

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Fifty-fourth report



World Health
Organization

The World Health Organization was established in 1948 as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health. One of WHO's constitutional functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfils in part through its extensive programme of publications.

The Organization seeks through its publications to support national health strategies and address the most pressing public health concerns of populations around the world. To respond to the needs of Member States at all levels of development, WHO publishes practical manuals, handbooks and training material for specific categories of health workers; internationally applicable guidelines and standards; reviews and analyses of health policies, programmes and research; and state-of-the-art consensus reports that offer technical advice and recommendations for decision-makers. These books are closely tied to the Organization's priority activities, encompassing diseases prevention and control, the development of equitable health systems based on primary health care, and health promotion for individuals and communities. Progress towards better health for all also demands the global dissemination and exchange of information that draws on the knowledge and experience of all WHO's Member countries and the collaboration of world leaders in public health and the biomedical sciences. To ensure the widest possible availability of authoritative information and guidance on health matters, WHO secures the broad international distribution of its publications and encourages their translation and adaption. By helping to promote and protect health and prevent and control disease throughout the world, WHO's books contribute to achieving the Organization's principal objective – the attainment by all people of the highest possible level of health.

The *WHO Technical Report Series* makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO. To purchase WHO publications, please contact: WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel. +41 22 791 3264; fax: +41 22 791 4857; email: bookorders@who.int; <http://www.who.int/bookorders>).

W H O T e c h n i c a l R e p o r t S e r i e s
1 0 2 5

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Fifty-fourth report

*This report contains the views of an international group of experts and
does not necessarily represent the decisions or the stated policy of the World Health Organization*



**World Health
Organization**

WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report

(WHO Technical Report Series, no. 1025)

ISBN 978-92-4-000182-4 (electronic version)

ISBN 978-92-4-000183-1 (print version)

© World Health Organization 2020

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020 (WHO technical report series; no. 1025). Licence: [CC BY-NC-SA 3.0 IGO](https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

This publication contains the collective views of an international group of experts and does not necessarily represent the decisions or the policies of WHO.

Printed in Italy

Contents

Abbreviations	vi
WHO Expert Committee on Specifications for Pharmaceutical Preparations	ix
Declarations of interest	xiv
PRIVATE SESSION	1
Opening	1
Election of chairpersons and rapporteurs	2
1. General policy	3
1.1. Participation in meetings of the Expert Committee on Specifications for Pharmaceutical Preparations	3
OPEN SESSION	4
Introduction and welcome	4
1.2. Process for development of WHO norms and standards	5
2. General updates and matters for information	7
2.1. Cross-cutting pharmaceuticals quality assurance issues	7
2.2. International collaboration	13
3. Quality assurance – collaboration initiatives	16
3.1. International meetings of world pharmacopoeias	16
4. Nomenclature, terminology and databases	17
4.1. International Nonproprietary Names for pharmaceutical substances	17
4.2. Quality assurance terminology	18
4.3. Guidelines and guidance texts adopted by the ECSP	18
5. Prequalification of priority essential medicines and active pharmaceutical ingredients	19
5.1. Update on the prequalification of medicines	19
5.2. Update on the prequalification of active pharmaceutical ingredients	19
6. Quality control – prequalification and WHO monitoring projects	21
6.1. Update on the prequalification of quality control laboratories	21
7. Quality control – national laboratories	23
7.1. External Quality Assurance Assessment Scheme	23
PRIVATE SESSION	25
8. Quality control – specifications and tests	25
8.1. <i>The International Pharmacopoeia</i>	25
8.2. Procedure for the development of monographs and other texts for inclusion in <i>The International Pharmacopoeia</i>	27

8.3. General policy	28
8.4. General chapters	29
8.5. General monographs for dosage forms and associated method texts	31
8.6. Specifications and draft monographs for medicines, including paediatric and radiopharmaceutical medicines	31
9. Quality control – international reference materials	39
9.1. Update on International Chemical Reference Substances	39
10. General policy – chemistry	40
10.1. Revision of guidance on representation of graphic formulae	40
11. Quality assurance – good manufacturing practices and inspection	41
11.1. Inspection guidelines and good practices with partner organizations	41
11.2. Update on the cleaning validation	43
11.3. Update on water for injection	44
11.4. Guidance on good data and record management practices	45
11.5. Update on the development of good chromatography practices	46
11.6. Quality management system requirements for national good manufacturing practice inspectorates	47
11.7. Environmental aspects of manufacturing for the prevention of antimicrobial resistance	47
11.8. Update and recommendations from the meeting on Good Practices for Health Products Manufacture and Inspection	49
12. Quality assurance – distribution and supply chain	50
12.1. Update of the <i>Good storage and distribution practices</i> guideline	50
12.2. Shelf-life for supply and procurement of medical products	50
12.3. Update and new WHO guidance, procedures and operational documents for pharmaceutical procurement	51
13. Regulatory guidance and model schemes	53
13.1. Proposal to waive in vivo bioequivalence requirements for medicines included in the <i>WHO Model List of Essential Medicines</i>	53
13.2. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce	56
13.3. Guideline on the implementation of quality management systems for national regulatory authorities	57
13.4. Update on good regulatory practices	58
13.5. Update on new regulatory concepts and tools	59
14. Closing remarks	61
15. Summary and recommendations	62
15.1. Guidelines and decisions adopted and recommended for use	62
15.2. Texts adopted for inclusion in <i>The International Pharmacopoeia</i>	63
15.3. Recommendations	65
Acknowledgements	68
References	83

Annex 1	
Procedure for the elaboration, revision and omission of monographs and other texts for <i>The International Pharmacopoeia</i>	87
Annex 2	
International Atomic Energy Agency and World Health Organization guideline on good manufacturing practices for radiopharmaceutical products	93
Annex 3	
Production of water for injection by means other than distillation	109
Annex 4	
Good chromatography practices	115
Annex 5	
Quality management system requirements for national inspectorates	129
Annex 6	
Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance	143
Annex 7	
Good storage and distribution practices for medical products	157
Annex 8	
Points to consider for setting the remaining shelf-life of medical products upon delivery	189
Annex 9	
World Health Organization/United Nations Population Fund Prequalification Programme guidance for contraceptive devices: male latex condoms, female condoms and intrauterine devices	201
Annex 10	
World Health Organization/United Nations Population Fund technical specifications for male latex condoms	221
Annex 11	
World Health Organization/United Nations Population Fund specifications for plain lubricants	253
Annex 12	
WHO “Biowaiver List”: proposal to waive in vivo bioequivalence requirements for <i>WHO Model List of Essential Medicines</i> immediate-release, solid oral dosage forms	267
Annex 13	
WHO guideline on the implementation of quality management systems for national regulatory authorities	273

Abbreviations

AMR	antimicrobial resistance
AMRH	African Medicines Regulatory Harmonization
APEC	Asia-Pacific Economic Cooperation
API	active pharmaceutical ingredient
APIMF	active pharmaceutical ingredient master file
ASEAN	Association of South-East Asian Nations
AUDA-NEPAD	African Union Development Agency-New Partnership for Africa's Development
AWaRe	access, watch and reserve
BCS	Biopharmaceutics Classification System
CRP Lite	collaborative registration procedure-Lite
EAP	WHO Expert Advisory Panel on <i>The International Pharmacopoeia</i> and Pharmaceutical Preparations
ECBS	Expert Committee on Biological Standardization
EC-EML	Expert Committee on the Selection and Use of Essential Medicines
ECSPP	Expert Committee on Specifications for Pharmaceutical Preparations
EDQM	European Directorate for the Quality of Medicines and HealthCare
EQAAS	WHO External Quality Assurance Assessment Scheme

5, 2020

预览已结束，完整报告链接和

<https://www.yunbaogao.cn/report/index/report>