

Technical Guide

for the elaboration of monographs

European Pharmacopoeia

European Directorate for the Quality of Medicines & HealthCare



6th Edition - 2011

Technical Guide For The Elaboration Of Monographs

Joachim Ermer, Phil W. Nethercote



Technical Guide For The Elaboration Of Monographs:

Technical Guide for the Elaboration of Monographs Agnès Artiges, 1996

Specification of Drug Substances and Products Christopher M. Riley, K. Lien Nguyen, 2024-09-22

Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals. There have been several recent developments in the ICH Guidelines which were not captured in previous editions, notably the new guideline on Development of Analytical Procedure and the revisions to the validation guidelines and the specification guidelines. This edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mRNA based products. This substantially expanded revision of the 2nd edition will serve as a practical comprehensive reference for scientists, managers, educators, and consultants involved in the development and regulation of pharmaceutical products. Presents critical assessment, potential impact, and application of the recent revisions to ICH guidelines on method validation Q2 as well as the latest guideline on Analytical Method Development Q14 and the special regional requirements in non-ICH regions. Addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis, control, and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins, mRNA based drugs, vaccines, and gene therapy. This book will also address drug device combination products such as digital drug delivery systems, transdermal systems, and inhalation products. Presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data, method specification setting, and shelf life prediction based on stability data.

Peptide Therapeutics Ved Srivastava, 2019-08-16

Peptide therapy has become a key strategy in innovative drug development; however, one of the potential barriers for the development of novel peptide drugs in the clinic is their deficiencies in clearly defined chemistry, manufacturing, and controls (CMC) strategy from clinical development to commercialization. CMC can often become a rate-limiting step due to lack of knowledge and lack of a formal policy or guidelines on CMC for peptide-based drugs. Regulators use a risk-based approach reviewing applications on a case-by-case basis. **Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing, and Controls** covers efficient manufacturing of peptide drug substances, a review of the process for submitting applications to the regulatory authority for drug approval, a holistic approach for quality attributes and quality control from a regulatory perspective, emerging analytical tools for the characterisation of impurities, and the assessment of stability. This book is an essential reference work for students and researchers in both academia and industry with an interest in learning about CMC and facilitating development and manufacture of peptide-based drugs.

Technetium-99m Pharmaceuticals Ilse Zolle, 2007-01-28

Radioactive drug development is a multi-disciplinary task; therefore, in a concerted effort, dedicated scientists and experts from different fields of specialisation have contributed to this

book It is presented in two sections Section 1 contains basic principles and methods used for analysis information on the chemistry of technetium and on radiopharmaceuticals labelled with technetium 99m the characteristics of the 99 Mo 99mTc generator of kits and formulations for in vitro labelling and special safety aspects for in vivo labelling of blood cells Section 2 contains monographs of 99mTc radiopharmaceuticals used in nuclear medicine Each monograph includes information on the chemistry formulation commercial products and trade names factors affecting in vivo performance clinical information on pharmacokinetics as well as details concerning the clinical application and the radiation dose to patients **NMR in**

Pharmaceutical Science Jeremy R. Everett, Robin K. Harris, John C. Lindon, Ian D. Wilson, 2015-08-24 NMR in Pharmaceutical Sciences is intended to be a comprehensive source of information for the many individuals that utilize MR in studies of relevance to the pharmaceutical sector The book is intended to educate and inform those who develop and apply MR approaches within the wider pharmaceutical environment emphasizing the toolbox that is available to spectroscopists and radiologists This book is structured on the key processes in drug discovery development and manufacture but underpinned by an understanding of fundamental NMR principles and the unique contribution that NMR including MRI can provide After an introductory chapter which constitutes an overview the content is organised into five sections The first section is on the basics of NMR theory and relevant experimental methods The rest follow a sequence based on the chronology of drug discovery and development firstly Idea to Lead then Lead to Drug Candidate followed by Clinical Development and finally Drug Manufacture The thirty one chapters cover a vast range of topics from analytical chemistry including aspects involved in regulatory matters and in the prevention of fraud to clinical imaging studies Whilst this comprehensive volume will be essential reading for many scientists based in pharmaceutical and related industries it should also be of considerable value to a much wider range of academic scientists whose research is related to the various aspects of pharmaceutical R for them it will supply vital understanding of pharmaceutical industrial concerns and the basis of key decision making processes About eMagRes Handbooks eMagRes formerly the Encyclopedia of Magnetic Resonance publishes a wide range of online articles on all aspects of magnetic resonance in physics chemistry biology and medicine The existence of this large number of articles written by experts in various fields is enabling the publication of a series of eMagRes Handbooks on specific areas of NMR and MRI The chapters of each of these handbooks will comprise a carefully chosen selection of eMagRes articles In consultation with the eMagRes Editorial Board the eMagRes handbooks are coherently planned in advance by specially selected Editors and new articles are written to give appropriate complete coverage The handbooks are intended to be of value and interest to research students postdoctoral fellows and other researchers learning about the scientific area in question and undertaking relevant experiments whether in academia or industry Have the content of this handbook and the complete content of eMagRes at your fingertips Visit www.wileyonlinelibrary.com ref eMagRes

Drug Stereochemistry Krzysztof Jozwiak, W. J. Lough, Irving W. Wainer, 2012-04-23 Drug Stereochemistry Analytical

Methods and Pharmacology Third Edition covers all aspects of chiral drugs from academic governmental industrial and clinical perspectives reflecting the many advances in techniques and methodology Topics include The use of enzymes in the synthesis and resolution of enantiometrically pure compounds in drug disc **European Pharmacopoeia** ,2001

Method Validation in Pharmaceutical Analysis Joachim Ermer, Phil W. Nethercote, 2014-11-10 This second edition of a global bestseller has been completely redesigned and extensively rewritten to take into account the new Quality by Design QbD and lifecycle concepts in pharmaceutical manufacturing As in the first edition the fundamental requirements for analytical method validation are covered but the second edition describes how these are applied systematically throughout the entire analytical lifecycle QbD principles require adoption of a systematic approach to development and validation that begin with predefined objectives For analytical methods these predefined objectives are established as an Analytical Target Profile ATP The book chapters are aligned with recently introduced standards and guidelines for manufacturing processes validation and follow the three stages of the analytical lifecycle Method Design Method Performance Qualification and Continued Method Performance Verification Case studies and examples from the pharmaceutical industry illustrate the concepts and guidelines presented and the standards and regulations from the US FDA European EMA and global ICH regulatory authorities are considered throughout The undisputed gold standard in the field **WHO Expert Committee on Specifications for Pharmaceutical Preparations** World Health Organization, 2019-05-29 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 consensusbuilding process The following new guidelines were adopted and recommended for use Procedure for development of the WHO medicines quality assurance guidelines Guidelines on Good Manufacturing Practices GMP for heating ventilation and air conditioning systems HVAC illustrative part Guidance on GMP for Validation including the general main text analytical procedure validation validation of computerized systems and qualification in the area of interchangeability of multisource medicines the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver Guidelines on Import Procedures for pharmaceutical products and the Good Practice Guidance document on implementing the collaborative procedures All of the above are included in this report and recommended for implementation Reference

Materials for Chemical Analysis Markus Stoeppler, Wayne R. Wolf, Peter J. Jenks, 2008-07-11 There are many academic references describing how RMs are made but few that explain why they are used how they should be used and what happens when they are not properly used In order to fill this gap the editors have taken the contributions of more than thirty RM practitioners to produce a highly readable text organized in nine chapters Starting with an introduction to historical theoretical and technical requirements the book goes on to examine all aspects of RM production from planning preparation

through analysis to certification reviews recent development areas RMs for life analysis and some important general application fields considers the proper usage of RMs gives advice on availability and sources of information and lastly looks at future trends and needs for RMs This book is intended to be a single point of information that both guides the reader through the use of RMs and serves as a primary reference source It should be on the reading list of anyone working in an analytical laboratory and be found on the library shelf of all analytical chemical laboratories

Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection

World Health Organization, 2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry

International Pharmaceutical Product Registration

Anthony C. Cartwright, Brian R. Matthews, 2016-04-19 Discover the latest ICH news from international experts in the pharmaceutical industry academia and regulatory bodies The recent International Conference on Harmonisation ICH revisions of regulatory requirements for quality nonclinical and clinical pharmaceutical product registration are the focus of this timely update This cutting edge resou

Chiral Separations by Capillary Electrophoresis

Ann Van Eeckhaut, Yvette Michotte, 2009-11-11 Covers the Fundamentals of Chiral Separation Available Chiral Selectors and Numerous Applications of Chiral Separation by Capillary Electrophoresis Since the 1980s modern analytical tools have enabled capillary electrophoresis to become a standard part of the chemist's toolkit With contributions from international experts Chiral Separations by

Methods of Therapeutic Drug Monitoring Including Pharmacogenetics

Georg Hempel, 2019-10-17 Methods of Therapeutic Drug Monitoring Including Pharmacogenetics Second Edition Volume Seven in the Handbook of Analytical Separations series covers all aspects of drug monitoring including laboratory work pharmacokinetic analysis and clinical aspects thus enabling readers from different fields to understand the whole process of therapeutic drug monitoring and how to avoid common pitfalls The book contains analytical techniques for the quantification of drugs along with pharmacogenetic and pharmacogenomic methods Also included are updates on sample preparation including dried blood spot technology and microextraction methods In addition the book includes new drugs such as tyrosine kinase inhibitors and the monitoring of immunosuppressant drugs Presents a unique interdisciplinary approach that appeals to a wide range of users Written by authors from international labs providing a global perspective that can be applied in various regulatory environments Features additional therapeutic drugs to reflect the rising number of immunocompromised patients Includes a new mass spectroscopic methods chapter to capture the frequent use in TDM and the improved availability of LC MS across laboratories

Quality assurance of pharmaceuticals: a compendium of guidelines and related materials, tenth edition.

Volume 1. Good practices and related regulatory guidance World Health Organization, 2024-10-24 This publication represents a significant achievement in our ongoing effort to ensure that everyone can reach the highest possible level of health Over the last three decades we have seen the transformation of the pharmaceutical industry and the increasing intricacy of the product life cycle The challenges we face today are very different from those we faced when the first edition of this Compendium was published in 1997 However our mission remains the same to promote health keep the world safe and serve the vulnerable The new edition reflects the collective knowledge and expertise of countless professionals who have worked diligently to develop revise and implement WHO guidelines for pharmaceuticals This includes experts from WHO Member States our Expert Advisory Panels and Expert Committees on Specifications for Pharmaceutical Preparations and other organizations and has undergone extensive consultation with stakeholders worldwide This Compendium covers development through manufacturing and quality control to post marketing surveillance It provides a comprehensive framework for quality assurance that is both strong and flexible capable of meeting the requirements of a rapidly changing global health landscape The 10th edition is a collection of knowledge and tools for empowerment enabling all stakeholders in the pharmaceutical industry to make informed decisions that prioritize patient safety and well being **Practical Pharmaceutics** Paul Le Brun, Sylvie Crauste-Manciet, Irene Krämer, Julian Smith, Herman Woerdenbag, 2023-06-15 Practical Pharmaceutics contains essential knowledge on the preparation quality control logistics dispensing and use of medicines It features chapters written by experienced pharmacists and scientists working in hospitals academia and industry throughout Europe including practical examples as well as information on current GMP and GMP based guidelines and EU legislation In this second edition all chapters have been updated with numerous new as well as didactically revised illustrations and tables A completely new chapter about therapeutic proteins and Advanced Therapy Medicinal Products was added From prescription to production from usage instructions to procurement and the impact of medicines on the environment the book provides step by step coverage that will help a wide range of readers students as well as professionals It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the required medicine available to store medicines properly to adapt medicines if necessary and to dispense medicines with the appropriate information for patients as well as caregivers about product care and how to maintain the quality of the product The basic knowledge presented in the book will also be valuable for industrial pharmacists to remind and focus them on the application of the medicines manufactured The basic and practical knowledge on the design preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and in industry Undergraduate as well as graduate pharmacy students will find knowledge presented in a coherent way and fully supported with relevant examples Practical Pharmaceutics has become a reliable and recognised source for the acquisition of pharmaceutical technological knowledge The book is used in the curriculum of a number of international universities and

schools of Pharmacy **Practical Pharmaceutics** Yvonne Bouwman-Boer,V'Iain Fenton-May,Paul Le Brun,2015-08-24 This book contains essential knowledge on the preparation control logistics dispensing and use of medicines It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe complete with practical examples as well as information on current EU legislation From prescription to production from usage instructions to procurement and the impact of medicines on the environment the book provides step by step coverage that will help a wide range of readers It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available to store medicines properly to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured The basic and practical knowledge on the design preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples *Handbook of Nuclear Medicine and Molecular Imaging for Physicists* Michael Ljungberg,2022-03-22 This state of the art handbook the third and final in a series that provides medical physicists with a comprehensive overview into the field of nuclear medicine focuses on highlighting the production and application of radiopharmaceuticals With this the book also describes the chemical composition of these compounds as well as some of the main clinical applications where radiopharmaceuticals may be used Following an introduction to the field of radiopharmacy three chapters in this book are dedicated towards in depth descriptions of common radionuclides and radiopharmaceuticals used during diagnostic studies utilizing planar Single Photon Emission Computed Tomography SPECT imaging in addition to during Positron Emission Tomography PET imaging and finally radiotherapy These chapters are followed by those describing procedures relating to quality control and manufacturing good manufacturing practices also encompassing aspects such as environmental compliance Furthermore this volume illustrates how facilities handling these chemicals should be designed to comply with set regulations Like many pharmaceuticals the development of radiopharmaceuticals relies heavily on the use of mouse models Thus the translation of radiopharmaceuticals i e the process undertaken to assure that the functionality and safety of a newly developed drug is maintained also in a human context is covered in a later chapter This is followed by a chapter emphasising the importance of safe waste disposal and how to assure that these procedures meet the requirements set for the disposal of hazardous waste Several chapters have also been dedicated towards describing various medical procedures utilizing clinical nuclear medicine as a tool for diagnostics and therapeutics As physicists may be involved in clinical trials a chapter describing the procedures and regulations associated with these types of studies is included This is followed by a chapter focusing on patient safety and another on an imaging modality not based on ionizing radiation

ultrasound Finally the last chapter of this book discusses future perspectives of the field of nuclear medicine This text will be an invaluable resource for libraries institutions and clinical and academic medical physicists searching for a complete account of what defines nuclear medicine The most comprehensive reference available providing a state of the art overview of the field of nuclear medicine Edited by a leader in the field with contributions from a team of experienced medical physicists chemists engineers scientists and clinical medical personnel Includes the latest practical research in the field in addition to explaining fundamental theory and the field s history *British Pharmacopoeia 2003* British Pharmacopoeia Commission,2003 This three volume collection with CD ROM contains the authoritative standard reference for medicines in the United Kingdom It provides information on the quality of substances used throughout medicine and pharmaceuticals Two volumes contain the Pharmacopoeia while a third volume presents British Pharmacopoeia Veterinary Charged Aerosol Detection for Liquid Chromatography and Related Separation Techniques Paul H. Gamache,2017-05-08 The first book devoted exclusively to a highly popular relatively new detection technique Charged Aerosol Detection for Liquid Chromatography and Related Separation Techniques presents a comprehensive review of CAD theory describes its advantages and limitations and offers extremely well informed recommendations for its practical use Using numerous real world examples based on contributors professional experiences it provides priceless insights into the actual and potential applications of CAD across a wide range of industries Charged aerosol detection can be combined with a variety of separation techniques and in numerous configurations While it has been widely adapted for an array of industrial and research applications with great success it is still a relatively new technique and its fundamental performance characteristics are not yet fully understood This book is intended as a tool for scientists seeking to identify the most effective and efficient uses of charged aerosol detection for a given application Moving naturally from basic to advanced topics the author relates fundamental principles practical uses and applications across a range of industrial settings including pharmaceuticals petrochemicals biotech and more Offers timely authoritative coverage of the theory experimental techniques and end user applications of charged aerosol detection Includes contributions from experts from various fields of applications who explore CAD s advantages over traditional HPLC techniques as well its limitations Provides a current theoretical and practical understanding of CAD derived from authorities on aerosol technology and separation sciences Features numerous real world examples that help relate fundamental properties and general operational variables of CAD to its performance in a variety of conditions Charged Aerosol Detection for Liquid Chromatography and Related Separation Techniques is a valuable resource for scientists who use chromatographic techniques in academic research and across an array of industrial settings including the biopharmaceutical biotechnology biofuel chemical environmental and food and beverage industries among others

Unveiling the Magic of Words: A Review of "**Technical Guide For The Elaboration Of Monographs**"

In some sort of defined by information and interconnectivity, the enchanting power of words has acquired unparalleled significance. Their power to kindle emotions, provoke contemplation, and ignite transformative change is truly awe-inspiring. Enter the realm of "**Technical Guide For The Elaboration Of Monographs**," a mesmerizing literary masterpiece penned by way of a distinguished author, guiding readers on a profound journey to unravel the secrets and potential hidden within every word. In this critique, we shall delve in to the book is central themes, examine its distinctive writing style, and assess its profound affect the souls of its readers.

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