Egypt. J. Pharm. Sci. **35**, No. 1-6, pp. 365-381 (1994)

Formulation and Evaluation of Sucralfate Suspension

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AS is often the case with gastro-enteric therapy, the activity of a product is linked to the surface area, which offers the rational basis for the development of liquid dosage forms. Hence, eight sucralfate suspension formulae were layed down and prepared using, various suspending agents as hydroxypropyl methylcellulose K4M, methyl cellulose, Carbopol 934, avicel RC 591, sorbitol, in addition to preservatives, flavouring and sweetening agents. The in-vitro pharmaceutical studies in terms of sedmintation volume, scum formation were carried out. The physically stable formulations were subjected to rheological investigation as well as in-vivo studies on rats to illustrate its protective effect on ethanol induced gastric ulceration. Results of in-vitro studies showed that products of formula 6 containing avicel RC 591, sorbitol, glycerin and formula 8 composed of avicel RC 591, hydroxypropyl methylcellulose, as dispersent system exhibited the optimum characteristics of antacid suspensions. They showed reasonable rapidly redispersible sediments and homogeneous dense adherant scums. Also rheological studies of these two products showed pseudoplastic thixotropic flow patterns which were kept stable on storage for 6 months. The in-vivo studies on rats using suspensions of formulae 6 and 8 in comparison to plain sucralfate suspension (formula 1) showed that there is a significant protective effect which was more apparent through suspension of formula 6. This suspension could be successfully used in the prophylaxis of ulceration induced by ethanol as shown from its low ulcer index and high preventive index.

Sucralfate is a basic aluminium salt of the disaccharide sucrose octasulfate. It is an antiulcer drug, used in the treatment of duodenal and gastric ulcer but differs from antacids and H_2-receptor blockers in its mode of action. It is virtiually unabsorbed and exerts a local rather than systemic action [1]. It acts nonsystemically as a barrier to acid, pepsin and bile at the ulcer site [2]. After initial contact with gastric acid, some of aluminium hydroxide radicle dissociate leaving sucrose with one to seven ionised sulfate groups. These negatively charged ions are insoluble, viscous and adherent to positively charged necrotic tissue proteins. This cytoprotecive barrier protects the ulcer from the potential ulcerogenic properties of acid, bile and pepsin [3]. Sucralfate also inhibits pepsin activity and has found to bind bile salts [4]. Sucralfate adhers prefereably to exposed tissues, but also binds to normal tissues [5]. It is concluded that sucralfate could be used for the relief of gastrointestinal symptoms associated with the use of non-steroidal anti-inflammatory analgesics without affecting their bioavalability [6]. Studies performed by Borrero *et al* [7], indicate that sucralfate may be as effective as antacid in the prophylaxis of gastrointestinal bleeding in critically ill patients. Sucralfate offers an advantage over antacids and histamine H_2 antagonsits in the prophylaxis, prevention and treatment of stress induced ulcers [8,9]. Previous studies in man have determined that sucralfate has no significant effect on the bioavailability of digoxin [10], ibuprofen [11] warfarin [12], acetaminophen [13], but with phenytoin [14], small decrease in rate or extent of absorption, or both occurs. Recent evidence suggests that sucralfate may enhance the prodution of endogenous mucosal prostaglandins E_2 [15].

The drug in suspesion dosage form (freshly prepared from tablet) has been used in the treatment of mouth and oesophageal ulcers due to radiation, chemotherapy and sclerotherapy [5, 16]. Literature review, according to our knowledge is lacking any information about sucralfate suspension formulation. The present study was designated to formulate sucralfate in suspension form. The prepared products are subjected to in-vitro and in-vivo pharmaceutical evaluation to select the optimum and effective formula.

Experimental

Material and equipment

Sucralfate, supplied kindly from El-Nasr Pharmaceutical Chemicals Co., Abu Zaabal, Eygpt.; Hydroxypropyl methylcellulose K4M (HPMC), Tama, Japan; Methyl cellulose 4000 (MC), Aldrich, USA; Carbopol 934 (CP), Goodrich, USA; Sorbitol 70%, Aldrich, USA; Microcrystaline cellulose, Avicel RC 591 (MCC), FMC corporation, Philadelphia, USA; Absolute ethyl alcohol, Merck, Germany; Pure grades of methyl paraben (MP), propyl paraben (PP), oil of mentha (OM), oil of anise (OA), triethanol amine (TEA) and aspartame (A).

Rotary viscometer (Boulten self and Lee Ltd, England, UK). pH meter (CG 820 Scott Gerate, Germany). Rats, male Sprague Dawley strain rats weighing 120-140 g (Kindly provided by El-Nasr Pharmaceutical Chemicals Co., Abu Zaabal, Egypt).

Methods

1. Formulation of sucralfate suspensions

Nine formulations were layed down as mentioned in Table 1, using different adjuvants, in addition to preservatives (MP, PP), flavouring agents (OM, OA) and sweetening agent (A). The products were prepared according to the following general procedure:

1. Levigate thorougly 10 gm of sucralfate with approximately 20 ml water for injection (WFI) or sorbitol 70% if present in the formula using mortar and pestle.

2. The adjuvant solution or magma was then added with trituration to form a smooth paste.

3. Blend of propyl paraben and methyl paraben by the ratio of 0.05 & 0.15 % respectively, was added and the suspension was transferred to 100 ml glass stoppered measuring cylinder.

4. Flavouring agent (OM, ON) and sweetening agent (A) with approximately 10 ml of WFI were added, the product was then mixed well and adjusted to volume with WFI and subjected to homogenization.

TABLE 1. Proposed formulations of sucralfate suspensions.

Ingredients	Formulation No.								
	1	2	3	4	5	6	7	8	9
Sucrafate	10	10	10	10	10	10	10	10	10
HPMC	-	0.5	-	-	-	-	2	4	4
MC	-	-	0.5	--	-	-	-	-	-
Cp	-	-	-	0.5	-	-	-	-	-
MCC	-	-	-	-	-	1	2	2	2
Sorbitol 70 %		-	-	-	10	10	-	-	40
Glycerin		-	-	-	10	10	-	-	-
Presevatives (Mp + PP)	0.15+0.0.5	0.15+0.0.5	0.15+0.0.5	0.15+0.0.5	0.15+0.0.5	0.15+0.0.5	0.15+0.0.5	0.15+0.0.5	0.15+0.0.5
Flavouring agents (OM + OA)	0.1+0.1	0.1+0.1	0.1+0.1	0.1+0.1	0.1+0.1	0.1+0.1	0.1+0.1	0.1+0.1	0.1+0.1
Sweetening agent (A)	0.5	0.5	0.5	-	-	-	0.5	0.5	0.5
WFI 10	100	100	100	100	100	100	100	100	100

2. *Evaluation of sucralfate suspensions*

(A) *Pharmaceutical evaluation*

1. *Sedimentation volume (V_u/V_o) and redispersibility*: The ratio between the height of the sediment volume to the original height of the sample at appropriate time intervals was measured. After sedimentation equilibrium, the suspension supernatant was evaluated for its degree of clarity. The redispersibility was determined as the number of upside down inversions of the suspension contained in the measure to be homogeneously redispersed.

2. *Scum formation*: 10 ml of sucralfate suspension, were addad at once to 50ml of 0.1 N hydrochloric acid solution in a 100 ml beaker. The scum formed was examined within the first hour for:

a - time of complete formation.

b - homogeneity

c - clarity of supernatant.

d - mobility.

These parameters were reevaluated after 2 hr whenever possible.

3. *Acid neutralizing capacity (ANC)*: There are many methods for determining acid neutralizing capacity of antacids in-vitro like schaub's test modified Reheis reaction velocity test [17] and USP method [18]. The USP XXII method was adopted in this study, using a volume of one dose (10 ml).

4. *Rheological characteristics*: Suspensions exhibiting adequate physical stability were examined for their flow behaviours when fresh and after storage for six months.

(B) *In-vivo evaluation*

The selected products were evaluated through their efficiency as protecive antiulcer using ethanol ulcer induction method [19,20]. Thirty male, Sprague Dawley strain rats weighing 120-140 g were utilized. The method of Robert *et al* [19] and Konturek *et al* [20] was used for induction of ulcer. Animals were fasted for 48 hr prior to the experiment but had free access to water. On the day of experiment, animals were housed

singly in a metal cages with widen meshed flat bottom at a temperature (22 ± 1°) and humidity (65-70%). Rats were divided into five equal groups each consists of six rats.

group I : received 1 ml saline.

group II : received 1 ml saline, (control)

group III: received 1 ml of sucralfate suspension formula 1.

group IV: received 1 ml of sucralfate suspension formula 6.

group V : received 1 ml of sucralfate suspension formula 8.

The rats received saline or the specific formula by using a metal orogastric tube as a single dose. Thirty minutes later, each animal received an oral bolus of absolute ethanol (6.6 mg/kg) except those of group I which received equal volume of saline. The absolute ethanol or saline are instilled directly into the stomach using the same orogastric tubing system as a single dose. Fifteen minutes later, the animals were sacrificed by cervical dislocation, abdominal cavity was opened, and the stomach of each rat was removed, opened along the greater curvature, rinsed with saline and stretched out by means of pins on card board with cork underlying. The prepared stomach were fixed in 10% formalin for 30 min. the mucous was examined by an observer for presence of ulceration. Gastric ulcerations were evaluated as the ulcer index (UI) [21] according to the following equation:

UI = mean number of ulcer / rat + mean severity / rat + incidence of ulceration / 10.

The preventive effect against gastric ulceration was expressed as the preventive index (PI%) [22], as follows:

$$PI\% = \frac{\text{UI of control gp - UI of drug treated gp}}{\text{UI of control gp}} \times 100$$

3. *Stability and follow up*:

The prepared suspensions were stored at room temperature and reexamined after six month for:

1. sedimentation volume and redispersibility.
2. scum formation.
3. acid neutralizing capacity.
4. rheological characteristics.

Results and Discussion

The proposed formulae were prepared according to the stated procedure and assured to contain the stated amount of active ingredient through aluminium ion and sulphate ion content determinations [23]. As sucralfate suspension was intended to be formulated in suspension form to act as antiulcer product, it deemed necessary to have good suspension properties as well as optimum scum formation potenials. Hence the products prepared were subjected to sedimentation and rheological studies and scum formation characteristics.

Table 2 shows the sedimentation results of the proposed 8 formulae (F 2-9), in comparison to F 1 containing sucralfate alone as a reference. The data revealed that the reference product, F I, sedimented rapidly to form a caked product which was difficult to redisperse. On the other hand product prepared according to F9, although sedimented very slowly, it was too viscous to be redispersed or poured from the container. Products prepared through formulae 2-9 stabilized using adjuvants of different nature exhibited different sedimentation patterns to equilibrate after about 3 months. The apparent sequence of sedimentation patterns of the products was as follows: F9 > F8 > F7, F6, F5 > F4 > F 3. Such sequence was estimated according to both sedimentation rate as well as initial sediment volume measured. It is worthy stating that during the initial sedimentation period products of F 1-5 showed a clear supernatants, while those of F 6-9 acquired variable turbidities. Upon storage of products for 6 months, products prepared according to F 1 and F 2 showed increasing turbidity after redispersion.

Satisfactory suspension products should be easily redispersed upon gentle shaking and should remain homogeneous for at least a period of time necessary to disperse the required dose. Taking the number of inversions of the sedimented products as a measure of their suspension

TABLE 2. Sedimentation results of sucralfate supensions.

Formula No.	Sedimentation volume after (days)								No. of Inversion after 3M.	Clarity of supernatant after 3M.	Clarity of supernatant after 6M.
	5	10	15	20	30	45	60	90			
1	0.27	0.27	0.25	0.25	0.25	0.25	0.25	0.25	> 40	clear	turbid
2	0.42	0.40	0.38	0.39	0.39	0.35	0.33	0.33	8	clear	turbid
3	0.30	0.26	0.26	0.25	0.25	0.24	0.24	0.23	10	clear	clear
4	0.27	0.25	0.25	0.25	0.24	0.24	0.24	0.24	34	clear	clear
5	0.27	0.27	0.27	0.27	0.27	0.26	0.25	0.25	2	clear	clear
6	0.28	0.28	0.26	0.25	0.25	0.25	0.25	0.25	1	slightly turbid	slightly turbid
7	0.30	0.28	0.27	0.26	0.26	0.26	0.25	0.25	9	turbid	turbid
8	0.36	0.35	0.32	0.31	0.30	0.30	0.30	0.30	3	slightly turbid	turbid
9	0.49	0.48	0.48	0.47	0.46	0.46	0.46	0.46	-	turbid	turbid

efficiency, the data in Table 2 could contribute for the selection of optimum suspension products. It is obvious that suspension prepared according to F 6 showed the maximum redispersibility after one inversion inspite of its low sedimentation potenial. The promising products prepared could be arranged acording to their descending redispersibility as follows : F 6 > F 5 > F 8 >> F 2 > F 7 > F 3 and lastly F 4 which showed very low dispersibility potenial.

A successful local antiulcer product could be evaluated through its efficient scum formation. A satisfactory formula should form an extremely homogeneous adhering scum as soon as possible. The parameters measured in Table 3 gave a good contribution for the evaluation of the scum formation of the prepared products. Product of F 5 showed the minimum time of scum formation (2 min.) followed by those of F 6, F 7 and F 8 (7 min.) < F 2 < F 4 < F 3 which showed nearly the same time of the reference formula (1). Again, sucralfate suspension of F 9 showed the longest and worthest scum formation time. The scums formed by products F 6 and F 8 showed the optimum characterstics being homogeneous, dense and adhering to the beaker bottom followed by those formed by F 5 and F 7 being homogeneous but fluffy scums. All the products showed various degrees of turbidity of supernatants above scums which gradually cleared. After two hours, all supernatants were completely clear except those of products 7-9. Hence, products prepared according to F 6 and F 8

TABLE 3. Scum characteristics of sucralfate suspensions.

Formula No.	1	2	3	4	5	6	7	8	9
Time of formation (minutes)	12	8	13	10	2	7	7	7	20
Homogeneity (Scored)*	1	1	1	1	2	3	2	3	1
Clarity of supernatant.									
Fresh	N.C.	N.C.	N.C.	N.C.	N.C.	N.C.	N.C.	N.C.	N.C.
After 2 hr.	clear	clear	clear	clear	clear	clear	turbid	turbid	turbid

*1. Granular internpted, fluffy scum. 2. Homogenous fluffy scum.
3..Homogenous dense scum. N.C. Not clear.

appeared to exhibit optimum scum of shortest formation time, complete homogeneity, least mobility and clarity of their supernatants.

Acid neutralizing capacity, although has no significance in sucralfate products (8), showed a mean value of 12.6 mEq./g which slightly increased on storage for 6 months (14.44 mEq./g).

The rheological behaviours of certain selected sucralfate suspensions appear in Fig. 1. It is apparent that most suspensions exhibited plastic or pseudoplastic behaviour with varying degrees of thixotropy, which is the required rheological pattern of flocculated suspensions. Fresh plain sucralfate suspension acquired a highly pseudoplastic behaviour as shown by its low index of pseudoplasticity (N value) of 0.2. On storage it forms a hard caked product which could not be rheologically tested. On the other hand, product of F 2 behaved as slightly nearly plastic (N = 0.85) thixotropic product which lost its thixotropy on storage (N = 0.83), while product F 3 showed a pseudoplastic product without thixotropy with N = 0.39 which increased on storage (N = 0.48). Sucralfate suspensions of F 6 and F 8 showed pseudoplastic thixotropic behaviours (N = 0.34, 0.45 respectively) which maintained nearly their thixotropy with slight increased pseudoplasticty (N = 0.55 and 0.53) on storage. Their viscosities ranged between (81.2 and 105.2 cp) respectively.

TABLE 4. Mean parameters of in-vivo - studies of selected sucralfate suspensions.

Parameter	gp I (saline)	gp II (control)	gp III (F 2)	gp IV (F 6)	gp V (F 8)
Mean No. of ulcer/rat ± SE	zero	12.5 ± 0.885	5.5 ± 1.0879	0.66 ±0.1241	4.33 ± 0.2191
Mean severity / rat ± SE	zero	4 ± 0	2.33 ± 0.3334	0.66 ±0.1241	2.33 ± 0.2108
Incidence /10	zero	10	10	6.66	10
Ulcer inde (UI)	zero	26.5	17.83*	7.98*	16.66*
Preventive index (PI)	zero	-	32.71 %	69.88 %**	37.31 %
Number of animals	6	6	6	6	6

* Sig. at $p < 0.01$ comparing the results to gp II.

** Sig. at $p < 0.01$ comparing the results to gp III.

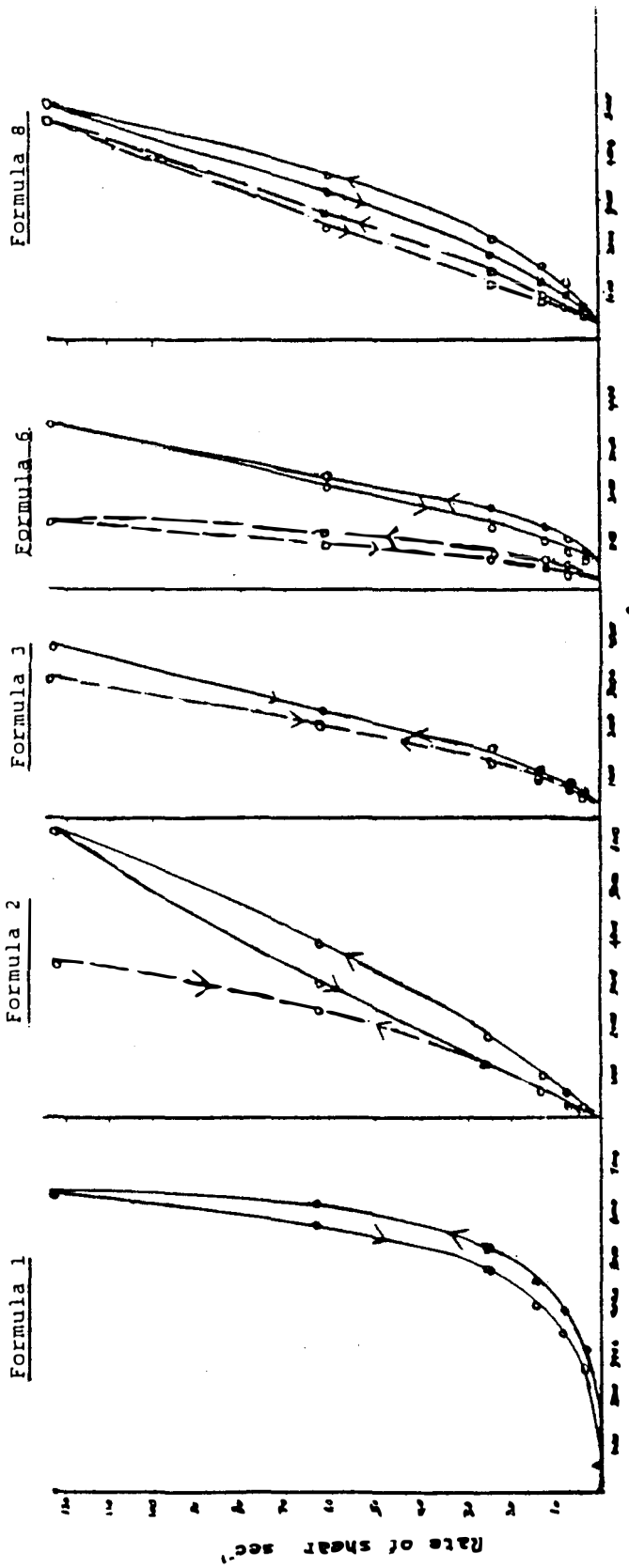

Fig. 1: Rheograms of the selected sucralfate suspensions, o ——— o
Fresh, o-----o stored for 6 months.

Suspensions of F 6 and F 8, being of suitable sedimentation and optimum scum formation and rheological characters, were further subjected to in-vivo ulcer protective studies.

In - vivo study of antiulcer activity of selected sucralfate suspesion formulae was evaluated through a number of parameters. The evaluation parameters were ulcer index (UI) and preventive index (PI) which were computed through the experimental parameters measured viz., mean number of ulcers / rat, mean severity of ulcers / rat and ulceration incidence / 10.

Table 4 shows the experimentally measured data of mean number of ulcers / rat, mean severity of ulcers / rat and ulceration incidence / 10, while the computed UI and PI are shown in Fig. 2 and 3 respectively.

From the experimental work, rats of group I were healthy all over the experimental period, and on stomach examination they showed normal stomach wall with no inflammation, no hemorrhage or any patches of hyperemia. Some rats of group II (control-died after 5-10 min. after alcohol administration, while the rats remained alive, seemed ill, drowsy and kept stagnant without movement in their cages to the end of experiment. The mucosa of their stomach showed marked red elongated patches of ulcers ranging from 1-15 mm length, and 1-3 mm width, parallel to the long axis of the stomach and mostly confined to the corpus and less common in the antrum. Lesions of mucosal capillaries, hemorrhagic gastritis associated with physiological stress and mucosal ischemia were also noticed. Furthermore, stomach wall dehydration, constriction of the smooth muscles, intestinal hemorrhage and necrosis of luminal epithelial cells.

Animals of group III and V showed no signs of drug traces in their stomach indicating rapid drug empyting of the stomach. Also, the stomach wall showed less signs of capillary congestion, some hemorrhagic patches, reddness, inflammation, wheeling and vessel constriction. On the other hand, the rats of group IV kept healthy and of nearly normal activity during experimental period. Stomach examination of group IV showed residual drug adhering to the mucosal wall indicating homogeneous drug coating which correlates with what had been stated under scum

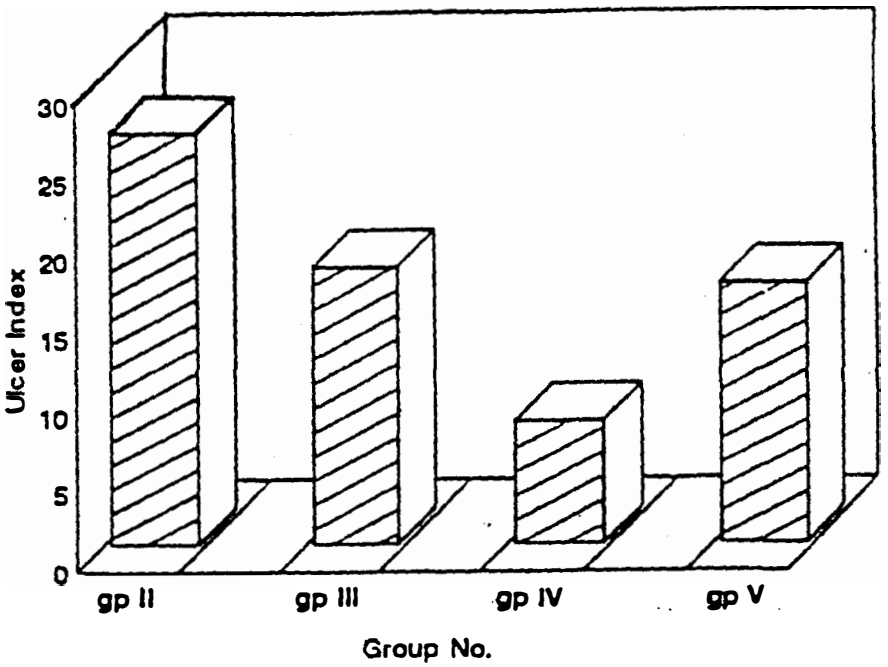

Fig. 2: Computed ulcer index values of the tested groups using sucralfate as antiulcer drug.

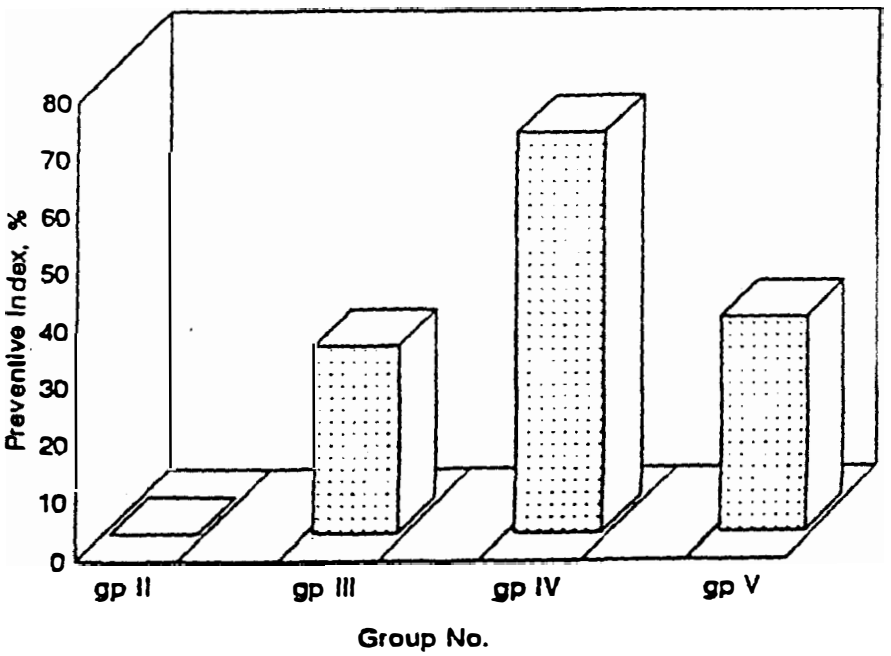

Fig. 3: Computed preventive index (%) values of the tested groups using sucralfate as antiulcer drug.

formation. The least capillary congestiong of stomach wall with no hemorrhage or hyperemia were highly apparent in this group.

The graphical representation of the results revealed that products prepared according to F 6 nad F 8 were more efficient protective against ulceration than plain product (F 1). Both F 6 and F 8 showed lower values of mean ulcer number, severity and ulcer index, while F 6, additionally showed lower incidences. All the results showed highly significant difference in relation to that of the plain product ($P < 0.01$). Furthermore, suspension of F 6 proved to be of superior efficiency in comparison to that of F 8 as shown by its lower ulcer index and higher ulcer preventive index which proved to be at highly significant difference at $p < 0.01$.

Acknowledgement: The authors would like to thank sincerely El-Nasr Pharmaceutical Chemicals Company, Abu Zaabal, for their contribution in the in-vivo studies.

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(*Received* 1/193; *accepted* 9/93)

صياغة وتقييم معلق السكرلفات

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استهدف هذا البحث تحضير معلق السكرلفات فى صياغات مختلفة لإستخدامه فى الوقاية من قرحة المعدة وقد تم تحضير عدة صياغات باستخدام مشتقات مختلفة مثل الهيدركسى بروبيل مثيل السيللوز ، وميثيل السيللوز ، والكاربوبول ٩٣٤ ، والافسيل (RC 591) والسوربيتول والجلسرين بالاضافة الى المواد الحافظة ومكسبات الطعم والرائحة . كما تمت دراسة تأثير هذه المضافات فى الصيغ المختلفة على الثبات الطبيعى لمعلق السكرلفات وهو طازج وكذلك بعد تخزينه لمدة ستة اشهر . شملت الدراسة ايضا الصفات الانسيابية لإحسن الصياغات المقترحة . وتم اجراء دراسة فارماكولوجية مقارنة لمعرفة مدى فعالية هذه المعلقات على قرح المعدة المحدثة تجريبيا بالكحول الايثلى على الفئران .

تبين من هذه الدراسة على الصيغ المختلفة لمعلقات السكرلفات ان الصيغة رقم ٦ والمحتوية على الأفسيل (RC 591) والسوربيتول والجلسرين وكذلك الصيغة رقم ٨ والمحتوية على الهيدركسى بروبيل مثيل السيللوز الأفسيل (RC 591) ان كلا منهما تعطى صفات مميزة لمعلقات الأدوية المضادة للحموضة من حيث سرعة المزج وتكوين طبقة حماية متجانسة عند اضافتها الى حمض الهيدروكلوريك كذلك اوضحت النتائج ان المعلقات لصيغتى

(٦ ، ٨) كانتا اكثر المعلقات ثباتا وافضلها فى الانسيابية حيث اعطت صفة انسيابية مناسبة استمر ثباتها حتى بعد تخزين للمستحضرات لمدة ستة اشهر .

وقد اظهرت النتائج ان اعطاء السكرلفات فى المعلقات السابقة الذكر صياغتى (٦ ، ٨) يقلل ويقى المعدة من حدوث القرحة المحدثة بالكحول الاثيلى وتبين ذلك اكثر وضوحا فى الصياغة رقم ٦ وذلك بتقليل معامل تكون القرح وزيادة معالم الوقاية من القرحة فى معدة الفئران على المجموعات المعالجة بمعلق السكرلفات مقارنة بصيغة مرجعية تتكون من الدواء فقط .