

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: Release procedure for International Chemical Reference Substances; WHO guidelines on quality risk management; WHO guidelines on variations to a prequalified product; and the Collaborative procedure between the World Health Organization Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products.

# WHO Expert Committee on Specifications for Pharmaceutical Preparations

Forty-seventh report

WHO Expert Committee on Specifications for Pharmaceutical Preparations • WHO Technical Report Series



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# WHO Expert Committee on Specifications for Pharmaceutical Preparations

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# Contents

<b>WHO Expert Committee on Specifications for Pharmaceutical Preparations</b>	vi
<b>1. Introduction</b>	1
<b>2. General policy</b>	2
2.1 Cross-cutting pharmaceutical quality assurance issues	2
2.2 International collaboration	2
2.2.1 Collaboration with international organizations and agencies	2
2.2.2 Pharmacopoeial Discussion Group	3
2.2.3 International Conference on Harmonisation	3
2.2.4 International Conference of Drug Regulatory Authorities	4
2.2.5 World Health Assembly resolution on new Member States' mechanism on substandard/spurious/false-labelled/falsified/counterfeit medicines	4
<b>3. Quality control – specifications and tests</b>	5
3.1 <i>The International Pharmacopoeia</i>	5
3.1.1 Fourth Edition update	5
3.1.2 Annotated work plan	5
3.2 Specifications for medicines, including children's medicines	5
3.2.1 Medicines for human immunodeficiency virus and related conditions	5
3.2.2 Antituberculosis medicines	6
3.2.3 Antimalarial medicines	6
3.2.4 Anti-infectives	8
3.2.5 Other medicines	9
3.3 Harmonized texts	10
3.3.1 Revision of monograph on General method 5.5 Dissolution test for solid oral dosage forms	10
3.4 Preface, general notices and supplementary information sections of <i>The International Pharmacopoeia</i>	10
3.4.1 Proposal for revision of monograph on capsules	10
3.4.2 Proposal for revision of general monographs: parenteral preparations	11
3.4.3 Proposal for revision of 5.1 Uniformity of content for single-dose preparations	11
3.4.4 Proposal for revision of high-performance liquid chromatography	12
3.4.5 General method for the supplementary information section of the Fourth Edition of <i>The International Pharmacopoeia</i> : Resistance to crushing of tablets	12
3.4.6 General method for the supplementary information section of the Fourth Edition of <i>The International Pharmacopoeia</i> : Measurement of consistency by penetrometry	12
3.4.7 General method for the supplementary information section of the Fourth Edition of <i>The International Pharmacopoeia</i> : Softening time determination of lipophilic suppositories	13
3.4.8 Bacterial endotoxin	13
<b>4. Quality control – International Reference Materials (International Chemical Reference Substances and Infrared Reference Spectra)</b>	14
4.1 Update on International Chemical Reference Substances	14
4.1.1 Overview	14

4.1.2	Report on activities of the host organization related to International Chemical Reference Substances	14
4.1.3	Adoption of established International Chemical Reference Substances	15
4.1.4	Supplementary information section of <i>The International Pharmacopoeia</i> : 4. Reference substances and reference spectra	16
4.1.5	New release procedure for International Chemical Reference Substances	16
4.1.6	Policy on naming International Chemical Reference Substances in <i>The International Pharmacopoeia</i>	17
4.1.7	Proposal to reduce analytical testing of high-purity candidate material	17
<b>5.</b>	<b>Quality control – national laboratories</b>	<b>19</b>
5.1	External Quality Assurance Assessment Scheme	19
5.1.1	Overview	19
5.1.2	Final report of Procedure 4	19
5.1.3	Preliminary report of Procedure 5 and additional information with regard to possible sources of error	19
5.1.4	Proposal for Phase 6	19
<b>6.</b>	<b>Quality assurance – good manufacturing practices</b>	<b>21</b>
6.1	Updates of WHO GMP texts	21
6.2	Training materials	21
<b>7.</b>	<b>Quality assurance – new approaches</b>	<b>22</b>
7.1	Quality risk management	22
7.2	Pharmacopoeial harmonization	22
7.3	Screening technologies	24
7.4	Survey on laboratories report	24
<b>8.</b>	<b>Quality assurance – distribution and trade of pharmaceuticals</b>	<b>25</b>
8.1	Revision of model quality assurance system for procurement agencies	25
8.2	Assessment tool based on the model quality assurance system	25
8.3	Monitoring and surveillance of national supply chain	25
8.4	Proposal for revision of good trade and distribution practices	26
<b>9.</b>	<b>Prequalification of priority essential medicines including active pharmaceutical ingredients</b>	<b>28</b>
9.1	Update on the Prequalification of Medicines Programme managed by WHO	28
<b>10.</b>	<b>Prequalification of active pharmaceutical ingredients</b>	<b>29</b>
10.1	Update on the prequalification of active pharmaceutical ingredients	29
<b>11.</b>	<b>Prequalification of quality control laboratories</b>	<b>30</b>
11.1	Update on the prequalification of quality control laboratories	30
11.2	Update on WHO quality monitoring projects	30
<b>12.</b>	<b>Regulatory guidance</b>	<b>31</b>
12.1	Extemporaneous dispensing and administration of medicines to children	31
12.2	Guidance on variations to a prequalified product	32
12.3	Collaborative procedure between the WHO Prequalification of Medicines Programme and national medicine regulatory authorities in the assessment and accelerated registration of national WHO-prequalified pharmaceutical products	32

12.4	Proposal for a procedure on sampling and market surveillance survey	33
12.5	Comparator products	33
12.6	Biowaiver	34
<b>13.</b>	<b>Nomenclature, terminology and databases</b>	<b>35</b>
13.1	Quality assurance terminology	35
13.2	International Nonproprietary Names for pharmaceutical substances	35
<b>14.</b>	<b>Miscellaneous</b>	<b>36</b>
14.1	Quality assurance of pharmaceuticals: a compendium of guidelines and related materials	36
14.2	Strategy	36
<b>15.</b>	<b>Summary and recommendations</b>	<b>37</b>
	<b>Acknowledgements</b>	<b>44</b>
	<b>Annex 1</b>	
	Release procedure for International Chemical Reference Substances	59
	<b>Annex 2</b>	
	WHO guidelines on quality risk management	61
	<b>Annex 3</b>	
	WHO guidelines on variations to a prequalified product	93
	<b>Annex 4</b>	
	Collaborative procedure between the World Health Organization Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products	155

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## Members

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Professor T.G. Dekker, Research Institute for Industrial Pharmacy, North-West University, Potchefstroom, South Africa

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Ms L. Slamet, Deputy for Therapeutic Products, Narcotics, Psychotropic and Addictive Substance Control, National Agency of Drug and Food Control, Jakarta Pusat, Indonesia<sup>1</sup>

## Temporary advisers

Professor J.B. Dressman, Director, Institute of Pharmaceutical Technology, Johann

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