

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: Release procedure for International Chemical Reference Substances; WHO guidelines on quality risk management; WHO guidelines on variations to a prequalified product; and the Collaborative procedure between the World Health Organization Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products.

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Forty-seventh report

WHO Expert Committee on Specifications for Pharmaceutical Preparations • WHO Technical Report Series



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Forty-seventh report

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