ĞŒõşá ĞŒĥDZÀŋ ĞŒəÅŒŧŒõ gáÅŋ :**RS (Neamine)** ĸŋÅŒÃõã

RS (Neomycin B sulfate) B: ƙÊ ŁÅŋƶĒÅõã ğÅÅŸè

ĞĒĤDƶÀŋ ĞĒəÅĒŧĒõ gáÅŋ :*INN* øŸõ ŁĤĞƙ **RS (Framycetin sulfate)** ƙǫĒÊĒŋãÀÅõã ğÅÅŸè) øã ǫèŗã ȯÆĞǫèã .ĞĒõşá

.ĞĒõşá ĞĒĤDƶÀŋ ĞĒəÅĒŧĒõ gáÅŋ :**RS (Neostigmine metilsulfate)** ƙŧ8ǫèƶĒÅõã ğÅÅŸè ÕĒǫĒŋ

.(124 ĞĤŲÅÔõã Û1963 ÛSRIP) $C_{15}H_{17}ClN_4$ ÜC.I. âÅèɟã gÀŧΣã ÜC.I. 50040 :**R (Neutral red)** ĞõáÅĤǫŧã gÀŧΣã

:**TS (Neutral red/ethanol)** ȯƶφÅŽŁqã /ĞõáÅĤǫŧã gÀŧΣã

100 ƷÅǫφq TS (ȯ/Ĥ375~) ȯƶφÅŽŁqã ȯbŋ ĞĒƶÅõ ĞĒŧõ Ž R ĞõáÅĤǫŧã gÀŧHŲŸõ Ĥ 0.1 ããØŁ :*Procedure ȯãÄĎƶqã* .Ōŋ

.ĞĒõşá ĞĒĤDƶÀŋ ĞĒəÅĒŧĒõ gáÅŋ :**RS (Nifurtimox)** È õƶŧĒƙ øƶÅĒÅõã

.ĞĒõşá ĞĒĤDƶÀŋ ĞĒəÅĒŧĒõ gáÅŋ :**RS (Niridazole)** ȯşàãÆŁKÅõã

ĞĒəÅĒŧĒõ ĞĒĤDƶÀŋ gáÅŋ :**RS (Niridazole-chlorethylcarboxamide)** ÆĒŋÅÊõƶãøÅõ ÕĒŽŁÛ øƶŸõ-ȯşàãÆŁKÅõã .ĞĒõşá

.ĞĒõşá ĞĒĤDƶÀŋ ĞĒəÅĒŧĒõ gáÅŋ :**RS (Nitrofurantion)** ȯbŁƶǫãøƶƶşÀǫĒÅõã

.CH_3NO_2 :**R (Nitromethane)** JÅŽĒŋşÀǫÅõã

.JƶŸõã CÆŽ ŲøǫŁà ÕəÅè :*Description Ƶȯƶõã*

.R ÆĒŋÅŋøƶƶ ŌĒŽĒŋ ŲəÅÅõş R Kǫɟãş TS (ȯ/Ĥ750~) ȯƶφÅŽŁqãş øÅŧÅã ƷşÂŋ :*Miscibility ĞĒDƶşÂŧã*

.ŁĞŁÀÕõ ρ_{20}= ȯ/ŋõ 1.13:*(Mass density) ĞŸǫÓõã ĞƶÅŽõ*

.ŁĞŁÀÕõ n_D^{20} =1.380 :*Refractive index øÅÊÓφŗã ÆÊŁŋ*

.ŁĞŁÀÕõ °ȳ 101 :*(Boiling temperature) JÅŸ8ãã gøãÄg ĞDƶøã*

.ĞĒõşá ĞĒəÅĒŧĒõ ĞĒĤDƶÀŋ gáÅŋ :**RS (Noscapine)** ƙãÅÒèƶÅõã

.ĞĒõşá ĞĒəÅĒŧĒõ ĞĒĤDƶÀŋ gáÅŋ :**RS (Nystatin)** ƙƙÅǫÊÅõã

.$C_8H_{16}O_2$ ÛÕĒŸŁÀãÅÒõã Ŕþ :**R (Octanoic acid)** ÕŁƶφÅǫõşɟã Ŕþ

.JƶŸõã CÆŽ ŲøǫŁà ÕəÅè :*Description Ƶȯƶõã*

.ŁĞŁÀÕõ °ȳ 237 :*(Boiling temperature) JÅŸ8ãã gøãÄg ĞDƶøã*

.ŁĞŁÀÕõ ȯ/ŋõ 0.92= ρ_{20} :*(Mass density) ĞŸǫÓõã ĞƶÅŽõ*

JƶÆõãÀŽφÅƶφÅŸǫÅ-4-ƶĒÆŋÅ ÕĒŽŋ-1 ȯbŋ ŽŁÂŋ Ü19 ÆŁØŧã Ğęøà :**R (Oracet blue B) B** ŘĒèãøşɟã Ğęøà

.($C_{20}H_{14}N_2O_2$) ƙAŒõäÀŽŒąÜžAŒŸŒąÜ-4-žAŒnÜ-1ş ($C_{21}H_{16}N_2O_2$)

:**TS (Oracet blue B/acetic acid)** ÕŒQŒèjä Řþ/B ŘŒèäósjä Čęóà

R1 ƱDzŸžóä ÕŒQŒèjä Řþ dnę ČŒžÅõ ČŒłõ Ž R B ŘŒèäósjä Čęóà dnę ȟ 0.5 ãäØΛ :*Procedure ŏäÄDŽqä*

.Ōę 100 žÅQąq

.(131 ČƱÅÔöä Û1963 ÛSRIP) $C_2H_2O_4,2H_2O$:**R (Oxalic acid)** ÕŒöÅÊõsjä Řþ

dnę ȟ 0.05 ąŸ3 Ƀžąž R ÕŒöÅÊõsjä ŘłΣ ȯžŸŢ :**TS** (ȯ/ȟ**0.05**) **(Oxalic acid)** ÕŒöÅÊõsjä Řþ

.Ōę 1000 Ž $C_2H_2O_4$

.Ōę 1000 žÅQąq ŏÅţä dnę ČŒžÅõ ČŒłõ Ž R ÕŒöÅÊõsjä Řþ dnę ȟ 0.07 ãäØΛ :*Procedure ŏäÄDŽqä*

.ČŒösä ČŒəÅŒłŒõ ČŒHDZÄę gäÅę :**RS (Oxamniquine)** ƙÒŒAnÅÊõsjä

.ČŒösä ČŒəÅŒłŒõ ČŒHDZÄę gäÅę :**RS (Oxytetracycline dihydrate)** ƙŸÒŒèäÄQƙ ƱÊõsjä ğäóÁŒŒŁ ƱəÅÅą

Ž Žòş Åłõ ȯžnÅQŒèäóÅGöä :**R (Paracetamol,4-aminophenol-free)** Äg-ȯžAŒžžAŒnÜ-**4** Ûȯžn̊ÅQŒèäóÅGöä

:ƁÅQöä óÅGQnŸö ÆŒDzQÊΛ ąóQg ŏÅţä dnę ¢ƙózŸæ äÅHţä ȯžn̊ÅQŒèäóÅGöä şÜ Û237 ČƱÅÔöä ÛČòÅ]ä gäşÄžjä

ǰΛÂţä äØŏ Ōę 100 ąóQg ŽÅƆş ŏÅţäş R ȯžφÅžŒţä dnę ȳžDzΣä ȯäÅHQę ǰΛÂę Ž ČžÅąä gäÅţä dnę ȟ 5 ãäØΛ

ɟžö ǰQAΛ ƒ ÜČÕŒęä 30 gÆę ÄÕQÊŒö ōÄQΛş ÛžÂƆ ÛTS ƁžŸÕöä ȳžΛäžÔöä ÆŒèşÄäşÄQφ Ōę 1.0 ȣÅÊΛ .ÆΛØţä

.ÄÊnÜ şÜ ȧóäÜ

.$(CH_2O)_n$:**R (Paraformaldehyde)** ÁŒŁÆöÅnóžąäóÅä

.ÆŒŁÆöÅnóžÅŸö gÂŒư ČƱəäÄöä ÜÈŒäÜ ƁóžŸæ ȧžHÊę :*Description Žòžöä*

ÜÆŒŁÆöÅnóžÅöä evolution ƙŢŢƙ ȝę ÛóÅΣä ŏÅţä Ž JÅäşØöä Äg ÛäóÅGöä ŏÅţä Ž ŏÙGæ ãäşæ :*Solubility ČŒφÅäşØöä*

.R ƙǫjäş TS (ȯ/ȟ750~) ȯžφÅžΛqä Ž ÑŒŸłȝ ãäşæ ƙdę

ȯžŸŢ ǰQAΛ ÜTS (ȯ/ȟ100~) ÅŒφžnjä dnę Ōę 10 Ž ȟ 1 ãäØΛ :*Solubility in ammonia* ÅŒφžnjä Ž ČŒφÅäşØöä

.JžŸöä CÁȝş ÑŒŸłȝ ȣÅò

.ȟ/ŋŸę 1.0 ȣȝ ÁΛÂΛ ƒ :*Sulfated ash ŘÁŸÊţä äÅnÄöä*

ČgÅÌÀöä JžÒƙ ÜĠÌÀΛş gÁgäş ČÕŒęä gÁę ŏÅę Ōę 20 ȝę ȟ 1 ȝÀΛ :*Acidity or alkalinity ĠΛžŸÕöä ôžłΣä*

.ÈłÎöä äÅGȝ ȧóžö (ĠΛäÅŒg) ČöäÅHQę

.ČŒösä ČŒəÅŒłŒõ ČŒHDZÄę gäÅę :**RS (Paromomycin sulfate)** ƙÊŒnžnóÅGöä ğÅAŸè

.$C_5H_{11}NaO_3S,H_2O$:**R (1-Pentanesulfonic acid sodium salt)** ȬńóźÀŸè ȷÀǫÀæ-**1** Ŕþ ȳźńåźò ĆŸŋ
.Ŕłæů Ƀóźŷæ ȧźĦůÊŋ :*Description Ƶòźóā*
.ŏÀţā Ž ā̄ąśæ :*Solubility ĞłφłæşØóā*
.ȷźŸóā Ćźʒş ńłźÀò ŏÀţā ďŋ Ō̄ŋ 25 Ž ħ 1 òźŸŢ ȷźÒń :*Clarity and colour of solution òźŸ≠ā ȷźóş ŏÀÁÔóā*
.ħ/ŋŸŋ 20 ďŋ ÀŽõŮ ȷźÒń ŕ ÜÀÎłź ȯóÀłõ ĞÕńÀÛæ ĸĦń :*Water ŏÀţā*
:**(1-Pentanesulfonic acid)** ȬńóźÀŸè ȷÀǫÀæ Ŕþ-**1**
Ŕþ ďŋ Ō̄ŋ 1000 Ž R ȬńóźÀŸè ȷÀǫÀæ-1 Ŕþ ȳźńåźò ĆŸŋ ďŋ ħ 0.960 ā̄ąØń :*Procedure ŏāÄDźqā*
ĆŋŀÀń .TS (ȯ/ħ260~) ÀłφźŋŋÀæ 4.3 ɔøǫǵ ŏÀŁÀĞóā ʔźÊńş TS (ȯ/ħ5.0) ŏāźŢā ţşÂøÀţā Ȭłǫłèŋā
.ȯÀŁĦǫèŕā Ō̄ĞĢ ŏāźŢā ţÂøÀńş
:**VS (ȯ/ȯźŋ 0.1) (Perchloric acid/dioxan)** ȷÀÊõźńÆóā/ȬńóźŸõĸĞóā Ŕþ
R ȷÀÊõźńå ďŋ ĞłźÀõ ĞłŁõ ʒŋ TS (ȯ/ħ1170~) ȬńóźŸõĸĞóā Ŕþ ďŋ ȯźŋ 8.5 ʒÂɛ :*Procedure ŏāÄDźqā*
.Ō̄ŋ 1000 ʒÀǫφq ÛŏāÂǫŋŕÀæ łłÔłÊÔń ɔŌÀţā
ğŕÀŽź ďŋ ħ 0.7 ğńÀłÀĦŋ òźŸ≠ ŕźĞŘţā ÂłõÀǫóā ďŋ Ğłźǫóā Ƀńz :*Method of standardization ğłńÀłĦţā ĞÕńÀù*
ÀŁõ ÛA ĞÕńÀÛóā ȳāÆÁǫèłÀæ ÛĞʒÀè 2 ğÆŋ °ȳ120 ĞDźØÆæ łłÕæÀè ĞÀÀƒş ÛĞłùźĞŘŋ Ğφşńźŋ ÛR ȳźłèłĦźĞóā ĸDźşØÆłŁ
Ō̄ŋ 1 Ō̄õ .(142 ĞĦÀÔóā Û1 ÆŸŎā) "Non-aqueous titration ŦəÀŋŸóā Ùèźóā Ž ğńÀłĦţā" ȷźźʒ ĞƠ ȸźòźŋźŁ
.$C_8H_5KO_4$ ďŋ ŋŸŋ 20.42 ùźÀÒń VS (ȯ/ȯźŋ 0.1) ȷÀÊõźńÆóā/ȬńóźŸõĸĞóā Ŕþ ďŋ
:**VS (ȯ/ȯźŋ 0.02) (Perchloric acid)** ȬńóźŸõĸĞóā Ŕþ
Ŕþ ďŋ ĞłźÀõ ĞłŁõ ʒŋ VS (ȯ/ȯźŋ 0.1) ȬńóźŸõĸĞóā Ŕþ ďŋ Ō̄ŋ 20 ā̄ąØń :*Procedure ŏāÄDźqā*
.Ō̄ŋ 100 ʒÀǫφq R1 ŦDźŸŽóā Ȭłǫłèŋā
ƀńzş ŏÀţā ʔźǫŢ ğńÀìÀĞŋ ȳāÆÁǫèłā Ō̄ĞĢ ĸĦń :*Water and method of standardization ğłńÀłĦţā ĞÕńÀùş ŏÀţā*
ÛVS (ȯ/ȯźŋ 0.1) ȬńóźŸõĸĞóā Ŕþ ȷźźʒ ĞƠ Ğźźòźţā ĞÕńÀÛóā ţÀĞĸÀæ òźŸĦłŁŸõ ŕźĞŘţā ÂłõÀǫóā ďŋ Ğłźǫóā
.213 ĞĦÀÔóā Û1 ÆŸŎā
.$C_6H_8N_2,2HCl$:**R (1,4-Phenylenediamine dihydrochloride)** ĸŋńÀńå ĸŸłÆłź-**4Û1** ÆńóźŸõşØÆłŁ ŦəÀńǫ
ƀů ÆŸÕńń ÛÆǵÀì (ÈłÎóÀæ ÆŸɔæóāÀƨā ȷźõ) tan ʒÀÊǫŋ ƀů Ŕłæů Ƀóźŷæ ȧźĦůÊŋ :*Description Ƶòźóā*
.ŏāźŢŸõ ô ÀĦǫóā ÆÀʒ ŦŸÀφÀę
.R Ğǫȷāş TS (ȯ/ħ750~) òźφÀŽńqā Ž ȷÀæşØóā ĞłĦùì ÜŏÀţā Ž ȷÀæşØóā Àǵ :*Solubility ğłφłæşØóā*
.ŏźÊóā ďŋ ɔłʒ ȷÜş ÛłłÆłDź ĞÕŸ8ŋ ĞńşÀǵ Ž ŞÀʒ :*Storage ďńÀÁǫóā*

:TS (Phenylhydrazine/hydrochloric acid) ÕłózŷõşóÆłŧã Ŕþ/ȼłàãóÆłŧ Õłłłłłõã
ȼŋ ȟ2 ȝŋ ȝÀłşõÀţã ȼŋ Õŋ 50 Ž R ȼłàãóÆłŧ Õłłłłłõã ÆłózŷõşóÆłŧ ȼŋ ȟ 0.75 ããØł :*Procedure õãÄDZqã*
.Õŋ 200 ȝÀQqq õÀţã ȼŋ ĞłzÀõ Ğłŧõş TS (ȯ/ȟ420~) ÕłózŷõşóÆłŧã Ŕþ ȼŋ 25 8ÀŔł ÛĞĩÀł ÛR ȴHuÀõã
ÆłózŷõşóÆłŧ ȯzŷŢ :**TS (ȯ/ȟ10) (Phenylhydrazine hydrochloride)** ȼłàãóÆłŧ Õłłłłłõã ÆłózŷõşóÆłŧ
.Õŋ 1000 Ž $C_6H_8N_2$,HCl ȼŋ ȟ10 ɔŷȝ ƀzQȝ R ȼłàãóÆłŧ Õłłłłłõã
ããÀÎQèã Ž ȳÆÁQÊł ǰłÂŋ ȼŋ ĞŧaŶŋ ĞDZóå :**R (Phenyl/methylpolysiloxane)** ȴÀÊõzŷłè Ƀzã ÕłŽłŋ/Õłłłłz
.ȟ 100 øõã Ž ȴÀÊõzŷłè Ƀzã ÕłŽłŋ ȼŋ ȟ95 ş ȴÀÊõzŷłè Ƀzã ÕłłłłŽ ȼŋ ȟ 5 ȼŋ ÆõÀŋ ãÀ8õã
: **TS Û7.4** õÀŁÀã Û**Phosphate buffer** ğÀÀèzÀõã Ğəóãå
Õŋ 393.4 8ÀŔłş õÀţã ȼŋ Õŋ 250 ȳzłèÀkzGõã ƙDZşóÆłŧ ƀəÀłQ ğÀÀèzz ȼŋ ȟ6.8 ããØł :*Procedure õãÄDZqã*
.VS (ȯ/ȯzŋ 0.1) ȳzłźzÔõã ÆłÊõşóÆłŧ ȼŋ
:TS Û7.6 õÀŁÀã Û**Phosphate buffer** ğÀÀèzÀõã Ğəóãå
200 ÀZQÀHè ĞłŧDzg ĞŶDZzg Ž R ȳzłèÀkzGõã ƙDZşóÆłŧ ƀəÀłQ ğÀÀèzz ȼŋ ȟ 1.36 ȝŕzł :*Procedure õãÄDZqã*
.õÀţÀã ȴDzg БŬ ZÁƧş ÛVS (ȯ/ȯzŋ 0.2) ȳzłźzÔõã ÆłÊõşóÆłŧ ȼŋ Õŋ 42.4 8ÀŔł ÛõÀţÀã ããØł ÛÕŋ
: **TS Û8.0** õÀŁÀã Û**Phosphate buffer** ğÀÀèzÀõã Ğəóãå
ğÀÀèzz ȼŋ ȟ 0.50ş R ĞłəÀŋŶõã ȳzłźzÔõã ƀəÀłQ ƙDZşóÆłŧ ğÀÀèzz ȼŋ ȟ 8.95 ããØł :*Procedure õãÄDZqã*
.Õŋ 1000 ȝÀQqq õÀţã ȼŋ ĞłzÀõ Ğłŧõ Ž R ȳzłèÀkzGõã ƙDZşóÆłŧ ƀəÀłQ
دارئة الفوسفات العقيمة Phosphate buffer, sterile، باهاء 7.8، TS:
ȼŋ 45.2 8ÀŔłş ÛõÀţã Ž R ȳzłèÀkzGõã ƙDZşóÆłŧ ƀəÀłQ ğÀÀèzz ȼŋ ȟ 6.8 ããØł :*Procedure õãÄDZqã*
ÛğşÀŔõã ÆłȝÛõÀŁÀGõã ĞłHuÔł .Õŋ 1000 ȝÀQqq õÀţã ȼŋ ĞłzÀõ Ğłŧõş VS (ȯ/ȯzŋ 1) ȳzłźzÔõã ÆłÊõşóÆłŧ
gÆłŋ ȯzŷ∓ã ȴÕłł Ż TS (ȯ/ȟ110~) ȳzłèÀkzGõã ÆłÊõşóÆłŧõ şÛ TS (ȯ/ȟ1440~) Õłózłèzłõã Ŕłłłł 7.8 ɔøQg
.°ȳ 120 ĞDZóÆã gÆòzţłã ĞÕłłęå 20
:TS1 Û10.5 õÀŁÀã Û**Phosphate buffer,sterile** ĞłŧłÕłłõã ğÀÀèzÀõã Ğəóãå
ȼŋ Õŋ 20 8ÀŔł ÛõÀţÀã R ȳzłèÀkzGõã ƀəÀłQ ƙDZşóÆłŧ ğÀÀèzz ȼŋ ȟ 35.0 ããØł :*Procedure õãÄDZqã*
ɔøQg gşÀŔõã ÆłȝõÀŁÀGõã ĞłHuÔł .Õŋ 1000 ȝÀQqq õÀţã ȼŋ ĞłzÀõ Ğłŧõş VS (ȯ/ȯzŋ 1) ȳzłźzÔõã ÆłÊõşóÆłŧ
20 gÆłŋ ȯzŷ∓ã ȴÕłł Ż TS (ȯ/ȟ110~) ȳzłèÀkzGõã ÆłÊõşóÆłŧõ şÛ TS (ȯ/ȟ1440) Õłózłèzłõã Ŕłłłł 10.5
.°ȳ 120 ĞDZóÆã gÆòzţłã ĞÕłłęå

Phosphate/citrate buffer (pH 6.0): Mix 35 ml of 0.1 M citric acid and 60 ml of 0.2 M disodium hydrogen phosphate. Adjust the pH to 6.0 if necessary.

Procedure: Add 0.1 g of potassium metabisulfite and 0.5 g of EDTA to 100 ml of the buffer.

Phosphate standard (1 mg/ml PO4): Dissolve 1.433 g of anhydrous potassium dihydrogen phosphate in water and dilute to 1000 ml.

Procedure: Add 1 ml of 10 N sulfuric acid and 100 ml of 0.1 M sodium molybdate solution.

Phosphoric acid (105%): Mix 885 g of 85% phosphoric acid with 115 g of water.

Procedure: Add 1440 g of 85% phosphoric acid to 250 g of potassium dihydrogen phosphate.

Phosphotungstic acid: Dissolve 25 g of phosphotungstic acid in 75 ml of water. Add 18.75 ml of 6 N sulfuric acid.

Procedure: Add 1440 g of 85% phosphoric acid to 250 g of potassium dihydrogen phosphate.

Storage: Keep in a cool place.

R (Piperidine): $C_5H_{11}N$.

Description: Colorless liquid.

Miscibility: Miscible with water.

Mass density: ρ_{20} = 0.86 g/ml.

Refractive index: n_D^{20} = 1.454.

Boiling temperature: 106 °C.

Congealing temperature: 12 °C.

R (Potassium antimonate): $KSbO_3$ (MW 263.9).

TS (Potassium antimonate): Mix 95 ml of 2 N potassium hydroxide with 5 ml of 1 N potassium antimonate solution.

Procedure: Add 50 ml of 1 N potassium antimonate solution to 150 ml of 24 g/dl NaCl solution.

Sensitivity to sodium: 7 ml of 0.1 N potassium antimonate solution to 10 ml of 15 g/dl potassium chloride solution.

.ÅDZàÅù TS ȳzÆèÅǩzGõã ğÅφzŧQφÛ ƚKÊƠ Æz :*ČŢǵŸŋ*

БÛ ŏÅţã Ž ČzããÓŋ ÛR ȳzÆèÅǩzGõã ğÅŋsÀã :**VS** (ȯ/ȯzŋ **0.00833**) **Potassium bromate** ȳzÆèÅǩzGõã ğÅŋsÀã
.Ōŋ 1000 Ž $KBrO_3$ ȯŋ ȟ 1.392 ʔzQŢ

.$K_2CO_3,1_{1/2}H_2O$:**R (Potassium carbonate)** ȳzÆèÅǩzGõã ğÅφzãÀõ
.gƚ8ò ČÆGÆGǵ ğãózŸã :*Description* *Ζȯzõã*
.TS (ȯ/ȟ 750~) ȯzφÅǰÅqã Ž ÅÆŸŧȝ ããsá Ƚd ÜŏÅţã Ž ãÆDZ ããsá :*Solubility* *ČÆφÅãsÓõã*

.K_2CO_3 :**R (Potassium carbonate,anhydrous)** ČÆəÅŋŸõã ȳzÆèÅǩzGõã ğÅφzãÀõ
.ÆùÀQÊŋ ÜÆGŢ ȧzHÜÊŋ sÛ ğÅGÆGǵ :*Description* Ζȯzõã
.TS (ȯ/ȟ750~) ȯzφÅǰÅqã Ž ÅÆŸŧȝ ããsá Ƚd ÜŏÅţã ȯŋ Ágãs ŏÂDZ Ž ããsá :*Solubility* *ČÆφÅãsÓõã*

100 ČzããÀę ʔŸȝ ƁzQȝ R ȳzÆèÅǩzGõã ÁÅózŸÒõ ȯzŸŢ :**TS** (ȯ/ȟ**100**) **(Potassium chloride)** ȳzÆèÅǩzGõã ÁÅózŸõ
.ÀQŸõã Ž KCl ȯŋ ȟ

:**PbTS (Potassium cyanide)** ȳzÆèÅǩzGõã ÁÆφÅÆè
ÁÆÊõsƚã ȯŋ Ōŋ 2 ȣÅÊÅ ÛŏÅŋ Ōŋ 90 Ž R ȳzÆèÅǩzGõã ğÅφÅÆè ȯŋ ȟ 10 ããÓÅ :*Procedure* *õãÄDZqã*
.ǴìÀÅs ÛŌŋ 100 ʔøQǵ ŏÅţã ΖÅȘ Û ǴȝÅè 24 gÁŋ ÀÕQÊõ õÀQÅ ÛTS (ȯ/ȟ60~) ƚDZsØÁÆTã

:**TS2 (Potassium dichromate)** ȳzÆèÅǩzGõã ğÅŋsÀõ ƱəÅÅQ
ȯŋ Ōŋ 7.5 øÓШ ȣÅÊÅs ŏÅŋ Ōŋ 60 Ž R ȳzÆèÅǩzGõã ğÅŋsÀõ ƱəÅÅQ ȯŋ ȟ 1 ããÓÅ :*Procedure* *õãÄDZqã*
.TS (ȯ/ȟ1760~) ÕÅózÅŸÊõã Ŕβ

:**TS3 (Potassium dichromate)** ȳzÆèÅǩzGõã ğÅŋsÀõ ƱəÅÅQ
ÕÅózÅŸÊõã Ŕβ ȯŋ ČÆzÅõ ČÆŧõ Ž R ȳzÆèÅǩzGõã ğÅŋsÀõ ƱəÅÅQ ȯŋ ȟ 0.5 ããÓÅ :*Procedure* *õãÄDZqã*
.Ōŋ 100 ȝÅQφq TS (ȯ/ȟ100~)

ğÅÀèzÅõ ȯzŸŢ :**TS** (ȯ/ȟ**100**) **(Potassium dihydrogen phosphate)** ȳzÆèÅǩzGõã ƚDZsØÁÆŁ ƱəÅÅQ ğÅÀèzz
.ÀQŸõã Ž KH_2PO_4 ȯŋ ȟ 100 ČzããÀę ƁzȝR ȳzÆèÅǩzGõã ƚDZsØÁÆŁ ƱəÅÅQ

ğÅÀèzÅõ ȯzŸŢ :**TS** (ȯ/ȟ**27.2**) **(Potassium dihydrogen phosphate)** ȳzÆèÅǩzGõã ƚDZsØÁÆŁ ƱəÅÅQ ğÅÀèzz
.(ȯ/ȯzŋ 0.2) ÀQŸõã Ž KH_2PO_4 ȯŋ ȟ 27.2 ƁzȝR ȳzÆèÅǩzGõã ƚDZsØÁÆŁ ƱəÅÅQ

:**TS** (ȯ/ȟ**13.6**) **(Potassium dihydrogen phosphate)** ȳzÆèÅǩzGõã ƚDZsØÁÆŁ ƱəÅÅQ ğÅÀèzz
.(ȯ/ȯzŋ 0.1) ÀQŸõã Ž KH_2PO_4 ȯŋ ȟ 13.6 ƁzȝR ȳzÆèÅǩzGõã ƚDZsØÁÆŁ ƱəÅÅQ ğÅÀèzÅõ ȯzŸŢ

ɔŸʒ Ƀzƶʒ ȳzŁèÅǩzǤõã ğãǎzŁõ ȴDZàÅù ÀŘŢ ȯzŸŢ :TS (ȯ/ŋŸŋ 3.6) **(Potassium iodate)** ȳzŁèÅǩzǤõã ğãǎzʌ
.ÀǫŸõã Ž KIO_3 ɗŋ ŋŸŋ 3.6

Ž KI ɗŋ ȟ 100 ǦããÀę Ƀzƶʒ ȳzŁèÅǩzǤõã ÆʌǎzŁõ ȯzŸŢ :TS (ȯ/ȟ100) **(Potassium iodide)** ȳzŁèÅǩzǤõã Æʌǎzʌ
.ÀǫŸõã

:TS2 **(Potassium iodoplatinate)** ȳzŁèÅǩzǤõã ğÅAŁǩŸãȘ ǎzʌ
Æʌǎzʌ ɗŋ Ōŋ 45 ȣÅŘʌ ÛŏÅţã ɗŋ Ōŋ 2.5 Ž R ŐŁAŁǫʌŸǤõã ÆʌózŸõ ɗŋ ȟ 0.25 ããØʌ :*Procedure ŏãÄDZqã*
.Ōŋ 100 ʒÅǫq R ȷzǫŁèȷã ɗŋ ǦŁzÅõ ǦŁtȮã ZÅƧȘ ÛTS (ȯ/ȟ100) ȳzŁèÅǩzǤõã

ɔŸʒ Ƀzƶʒ ȳzŁèÅǩzǤõã ğÅǫÅ8ʌŋǩǤȯ ȯzŸŢ :TS (ȯ/ȟ25) **(Potassium permanganate)** ȳzŁèÅǩzǤõã ğÅǫÅ8ʌŋǩã
.ÀǫŸõã Ž $KMnO_4$ ɗŋ ȟ25

ɔŸʒ Ƀzƶʒ R ȳzŁèÅǩzǤõã ğÅǫÅŁèzŁŽȯ ȯzŸŢ :TS (ȯ/ȟ200) **(Potassium thiocyanate)** ȳzŁèÅǩzǤõã ğÅǫÅŁèzŁǫ
.ÀǫŸõã Ž KCNS ɗŋ ȟ 200

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Praziquantel)** ŌŁǫǫãzȮʌàãÃõã

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Prednisolone acetate)** ȷzȯȘÂøʌʌǎÃõã ğÅǫŁèÙ

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Prednisolone sodium phosphate)** ȷzȯȘÂøʌʌǎÃõã ȳzʌǎzȯ ğÅÀèzz

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Probenecid)** ÆŁÊʌãȘÃõã

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Procarbazine hydrochloride)** ɗʌàÅãøÅõȘÃõã ÆʌózŸõȘøÆŁŁ

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Protionamide)** ÆŁŋÅǫzǫʌȘÃõã

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Pyrantel embonate)** ŌŁǫǫãǩǤõã ğÅǫzǤŋÙ

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Pyrazinamide)** ÆŁŋÅAʌàãǩǤõã

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Pyrimethamine)** ǩŋÅŽŁƧǩǤõã

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Rifampicin quinone** ǩÊŁǤŋÅAʌÀõã ȷzʌŁõ

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Rifampicin)** ǩÊŁǤŋÅAʌÀõã

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Salbutamol)** ȯzŋÅǩzǤõÅÊõã

.ǦŁõȘǎ ǦŁəÅŁtŁõ ǦŁȴDZÀŋ ǥǎÅŋ :RS **(Salbutamol sulfate)** ȯzŋÅǩzǤõÅÊõã ğÅAŸè

.$C_7H_6O_2$:R **(Salicylaldehyde)** ÆŁŁÆõŸŁÊõÅè

.àzŸõã ¢GÎk gÀąą ĞHuaãÀõã Ü8ÅÒ ązŸõã CÆ3 Ułą¶à ÕaÅè :*Description Ząòzõã*

.R Ką̇ąąş TS (ȯ/ȟ750~) ȯzφÅŽ1qą Ž ãąşą́ ÜõÅţą Ž ąÅąşØõã ĞEHuì :*Solubility ĞEφÅąşØõã*

. $d_D^{20} = 1.17$:*Relative density* ĞEGÊÅõã *ĞzÅŽØõã*

:**TS (Salicylaldehyde)** ÆEŁÆEõŸEÊõÅè

Ąąą ąąą Õąą 0.1 8ÅÃ1ş R ȯzφÅŽEţą ąąą Õąą 100 Ž R ÆEŁÆEõŸEÊõÅè ąąą ȟ 2 ŽÂz :*Procedure ŏãÄDZqã*

.TS (ȯ/ȟ420~) Õ1ózŸõşóÆEŁTã

.(UV 254) 60 ÅÒEŸEÊõã ĞąŸŁ :**R6 (Silica gel)** ÅÒEŸEÊõã ĞąŸŁ

.ÀąąąÅą 6 :*Average pore size ĮłÊłã ĮDzg UÛèş*

Ąáą ĘõüÕąą ÄĦÎąą ąŸŽ ązÕơ (ÀÕąąşÀÒąą 15 UÛèzõã ĮEÊąã ĮDzg) ÅÒEŸEÊõã ĞąŸŁ :*Composition ÆłÕÄÕõã*

.(ąõ/ȟ15 ĞããÀę) ÀÕąąφÅą 254 ĞDZzą ȯzÛã ąŸŽąą gÆì

:**TS(ȯ/ȟ100) Silver nitrate** ĞÃÅõã ğãÀÕą

.Õąą 1000 Ž $AgNO_3$ ąąą ȟ 100 ąŸŽ ązÕŽ ĞÃÅõã ğãÀÕÅõ ȯzŸŢ

:**VS(ȯ/ȯzą 0.01) Silver nitrate** ĞÃÅõã ğãÀÕą

.ÀÕŸõã Ž $AgNO_3$ ąąą ȟ 1.699 ązÕŢ Ł ŏÅţã Ž ĞããØą ÛĞÃÅõã ğãÀÕą

Ğzzòzţã ĞÕÅÀÛõã ţÅĞkÅã ȯzŸHułŸõ ązGÃţã ÂEõÀÕõã ąąą ĞĞŽÕõã ÐÀz :*Method of standardization gÄÅÄŏţã ĞÕÅÄü*

.202 ĞHuÅÔõã Û1 ÆŸŎã ÛVS (ȯ/ȯzą 0.1) ĞÃÅõã ğãÀÕą ązÅ3 ĞÕ

:**TS (Silver nitrate/methanol)** ȯzφÅŽEţã/ĞÃÅõã ğãÀÕą

.R ȯzφÅŽEţã Ž R ĞÃÅõã ğãÀÕÅã ŽGÎą ȯzŸŢ ÀÃŽ :*Procedure ŏãÄDZqã*

:**VS (ȯ/ȯzą 0.1) (Sodium acetate/glacial acetic acid)** UDzŸŽõã ÕEÕEèąã Ąą/ȳzÅźÔõã ğÅÕEèÜ

Ąą ąąą Õąą 100 Ž K8ò ĮÊę Ž R ĞEąÅąŸõã ȳzÅźÔõã ğÅφzãÀõ ąąą ȟ5.3 ããØÅ :*Procedure ŏãÄDZqã*

ŽÅÕφq R1 UDzŸŽõã ÕEÕEèąã Ąą ąąą ĞEzÅõ ĞEłõ 8ÅÃ1ş ÛĞzÅrÜ Õõ ÆĞã ãÆEDZ õÀƠ ÛR1 UDzŸŽõã ÕEÕEèąã

.Õąą 1000

:ÐÅÕõã ãzŸèąã ţÅĞkÅã ȯzŸHułŸõ ązGÃţã ÂEõÀÕõã ąąą ĞĞŽÕõã ÐÀz :*Method of standardization gÄÅÄŏţã ĞÕÅÄü*

ĞEDzÊÅAGõã ąąą ğãÀÛę 3-2 ȳãÆÅÕèÅã VS (ȯ/ȯzą 0.1) Õ1ózŸõKGõã Ąą ąąą Õąą 15.0 ÕãÅÕą ȯzŸ‡ã ÀÅĦÅ

ąąą ĄŸą 8.203 ŏżÅÒÅ VS (ȯ/ȯzą 0.1) Õ1ózŸõKGõã Ąą ąąą Õąą 1 Õõ .TS ÕEÕEèąã Ąą/gózŸGÕţã

.$C_2H_3NaO_2$

:TS (ȯ/ȟ10) (Sodium alizarinsulfonate) ȳȚʌǎȚÔöä ǧȦφȚȦŸè ȣʌóäÂÆöŬ
.ÀǫŸöä Ž $C_{14}H_7NaO_7S$ ȣȵ ȟ 10 ǦääÀę ɔŸȝ ƀȚǫȚȝ ȳȚʌǎȚÔöä ǧȦφȚȦŸè ȣʌóäÂÆöø ȯȚŸȚ

:TS (ȯ/ȟ400) Sodium choride ȳȚʌǎȚÔöä ÉʌóȚŸõ
.ÀǫŸöä Ž NaCl ȣȵ ȟ 400 ǦääÀę ɔŸȝ ƀȚǫȚȝ ȳȚʌǎȚÔöä ÉʌóȚŸõ ȣȵ ȝǦÎȵ ȯȚŸȚ

:TS (ȯ/ȟ10) Sodium choride ȳȚʌǎȚÔöä ÉʌóȚŸõ
.ÀǫŸöä Ž NaCl ȣȵ ȟ10 ǦääÀę ɔŸȝ ƀȚǫȚȝ ȳȚʌǎȚÔöä ÉʌóȚŸÒö ȯȚŸȚ

.ǦÆöşǎ ǦÆəÀÆŧÆõ ǦÆȞDZÀȵ gǎÀȵ **:RS (Sodium cromoglicate)** ȳȚʌǎȚÔöä ǧÀÒÆŸdȚȵşÀõ
ǧÀÀèȚȚ ȯȚŸȚ **:TS (ȯ/ȟ 275) (Sodium dihydrogen phosphate)** ȳȚʌǎȚÔöä ƙDȚşóÆÆŁ ƱəÀÀǫ ǧÀÀèȚȚ
.ÀǫŸöä Ž NaH_2PO_4 ȣȵ ȟ 275 ǦääÀę ɔŸȝ ƀȚǫȚȝ ȳȚʌǎȚÔöä ƙDȚşóÆÆŁ ƱəÀÀǫ

.$CHNaO_2$ **:R (Sodium formate)** ȳȚʌǎȚÔöä ǧÀȵóȚȚ
.ǦÀÆÀȵ ÕÆȵóȚȚ Ȑƥ ǦHƱəäó ¢ö ÜtȚ ÆȵÛ ÛȐÆäÛ ƀóȚŸä şÛ ÆǦȚ ȧȚHƱÊȵ :*Description ȜȯȚöä*
.°ȳ 253 :*Melting temperature óÀŤÔφŤä ǦDȚóǎ*

:TS(Sodium hydroxide/ethanol) ȯȚφÀǮʌqä/ȳȚʌǎȚÔöä ÆÆÊõşóÆÆŁ
TS (ȯ/ȟ750~) ȯȚφÀǮʌqä ȣȵ ǦÆȚÀõ ǦÆŧõ Ž R ȳȚʌǎȚÔöä ÆÆÊõşóÆÆŁ ȣȵ ȟ 50 ä äØʌ :*Procedure öäÄDȚqä*
.Ôȵ 1000 ǮÀǫφq

:TS (ȯ/ȟ50) Sodium hydroxide ȳȚʌǎȚÔöä ÆÆÊõşóÆÆŁ
.ÀǫŸöä Ž NaOH ȣȵ ȟ50 ǦääÀę ɔŸȝ ƀȚǫȚȝ ȳȚʌǎȚÔöä ÆÆÊõşóÆÆT ȯȚŸȚ

:TS (ȯ/ȟ35) Sodium nitrite ȳȚʌǎȚÔöä ǨʌÀǫφ
.(ÀǦʌÀÔÕk ȯȚȵ 0.5) ÀǫŸöä Ž $NaNO_2$ ȣȵ ȟ35 ǦääÀę ɔŸȝ ƀȚǫȚȝ R ȳȚʌǎȚÔöä ǨʌÀǫÀö ȯȚŸȚ
ɔŸȝ ƀȚǫȚȝ R ȳȚʌǎȚÔöä ÆÆèşÀäşÀǫÀö ȯȚŸȚ **:TS (ȯ/ȟ8.5) Sodium Nitroprusside** ȳȚʌǎȚÔöä ÆÆèşÀäşÀǫφ
.ÀǫŸöä Ž $Na_2Fe(NO)(CN)_5$ ȣȵ ȟ 8.5 ǦääÀę

:TS (Sodium Nitroprusside, alkaline) ƀȚŸÔöä ȳȚʌǎȚÔöä ÆÆèşÀäşÀǫφ
ǦÆȚÀõ ǦÆŧõ Ž R ȳȚʌǎȚÔöä ǧÀφȚäÀõ ȣȵ ȟ 1ş R ȳȚʌǎȚÔöä ÆÆèşÀäşÀǫφ ȣȵ ȟ 1 ä äØʌ :*Procedure öäÄDȚqä*
.Ôȵ 100 ǮÀǫφq ǒÀŧä ȣȵ

.(191ǦHƱÀÔöä Û1963 ÛSRIP) Na_2O_2 **:Sodium peroxide** ȳȚʌǎȚÔöä ÆÆÊõşƙä
ȣȚòȚȵ ȚŁ Àŧõ ȳȚʌǎȚÔöä ǧŸÆÊÆöÀè ȳÆÁǫÊǩ .$C_7H_5NaO_3$**:R (Sodium salicylate)** ȳȚʌǎȚÔöä ǧŸÆÊÆöÀè

.217 ǦHuȦÔöä Û2 ÆŸŎä Ž gǻşÀzɟä Ž

11.5 ɔŸȝ ƀzǫȝ R ȳzΛǻzÔöä ǧYŧÊŧöȦÊö ȯzŸȚ :TS (ȯ/ȟ 11.5) **Sodium salicylate** ȳzΛǻzÔöä ǧYŧÊŧöȦè

.ÀǫŸöä Ž $C_7H_5NaO_3$ ȣȵ ȟ

.(196 ǦHuȦÔöä Û1963 ÛSRIP) $Na_2SO_3,7H_2O$:**TS (Sodium sulfite)** ȳzΛǻzÔöä ǨŧȦŸè

.Ǧŧöşǻ ǦŧəȦŧŧõ ǦŧȞDZÀȵ ǻǻȵ :**RS (Spectinomycin hydrochloide)** ƙÊΛȵzǫŧÒǦÊöä ÆΛózŸõşóÆŧŧ

.Ǧŧöşǻ ǦŧəȦŧŧõ ǦŧȞDZÀȵ ǻǻȵ :**RS (Spironolactone)** ɟzǫõŦzφşƙǦÊöä

.$C_{30}H_{62}$ ÜɟäzṏÀǫǨ ÕŧƷŧȵ Ułèäǽè-23Û19Û15Û10Û6Û2 :**R(Squalane)** ɟŦäzȮÊöä

.ɟzŸöä CǼȝ Ułφ̈Λà ÕəȦè :*Description Ζȯzöä*

ȯzφȦƷΛqäş R ɟzǫŧèɟä Ž ɟȦäşØöä ǦŧHuì ÜR ȳzzşózŸÒöäş R Ƙǫɟä Ž ɟȦäşØöä Àǵ :*Solubility ǦŧφȦäşØöä*

.TS (ȯ/ȟ750~)

. $d_{20}^{20} = 0.811 - 0.813$:*Relative density ǦŧǦÊΛöä ǦzȦƷÒöä*

. $n_D^{20} = 1.451 - 1.453$: Refractiv index*øȦÊÒφŦä ÆÊΛȵ*

:**R (Sudan red)** ɟäǻzÊöä gÀƀ

.$C_{22}H_{16}N_4O$ ÜC.I. 26100 Ü23 ÆΛØŧä gÀƀ ÜIII ɟäǻzè Üȯzǫzȵφ-2-(şàYŧÆzşàYŧÆz-4)-1

.ÀŧȚ Ułφ̈ ȧzHuÊȵ :*Description Ζȯzöä*

.R ȳzzşózŸÒöä Ž ā̈äşǽ ÜŏȦŧä Ž ā̈äşǽ Ƙdȵ ÆŸŧȝ :*Solubility ǦŧφȦäşØöä*

:**TS (Sudan red)** ɟäǻzÊöä gÀƀ

.R1 ŦDzŸŽöä Õŧǫŧèɟä Ŕƀ ȣȵ 100 Ž R G ɟäǻzÊöä gÀƀ ȣȵ ȟ 0.5 ā̈äØΛ :*Procedure ŏäÄDZqä*

.Ǧŧöşǻ ǦŧəȦŧŧõ ǦŧȞDZÀȵ ǻǻȵ :**RS (Sulfacetamide)** ÆŧȵȦǫŧèȦŸÊöä

.Ǧŧöşǻ ǦŧəȦŧŧõ ǦŧȞDZÀȵ ǻǻȵ :**RS (Sulfadimidine)** ɟşÆŧƨǻȦŸÊöä

.Ǧŧöşǻ ǦŧəȦŧŧõ ǦŧȞDZÀȵ ǻǻȵ :**RS (Sulfadoxine)** ƙÊõşǻȦŸÊöä

H_3NO_3S ȣȵ ȟ5 ǦäÀę ɔŸȝ ƀzǫȝ R ÕŧȵȦŸÊöä ŔŧΣ ȯzŸȚ :**TS (ȯ/ȟ5) (Sulfamic acid)** ÕŧȵȦŸÊöä Ŕƀ

.ÀǫŸöä Ž

:**TS (Sulfanilic acid, diazotized)** ÂΛÆŧä ÕŧŸŧφȦŸÊöä Ŕƀ

VS (ȯ/ȯzȵ 1) ÕΛózŸõşóÆŧTä Ŕƀ ȣȵ Õȵ 20 Ž ÕŧŸŧφȦŸÊöä Ŕƀ ȣȵ ȟ 0.2 ā̈äØΛ :*Procedure ŏäÄDZqä*

(ȯ/ȟ35) ȳzΛǻzÔöä ƙΛÀǫφ ȣȵ Õȵ 2.5 ÀŧǫÊŧä ÕΛÀHuǫöä ȝȵ gÀÛę ÀǫÙ gÀÛę 8ȦŘΛ ÛÆŧŸƨä Ž ǻƎΛ ÛƙǺÊǫöä ȝȵ

.TS (ȯ/ȟ50) Ős̄ŋĺÁŸÊöä Ŕƥ ȡŋ Ōŋ 1 Ȣ ÁŘ ȯ Ę ǝÁęǎ 10 gÆŋ ÆŸƨä Ž ÀŐǫÊŋö ōÀǫ ÛTS

.ǦŋöŞǎ ǦŋǝÁŋŧŋõ ǦŋŐDZÀŋ gǎÁŋ :**RS (Sulfasalazine)** ȡ ȡÀŋŘÁŸÊöä

:**TS (Sulfuric acid/methanol)** ȯǫǫÁŐŋŧä/Ős̄ȯǫÁŸÊöä Ŕƥ

.R ȯǫǫÁŐŋŧä ȡŋ Ōŋ 90ş TS (ȯ/ȟ1760~) Ős̄ȯǫÁŸÊöä Ŕƥ ȡŋ Ōŋ 10 ŧŸÔÁŋ ǎƎ :*Procedure öäÄDZqä*

.Ž Ûŷä ŽÂŞ Ûȷ ÁÒŋqä øÆę ǎǎøÁä ȯǫŸ ŧä ŞÁŽ Ûȯǫǫ ÁŐŋŧä Ę Ŕŧ Σä ÆÆÆì øØШ Ȣ ÁŘ

Ę ŏÁŧŋÁä Ž ÁƆ ÛTS (ȯ/ȟ1760~) Ős̄ȯǫÁŸÊöä Ŕƥ :**VS (ȯ/ȯǫŋ 0.125) (Sulfuric acid)** Ős̄ȯǫÁŸÊöä Ŕƥ

.Ōŋ 1000 Ž H_2SO_4 ȡŋ ȟ 12.52 ǫŞ

Ğǫǫòǫŧä ǦŐÆÀÛöä ŧ ÁǦkÁä ȯǫŸHŧŸö ŕǫŞŔŧä ÂŋõÀǫöä ȡŋ ǨŋŐöä ÞÀz :*Method of standardization gÄÁÁĤŧä ǦŐÆÁü*

.209 ǦHŧÁÔöä Û1 ÆŸŐä ÛVS (ȯ/ȯǫŋ 0.5) Ős̄ȯǫÁŸÊöä Ŕƥ ȷ ǫÁ3 ǨƠ

.(205 ǦHŧÁÔöä Û1963 ÛSRIP) $C_{76}H_{25}O_{46}$:**R (Tannic acid)** Ős̄ŋÁǫöä Ŕƥ

Ž $C_{76}H_{25}O_{46}$ ȡŋ ȟ 50 ǦäÄę ǫŸ3 ÞǫŐ3 R Ős̄ŋÁǫöä Ŕŧ Σ ȯǫŸ :**TS (ȯ/ȟ50) (Tannic acid)** Ős̄ŋÁǫöä Ŕƥ

.ÀǫŸöä

ȡŋ ȟ 200 ǦäÄę ǫŸ3 ÞǫŐ3 Ős̄ÀùÀÛöä Ŕŧ Σ ȯǫŸ :**TS (ȯ/ȟ200) (Tartaric acid)** Ős̄ÀùÀÛöä Ŕƥ

.ÀǫŸöä Ž $C_4H_6O_6$

.ǦŋöŞǎ ǦŋǝÁŋŧŋõ ǦŋŐDZÀŋ gǎÁŋ :**RS (Testosterone enantate)** ȷ ŞǨǫèǫǫÊǫöä ğ ÁǫŋÁÁÀÛ

:**(Tetrabutylammonium hydroxide/methanol) TS** ȯǫǫÁŐŋŧä/ȳǫŋǫǫŋȷä ŌŋǨǫä Ȣ3ÁäØ ÆŋÊõŞØÆŋŁ

ȯǫÔΣä ǫØǫǵ ȯǫǫÁŐŋŧÁä TS ȳǫŋǫǫŋȷä ŌŋǨǫä Ȣ3ÁäØ ÆŋÊõŞØÆŋŁ ȡŋ Ȣ ÁõŋÁDzǵ ǫÁƆ :*Procedure öäÄDZqä*

.ÀǫÖ ȢŸŧä Ž $C_{16}H_{37}NO$ ȡŋ ȟ 0.25 ǫŸ3 ÞǫŐ3 ȯǫŸ ǫŸ3

.$C_{16}H_{37}NO$:**TS (Tetrabutylammonium hydroxide)** ȳǫŋǫǫŋȷä ŌŋǨǫä Ȣ3ÁäØ ÆŋÊõŞØÆŋŁ

.(ȯ/ȯǫŋ 1.5~) ÀǫŸöä Ž $C_{16}H_{37}NO$ ȡŋ ȟ 400 ǦäÄę ÞǫŐ3 ŏÁŧä Ž ȯǫŸ

.C_4H_8O :**R (Tetrahydrofuran)** ȷ äØǫǫŞØÆŋŁ Ȣ3ÁäØ

.Ğ3ǽŕ ÛgÂŋư ǦHŧäÄöä ÜȷǫŸöä CÆ3 ŌǝÁè :*Description Ƒȯǫöä*

.ŐǫÀÔk °ȳ 66 :*Boiling point ȷÁŸ8öä ǦÛÔǫ*

. ρ_{20} = ȯ/ŋõ 0.886-0.884 :*Mass density ǦŸǫÓöä ǦǫÁŐõ*

.ȯǫŔöä ȡŋ ǫŧHŧŞ ÛŐÆŋDZ gȯǫŸư gK8ò ğÁŞÁg Ž ȷÂƆ :*Storage ȡÂÁǫöä*

.Łŋèǫǫöä ǦǝÁÔö ǫŸ3 Û%0.1 ȡ3 ÆÂÁ ŕ ÛŁǝŸŋ ŞǫÁg ÞŸ ÂŋõÀǩŞ Łèä ȷÁŋä Æz :*Labelling Łŋèǫǫöä*

.ĞŁõşǻ ĞŁəÀŁŧŁõ ĞŁĦDZÀŋ ǵǻŋ :**RS (Thioacetazone)** ɟşàÀǾŁèÜzŁŽõä

.ĞŁõşǻ ĞŁəÀŁŧŁõ ĞŁĦDZÀŋ ǵǻŋ :**RS (Tiabendazol)** ȯşàÀǾàÀŁǾõä

ȣŋ %15 ĞääÀę ɔŸȝ Ƀz0Ʒ ȳzŁǾÀǾŁǾõä ÆΛózŸõ ȣǾŸŽõ ȯzŸŢ :**R (Titanium trichloride)** ȳzŁǾÀǾŁǾõä ÆΛózŸõ ȣǾŸǾ

.(208 ĞĦȣÁÔõä Û1963 ÛSRIP) $TiCl_3$

.ρ_{20}= ȯ/ŋõ 1.2~ :*Mass density ĞŸǾȮõä ĞzÁŽõ*

ȳzŁǾÀǾŁǾõä ÆΛózŸõ ȣǾŸǾ ȣŋ Ȯŋ 100 ZÁƩ :**vs** (ȯ/ȯzŋ **0.1**) **(Titanium trichloride)** ȳzŁǾÀǾŁǾõä ÆΛózŸõ ȣǾŸǾ ÆŁÊõÜ ȣəÀÁǾ ȣŋ ƁÁ ŋ ä õÁŋä ȣŋ ĞŁzÀõ ĞŁŧõ ȣÁÑΛş TS (ȯ/ȟ250~) ÕΛózŸõşǻÆŁTä Ř ƥ ȣŋ Ȯŋ 200 øä R .Ȯŋ 1000 ƷÀǾǾq R ɟzäÀȮõä

Ɜŋ .ȳäÆÁǾèŕä ȮĞę gÀÌÀĞŋ îzĞŘŋä ÂŁõÀǾõä ȣŋ ŘĞƷǾõä ƁÀz :*Method of standardization gÀÁÁĦŋä ĞÕΛÁÜ* Ž TS (ȯ/ȟ100~) ÕΛózÁŸÊõä Ř ŧШ ĞŘŧŢ VS (ȯ/ȯzŋ 0.1) ÕΛKÁõä ȳzŁǾzŋÜ ǵÁÁŸè ȣŋ Ȯŋ 25 ÀΛÁĦΛ ȯzŸŧä Ȯõ .ÀĦÎŧõ ĞΛÁŸÁõä ĞÛÕǾ ȮĞę ĞşzHŸŋ TS (ȯ/ȟ75) ȳzŁǾzŋjä ǵÁǾÁŁèzŁǾ ĞzÁŕŭä ÛR ɟzäÀȮõä ÆŁÊõÜ ȣəÀÁǾ ȣŋ zDZ .$TiCl_3$ ȣŋ ŋŸŋ 15.43 øõ ùzÁȮΛ VS (ȯ/ȯzŋ 0.1) ÕΛKÁõä ȳzŁǾzŋÜ ǵÁÁŸè ȣŋ Ȯŋ 1

.(208 ĞĦȣÁÔõä Û1963 ÛSRIP) $C_{28}H_{19}N_5Na_2O_6S_4$:**R (Titan yellow)** ɟÀǾŁǾõä ǵÀÁò

:**TS (Titan yellow)** ɟÀǾŁǾõä ǵÀÁò

.Ȯŋ 100 ƷÀǾǾq ǻÁŋä ȣŋ ĞŁzÁõ ĞŁŧõ Ž R ɟÀǾŁǾõä ǵÀÁò ȣŋ ȟ0.05 ãäØΛ :*Procedure ǻäÁDZqä*

.ĞŁõşǻ ĞŁəÀŁŧŁõ ĞŁĦDZÀŋ ǵǻŋ :**RS (Trihexyphenidyl hydrochloride)** ÕΛÆŁÁŁÁŁÒÊŦΛÀǾõä ÆΛózŸõşǻÆŁŁ

:**TS (Triketohydrindene/butanol)** ȯzǾÁŽzä/ȣΛÆΛóÆŁŁzǾŁõ ȣǾŸǾ

ĞĦĞÎŋ ȯzǾÁŽzä-1 ȣŋ ĞŁzÁõ ĞŁŧõ Ž R ȣΛÆΛóÆŁŁzǾŁõ ȣǾŸǾ ǵäóÆŁŁ ȣŋ ȟ 0.1 ãäØΛ :*Procedure ǻäÁDZqä*

.Ȯŋ 100 ƷÀǾǾq ǻÁŋÁä ŸĞę

zǾŁõ ȣǾŸǾ ǵäóÆŁT ȯzŸŢ :**TS** (ȯ/ȟ1) **(Triketohydrindene hydrate)** ȣΛÆΛóÆŁŁzǾŁõ ȣǾŸǾ ǵäóÆŁŁ .ÀǾŸõä Ž $C_9H_4O_3$ ȣŋ ȟ 1 ĞääÀę ɔŸȝ Ƀz0Ʒ R ȣΛÆΛóÆŁŁ

:**TS (Triketohydrindene/methanol)** ȯzǾÁƷŁŋ/ȣΛÆΛóÆŁŁzǾŁõ ȣǾŸǾ

ƷÀǾǾq R ɟzǾÁƷŁŋä ȣŋ ĞŁzÁõ ĞŁŧõ Ž R ȣΛÆΛóÆŁŁzǾŁõ ȣǾŸǾ ǵäóÆŁŁ ȣŋ ȟ 1.0 ãäØΛ :*Procedure ǻäÁDZqä*

.Ȯŋ 100

.ÂDZÀÀù ȯzǾÁƷŁŋ/ȣΛÆΛóÆŁŁ ȣǾŸǾ KÎŘƠ ÆŁz :ĞŢǵŸŋ

:**TS (Triketohydrindene/pyridine/acetone)** ɟzǾŁèÜ/ȣΛÆΛKä/ȣΛÆΛóÆŁŁzǾŁõ ȣǾŸǾ

:TS (Triketohydrindene/pyridine/acetone) ȯzφÅǩzä/ȣΛÆΛǩä/ȣΛÆΛøÆŁzφŁõ ȕφŸφ ȣη ǧ 0.25 ãäØΛ :*Procedure ŏäÄDZqä*

.R ȷzφŁèȷäȘ R

:TS (Triketohydrindene/stannous chloride) ÀΛÆÔÎöä ÆΛøzŸõ/ȣΛÆΛøÆŁzφŁõ ȕφŸφ ȣη ǧ 1 ãäØΛ :*Procedure ŏäÄDZqä*

.Îη 100 ȝÅφφq R ȯzφÅǩzä-1

.ÄDZàÅù ℂKŘƠ Æz :*ĞŢǵŸη*

:TS (Triketohydrindene/pyridine/acetone) ȯzφÅǩzä/ȣΛÆΛǩä/ȣΛÆΛøÆŁzφŁõ ȕφŸφ ȣη ǧ 4 ãäØΛ :*Procedure ŏäÄDZqä*

ȯzȮŁŸd ÎŁȝŁη ÆŁǵȘ ǨφÙ ȣη ǧ 1 ȝη ZÛŸä ȝÀł .R (ethylene glycol monomethyl ether) ǩŸŁȝΛqä

Ž R ƀÀΛÆÔÎöä ÆΛøzŸõ ȣη ǧ 0.16 ãäØΛ .(A ȯzŸ∓ä) ǴΠÀłȘ (ÀφηȘÀȮη 840-ÀφηȘÀȮη 300) exchange resin

.(B ȯzŸŢ) TS Û5.5 ŏÅŁÅä Ûǧ ÅφŁèȷä ǦəøäÅ ȣη ǧ 100

.ǩȯzŸ∓ä ȣη ǦöäÅǩφη ȕzDzǵ ȝÂφ ÛǵÀÌÅǴη ȕäÉÅφèrä ÎǴφ

.(129 ǦHÙÅÔöä Û1963 ÛSRIP) C_8H_{18} Ü*iso*-Octane :**R (2.2.4-Trimethylpentane)** ȷÅφÅä ÎŁȝŁη ȕφŸφ**-4.2.2**

.$C_{18}H_{15}Sb$:**R (Triphenylantimony)** ȷzŁŁφrä ÎŁÆÆz ȕφŸφ

.ÄǴΛÀÎǩ °ȳ 55 :*Melting temperature øÅŢÔφrä ǦDZøÅ*

.$Na_3PO_4,12H_2O$:**R (Trisodium orthophosphate)** ȕzΛÅzÔöä ȕφŸφ ǧÅÅèzzzφøȘÛ

.ŘŁäÛ ƀøzŸä ȧzHÙÊη ȘÛ ȷzŸöä ǦƐÆ3 ǧäøzŸä :*Description ZÖzöä*

ÆŁÅŸè ȕ3ÅÅφ Ž rȘ TS (ȯ/Ĥ750~) ȯzφÅȝΛqä Ž ÄŁŸŁ3 ãäȘä Ǩd ÜöÅŁä Ž ȷÅäȘÓöä Àǵ :*Solubility* ǦŁφÅäȘÓöä

.R ȷzäÀȮöä

ȕφŸφ ǧÅÅèzzzφøȘÛ øÛ ȯzŸŢ **TS** :(ȯ/Ĥ2)**(Trisodium orthophosphate)** ȕzΛÅzÔöä ȕφŸφ ǧÅÅèzzzφøȘÛ

.ÀφŸöä Ž Na_3PO_4 ȣη ĤäÅÅę ƨŸ3 ƀzφȝ ȕzΛÅzÔöä

.1-β-D-Ribofuranosyluracil Ü$C_9H_{12}N_2O_6$:**R (Uridine)** ȣΛÆΛøzŁöä

.ŏÅŢä Ž ãäȘä :*Solubility ǦŁφÅäȘÓöä*

.ÄǴΛÀÎǩ °ȳ 165 :*Melting temperature øÅŢÔφrä ǦDZøÅ*

.ÅøÅä ȷÅȮη Ž ȷÂƐ :*Storage ȣΛÂÁφöä*

.ǦŁöȘÅ ǦŁƀÅŁŁŁõ ǦŁHDZÀη ǵÅη :**RS (Valproic acid)** ÎΛȘΞöÅÅöä Řƀ

.V_2O_5 :**R (Vanadium pentoxide)** ȳȚȴȷȵȶȸȹȻȼȽȾ ȿɀȀȂȃȄȅ ȆȇȈȉȊȋȌȍȎȏȐȑȒȓȔȕȖȗȘșȚțȜȝȞȟ

.ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ :*Description* *ȚȜȚȝȞȟ*

Ž ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ Ž ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ :*Solubility* *ȚȜȚȝȞȟ*

.TS (ȯ/ȟ750~) ȯȚȜȚȝȞȟ

:**TS (Vanadium/sulfuric acid)** ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ

ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ 4 Ž R ȳȚȴȷȵȶȸȹȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ ɖȡ ȟ 0.20 ȢȣȤȥ :*Procedure* *ȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ*

.ȟ 100 ɔøɋɡ ȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ ȺȽȾȿ TS (ȯ/ȟ1760~)

:**TS (Vanillin/hydrochloric acid)** ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ

TS (ȯ/ȟ250~) ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ ȠȡȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ ɖȡ ȟ 1.0 ȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ :*Procedure* *ȢȣȤȥȦȧȨȩȪȫȬȭȮȯȰȱȲȳȴȵȶȷȸȹȺȻȼȽȾȿɀɁɂɃɄɅɆɇɈɉɊɋɌɍɎɏɐɑɒɓɔɕɖɗɘəɚɛɜɝɞɟɠ*

.ȟ 100 ȝȜȜȜ