

PHARMACOPŒIAS AND FORMULARIES

REVIEW OF BRITISH PHARMACOPŒIA 1953

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THE British Pharmacopœia 1953 was published on March 2, to be official on September 1, 1953. This eighth edition is the first to appear on the new 5-year revision schedule. It boasts radical innovations, the greatest of which is doubtless the use of English titles throughout; Latin and abbreviated Latin titles of the B.P. 1948 are carried over only as subsidiary titles and none have been coined for the new monographs. This results in a radical alphabetical rearrangement which will surely be the source of many complaints at first. However, it is safe to predict that the new arrangement will prove steadily more popular because of greater usefulness, if only in bringing all of the monographs of each drug into juxtaposition. Thus, with the volatile and fixed oils listed according to the first word of their titles, they no longer form a group of monographs under "Oleum". The total number of monographs has been reduced by nearly 100; the 158 deletions are replaced by only 63 additions and show further the trend away from polypharmacy. Many of the galenical preparations, all the pills, all but one of the lozenges (penicillin) and most suppositories have been deleted.

However, the B.P. 1953 is still a working manual for the pharmacist, and many preparations are formulated for quantities which the pharmacist might be expected to make. Several additions and changes occurring amongst the formulated preparations attract attention. Capsules and sterile implants form two new groups of medicaments of special interest to pharmacists and physicians. Calamine Lotion is a phenolated preparation with bentonite as the suspending agent, which goes counter to the unsatisfactory experience with bentonite in the United States. Improvements have been made in a number of ointments by the introduction of Cetostearyl Alcohol, and changes have been made in Strong Ointment of Mercuric Nitrate in the interest of stability.

A three-page chapter on tablets is included at its alphabetical place in the monographs. While sugar-coating is recognised, the addition of colouring or flavouring agents is not official. Limits are given for the uniformity and the overall weight of tablets and for the weight of the drug therein, based on the average of 20; limits are placed on individual weights in that not more than 2 of the 20 tablets may deviate from the average weight by a stated percentage. Allowance is made for variation in the standards of purity and for other causes. For situations where 20 tablets are not available the tolerances are widened for samples of 15, 10 or 5 in accordance with a table provided. The disintegration test, based on disintegration or softening to the point of yielding on a slight

touch, is limited to 15 minutes for uncoated tablets and 1 hour for sugar coated tablets, unless otherwise stated.

Of the few crude drugs still retained, the anthraquinone purgatives rhubarb, cascara and senna are included, but the more drastic purgatives have been discarded. It is interesting to note that the monographs on senna and its preparations contain no biological assay, although an excellent one is available. *Strophanthus* has been deleted and ouabain retained. Digoxin is the only purified glycoside of *digitalis* included. Ergot is now represented only by the two purified alkaloids, ergometrine and ergotamine; the former is assayed entirely by the familiar colorimetric reaction with dimethylaminobenzaldehyde; with ergotamine tartrate the injection is so measured but the tablets are assayed gravimetrically. A striking deletion amongst the potent drugs is that of diamorphine hydrochloride, reflecting the prevailing opinion that the drug should not be recognised in official works of reference because of its high addiction liability.

Unlike the U.S.P. XIV, vitamin D₂ is the only form of vitamin D recognised; in the omission of vitamin D₃ there is no recognition of the needs of poultry feeders for whom official standards for the "sunshine vitamin" are important. Another important omission is that of suspensions of penicillin and its salts in oil with aluminium monostearate, and several additions and deletions in the penicillin preparations have been made. The sterile cream and oily injection have been deleted, and tablets and two new injections have become official. Of the newer antibiotics, Aureomycin Hydrochloride is added.

From a pharmacopœial standpoint a noteworthy and unique newcomer in the group of biological products is *Bacillus Calmette-Guérin* Vaccine, the labelling of which must indicate that it must be used within 14 days after manufacture. This requires an abbreviated sterility test to permit a decision after 2 days if the culture tubes are negative; the regular 5-day sterility test is notably shorter than those of other pharmacopœias. The tests for toxicity and virulence of BCG Vaccine require longer and outrun by far the life span of the product, requiring up to 6 months' observation. This is obviously for the purpose of controlling the process of manufacture rather than the intimate quality of each lot of vaccine. Further additions to the diagnostic, prophylactic and therapeutic biological products include agents for the Dick Test of scarlet fever susceptibility, under the unfamiliar names Dick Test Toxin and Dick Control and Scarlet Fever Antitoxin and Prophylactic.

Whole posterior pituitary has been dropped in favour of the two isolated principles Oxytocin and Vasopressin. Neither Chorionic nor Serum Gonadotrophin is required to meet a pyrogen test, notwithstanding reports that the former may be so highly pyrogenic as to limit its clinical usefulness. The pyrogen test, itself, is given under Water for Injection, although it is called upon in connection with several other monographs, and some complaint may arise from its lack of details.

Although the largest of the appendices provides the reagent and test solutions, most of the others are concerned with biological assays. There

is an excellent general chapter on biological assays giving in simple terms the biometric principles upon which the biological assays are designed and calculated. Clear examples enable the operator to carry out the calculation for each type of test without reference to standard biometric texts. A useful table of the reference standard preparations of the biological assays is included. The limits of error apply to a probability of 0.95 in contrast to $P = 0.99$ for B.P. 1948. The spectrophotometric assay for vitamin A is the subject of another appendix; the directions for this procedure, which is ordinarily considered most exacting, allow the operator wide latitude. It is provided that if there is evidence that irrelevant absorption is present as a result of some constituent of the vitamin A preparation the sample may then be fractionated to remove the interfering substance without, however, any indication of what is considered to be a suitable procedure. The sterilisation of parenteral injections and their dispensing is treated lucidly in another appendix which includes a test for limit of alkalinity of glass. There is no mention of the vexing problem of the clarity test for particulate matter in injections.

On general points, it is of interest to see that doses are given mostly in the metric system, although both the metric and Imperial doses are stated for the preparations still commonly prescribed in the Imperial system; for melting-point values obtained in the identification tests, the simple qualification "about" indicates the approximate nature of the determination; the graphic formulae are clear, those of the carbohydrates attracting attention by the introduction of spatial arrangement to show the respective positions of the carbon atom substituents in the closed lactone ring.

The book is an excellent example of the printer's art, and the paper is of very good quality. Changes of type both in the headings, sub-headings and in the tests and assays make it easier reading.

The Commission, under Professor D. M. Dunlop as Chairman, and Mr. T. C. Denston, the new Secretary since 1950, is to be congratulated on the punctual appearance of this edition. Credit must also be given to Dr. C. H. Hampshire who was Secretary of the Commission during the early stages of preparation of this edition, which is so worthy an heir to the prestige enjoyed by the British Pharmacopœia.