

BASIC TESTS FOR DRUGS

Pharmaceutical substances,
medicinal plant materials
and dosage forms



World Health Organization
Geneva

Basic Tests For Pharmaceutical Substances

World Health Organization



Basic Tests For Pharmaceutical Substances:

Basic Tests For Pharmaceutical Substances, 1/Ed. ,2007 **Basic Tests for Drugs** World Health Organization,1998 This book provides a step by step guide to simple methods for verifying the identity of commonly used pharmaceutical substances and dosage forms The basic tests described can also be used to detect mislabeled substandard or counterfeit products when the labeling or physical attributes give rise to doubt Intended for use in developing countries where resources and specialized skills may be scarce all tests rely on a limited range of easily available reagents and equipment and need not be performed in a fully equipped laboratory or by persons with specialized training in pharmacy or chemistry The book describes tests for 23 pharmaceutical substances and 58 pharmaceutical dosage forms most of which are included in the WHO Model List of Essential Drugs Basic tests for confirming the identity of four commonly used medicinal plant materials are also included As stressed in the text these tests which merely confirm identity are intended for use as primary screening tools and may need to be followed in cases of adverse test results by a full pharmacopoeial analysis The book opens with a brief description of the importance of basic tests as one of the many steps needed to ensure a supply of safe and effective drugs Chapter two describes several collections of more sophisticated tests including volumetric or spectrophotometric analysis and thin layer chromatography that can be useful in the primary screening of imported pharmaceutical substances and dosage forms Information on how to obtain and use these guides to tests which have not been published by WHO is also provided Against this background the main part of the book sets out test procedures for verifying the identity of selected pharmaceutical substances pharmaceutical dosage forms and medicinal plant materials The book concludes with a cumulative index of test procedures described here and in the related WHO publications **Basic Tests for Pharmaceutical Substances** and **Basic Tests for Pharmaceutical Dosage Forms** **Basic Tests for Pharmaceutical Substances** World Health Organization,1986 **Basic Tests for Pharmaceutical Dosage Forms** World Health Organization,1991 **Basic Tests for Pharmaceutical Substances** ,1986 **Quality Assurance of Pharmaceuticals** World Health Organization,2007 Quality assurance of pharmaceutical products is a continuing concern of WHO Despite efforts made around the world to ensure a supply of quality and effective medicines substandard spurious and counterfeit products still compromise health care delivery in many countries To respond to the global need for adequate quality assurance of pharmaceuticals WHO s Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices GMP Important texts on inspection are also included Most of the material has been published separately in the Expert Committee s reports This compendium brings it together to make it more accessible and of greater

practical value to those working in faculties of pharmacy in medicines regulation and control and in the pharmaceutical industry This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series

Quality Control and Standardization Of Herbals Dr. Dillip Kumar Jena, Dr. Pankaj Pradhan, 2021-04-14 Purchase the e Book version of Quality Control and Standardization of Herbals for B Pharm 8th Semester meticulously aligned with the PCI Syllabus Published by Thakur Publication this digital edition offers a comprehensive exploration of advanced instrumentation techniques at your fingertips Upgrade your learning experience with the convenience and portability of an e Book Dive into the world of cutting edge pharmaceutical instrumentation with ease Get your copy today and embark on a journey of enhanced understanding

WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization, 2005-11-11 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 Important topics were addressed such as regulatory guidance on interchangeability of medicines fix dose combinations how to regulate them new guidance in the area of good manufacturing practices GMP and stability testing and counterfeit medicines In addition some 12 new monographs for antiretrovirals 6 new ones on TB drugs including 2 3 and 4 fixed dose preparations as well as monographs for antimalarial medicines are discussed in detail Seven new specifications for antiretrovirals were adopted The report also includes newly International Chemical Reference Substances for the series of artemisinin derivatives The following new WHO guidelines were adopted and are annexed to the report GMP requirement for the sampling of starting materials amendment to current text GMP water for pharmaceutical use guideline for sampling of pharmaceuticals and related materials guidelines for registration of fixed dose combination medicinal products

The International Pharmacopoeia World Health Organization, 1979 The International Pharmacopoeia contains a collection of recommended methods for analysis and quality specifications for pharmaceutical substances excipients and products Volume five of this publications describes methods and procedures for the quality control of pharmaceutical substances and tablets tests for dosage forms for suppositories and ophthalmic preparations and a new section on quality control of anti malarials Supplementary information on International Chemical Reference Substances and International Reference Spectra and on the establishment maintenance and distribution of chemical reference substances are also included

WHO Expert Committee on Specifications for Pharmaceutical Preparations WHO Expert Committee on Specifications for Pharmaceutical Preparations, World Health Organization, 2007 This report sets out the recommendations of an international group of experts relating to developments in the quality assurance of medicines and specifications for drug substances and dosage forms It contains guidelines of direct relevance to the UN Prequalification Programme for Priority Essential Medicines and for quality control laboratories including procedures governing the assessment of pharmaceutical products for procurement by UN agencies and for assessing the acceptability of

quality control laboratories It also includes discussion regarding several monographs for inclusion in the International Pharmacopoeia relating to antiretrovirals including fixed dose combinations TB medicines and antimalarial and paediatric medicines

Quantitative and Qualitative Determination Technologies of Counterfeit Drugs Ronny Priefer, 2023-08-10 Drugs are often counterfeited to reduce manufacture costs while still marketing it as an authentic product Increased incidence of drug counterfeiting is most noticeable in developing countries which may not have the resources to supply counterfeit detection devices on a large scale It is important to consider the problems caused and to propose options for controlling and reducing the prevalence of counterfeit medications Various technologies are needed to identify the chemical properties of a questioned medicinal product which can then be used to determine its authenticity This volume focuses on current technological approaches that are able to detect counterfeited pharmaceuticals Features Focuses on current technological approaches that are able to detect counterfeited pharmaceuticals Assesses the chemical methods of identifying counterfeit medicinal products and explains the theoretical underpinnings of the methods Provides case study type examples of the application for analysis of suspected counterfeit pharmaceuticals Discusses the detection and analysis of counterfeit drugs and appropriate tools for combating this issue The editor draws on his experience as a respected chemist and prolific author in the field to provide this unique text on drug counterfeiting detection

Quality Control Methods for Medicinal Plant Materials World Health Organization, 1998 A collection of test procedures for assessing the identity purity and content of medicinal plant materials including determination of pesticide residues arsenic and heavy metals Intended to assist national laboratories engaged in drug quality control the manual responds to the growing use of medicinal plants the special quality problems they pose and the corresponding need for international guidance on reliable methods for quality control Recommended procedures whether involving visual inspection or the use of thin layer chromatography for the qualitative determination of impurities should also prove useful to the pharmaceutical industry and pharmacists working with these materials

Fundamentals of Analytical Toxicology Robert J. Flanagan, Eva Cuypers, Hans H. Maurer, Robin Whelpton, 2020-08-03 Fundamentals of Analytical Toxicology is an integrated introduction to the analysis of drugs poisons and other foreign compounds in biological and related specimens Assuming only basic knowledge of analytical chemistry this invaluable guide helps trainee analytical toxicologists understand the principles and practical skills involved in detecting identifying and measuring a broad range of compounds in various biological samples Clear easy to read chapters provide detailed information on topics including sample collection and preparation spectrophotometric and luminescence techniques liquid and gas liquid chromatography and mass spectrometry including hyphenated techniques This new edition contains thoroughly revised content that reflects contemporary practices and advances in analytical methods Expanding the scope of the 1995 World Health Organization WHO basic analytical toxicology manual the text includes coverage of separation science essential pharmacokinetics xenobiotic absorption distribution and metabolism clinical toxicological and substance misuse

testing therapeutic drug monitoring trace elements and toxic metals analysis and importantly the clinical interpretation of analytical results Written by a prominent team of experienced practitioners this volume Focuses on analytical statistical and pharmacokinetic principles Describes basic methodology including colour tests and immunoassay and enzyme based assays Outlines laboratory operations such as method validation quality assessment staff training and laboratory accreditation Follows IUPAC nomenclature for chemical names and recommended International Non proprietary Name rINN for drugs and pesticides Includes discussion of designer drugs novel pharmaceutical substances NPS Fundamentals of Analytical Toxicology Clinical and Forensic 2nd Edition is an indispensable resource for advanced students and trainee analytical toxicologists across disciplines such as clinical science analytical chemistry forensic science pathology applied biology food safety and pharmaceutical and pesticide development *WHO Expert Committee on Specifications for Pharmaceutical Preparations* World Health Organization,2008-05-05 The Expert Committee on Specifications for Pharmaceutical Preparations works towards standards and guidelines for medicines quality assurance The forty second meeting adopted 11 new monographs for inclusion in The International Pharmacopoeia Ph Int and seven related new International Chemical Reference Standards ICRS The specifications currently developed are internationally applicable test methodologies for antimalarial antituberculosis antiretroviral and specifically also medicines for children The main principles for selection of INNs for biologicals were endorsed In order to serve the WHO managed Prequalification Program two new procedures were adopted namely on prequalification of intrauterine devices IUDs and of male latex condoms together with a new guidance on the assessment of active pharmaceutical ingredients for use in medicines Publisher s description **Clarke's Analytical Forensic Toxicology** Gail Cooper,Adam Negrusz,2013-05-28 This invaluable textbook written by international experts covers all the main elements of forensic toxicology and analytical toxicology techniques as well as the important parts of pharmacokinetics drug metabolism and pharmacology in general with a particular focus on drugs of abuse **TEXT BOOK OF QUALITY CONTROL AND STANDARDIZATION OF HERBALS** Dr. Rekha Tarasingh Rajput, Saurabh Khare, Dr. Vivek Srivastava, Dr. Prabhat Kumar Upadhyay, Dr. Shweta S. Saboo,2025-04-21 The Textbook of Quality Control and Standardization of Herbals is a comprehensive guide covering the principles techniques and regulatory requirements for ensuring the quality and safety of herbal medicines It provides essential knowledge for students researchers and professionals in the pharmaceutical and herbal drug industries The book begins with basic tests for pharmaceutical substances medicinal plant materials and dosage forms along with WHO guidelines for quality control of herbal drugs It discusses methods for evaluating commercial crude drugs intended for medicinal use A key focus is quality assurance detailing the implementation of cGMP GAP GMP and GLP in the herbal drug industry The WHO guidelines on Good Manufacturing Practices cGMP for Herbal Medicines are covered in detail The book also includes EU and ICH guidelines for the quality control of herbal drugs safety and efficacy research and stability testing of herbal formulations It highlights the

importance of pharmacovigilance systems for monitoring herbal medicine safety The role of chromatographic techniques such as HPTLC HPLC and GC in the standardization of herbal products is thoroughly explored The book also explains the regulatory requirements for herbal medicines including new drug applications export registration and GMP compliance The Herbal Pharmacopoeia section compares various global pharmacopoeias and emphasizes the role of chemical and biological markers in herbal drug standardization This book serves as a valuable resource for ensuring the authenticity purity and consistency of herbal medicines worldwide *The Selection and Use of Essential Medicines* World Health

Organization,2008 This report presents the recommendations of the Subcommittee of the WHO Expert Committee responsible for the WHO Model List of Essential Medicines The task of this Subcommittee was to draw up the first WHO Model List of Essential Medicines for Children The first part of the report contains a summary of the Committee s considerations and justifications for the inclusion of particular medicines in the Model List for Children Appendices to the main report include the first WHO Model List of Essential Medicines for Children a list of all the items it contains sorted according to their 5 level Anatomical Therapeutic Chemical ATC classification codes and a summary of medicines to be reviewed before the next meeting of the Subcommittee Profiles of Drug Substances, Excipients and Related Methodology

,1983-11-02 Profiles of Drug Substances Excipients and Related Methodology **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 *Bulletin of the World Health Organization* World Health Organization,1998

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