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BOOK REVIEW

WHO Expert Committee on specifications for pharmaceutical preparations. Forty-second report. Geneva, World Health Organization, 2008. 138p. (WHO Technical Report Series 948). ISBN 978 92 4 120948 9; ISSN 0512-3054.

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 standards and guidelines were adopted and recommended for use: the current list of available International Chemical Reference Substances and International Infrared Reference Spectra; guidelines on the active pharmaceutical ingredient master file procedure; the procedure for assessing the acceptability of male latex condoms and that of intrauterine devices for purchase by United Nations and other agencies; and a review of International Nonproprietary Names for biological and biotechnological substances.

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. Prequalification of priority essential medicines and devices; 11. Prequalification 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. **Annex 1:** List of available International Chemical Reference Substances and International Infrared Reference Spectra; **Annex 2:** Procedure for assessing the acceptability, in principle, of male latex condoms for purchase by United Nations agencies; **Annex 3:** Procedure for assessing the acceptability, in principle, of TCu380A intrauterine devices for purchase by United Nations agencies; **Annex 4:** Guidelines on active pharmaceutical ingredient master file procedure; **Annex 5**: International Nonproprietary Names for biological and biotechnological substances: a review.

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