Contents

Abb	revia	tions										vi
who	Exp	ert C	ommitt	ee on S	pecifica	ations	for P	harma	ceutica	l Prep	arations	ix
Intro	duc	tion										1
1.	General policy									4		
	1.1 1.2	Proces	s for	the meeting	developr s of the Ex		of ommitte	WHO ee on S	norms pecificatio	and ns for	standards	4
	1.3	-1									5 6	
		1.3.1	Introdu	ction and	d welcome	е						6
2.	General updates and matters for information									8		
	2.1	2.1.1 2.1.2 2.1.3 2.1.4 2.1.5 2.1.6	Local m Member Expert (Expert (Essen Antimicr Internati	anufacture State modernitte Committe cobial resonal Corollaborat	echanism e on Biolo e - selection istance ofference of	ogical Son and tial	tandar use of Regula	dization the <i>WH</i>	Medicino			8 9 9 10 11 12 12
		2.2.2	United N	Nations C	Discussio Children's F	- und						13 13
3.	 Quality assurance - collaboration initiatives 3.1 International meetings of world pharmacopoeias 3.2 Inspection guidelines and good practices 3.2.1 Revision of WHO good manufacturing practices for sterile pharmaceutical products 3.2.2 Good manufacturing practices for biotherapeutic products 						products	15 15 15 15 16				
4.	Nom	encla	iture, to	ermino	logy an	d data	base	s				18
	 4.1 International Nonproprietary Names for pharmaceutical substances 4.2 Quality assurance terminology 4.3 Guidelines and guidance texts adopted by the Expert Committee 							18 18 18				
5.	Prequalification of priority essential medicines and active											
	pharmaceutical ingredients									20		
	5.1 5.2	•			cation of mation of a			eutical	ingredients	S		20 20
6.	Quality control - prequalification and WHO monitoring projects									22		
	6.1	3.1 Update on the prequalification of quality control laboratories								22		

7.	Qua	lityco	ontrol - national laboratories	23				
	7.1	Extern	al Quality Assurance Assessment Scheme	23				
8.	Quality control - specifications and tests: The International							
	Pharmacopoeia							
	8.1	Update	9	24				
	8.2	•	lan 2018-2019	24				
	8.3		dure for the development, revision and omission of monographs and					
			exts for The International Pharmacopoeia	26				
	8.4	Genera	al policy - transition from microbiological to physicochemical assays					
		in mor	nographs on capreomycin active pharmaceutical ingredient and products	27				
	8.5	Gener	al chapters	27				
		8.5.1	Limit test for heavy metals	27				
		8.5.2	Polymorphism	28				
		8.5.3	Dissolution test for solid oral dosage forms	29				
		8.5.4	General notice: solubility	29				
	8.6	Specif	ications and draft monographs for medicines, including paediatric and					
		radiop	harmaceutical medicines	29				
		8.6.1	Medicines for maternal, newborn, child and adolescent health	29				
			Antimalarial medicines	31				
		8.6.3	Antituberculosis medicines	31				
		8.6.4	Antiviral medicines including antiretrovirals	32				
		8.6.5	Medicines for tropical diseases	33				
		8.6.6	Ophthalmological and dermatological medicines	34				
9.	Quality control - international reference materials							
	9.1	Update	e on International Chemical Reference Substances, including the report					
		of the	custodial centre of the dedicated ECSPP subgroup on the International					
		Chem	ical Reference Substances	35				
10.	Ger	neral p	olicy - chemistry	36				
	10.1	Revis	ion of guidance on representation of graphic formulae	36				
11.	Qua	ality as	ssurance - good manufacturing practices and inspection	37				
	11 1	Intern	retation of Guidelines on good manufacturing practices for heating,					
			ation and air-conditioning systems	37				
	11.2		manufacturing practices for validation	38				
			General main text	38				
		11.2.2	2 Analytical procedure validation	39				
		11.2.3	3 Validation of computerized systems	40				
		11.2.4	4 Qualification	40				
	11.3	3 Upda	te on review of existing WHO inspection guidance, including Guidelines					
		forin	spection of drug distribution channels and Quality system requirements for					
		natio	nal good manufacturing practice inspectorates	41				
		11.3.1	Guidelines for inspection of drug distribution channels	42				
		11.3.	2 Quality system requirements for national good manufacturing practice					
			inspectorates	42				
	11.		te and recommendations from inspectors' meeting, including on good					
		manu	ufacturing practices and environmental issues	42				

	11.5 Inquiry regarding production of water for injection"	43				
	11.6 Proposal for good chromatography practices	44				
12.	Quality assurance - distribution and supply chain	45				
	12.1 Guidelines on import procedures for medical products12.2 Update on review of existing WHO guidance, procedures and operational	45				
	documents for pharmaceutical procurement	45				
	12.2.1 New guidance on shelf-life for supply and procurement of medicines	45				
	12.2.2 Update of listing of stability conditions for WHO Member States	46				
13.	Regulatory guidance and model schemes	47				
	13.1 Proposal to waive in vivo bioequivalence requirements for medicines					
	included in the WHO Model List of Essential Medicines	47				
	13.1.1 Experimental pathway	48				
	13.1.2 Regulatory pathway	49				
	13.1.3 Prioritization exercise	49				
	13.2 WHO Certification Scheme on the Quality of Pharmaceutical Products Moving					
	in International Commerce	50				
	13.3 Good practice guidance document on implementing the collaborative procedures	51				
	13.4 Guidance document to support and facilitate the implementation of quality					
	management systems for national regulatory authorities	52				
	13.5 Good regulatory practices	52				
14.	Miscellaneous	53				
	14.1 Update of WHO/UNFPA prequalification guidance for contraceptive devices					
	and condoms	53				
15.	Closing remarks	54				
	55					
Ackr	60					
Refe	83					
Anne	ex 1					
	Procedure for the development of World Health Organization medicines quality					
	assurance guidelines	87				
Anne	ex 2					
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products						
	Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems					
	for non-sterile pharmaceutical products	93				
Anna						
Annex 3 Good manufacturing practices: quidelines on validation 119						
	Good manufacturing practices: guidelines on validation Appendix 1 Validation of heating, ventilation and air-conditioning systems					
	135					
	136					
	Appendix 3 Cleaning validation	137				
	Appendix 4 Analytical procedure validation	148				

	Appendix 5 Validation of computerized systems	160
	Appendix 6 Guidelines on qualification	181
	Appendix 7 Non sterile process validation	190
Αn	nex 4	
	Protocol to conduct equilibrium solubility experiments for the purpose of	
	Biopharmaceutics Classification System-based classification of active pharmaceutical ingredients for biowaiver	203
	ingrediente lei biowaivei	200
Αn	nex 5	
	Guidelines on import procedures for medical products	219
Αn	пех б	
	Good practices of national regulatory authorities in implementing the collaborative	
	registration procedures for medical products	233
	Appendix 1 An example of information to applicants for registration via the	
	WHO collaborative registration procedure	257
	Appendix 2 Verification for product submitted under the WHO	
	collaborative procedure	259
	Appendix 3 Abridged/abbreviated review for product submitted under the	
	WHO collaborative procedure	263
	Appendix 4 Additional information to be included in the screening checklist	279
	Appendix 5 Example of a national regulatory authority reliance model	
	approach: information, documentary evidence and assessment activity	281
	Appendix 6 Model acknowledgement or approval letter for variations of	
	products registered through the WHO collaborative procedure	283