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WHO Expert Committee on Specifications for Pharmaceutical Preparations

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Geneva, 2–6 December 1985

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WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Thirtieth report

The WHO Expert Committee on Specifications for Pharmaceutical Preparations met in Geneva from 2 to 6 December 1985. The meeting was opened on behalf of the Director-General by Dr J.F. Dunne, Chief, Pharmaceuticals Unit, who reviewed the substantial support offered by the Committee in its previous reports to countries seeking to establish basic systems of quality control for imported and domestically produced pharmaceutical products. In its work of developing *The International Pharmacopoeia* and promoting the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, one of the Committee's constant concerns was to encourage the rational use of drugs, as called for in Resolution WHA37.33 of the Thirty-seventh World Health Assembly and at the Conference of Experts on the Rational Use of Drugs held in Nairobi from 25 to 29 November 1985.

1. THE INTERNATIONAL PHARMACOPOEIA

1.1 Specifications for pharmaceutical substances

The Committee noted that with the publication of the third volume of the third edition of *The International Pharmacopoeia* in 1987, monographs will have been provided for almost all substances in the WHO Model List of Essential Drugs. The only exceptions are substances added to the Model List when it was last revised in December 1984. The monographs for these will be published as addenda once the necessary consultations with national drug regulatory authorities and pharmaceutical manufacturers have been completed and they have been formally adopted by the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations.

Efforts will be continued to replace the few remaining references to analytical procedures involving techniques that are beyond the

capacity of the model quality control laboratory described in the Committee's previous reports by tests in which classical methods of analysis are used. In doing this, every care will be taken to preclude any relaxation in standards of quality.

1.2 Specifications for dosage forms

If *The International Pharmacopoeia* is to respond fully to national needs, it must contain monographs on final dosage forms. General descriptions of dosage forms in conformity with the basic principles adopted in the Committee's twenty-seventh report and including definitions, physical requirements, and tests of performance for tablets, capsules, and parenteral preparations, will be included in the fourth volume of the third edition of *The International Pharmacopoeia*. In this connection the Committee makes the following recommendations:

1.2.1 *Uniformity of mass and content*

Solid dosage forms, including tablets, capsules, and preparations intended for reconstitution prior to parenteral administration, must conform in mass and content with the requirements in the monographs if reproducibility of clinical response is to be assured. Dosage units can easily be weighed in the simplest of laboratories, but quantitative determination of their chemical content is analytically demanding. The Committee therefore recommends that such analysis be considered only when the active drug substance accounts for 5% or less of the mass of the dosage form (i.e., only when the dosage form contains a relatively small quantity of a highly potent drug). This advice supersedes recommendations made in an earlier report.[1]

1.2.2 *Disintegration tests for tablets and capsules*

Disintegration of the dosage unit after ingestion is necessary for the release, dissolution, and consequent absorption of its active constituents. The process may be impaired, and bioavailability compromised, by basic errors in formulation or manufacture, including a lack of disintegrants, an excess of lubricants, or

[1] WHO Technical Report Series, No. 645, 1980.