

WHO Technical Report Series

992

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Forty-ninth report



World Health
Organization

Contents

WHO Expert Committee on Specifications for Pharmaceutical Preparations	vi
1. Introduction	1
2. General policy	3
2.1 International collaboration	3
2.1.1 Collaboration with international organizations and agencies	3
2.2 Cross-cutting pharmaceutical quality assurance issues	6
3. Quality control – specifications and tests	8
3.1 <i>The International Pharmacopoeia</i>	8
3.1.1 Workplan for <i>The International Pharmacopoeia</i>	8
3.2 Specifications for medicines, including paediatric medicines and radiopharmaceuticals	9
3.2.1 Maternal, newborn, child and adolescent health medicines	9
3.2.2 Antiviral medicines, including antiretrovirals	11
3.2.3 Antituberculosis medicines	11
3.2.4 Medicines for tropical diseases	11
3.2.5 Other anti-infective medicines	13
3.2.6 Medicines for anaesthesia, pain and palliative care	13
3.2.7 Radiopharmaceuticals	14
3.3 General monographs for dosage forms and associated method texts	15
3.3.1 General monographs	15
3.3.2 General policy	16
3.3.3 Analytical methods	17
3.4 Update on the process for development of monographs	17
3.4.1 General	17
3.4.2 Radiopharmaceuticals	18
4. Quality control – international reference materials (International Chemical Reference Substances and Infrared Reference Spectra)	19
4.1 Update on International Chemical Reference Substances	19
4.1.1 Report of the custodian centre	19
4.1.2 Report of the dedicated subgroup	19
5. Quality control – national laboratories	20
5.1 External Quality Assurance Assessment Scheme	20
5.1.1 Summary report on External Quality Assurance Assessment Scheme Phase 5	20
5.2 Training materials for quality control laboratories and microbiological laboratories	21
5.3 Report on implementation of WHO good practices for pharmaceutical control laboratories	21
6. Quality assurance – good manufacturing practices	22
6.1 Update of WHO good manufacturing practices for biologicals	22
6.2 Update of WHO good manufacturing practices: validation	22
6.2.1 Proposal for revision of the supplementary guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation	22

6.3	General guidance for inspectors on hold-time studies	23
6.4	Update of model inspection report	23
6.5	Update of questions and answers for WHO good manufacturing practices for active pharmaceutical ingredients	24
6.6	Proposal for new guidance on good data management	24
6.7	Training materials	25
7.	Quality assurance – new initiatives	26
7.1	International meetings of world pharmacopoeias	26
7.2	Good pharmacopoeial practices	26
7.3	Screening technologies for “suspect” spurious/falsely-labelled/falsified/counterfeit medicines	27
7.4	Laboratory functions survey regarding testing of spurious/falsely-labelled/falsified/counterfeit medical products	28
7.5	FIP–WHO technical guidelines: points to consider in the provision by health-care professionals of children-specific preparations that are not available as authorized products	29
7.6	Sampling procedures for market surveillance	29
7.6.1	Sampling procedures for spurious/falsely-labelled/falsified/counterfeit medical products	30
8.	Quality assurance – distribution and trade of pharmaceuticals	31
8.1	WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce	31
8.2	<i>Monitoring and surveillance of the national supply chain</i>	31
8.3	Technical supplement materials to the WHO guidance for storage and transport of time- and temperature-sensitive pharmaceutical products	32
9.	Prequalification of priority essential medicines	35
9.1	Update on the Prequalification Team managed by WHO	35
9.2	Revision of the collaborative registration procedure for prequalification of products	36
10.	Prequalification of active pharmaceutical ingredients	37
10.1	Update on the prequalification of active pharmaceutical ingredients	37
11.	Prequalification of quality control laboratories	38
11.1	Update on the prequalification of quality control laboratories	38
11.2	Update on WHO quality monitoring projects	38
12.	Regulatory guidance	39
12.1	Recommendation for quality requirements – artemisinin starting materials	39
12.2	Guidelines on variations for multisource products	39
12.3	Guidelines on registration requirements to establish interchangeability (bioequivalence)	39
12.4	Guidance for organizations performing in vivo bioequivalence studies – revision	40
12.5	Update of Biowaiver list based on the WHO Model List of Essential Medicines	41
12.6	Update of International Comparator Products List and related guidance on selection of comparator products for equivalence assessment of interchangeable multisource (generic) products	41
12.7	Good review practice	42
12.8	Good regulatory practices project	43



13. Nomenclature, terminology and databases	45
13.1 Quality assurance terminology	45
13.2 International Nonproprietary Names for pharmaceutical substances	45
14. Miscellaneous	46
14.1 Strategy	46
14.2 Outreach	46
15. Summary and recommendations	47
Acknowledgements	53
Annex 1	
Procedure for the development of monographs and other texts for <i>The International Pharmacopoeia</i>	69
Annex 2	
Updating mechanism for the section on radiopharmaceuticals in <i>The International Pharmacopoeia</i>	73
Annex 3	
Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation	75
Annex 4	
General guidance on hold-time studies	87
Annex 5	
Technical supplements to Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products	95
Annex 6	
Recommendations for quality requirements when plant-derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients	123
Annex 7	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability	131
Annex 8	
Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products	185
Annex 9	
Good review practices: guidelines for national and regional regulatory authorities	191