

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 radiopharmaceuticals; WHO good manufacturing practices for pharmaceutical products: main principles; Model quality assurance system for procurement agencies; Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection; Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities; and Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part.

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Forty-eighth report



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Volume 2: monographs for pharmaceutical substances (P–Z); monographs for dosage forms and radiopharmaceutical preparations; methods of analysis; reagents.

2006 (1500 pages), also available on CD-ROM and online

First, second and third supplements: general notices; monographs for pharmaceutical substances; monographs for dosage forms; general and specific monographs; methods of analysis; International Chemical Reference Substances; International Infrared Reference Spectra; reagents, test solutions and volumetric solutions.

First supplement: 2008 (309 pages), also available on CD-ROM and online

Second supplement: 2011 (CD-ROM and online)

Third supplement: 2013 (CD-ROM and online)

Basic tests for drugs: pharmaceutical substances, medicinal plant materials and dosage forms

1998 (94 pages)

Basic tests for pharmaceutical dosage forms

1991 (134 pages)

Quality Assurance of Pharmaceuticals: WHO guidelines, related guidance and GXP training modules

Updated edition, 2013 (CD-ROM and online).

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Forty-sixth report.

WHO Technical Report Series, No. 970, 2012 (235 pages)

Forty-seventh report.

WHO Technical Report Series, No. 981, 2013 (188 pages)

International Nonproprietary Names (INN) for pharmaceutical substances

Cumulative List No. 15

2013 (available on CD-ROM only)

The selection and use of essential medicines

Report of the WHO Expert Committee (including the 17th WHO Model List of Essential Medicines and the 3rd WHO Model List of Essential Medicines for Children)

WHO Technical Report Series, No. 965, 2011 (263 pages)

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Sixty-second report

WHO Technical Report Series, No. 979, 2012 (366 pages)

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*This report contains the collective views of an international group of experts and
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