

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Thirty-ninth report

This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. Of particular relevance to drug regulatory authorities and pharmaceutical manufacturers, this report discusses the monographs on antiretrovirals proposed for inclusion in *The International Pharmacopoeia* and specifications for radiopharmaceuticals, quality specifications for antituberculosis drugs and the revision of the monograph on artemisinin derivatives, as well as quality control of reference materials, good manufacturing practices (GMP), inspection, distribution and trade and other aspects of quality assurance of pharmaceuticals, and regulatory issues.

The report is complemented by a number of annexes, including an amendment to good manufacturing practices: main principles regarding the requirement for the sampling of starting materials, guidelines on good manufacturing practices regarding water for pharmaceutical use, guidelines on the sampling of pharmaceutical products and related materials and draft guidelines for registration of fixed-dose combination medicinal products.

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Geneva, 25–29 October 2004

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