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IRAN NATIONAL LABORATORY FOR PHARMACEUTICAL QUALITY CONTROL

by

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Iran National Laboratory for Pharmaceutical Quality Control shares the responsibility for assuring users and prescribers of drugs of their safety, efficacy, identity, strength, purity and quality. The National Laboratory for Pharmaceutical Quality Control is situated at the Nejat Hospital, Pahlavi and Sepah Avenues and at present has about 2000 Sq. m. at its disposal.

The Government is supporting the National Laboratory materially by allotment of large sums. From the governmental budget all the chemicals, reagents, glassware and laboratory apparatus and sundries have been procured. During the three years when the project was assisted by the WHO the laboratory has been furnished with further physico-chemical apparatus. The library has considerably enlarged and contains about 600 volumes of professional literatures and currently 17 kinds of periodicals are subscribed.

The personnel of the laboratory actually consists of 10 doctors of pharmacy and one chemical engineer some of them with experience from foreign countries, three trained and four untrained technicians, one store-keeper, two officers, two typists and three helpers. The laboratory is well equipped for physico-chemical analysis as well as for micro-biological assays and sterility tests.

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There exists already, at the laboratory, a collection of analytical methods covering most of the registered drugs which are imported.

Arrangements are under way in order to obtain complete record of analytical methods for pharmaceutical specialities manufactured in our country. The National Laboratory should cover not only the super control of productions in their final stages but also the imported drugs and raw materials when entering the country and further after the distribution of pharmaceutical preparations.

Nowadays there are more than 1000 samples evaluated and 600 analysed per year with the present staff. From the locally produced specialities, before delivery to the market, five samples of the first production should be given to the National Laboratory and the samples are evaluated and analysed.

It should be remembered that the National Laboratory's services cannot at present, make a sufficient number of analysis to control the quality of all pharmaceutical products on the market and even for future it will be impossible for the National Laboratory to examine and analyse completely every batch of every pharmaceutical preparation. The aim can be reached only if each manufacturer also exercises the most care and control throughout the entire drug production operation.

The quality of a pharmaceutical preparation depends on the purity of the materials used in its formulation, the care with which the ingredients are measured and the precision with which they are mixed and controlled.

The National Laboratory is performing also advisory work for the production control departments, elaborating judgments on the analytical procedures prepared and suggested by the producers, and at all occasions issuing expert opinions on technical quality control problems.

Many analytical procedures were developed and many existing methods were modified in the laboratory when solving various problems of evaluation of compound drugs.

The necessity for the work of the National Laboratory for Pharmaceutical Quality Control can be shown in the following instances of misinformation on labels.

A preparation labelled to contain three sulfas, including sulfamerazine, did not have it.

A preparation which, according to packing, contains acid acetylsalicylic, caffeine, phenobarbital and phenacetine, had only acid acetylsalicylic and caffeine.

A preparation labelled to contain Vitamin B12 contained none. However, as the laboratory's staff grows in size and experience, it will be possible to make more additional helpful contribution for assuring users and prescribers of drugs with safety, efficacy, identity and quality.