

## WHO TRS Annexes' Index

TRS	Yr.	Annex	Title
902	2002	1	List of available International Chemical Reference Substance
		2	List of available International Infrared Reference Spectra
		3	Good practices for national pharmaceutical control laboratories
		4	Considerations for requesting analysis of drug samples
		5	Basic elements of good manufacturing practices in pharmaceutical production
		6	Good manufacturing practices for sterile products
		7	Guidelines on pre-approval inspections
		8	Quality systems requirements for national good manufacturing practice inspectorates
		9	Guidelines on packaging for pharmaceutical products
		10	Model certificate of analysis
		11	Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products
		12	Guidelines on the use of International Nonproprietary Names (INNs) for pharmaceutical substances
908	2003	1	Recommendations on risk of transmitting animal spongiform encephalopathy agents via medicinal products
		2	The International Pharmacopoeia: revised concepts and future perspectives
		3	Guidelines on Good Manufacturing Practices for radiopharmaceutical products
		4	Good Manufacturing Practices for pharmaceutical products: main principles
		5	Model certificate of Good Manufacturing Practices
		6	Guidance on Good Manufacturing Practices (GMP): inspection report
		7	Application of Hazard Analysis and Critical Control Point (HACCP) method to pharmaceuticals
		8	Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies
		9	Guide to good storage practices for pharmaceuticals
929	2005	1	International Chemical Reference Substances and International Infrared Reference Spectra
		2	Good manufacturing practices: requirement for the sampling of starting materials (amendment)
		3	WHO Good Manufacturing Practices: water for pharmaceutical use
		4	WHO guidelines for sampling of pharmaceutical products and related materials

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		5	Guidelines for registration of fixed-dose combination medicinal products.
937	2006	1	List of available International Chemical Reference Substances and International Infrared Reference Spectra
		2	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms
		3	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines
		4	Supplementary guidelines on good manufacturing practices: validation <i>(Appendix 1: Validation of HVAC, Appendix 2: Validation of water systems for pharmaceutical use, Appendix 3: Cleaning validation, Appendix 4: Analytical method validation, Appendix 5: Validation of computer system, Appendix 6: Qualification of systems and equipment, Appendix 7: Non-sterile process validation – revised in TRS 992, 2015, Annex 3)</i>
		5	Good distribution practices for pharmaceutical products
		6	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on pre-qualification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products)
		7	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability
		8	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms
		9	Additional guidance for organizations performing in vivo bioequivalence studies
953	2009	1	List of available International Chemical Reference Substances and International Infrared Reference Spectra
		2	Stability testing of active pharmaceutical ingredients (API) and finished pharmaceutical products (FPP)
		3	Procedure for prequalification of pharmaceutical products
		4	Procedure for assessing the acceptability, in principle, of active pharmaceutical ingredients for use in pharmaceutical products
957	2010	1	WHO good practices for pharmaceutical quality control laboratories. <i>(QMS, Reagents, Reference materials, Traceability, Sampling, Retained samples, Testing, OOS, COA, Validation of analytical methods... etc.)</i>
		2	WHO good manufacturing practices for active pharmaceutical ingredients
		3	good manufacturing practices for pharmaceutical products containing hazardous substances
		4	WHO good manufacturing practices for pharmaceutical products
		5	WHO good distribution practices for pharmaceutical products
		6	Guidelines on the re-qualification of pre-qualified dossiers
		7	Guidelines for the preparation of a contract research organization master file

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961	2011	1	Release procedure of International Chemical Reference Substances
		2	WHO good practices for pharmaceutical microbiology laboratories. <i>(Appendix 1: Zones in which operations could be carried out, Appendix 2: Examples of maintenance of equipment, Appendix 3: Calibration of lab. equipment, Appendix 4: Equipment qualification and monitoring, Appendix 5: General use of reference cultures)</i>
		3	WHO good manufacturing practices: main principles for pharmaceutical products
		4	WHO good manufacturing practices for blood establishments (jointly with the Expert Committee on Biological Standardization)
		5	WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning (HVAC) systems for non-sterile pharmaceutical dosage forms.
		6	WHO good manufacturing practices for sterile pharmaceutical products
		7	WHO guidelines on transfer of technology in pharmaceutical manufacturing
		8	Good pharmacy practice: standards for quality of pharmacy services (joint FIP/WHO)
		9	Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products (jointly with the Expert Committee on Biological Standardization).. Revised in TRS 992, 2015, Annex 5.
		10	Procedure for prequalification of pharmaceutical products
		11	Guidelines on submission of documentation for prequalification of innovator finished pharmaceutical products approved by stringent regulatory authorities
		12	Prequalification of quality control laboratories. Procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies
		13	WHO guidelines for preparing a laboratory information file
		14	WHO guidelines for drafting a site master file
		15	Guidelines on submission of documentation for a multisource (generic) finished product: general format: preparation of product dossiers in common technical document format
970	2012	1	Development of monographs for The International Pharmacop.
		2	WHO GMP: water for pharmaceutical use.
		3	Pharmaceutical development of multisource (generic) pharmaceutical products - point to consider
		4	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Program
		5	Development of pediatric medicines: points to consider in formulation
		6	Recommendations for quality requirements for artemisinin as a starting material in the production of antimalarial active pharmaceutical ingredients.
981	2011	1	Release procedure for International Chemical Reference Substances

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		2	WHO guidelines on quality risk management (QRM).
		3	WHO guidelines on variations to a prequalified product
		4	Collaborative procedure between the World Health Organization Prequalification of Medicines Program and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products
986	2014	1	The International Pharmacopoeia – Updating mechanism for the section on radiopharmaceuticals
		2	WHO good manufacturing practices for pharmaceutical products: main principles ( <i>Quality risk management, Product quality review, Sanitation and hygiene, Qualification and validation, complaints, product recalls, Contract manufacturing, self-inspection and audits, training, documentation...</i> )
		3	Model quality assurance system for procurement agencies
		4	Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection
		5	Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities.
		6	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part
992	2015	1	Procedure for the development of monographs and other texts for The International Pharmacopoeia
		2	Updating mechanism for the section on radiopharmaceuticals in The International Pharmacopoeia
		3	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation ( <i>Lifecycle-based process validation</i> ).
		4	General guidance on hold-time studies
		5	Technical supplements to Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products
		6	Recommendations for quality requirements when plant-derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients
		7	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability
		8	Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products
		9	review practices: guidelines for national and regional regulatory auth.
996	2016	1	Good pharmacopeial practices
		2	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
		3	WHO good manufacturing practices for biological products
		4	Guidance on good manufacturing practices: inspection report
		5	Guidance on good data and record management practices
		6	Good trade and distribution practices for pharmaceutical starting

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			materials
		7	Guidelines on the conduct of surveys of the quality of medicines
		8	Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines
		9	Guidance for organizations performing in vivo bioequivalence studies
		10	WHO general guidance on variations to multisource pharmaceutical products
1003	2017	1	WHO guidelines for selecting marker substances of herbal origin for quality control of herbal medicines <sup>1</sup>
		2	The International Pharmacopoeia: revised concepts and future perspectives
		3	Prequalification of quality control laboratories: procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies
		4	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices
		5	General background notes on the list of international comparator pharmaceutical products
		6	Equilibrium solubility experiments for the purpose of classification of APIs according to the Bio-pharmaceutics Classification System, as an appendix to the WHO guidelines on Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, WHO Technical Report Series, No. 992, 2015)
1010	2018	1	Good herbal processing practices for herbal medicines
		2	Guidelines on good manufacturing practices for the manufacture of herbal medicines
		3	Considerations for requesting analysis of medicines samples
		4	Model certificate of analysis
		5	WHO guidance on testing of "suspect" falsified medicines
		6	Good pharmacopeial practices: Chapter on monographs for compounded preparations
		7	Good pharmacopeial practices: Chapter on monographs on herbal medicines
		8	Guidelines on heating, ventilation and air-conditioning (HVAC) systems for non-sterile pharmaceutical products.
		9	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions
		10	Stability testing of active pharmaceutical ingredients (API) and finished pharmaceutical products (FPP). <i>(Appendix 1: Examples of testing parameter, Appendix 2: Recommended labeling statements, Appendix 3: interpretation of storage statement for products approved in climatic Zone2 when products are to be distributed in zone 4)</i>
		11	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities.

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1019	2019	1	Procedure for the development of World Health Organization medicines quality assurance guidelines
		2	Guidelines on heating, ventilation and air-conditioning (HVAC) systems for non-sterile pharmaceutical products
		3	Good manufacturing practices: guidelines on validation
		4	Protocol to conduct equilibrium solubility experiments for the purpose of Biopharmaceutics Classification System-based classification of active pharmaceutical ingredients for biowaiver
		5	Guidelines on import procedures for medical products
		6	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products
1033	2021	1	Specifications for pharmaceutical preparations
		2	Points to consider when include health-based exposure limits (HBEL) in cleaning validation
		3	Water for pharmaceutical use
		4	Guideline on data integrity
		8	WHO Biowaiver list
		11	Good regulatory practices in the regulation of medicinal products
1044	2022	1	Specifications for pharmaceutical preparations
		2	Sterile pharmaceutical products
		3	Investigational radiopharmaceutical products
		4	Technology transfer in pharmaceutical manufacturing
		5	Medicinal gases
		6	R&D facilities of pharmaceutical products
		7	Investigational products
		8	Points to consider for setting remaining shelf-life of medicinal products
		9	Natural rubber latex male condom stability studies
		10	R&D facilities of pharmaceutical products
		11	BE requirements for immediate release SDF
1052	2024	2	WHO good manufacturing practices for excipients used in pharmaceutical products
		4	WHO good practices for pharmaceutical quality control laboratories
		7	WHO guideline on Biopharmaceutics Classification System-based biowaivers
1060	2025	2	WHO good practice considerations for the prevention and control of nitrosamines in pharmaceutical products
		3	WHO good manufacturing practices for excipients used in pharmaceutical products
		4	Good practice guidelines for blood establishments
		5	WHO Biowaiver List: proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines
		6	Guideline on bioanalytical method validation and study sample analysis

