Record Nr. UNINA9910454491403321 WHO Expert Committee on Specification for Pharmaceutical **Titolo** Preparations [[electronic resource]]: forty-second report Pubbl/distr/stampa Geneva, Switzerland, : World Health Organization, 2008 **ISBN** 1-281-74403-4 9786611744038 92-4-068310-0 Descrizione fisica 1 online resource (150 p.) Collana WHO technical report series, , 0512-3054;; 948 Disciplina 615.1 615/.1 Soggetti Drugs - Standards Pharmaceutical technology - Standards Drugs - Law and legislation Electronic books. Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Note generali Description based upon print version of record. Nota di bibliografia Includes bibliographical references. Nota di contenuto Preliminaries; Contents; 1 Introduction; 2 General policy; 3 Quality control specifications and tests: 4 Quality control International Chemical Reference Substances and International Infrared Reference Spectra: 5 Quality control national laboratories: 6 Quality assurance good manufacturing practices; 7 Quality assurance new approaches and risk analysis; 8 Quality assurance distribution and trade of pharmaceuticals; 9 Quality assurance stability; 10 Pregualification of priority essential medicines and devices; 11 Pregualification of active pharmaceutical ingredients 12 Prequalification of quality control laboratories 13 Active pharmaceutical ingredient master file; 14 Regulatory guidance; 15 Nomenclature terminology and databases; 16 Miscellaneous; 17 Summary and recommendations; Acknowledgements; and International Infrared Reference Spectra; condoms for purchase by United Nations agencies; intrauterine devices for purchase by United Nations agencies; Guidelines on active pharmaceutical ingredient mas

The Expert Committee on Specifications for Pharmaceutical

Sommario/riassunto

Preparations works towards clear, independent and practical standards and guidelines for medicines' quality assurance. Standards are developed by the Committee through worldwide consultation and an international consensus building process. The forty-second meeting adopted 11 new monographs for inclusion in The International Pharmacopoeia (Ph.Int.) and seven related new International Chemical Reference Standards (ICRS). The specifications currently developed are internationally applicable test methodologies for antimalarial, antitubercul