

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: Development of monographs for *The International Pharmacopoeia*; WHO good manufacturing practices: water for pharmaceutical use; Pharmaceutical development of multisource (generic) pharmaceutical products – points to consider; Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part; Development of paediatric medicines: points to consider in formulation; Recommendations for quality requirements for artemisinin as a starting material in the production of antimalarial active pharmaceutical ingredients.

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WHO Expert Committee on Specifications for Pharmaceutical Preparations

Forty-sixth report



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Forty-sixth report

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Geneva, 10–14 October 2011

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