

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Thirty-ninth report

This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. Of particular relevance to drug regulatory authorities and pharmaceutical manufacturers, this report discusses the monographs on antiretrovirals proposed for inclusion in *The International Pharmacopoeia* and specifications for radiopharmaceuticals, quality specifications for antituberculosis drugs and the revision of the monograph on artemisinin derivatives, as well as quality control of reference materials, good manufacturing practices (GMP), inspection, distribution and trade and other aspects of quality assurance of pharmaceuticals, and regulatory issues.

The report is complemented by a number of annexes, including an amendment to good manufacturing practices: main principles regarding the requirement for the sampling of starting materials, guidelines on good manufacturing practices regarding water for pharmaceutical use, guidelines on the sampling of pharmaceutical products and related materials and draft guidelines for registration of fixed-dose combination medicinal products.

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Contents

1. Introduction	1
2. General policy	2
2.1 Cross-cutting issues in the quality assurance of pharmaceuticals	2
2.2 Pharmacopoeial Discussion Group	3
2.3 International Conference on Harmonisation	3
2.4 International Conference of Drug Regulatory Authorities	3
2.5 Counterfeit drugs	4
3. Quality control — specifications and tests	5
3.1 <i>The International Pharmacopoeia</i>	5
3.2 Pharmacopoeial monographs on antiretrovirals	6
3.3 Specifications for radiopharmaceuticals	7
3.4 Quality specifications for antituberculosis drugs	7
3.5 Revision of <i>International Pharmacopoeia</i> monograph on artemisinin derivatives	8
3.6 Screening tests for antiretroviral drugs	8
3.7 Screening tests for antituberculosis products	8
4. Quality control — International Reference Materials	8
4.1 International Chemical Reference Substances	8
5. Quality control — national laboratories	9
5.1 External quality assurance assessment scheme	9
6. Quality assurance — good manufacturing practices	9
6.1 Concept of sampling starting materials	9
6.2 Heating, ventilation and air-conditioning	9
6.3 Manufacture of herbal medicines	10
6.4 Validation	10
6.5 Water for pharmaceutical use	10
7. Quality assurance — inspection	10
7.1 Sampling of pharmaceuticals and related materials	10
7.2 Training modules for inspectors	11
8. Quality assurance — distribution and trade-related	11
8.1 Good trade and distribution practices for pharmaceutical starting materials	11
8.2 WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce	12
8.3 WHO Scheme for the certification of pharmaceutical starting materials moving in international commerce	12
8.4 Good distribution practices for pharmaceutical products	12
9. Quality assurance — risk analysis	13
9.1 New approach to inspections and manufacture	13

10. Quality assurance — stability	13
10.1 Stability testing conditions	13
11. Quality assurance — drug supply	13
11.1 Prequalification project managed by WHO	13
11.2 Prequalification of quality control laboratories and procurement agencies	14
11.3 Update of prequalification procedure	15
12. Regulatory guidance on interchangeability for multisource medicines	15
12.1 Main guidelines for interchangeability	15
12.2 Medicines qualifying for waiver on in vivo bioequivalence studies	16
12.3 Dissolution testing	16
12.4 List of comparator products	16
13. Fixed-dose combination products for priority communicable diseases	17
13.1 Guidelines for registration of fixed-dose combination products	17
14. International Nonproprietary Names	17
15. Summary and recommendations	18
15.1 New standards and guidelines adopted and recommended for use	19
15.2 Activities that should be pursued and progress reported at the next Expert Committee meeting	20
15.3 New areas of work suggested	21
Acknowledgements	21
Annex 1 International Chemical Reference Substances and International Infrared Reference Spectra	30
Annex 2 Good manufacturing practices: requirement for the sampling of starting materials (amendment)	38
Annex 3 WHO Good Manufacturing Practices: water for pharmaceutical use	40
Annex 4 WHO guidelines for sampling of pharmaceutical products and related materials	59
Annex 5 Guidelines for registration of fixed-dose combination medicinal products	94

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Geneva, 25–29 October 2004

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