

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Thirty-sixth Report



World Health Organization

Geneva

Expert Committee Specifications Pharmaceutical Preparations

Yijin Wang



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WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization, 2009 The Expert Committee on specifications for pharmaceutical preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines Standards are developed by the committee through worldwide consultation and an international consensus building process *WHO expert committee on specifications for pharmaceutical preparations : thirty-first report ,1990* *WHO Expert Committee on Specifications for Pharmaceutical Preparations* World Health Organization, 2020-04-21 **WHO Expert Committee on Specifications for Pharmaceutical Preparations** WHO Expert Committee on Specifications for Pharmaceutical Preparations, 1972 **Report** WHO Expert Committee on Specifications for Pharmaceutical Preparations, 2009 *WHO Expert Committee on Specifications for Pharmaceutical Preparations* Światowa Organizacja Zdrowia. Expert Committee on Specifications for Pharmaceutical Preparations, 2017 **WHO Expert Committee on Specifications for Pharmaceutical Preparations** WHO Expert Committee on Specifications for Pharmaceutical Preparations, 2007 **WHO Expert Committee on Specifications for Pharmaceutical Preparations** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting, 1987 Technical Report Series ,1950 WHO Expert Committee on Specifications for Pharmaceutical Preparations WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting, World Health Organization, 2016 The World Health Organization WHO Expert Committee on Specifications for Pharmaceutical Preparations advises the Director General of WHO in the area of medicines quality assurance It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality safety and efficacy in all WHO Member States Its advice is developed through a broad consensus building process and covers all areas of quality assurance of medicines from their development to their distribution to patients In the area of quality control the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia and received the annual report of the European Directorate for the Quality of Medicines HealthCare EDQM the custodian centre for International Chemical Reference Substances ICRS The Committee adopted a number of monographs general texts and ICRS It noted the report on Phase 6 of the External Quality Assurance Assessment Scheme EQAAS and on new approaches to ensure sustainability of this scheme through user fees The Committee further acknowledged the progress of good pharmacopoeial practices GPhP and adopted the document on GPhP which was prepared by the consecutive international meetings of world pharmacopoeias In the various quality assurance related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices GMP distribution and trade of pharmaceuticals and regulatory practice It adopted 10 guidelines as listed below as well as 22 new specifications and general texts for inclusion in The International Pharmacopoeia The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory

practice project and welcomed the development of a comprehensive set of guidelines for all national regulatory authorities through this project *WHO Expert Committee on Specifications for Pharmaceutical Preparations* WHO Expert Committee on Specifications for Pharmaceutical Preparations,1965 *WHO Expert Committee on Specifications for Pharmaceutical Preparations* WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting,2019 *WHO Expert Committee on Specifications for Pharmaceutical Preparations* WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting,2015-05-11 The World Health Organization WHO Expert Committee on Specifications for Pharmaceutical Preparations advises the Director General of WHO in the area of medicines quality assurance It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality safety and efficacy in all WHO Member States Its advice is developed through a broad consensus building process and covers all areas of quality assurance of medicines from their development to their distribution to patients In the area of quality control the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia and received the annual report of the European Directorate for the Quality of Medicines Annex 2 Updating mechanism for the section on radiopharmaceuticals in The International Pharmacopoeia revision Annex 3 Supplementary guidelines on good manufacturing practices validation Appendix 7 non sterile process validation revision Annex 4 General guidance for inspectors on hold time studies new Annex 6 Recommendations for quality requirements when plant derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients revision Annex 7 Guidelines on registration requirements to establish interchangeability revision Annex 8 Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource generic products revision Annex 9 Good review practices guidelines for regulatory authorities new In addition 16 technical supplements to the WHO model guidance for the storage and transport of time and temperature sensitive pharmaceutical products were adopted for publication in a format which is appropriate to the large volume of this guidance Annex 5 The newly adopted monographs were adopted for inclusion in The International Pharmacopoeia Following the implementation of the revised general monograph on parenteral preparations the Committee adopted the proposed endotoxin limits for 11 parenteral dosage form monographs lacking such specification together with related updates to relevant monographs The Committee adopted 12 ICRS newly characterized by the custodian centre EDQM The Committee further adopted the workplan for new monographs to be included in The International Pharmacopoeia *WHO Expert Committee on Specifications for Pharmaceutical Preparations* Comité OMS d'experts des spécifications relatives aux préparations pharmaceutiques,2003 **WHO Expert Committee on Specifications for Pharmaceutical Preparations** WHO Expert Committee on Specifications for Pharmaceutical Preparations,1975-01-01 **WHO Expert Committee on Specifications for Pharmaceutical Preparations** WHO Expert Committee on Specifications for Pharmaceutical Preparations,World Health Organization,1996-01-01 Report (22nd) of

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