

Annex 4

Supplementary guidelines on good manufacturing practices: validation

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Annex 4 Supplementary Guidelines On Good Manufacturing

**WHO Expert Committee on
Specifications for Pharmaceutical
Preparations. Meeting, World Health
Organization**

Annex 4 Supplementary Guidelines On Good Manufacturing:

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 World Health Organization, 2024-04-26 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools The Expert Committee develops standards through worldwide consultation and an international consensus building process The following new guidance texts were adopted and recommended for use WHO good manufacturing practices for excipients used in pharmaceutical products revision IAEA WHO good manufacturing practices for in house cold kits for radiopharmaceutical preparations new WHO good practices for pharmaceutical quality control laboratories revision WHO UNFPA female condom generic specification new WHO Biowaiver List proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release updated solid oral dosage forms WHO guideline on Biopharmaceutics Classification System based biowaivers revision and Multisource generic pharmaceutical products guidelines on registration requirements to establish interchangeability republished All of the above are included in this report and recommended for implementation **WHO**

Guidelines on Good Agricultural and Collection Practices [GACP] for Medicinal Plants World Health

Organization, 2003-12-16 Medicinal plant materials are supplied through collection from wild populations and cultivation. Under the overall context of quality assurance and control of herbal medicines, WHO developed the Guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants, providing general technical guidance on obtaining medicinal plant materials of good quality for the sustainable production of herbal products classified as medicines. These guidelines are also related to WHO's work on the protection of medicinal plants, aiming at the promotion of sustainable use and cultivation of medicinal plants. The main objectives of these guidelines are to:

1. contribute to the quality assurance of medicinal plant materials used as the source for herbal medicines to improve the quality, safety, and efficacy of finished herbal products;
2. guide the formulation of national and/or regional GACP guidelines and GACP monographs for medicinal plants and related standard operating procedures; and
3. encourage and support the sustainable cultivation and collection of medicinal plants of good quality in ways that respect and support the conservation of medicinal plants and the environment in general.

These guidelines concern the cultivation and collection of medicinal plants and include certain post-harvest operations. Good agricultural and collection practices for medicinal plants are the first step in quality assurance on which the safety and efficacy of herbal medicinal products directly depend. These practices also play an important role in the protection of natural resources of medicinal plants for sustainable use.

WHO Expert Committee on Specifications for Pharmaceutical Preparations, 2021-04-26 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent, and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools. Standards are developed by the Expert Committee through worldwide consultation and an international consensus-building process. The following new guidance texts were adopted and recommended for use:

- Guidelines and guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations.
- Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation.
- Good manufacturing practices (GMP) for pharmaceutical use.
- Guideline on data integrity.
- WHO United Nations Population Fund recommendations for condom storage and shipping temperatures.
- WHO United Nations Population Fund guidance on testing of male latex condoms.
- WHO United Nations Population Fund guidance on conducting post-market surveillance of condoms.
- WHO Biowaiver List proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release solid oral dosage forms.
- WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce.
- Good reliance practices in the regulation of medical products: high-level principles and considerations.
- Good regulatory practices in the regulations of medical products.

All of the above are included in this report and recommended for implementation.

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Jordi Botet, 2015-09-28 Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the

manufacture of dosage forms until the safe reception of the finished product by the patient The entire chain comprises of several processes auditing materials purchase procurement production storage distribution quality control and quality assurance The quality standard for pharmaceutical production is current good manufacturing practice CGMP which is applied within the frame of a pharmaceutical quality system PQS This implementation however requires a scientific approach and has to take into account several elements such as risk assessment life cycle patient protection among other factors Hence pharmaceutical manufacturing is a complex subject in terms of regulation given the technical and managerial requirements This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance The book gives details about basic quality control requirements such as risk management quality hazards and management systems documentation clean environments personnel training and gives guidelines on regulatory aspects This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector

Data Integrity in Pharmaceutical and Medical Devices Regulation Operations Orlando Lopez, 2016-11-03 Data integrity is fundamental in a pharmaceutical and medical devices quality system This book provides practical information to enable compliance with data integrity while highlighting and efficiently integrating worldwide regulation into the subject The ideas presented in this book are based on many years experience in regulated industries in various computer systems development maintenance and quality functions In addition to case studies a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved

WHO Expert Committee on Biological Standardization World Health Organization. Expert Committee on Biological Standardization, World Health Organization, 2016 This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biological substances and the establishment of international biological reference materials Following a brief introduction the report summarizes a number of general issues brought to the attention of the Committee The next part of the report of particular relevance to manufacturers and national regulatory authorities outlines the discussions held on the development and adoption of new and revised WHO Recommendations Guidelines and guidance documents Following these discussions a WHO guidance document on Regulatory assessment of approved rDNA derived biotherapeutics was adopted along with WHO Guidelines on the stability evaluation of vaccines for use under extended controlled temperature conditions and on WHO good manufacturing practices for biological products In addition revised WHO Recommendations to assure the quality safety and efficacy of recombinant human papillomavirus virus like particle vaccines were also adopted by the Committee Subsequent sections of the report provide information on the current status and proposed development of international

reference materials in the areas of antibiotics biotherapeutics other than blood products blood products and related substances in vitro diagnostic device reagents and vaccines and related substances A series of annexes are then presented which include an updated list of all WHO Recommendations Guidelines and other documents on biological substances used in medicine Annex 1 The above four WHO documents adopted on the advice of the Committee are then published as part of this report Annexes 2 5 Finally all additions and discontinuations made during the 2015 meeting to the list of International Standards Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 6 The updated full catalog of WHO International Reference Preparations is available at <http://www.who.int/bloodproducts/catalogue/en>

Essential Oils in Food Processing: Chemistry, Safety and Applications Seyed Mohammed Bagher Hashemi, Amin Mousavi Khaneghah, Anderson de Souza Sant'Ana, 2017-10-06 A guide to the use of essential oils in food including information on their composition extraction methods and their antioxidant and antimicrobial applications Consumers food preferences are moving away from synthetic additives and preservatives and there is an increase demand for convenient packaged foods with long shelf lives The use of essential oils fills the need for more natural preservatives to extend the shelf life and maintaining the safety of foods Essential Oils in Food Processing offers researchers in food science a guide to the chemistry safety and applications of these easily accessible and eco friendly substances The text offers a review of essential oils components history source and their application in foods and explores common and new extraction methods of essential oils from herbs and spices The authors show how to determine the chemical composition of essential oils as well as an explanation of the antimicrobial and antioxidant activity of these oils in foods This resource also delves into the effect of essential oils on food flavor and explores the interaction of essential oils and food components Essential Oils in Food Processing offers a Handbook of the use of essential oils in food including their composition extraction methods and their antioxidant and antimicrobial applications Guide that shows how essential oils can be used to extend the shelf life of food products whilst meeting consumer demand for natural products Review of the use of essential oils as natural flavour ingredients Summary of relevant food regulations as pertaining to essential oils Academic researchers in food science R D scientists and educators and advanced students in food science and nutrition can tap into the most recent findings and basic understanding of the chemistry application and safe use of essential oils in food processing

Regulatory Affairs in Industrial Pharmacy in India Madhu Verma, Iti Chauhan, 2025-09-09 This book comprehensively explores the regulatory frameworks governing pharmaceutical manufacturing quality control and approvals in Indian pharmaceutical scenarios Tailored for industry professionals students and researchers it bridges the knowledge gaps in regulatory affairs in the pharmaceutical industry Covering key topics such as pilot plant scale up SUPAC Scale Up and Post Approval Changes technology transfer regulatory requirements and quality management systems it offers insights into navigating the complexities of Indian regulatory requirements A must read for those aiming to excel in pharmaceutical regulation the book serves as a roadmap for

ensuring efficiency safety and compliance in pharmaceutical industries operating in India WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization, 2006 This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms The report is complemented by a number of annexes These include a list of available international chemical reference substances and international infrared spectra supplementary guidelines on good manufacturing practices for heating ventilation and air conditioning systems for non sterile pharmaceutical dosage forms updated supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines supplementary guidelines on good manufacturing practices for validation good distribution practices for pharmaceutical products a model quality assurance system for procurement agencies recommendations for quality assurance systems focusing on prequalification of products and manufacturers purchasing storage and distribution of pharmaceutical products multisource generic pharmaceutical products guidelines on registration requirements to establish interchangeability a proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release solid oral dosage forms and additional guidance for organizations performing in vivo bioequivalence studies This is an excellent book with a misleading title a good reference work for anyone seeking to understand the concept of validation and looking for general guidance on validation for both Active Pharmaceutical Ingredients API and finished pharmaceutical products Annex 5 on Good distribution practices GDP for pharmaceutical products is an excellent Annex that splits the task of GDP into 20 small easy to digest sections that guide the reader through the process of understanding the complexity of controlling distribution of pharmaceutical products It contains a comprehensive glossary of terms used in GDP a useful reference book for anyone involved in Quality Assurance Manufacturing of marketed products Clinical Manufacturing and Development Industrial Pharmacy

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