992

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Forty-ninth 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 four to six such reports, costs CHF 150.00/US\$ 180.00 (CHF 105.00/US\$ 126.00 in developing countries). For further information, 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; order online: http://www.who.int/bookorders).

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Forty-ninth report

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 Library Cataloguing-in-Publication Data

Forty-ninth report of the WHO Expert Committee on specifications for pharmaceutical preparations.

(WHO technical report series: no. 992)

1. Pharmaceutical Preparations - standards. 2. Technology, Pharmaceutical - standards. 3. Drug Industry - legislation. 4. Quality Control. I. World Health Organization. II. Series.

ISBN 978 92 4 120992 2 ISBN 978 92 4 069396 8 (PDF) ISSN 0512-3054 (NLM classification: QV 771)

© World Health Organization 2015

All rights reserved. Publications of the World Health Organization are available on the WHO website (www.who.int) or can be purchased from 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).

Requests for permission to reproduce or translate WHO publications – whether for sale or for non-commercial distribution – should be addressed to WHO Press through the WHO website (www.who.int/about/licensing/copyright_form/en/index.html).

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 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 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.

All reasonable precautions have been taken by the World Health Organization 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 the World Health Organization 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 the World Health Organization.

Printed in Italy

Contents

WH	ОЕх	pert C	ommittee on Specifications for Pharmaceutical Preparations	٧		
1.	Intr	oduct	ion	1		
2.	General policy					
	2.1	Interna	ational 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					
	3.1	The In	ternational Pharmacopoeia	8		
		3.1.1	Workplan for The International Pharmacopoeia	8		
	3.2	-	ications for medicines, including paediatric medicines and	_		
			harmaceuticals	ç		
		3.2.1	Maternal, newborn, child and adolescent health medicines			
		3.2.2	Antiviral medicines, including antiretrovirals	11		
		3.2.3	Antituberculosis medicines	11		
		3.2.4 3.2.5	Medicines for tropical diseases	11		
		3.2.5	Other anti-infective medicines Medicines for anaesthesia, pain and palliative care	13 13		
		3.2.7	Radiopharmaceuticals	14		
	3.3		al monographs for dosage forms and associated method texts	15		
	3.3	3.3.1	General monographs	15		
		3.3.2	General policy	16		
		3.3.3	Analytical methods	17		
	3.4		e 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)					
	4.1	Update	e 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.	Qua	ality co	ontrol – national laboratories	20		
	5.1	Extern	al Quality Assurance Assessment Scheme	20		
		5.1.1	Summary report on External Quality Assurance Assessment			
			Scheme Phase 5	20		
	5.2		ng materials for quality control laboratories and microbiological laboratories	21		
	5.3	•	t on implementation of WHO good practices for pharmaceutical control			
		labora	tories	21		
6.	Quality assurance – good manufacturing practices					
	6.1	Update of WHO good manufacturing practices for biologicals				
	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 6.4	General guidance for inspectors on hold-time studies Update of model inspection report	23 23				
	6.5	Update of questions and answers for WHO good manufacturing practices for active pharmaceutical ingredients	24				
	6.6 6.7	Proposal for new guidance on good data management Training materials	24 25				
7.	Quality assurance – new initiatives						
	7.1 7.2	International meetings of world pharmacopoeias Good pharmacopoeial practices	26 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.	Qua	Quality assurance – distribution and trade of pharmaceuticals					
	8.1	WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce	31				
	8.2 8.3	Monitoring and surveillance of the national supply chain Technical supplement materials to the WHO guidance for storage and transport of time- and temperature-sensitive pharmaceutical products	31 32				
9.	Prequalification of priority essential medicines						
	9.1 9.2	Update on the Prequalification Team managed by WHO Revision of the collaborative registration procedure for prequalification of products	35 36				
10.	Pre	qualification of active pharmaceutical ingredients	37				
	10.1	Update on the prequalification of active pharmaceutical ingredients	37				
11.	Pre	qualification of quality control laboratories	38				
		Update on the prequalification of quality control laboratories Update on WHO quality monitoring projects	38 38				
12.	Regulatory guidance						
	12.2	Recommendation for quality requirements – artemisinin starting materials Guidelines on variations for multisource products Guidelines on registration requirements to establish interchangeability	39 39				
	12.5	(bioequivalence)	39				
	12.5	Guidance for organizations performing in vivo bioequivalence studies – revision Update of Biowaiver list based on the WHO Model List of Essential Medicines Update of International Comparator Products List and related guidance on selection	40 41				
	12.0	of comparator products for equivalence assessment of interchangeable multisource (generic) products	41				
		Good review practice	42				
	12 g	Good regulatory practices project	43				

13.	Nomenclature, terminology and databases	45
	13.1 Quality assurance terminology13.2 International Nonproprietary Names for pharmaceutical substances	45 45
14.	Miscellaneous	46
	14.1 Strategy 14.2 Outreach	46 46
15.	Summary and recommendations	47
Ack	nowledgements	53
Ann	nex 1	
	Procedure for the development of monographs and other texts for <i>The International Pharmacopoeia</i>	69
Ann	nex 2	
	Updating mechanism for the section on radiopharmaceuticals in <i>The International Pharmacopoeia</i>	73
Ann	nex 3	
	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation	75
Ann	nex 4	
	General guidance on hold-time studies	87
Ann	nex 5	
	Technical supplements to Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products	95
Ann	nex 6	
	Recommendations for quality requirements when plant-derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients	123
Ann	nex 7	
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability	131
Ann	nex 8	
	Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products	185
Ann	nex 9	
	Good review practices: guidelines for national and regional regulatory authorities	191

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Geneva, 13-17 October 2014

Members¹

Professor S.A. Bawazir, Advisor to the Chief Executive Officer, Saudi Food and Drug Authority, Riyadh, Saudi Arabia (*Co-Chairperson*)

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

Ms M. Hirschhorn, Head, Quality and Chemistry Sector, Comisión para el Control de Calidad de Medicamentos, Montevideo, Uruguay

Professor J. Hoogmartens, Professor Emeritus, Laboratorium voor Farmaceutische Analyse, Leuven, Belgium

Professor S. Jin, Chief Expert for Pharmaceutical Products, National Institutes for Food and Drug Control, Beijing, People's Republic of China

Professor H.G. Kristensen, Vedbaek, Denmark

Ms G.N. Mahlangu, Director-General, Medicines Control Authority of Zimbabwe, Harare, Zimbabwe (*Chairperson*)

Dr L. Stoppa, Inspections and Certification Department, Manufacturing Authorisation Office, Italian Medicines Agency, Rome, Italy (*Co-Rapporteur*)

Dr A.J. van Zyl, Cape Town, South Africa (Co-Rapporteur)

Temporary advisers²

Dr P. Aprea, Head, Biological Products Department, National Administration of Drugs, Food and Medical Technology (ANMAT), Ministry of Health, Ciudad Autonoma de Buenos Aires, Argentina

Dr AC Maraira Marina Arauja Drazilian Dharmacanaia Caardinatar Drazilian Haalth

预览已结束,完整报告链接和

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