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Nota di contenuto	Cover; Contents; WHO Expert Committee on Specifications for Pharmaceutical Preparations; 1. Introduction; 2. General policy; 2.1 Cross-cutting pharmaceutical quality assurance issues; 2.1.1 Update from the Expert Committee on the Selection and Use of Essential Medicines; 2.1.2 Update from the Expert Committee on Biological Standardization; 2.1.3 Temperature mapping of a storage area; 2.2 International collaboration; 2.2.1 Collaboration with international organizations and agencies; 2.2.2 Pharmacopoeial Discussion Group 2.2.3 International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) 2.2.4 International Conference of Drug Regulatory Authorities; 3. Quality control - specifications and tests; 3.1 The International Pharmacopoeia; 3.1.1 Monographs under elaboration; 3.1.2 Monographs proposed for elaboration or withdrawal from The International Pharmacopoeia; 3.2 Specifications for medicines, including children's medicines; 3.2.1 Maternal, newborn, child and adolescent health medicines; 3.2.2 Antimalarial medicines; 3.2.3

Antiviral medicines

3.2.4 Antituberculosis medicines 3.2.5 Medicines for neglected tropical diseases; 3.2.6 Other anti-infective medicines; 3.2.7 Other medicines; 3.3 General monographs for dosage forms and associated method texts; 3.3.1 Supplementary information; 3.3.2 Reagents, test solutions and volumetric solutions; 3.3.3 General policy; 3.3.4

Radiopharmaceuticals; 4. Quality control - International Reference Materials (International Chemical Reference Substances and Infrared Reference Spectra); 4.1 Update on International Chemical Reference Substances; 4.1.1 Overview

4.1.2 Release procedure for International Chemical Reference Substances 4.1.3 Report from the ICRS Board; 4.1.4 Draft chapter on reference substances and reference spectra for the Supplementary information section of The International Pharmacopoeia; 4.1.5

International Chemical Reference Substances - miscellaneous topics; 4.2 Report of the custodian centre for ICRS; 4.2.1 Annual report; 4.2.2 Update on the annual report; 5. Quality control - national laboratories;

5.1 External Quality Assurance Assessment Scheme; 5.1.1 Final report on EQAAS 5.6; 5.1.2 Preliminary report on EQAAS 5.7

5.1.3 EQAAS Phase 6 proposals 5.2 Networking; 5.3 Training materials for quality control laboratories and microbiological laboratories; 6.

Quality assurance - good manufacturing practices; 6.1 Updates of WHO good manufacturing practices; 6.2 Update of WHO good manufacturing practices: validation; 6.3 General guidance for inspectors on "hold-

time" studies; 6.4 Training materials; 7. Quality assurance - new initiatives; 7.1 International meetings of world pharmacopoeias; 7.2 Good pharmacopoeial practices; 7.3 FIP-WHO technical guidelines; 7.4 Screening technologies for "suspect" medicines

7.5 Laboratory functions survey regarding testing of spurious/falsely-labelled/falsified/counterfeit medical products

Sommario/riassunto

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 in addition to 20 monographs and general texts for inclusion in The International Pharmacopoeia and 11 new International Chemical Reference Substances. The International Pharmacopoeia - updating mechanism for the section on radioph