

Recent Publications

Quality control of essential drugs in developing countries: standardized methods

This manual, currently available only in the original French language version produced with the support of the French Ministry of Cooperation and Development (1), presents an approach to analytical aspects of drug control that is geared to the needs of developing countries. It emanates from a centre concerned with epidemiological studies and preventive medicine situated in a regional hospital in Nantes, France. However, the connection between drug control and preventive medicine is established all too clearly in the first paragraph of the preface. National procurement agencies in developing countries, the author claims, need to be particularly vigilant about the quality of drugs offered on open tender. Products sometimes contain less than the declared dose; they may contain unacceptable impurities; or they may be degraded. Sometimes legitimate products deteriorate in transit, but substandard drugs and bulk materials are also sometimes the end-product of the fraudulent activities of clandestine manufacturers.

The greater part of the manual is devoted to simple tests for verifying the identity of pharmaceutical substances and dosage forms included in WHO's Model List of Essential Drugs and, additionally, for checking the content and stability of these dosage forms. The scope of these tests is thus wider and more ambitious than that of earlier publications emanating from WHO's basic test programme which focused primarily on verification of identity (1, 2). Moreover, the methods described in this new publication, although simple and robust, require modest laboratory facilities. Those issued earlier were designed to be undertaken, when necessary, outside a formal laboratory setting.

Thus, the identity and degradation tests described in this manual are based exclusively on thin-layer chromatography, while the content of active ingredient is estimated either by chemical titration or by spectrophotometric methods. These methods are essentially comparative and, as such, their performance depends upon the availability of

reliable reference materials. In other respects, however, the requirements are not demanding. A short introductory section describes the required laboratory layout and the necessary equipment and glassware. It also indicates how basic documentation should be organized, and even provides a rudimentary description of the chemical and physical principles on which the proposed tests are based.

One important point, unfortunately, is not emphasized in this introductory material. The monographs that account for the greater part of the manual must not be regarded as replacing pharmacopoeial specifications. They do not provide a sufficient analytical basis on which to clear substances for use in pharmaceutical products, nor do they provide a basis for determining whether a finished dosage form complies with the labelled specification.

The value of the book is uncontested as a laboratory manual, but it would have been enhanced by the inclusion of a short explanation of the administrative safeguards, including the use of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, which should be applied whenever bulk materials or dosage forms are imported from a new supplier. Assurance of quality cannot be based on analytical procedures alone. It is a concept that requires definition in the light of fast-changing circumstances, and this is one of the major issues that will be placed before the WHO Expert Committee on Specifications for Pharmaceutical Preparations when it is next convened towards the end of 1994.

1. *Côntrole de qualité des médicaments essentiels dans les pays en développement: méthodes standardisées.* Vincent-Ballereau, F., Le Quay, L., Lafleuriel, M-T., Gomes-Mavoungou, L. Groupe d'Etudes Epidémiologiques et Prophylactiques et Centre Collaborateur de l'Organisation mondiale de la Santé pour l'étude de la stabilité des médicaments. Centre Hospitalier de Villeneuve-Saint-Georges, France, 1992.

2. *Basic Tests for Pharmaceutical Substances.* World Health Organization, Geneva, 1986. ISBN 92 4 154204 7.

3. *Basic Tests for Pharmaceutical Dosage Forms.* World Health Organization, Geneva, 1991. ISBN 92 4 154418 X.