

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Thirty-seventh Report



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 disease 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 adaptation. 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. An annual subscription to this series, comprising about six such reports, costs Sw. fr. 132.– or US\$ 106.– (Sw. fr. 92.40 in developing countries). For further information, please contact Marketing and Dissemination, World Health Organization, 20 avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 2476; fax: +41 22 791 4857; e-mail: bookorders@who.int).

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

WHO Technical Report Series

908

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Thirty-seventh Report



World Health Organization
Geneva 2003

WHO Library Cataloguing-in-Publication Data

WHO Expert Committee on Specifications for Pharmaceutical Preparations (2001: Geneva, Switzerland)
WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-seventh report.

(WHO technical report series; 908)

1.Pharmaceutical preparations — Standards 2.Technology, Pharmaceutical — standards 3.Drug industry — standards 4.Quality control 5.Reference standards 6.Guidelines I.Title II.Series

ISBN 92 4 120908 9
ISSN 0512-3054

(NLM classification: QV 771)

© World Health Organization 2003

All rights reserved. Publications of the World Health Organization can be obtained from Marketing and Dissemination, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel: +41 22 791 2476; fax: +41 22 791 4857; email: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to Publications, at the above address (fax: +41 22 791 4806; email: permissions@who.int).

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 the World Health Organization 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 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 the World Health Organization 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.

The World Health Organization does not warrant that the information contained in this publication is complete and correct and shall not be liable for any damages incurred as a result of its use.

This publication contains the collective views of an international group of and does not necessarily represent the decisions or the stated policy of the World Health Organization.

**Typeset in Hong Kong
Printed in Singapore**

2002/14377 — SNPBest-set/SNP — 7000

Contents

1.	Introduction	1
2.	General policy	1
2.1	Specifications for medicinal plant materials and for herbal products	1
2.2	Risk of transmitting animal spongiform encephalopathy agents via medicinal products	2
2.3	Stop TB programme	2
2.4	Roll Back Malaria programme	2
2.5	HIV/AIDS programme	2
2.6	Future of <i>The International Pharmacopoeia</i>	3
2.7	Pharmacopoeial Discussion Group (PDG)	3
2.8	International Conference on Harmonisation (ICH)	4
3.	Quality control — specifications and tests	4
3.1	Thin-layer chromatography screening tests for antimalarials	4
3.2	Radiopharmaceuticals	5
3.3	Pharmacopoeial monographs on antiretrovirals	5
3.4	Thin-layer chromatography screening tests for antituberculosis drugs	6
3.5	Draft monograph on rifampicin, isoniazid, pyrazinamide and ethambutol hydrochloride tablets	6
4.	Quality control — international reference materials	6
5.	Quality control — national laboratories	7
5.1	External quality assessment scheme	7
5.2	Cost estimate of equipment for model quality control laboratories	7
6.	Quality assurance — good manufacturing practices (GMP)	8
6.1	Specific GMP guidelines for radiopharmaceutical products	8
6.2	GMP guide for active pharmaceutical ingredients	8
6.3	WHO GMP: main principles for pharmaceutical products	8
6.4	WHO basic training modules on GMP	9
7.	Quality assurance — inspection	9
7.1	Model certificates of GMP	9
7.2	Guidance for GMP inspection report	10
8.	Quality assurance — distribution and trade-related	10
8.1	Good trade and distribution practices of pharmaceutical starting materials	10
8.2	WHO Scheme for the Certification of Pharmaceutical Starting Materials Moving in International Commerce: guidelines on implementation	10
8.3	WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce	10

9.	Quality assurance — risk analysis	11
9.1	Risk analysis in quality control and impurities	11
9.2	Application of hazard analysis and critical control point (HACCP) methodology for pharmaceuticals	11
10.	Quality assurance — drug supply	12
10.1	Procedure for assessing the acceptability for purchase of pharmaceutical products	12
10.2	Procedure for assessing the acceptability for purchase of pharmaceutical products for the treatment of HIV/AIDS	12
11.	Quality assurance — storage	13
11.1	WHO guidelines for stability testing of pharmaceutical products containing well-established drug substances in conventional dosage forms	13
11.2	Good storage practices	13
12.	International Nonproprietary Names (INNs) Programme	13
13.	Miscellaneous	14
13.1	Proposal to the WHO Expert Committee by the Scientific Working Group on Bioequivalence of the International Pharmaceutical Federation (FIP)	14
13.2	Dissolution tests for quality control	14
13.3	Electronic version of publications	14
13.4	Standardized reporting sheet	14
13.5	Distribution of documents for procedural consultation process	15
	Acknowledgements	15
	References	19
	Annex 1	
	Recommendations on risk of transmitting animal spongiform encephalopathy agents via medicinal products	21
	Annex 2	
	<i>The International Pharmacopoeia: revised concepts and future perspectives</i>	22
	Annex 3	
	Guidelines on Good Manufacturing Practices for radiopharmaceutical products	26
	Annex 4	
	Good Manufacturing Practices for pharmaceutical products: main principles	36
	Annex 5	
	Model certificate of Good Manufacturing Practices	90
	Annex 6	
	Guidance on Good Manufacturing Practices (GMP): inspection report	94

Annex 7	
Application of Hazard Analysis and Critical Control Point (HACCP) method to pharmaceuticals	99
Annex 8	
Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies	113
Annex 9	
Guide to good storage practices for pharmaceuticals	125

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Geneva, 22–26 October 2001

Members*

Professor I. Addae-Mensah, Vice-Chancellor, University of Ghana, Accra, Ghana
(*Chairperson*)

Ms K. Bremer, Director, Medicines, Norwegian Control Authority, Oslo, Norway
(*Co-Chairperson*)

Professor A.A. Haggag, Department of Biochemistry, College of Pharmacy, University of Tanta, Tanta, Egypt

Professor Jin Shaohong, Deputy Director, National Institute for the Control of Pharmaceutical and Biological Products, Beijing, China

Ms A. Poompanich, Senior Technical Advisor (Efficacy of Medicine), Department of Medical Sciences, Ministry of Public Health, WHO Collaborating Centre for Drug Quality Assurance, Nonthaburi, Thailand

Mr R.W. Tribe, Chief GMP Auditor, Conformity Assessment Branch, Therapeutic Goods Administration, Woden, ACT, Australia (*Rapporteur*)

Representatives of other organizations†

Council of Europe

Dr J.H.McB. Miller, Head of Division III (Laboratory), European Directorate for the Quality of Medicines, Council of Europe, Strasbourg, France

International Atomic Energy Agency (IAEA)

Dr H.V. Ruiz, Head, Industrial Applications and Chemistry Section, Vienna, Austria

International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

Dr O. Morin, Director, Regulatory and Scientific Affairs, IFPMA, Geneva, Switzerland

International Pharmaceutical Excipients Council (IPEC)

Dr P. Rafidison, Chairperson, GMP/GDP Committee, IPEC Europe, Opio, France

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_30193

