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Quality Control in the Production of Radiopharmaceuticals - International Atomic Energy Agency 2018-11-30
Advances have led to the production of new radiopharmaceuticals and availability of new production routes. Various new diagnostic agents in the field (such as Ga-68 radiopharmaceuticals and generators) as well as therapeutic agents (such as alpha emitters) have been added to the clinician's menu. It is essential that radiopharmaceuticals are prepared within a robust quality control system encompassing materials and personnel, with adequate documentation, and continuous review of ongoing results. This publication provides guidelines and best practices for the quality control of medical radioisotopes and radiopharmaceuticals. It was written by a group of experts with experience across a range of radiopharmaceuticals and is intended to support professionals in the preparation of good quality and safe products to be used in nuclear medicine procedures.
In Vitro-In Vivo Correlations - David B. Young 2013-03-08
This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in Sep tember, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery com pany specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Not tingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. lain Cumming, Elan Corporation Dr. John Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin

Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the devel opment of in vitro-in vivo relationships for ER products. The original idea went back ap proximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.
NIOSH Manual of Analytical Methods - John V. Crable 1977

Pharmaceutical Manufacturing Handbook - Shayne Cox Gad 2008-03-21
This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.
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: water 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; and Good regulatory practices in the regulations of medical products. All of the above are included in this report and recommended for implementation.
Indian Pharmacopoeia, 2007 - 2007

Pharmaceutical Dissolution Testing - Jennifer J. Dressman 2005-07-08
An expertly written source on the devices, systems, and technologies used in the dissolution testing of oral pharmaceutical dosage forms, this reference provides reader-friendly chapters on currently utilized equipment, equipment qualification, consideration of the gastrointestinal physiology in test design, the analysis and interpretation of data and procedure automation -laying the

foundation for the creation of appropriate and useful dissolution tests according to the anticipated location and duration of drug release from the dosage form within the gastrointestinal tract.

Systems Approaches to Public Sector Challenges Working with Change - OECD 2017-08-11

This report, produced by the OECD Observatory of Public Sector Innovation, explores how systems approaches can be used in the public sector to solve complex or “wicked” problems.

Martin's Physical Pharmacy and Pharmaceutical Sciences - Alfred N. Martin 2011

Martin's Physical Pharmacy and Pharmaceutical Sciences is considered the most comprehensive text available on the application of the physical, chemical and biological principles in the pharmaceutical sciences. It helps students, teachers, researchers, and industrial pharmaceutical scientists use elements of biology, physics, and chemistry in their work and study. Since the first edition was published in 1960, the text has been and continues to be a required text for the core courses of Pharmaceutics, Drug Delivery, and Physical Pharmacy. The Sixth Edition features expanded content on drug delivery, solid oral dosage forms, pharmaceutical polymers and pharmaceutical biotechnology, and updated sections to cover advances in nanotechnology.

Indian Pharmacopoeia 2010 - Government of India. Ministry of Health & Family Welfare 2010

Guidance on Water Supply and Sanitation in Extreme Weather Events - Centers of Disease Control 2011

Many countries in the European Region experienced a growing number of episodes of extreme weather events, often displaying distinctive features of disasters, associated with a significant burden of premature deaths, diseases and forced displacement of communities. Because of this the linkage between extreme weather events and population health, survival and well being has been increasingly recognized by the scientific and decision-making communities. To avoid or to limit these undesirable effects adaptation policies are called to include also risk management of natural hydro meteorological disasters through structural and non-structural measures including environmental and water management, land-use and urban planning, application of science and technology, partnership and networking, financial instruments and, last but not least, protection of crucial facilities like health services and water supply and sanitation utilities. Indeed water supply and sanitation utilities are key health determinants in critical conditions of extreme weather events requiring special attention in local and transboundary context implementation of adaptation measures to climate change and variability. Facing these new environmental scenarios of climate variability and change, recalling the main objective of the Protocol on Water and Health and in accordance with article 16 a Task Force on Extreme Weather Events (TFEWE) was established by the first Meeting of the Parties to the Protocol on Water and Health (Geneva, 17-19 January 2007) in order to assist Parties in the implementation of the provisions of the Protocol through the achievement of its approved 2007-2009 Work Programme. The Ministry of Environment of Italy took the leadership of the Task Force on Extreme Weather Events (TF EWE). Its main mandate was the

development of Guidance on Water supply and sanitation in extreme weather events. This Guidance is intended to provide an overview on why and how adaptation policies should consider the vulnerability of and new risk elements for health and environment arising from water services management during adverse weather episodes. Emerging risk factors in conditions of climate variability receive special attention, with a focus on the response capacity of the environment and health sectors, the role of the managers of water services managers, and information needs, including public communication strategy, as key elements of health risk reduction. Special emphasis is given to adaptation measures to ensure safe water supply and sanitation using existing infrastructure. This document addresses a broad audience, including policy makers, environment, health and water resources professionals, and water service managers. An integrated environment and health approach steered the development and discussion of the Guidance.

Environmental Consequences of the Chernobyl Accident and Their Remediation - International Atomic Energy Agency 2006

The explosion on 26 April 1986 at the Chernobyl nuclear power plant and the consequent reactor fire resulted in an unprecedented release of radioactive material from a nuclear reactor and adverse consequences for the public and the environment. Although the accident occurred nearly two decades ago, controversy still surrounds the real impact of the disaster. Therefore the IAEA, in cooperation with other UN bodies, the World Bank, as well as the competent authorities of Belarus, the Russian Federation and Ukraine, established the Chernobyl Forum in 2003. The mission of the Forum was to generate 'authoritative consensual statements' on the environmental consequences and health effects attributable to radiation exposure arising from the accident as well as to provide advice on environmental remediation and special health care programmes, and to suggest areas in which further research is required. This report presents the findings and recommendations of the Chernobyl Forum concerning the environmental effects of the Chernobyl accident.

OECD Series on Testing and Assessment Guidance Document on Good In Vitro Method Practices (GIVIMP) - OECD 2018-12-10

In the past several decades, there has been a substantial increase in the availability of in vitro test methods for evaluating chemical safety in an international regulatory context. To foster confidence in in vitro alternatives to animal testing, the test methods and conditions under which ...

Technical Report Series - 1950

Health Effects of Occupational Exposure to Respirable Crystalline Silica - 2002

In Vitro Drug Release Testing of Special Dosage Forms - Nikoletta Fotaki 2019-12-31

Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and development of the in vitro test methods need to take into account various aspects, including the dosage form design and the

conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special dosage forms' performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage Forms covers the in vitro release testing of: lipid based oral formulations; chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms Describes current regulatory conditions for in vitro drug release testing Features contributions from well respected global experts in dissolution testing In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmaceutics, and regulatory affairs.

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.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2018

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. The following new guidelines were adopted and recommended for use: - WHO guidelines on good herbal processing practices for herbal medicines; - Guidelines on good manufacturing practices for the manufacture of herbal medicines; - Considerations for requesting analysis of medicine samples; - WHO model certificate of analysis; - WHO guidance on testing of "suspect" falsified medicines; - Good pharmacopoeial practices - Chapter on monographs for compounded preparations; - Good pharmacopoeial practices - Chapter on monographs on herbal medicines; - Guidelines on heating, ventilation and air-

conditioning systems for non-sterile pharmaceutical products; - 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; - Stability testing of active pharmaceutical ingredients and finished pharmaceutical products; and - Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities.

Guide to Best Practices for Ocean Acidification Research and Data Reporting - Ulf Riebesell 2010

Difco and BBL Manual - Mary Jo Zimbro 2009

Who Expert Committee on Specifications for Pharmaceutical Preparations - WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting 2013

WHO's international guidelines, written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States, international organizations, United Nations agencies, regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria Programme, Stop TB, essential medicines and medicines for children. The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The International Pharmacopoeia,/I>. The specifications under development are internationally applicable test methodologies for anti-infective, antimalarial, antituberculosis, contraceptives and antiretroviral medicines, as well as medicines for children. In addition, the following four written standards were adopted in the area of quality assurance and are now available for implementation : * Release procedure for International Chemical Reference Substances (update); * WHO guideline on quality risk management (new) * WHO guideline on variations to a prequalified product (update) * Collaborative procedure between the WHO Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products (new).

3D Printed Microfluidic Devices - Savas Tasoglu 2019-01-10

This book is a printed edition of the Special Issue "3D Printed Microfluidic Devices" that was published in Micromachines

New Scientist - 1967

Government Reports Annual Index - 1983

Handbook of Stability Testing in Pharmaceutical Development - Kim Huynh-Ba 2008-11-16

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Specifications for Reagents Mentioned in the International Pharmacopoeia -

World Health Organization 1963

Recommended Methods for the Identification and Analysis of Amphetamine, Methamphetamine and Their Ring-substituted Analogues in Seized Materials - United Nations Office on Drugs and Crime. Laboratory and Scientific Section 2006

The growth in the use of amphetamine-type stimulants (ATS) has become a significant global problem over the last 10-15 years, often involving new and unfamiliar ATS and trafficking trends which present a challenge to both national law enforcement authorities and to scientists in drug testing forensic laboratories. Given the need for more accurate methods for identification and analysis, this manual reflects the discussions and conclusions of a UNODC Consultative Meeting held in London in September 1998.

The Use of Force in UN Peace Operations - Trevor Findlay 2002

One of the most vexing issues that has faced the international community since the end of the Cold War has been the use of force by the United Nations peacekeeping forces. UN intervention in civil wars, as in Somalia, Bosnia and Herzegovina, and Rwanda, has thrown into stark relief the difficulty of peacekeepers operating in situations where consent to their presence and activities is fragile or incomplete and where there is little peace to keep. Complex questions arise in these circumstances. When and how should peacekeepers use force to protect themselves, to protect their mission, or, most troublingly, to ensure compliance by recalcitrant parties with peace accords? Is a peace enforcement role for peacekeepers possible or is this simply war by another name? Is there a grey zone between peacekeeping and peace enforcement? Trevor Findlay reveals the history of the use of force by UN peacekeepers from Sinai in the 1950s to Haiti in the 1990s. He untangles the arguments about the use of force in peace operations and sets these within the broader context of military doctrine and practice. Drawing on these insights the author examines proposals for future conduct of UN operations, including the formulation of UN peacekeeping doctrine and the establishment of a UN rapid reaction force.

Guidelines for Evaluation of Environmental Health Services - Christina H. Drew 2000

A practical guide to concepts, methods, and instruments for conducting an evaluation of environmental health services. Noting that managers frequently overlook the importance of evaluation, the book also performs a persuasive function, serving to illustrate the advantages of evaluation for purposes ranging from the justification of continuing expenditure to assurance that public health is being adequately protected from hazards in food, air or water. Throughout the book, examples of evaluations conducted in European countries are used to show how different approaches work to resolve specific practical problems. The book has six chapters. The first provides a general introduction to the purpose, principles and components of evaluation, as well as procedures that are frequently used. Chapter two applies these general principles to the specific setting of environmental health services, where process, impact, relevance, and adequacy of services may need to be assessed. Factors that make such services difficult to evaluate through traditional mechanisms are also

briefly discussed. Against this background, a chapter on data and indicators provides detailed advice on the choice of indicators, concentrating on the use of process, environmental health, and urban indicators. Chapter four, on instruments for evaluation, outlines the strengths and weaknesses of several methods of data collection, giving particular attention to tools for economic analysis and qualitative evaluation. The remaining chapters cover the use of results in management decisions and set out five case studies of evaluations recently conducted in Europe.
Onsite Wastewater Treatment and Disposal Systems - 1980

The Challenge of Obesity in the WHO European Region and the Strategies for Response - World Health Organization. Regional Office for Europe 2007
In a brief, clear and easily accessible way, this summary illustrates the dynamics of the obesity epidemic and its impact on public health throughout the WHO European Region, particularly in eastern countries. It describes how factors that increase the risk of obesity are shaped in different settings, such as the family, school, community and workplace. It makes both ethical and economic arguments for accelerating action against obesity, and analyses effective programs and policies in different government sectors, such as education, health, agriculture and trade, urban planning and transport. The summary also describes how to design policies and programs to prevent obesity and how to monitor progress, and calls for specific action by stakeholders: not only government sectors but also the private sector - including food manufacturers, advertisers and traders - and professional consumers' and international and intergovernmental organizations such as the European Union.
Toxicological Profile for Asbestos (Update) - G. Douglas Hanley 2011-01
This is a print on demand edition of a hard to find publication. Asbestos is a group of 6 different fibrous minerals that occur naturally in the environment. All forms of asbestos are hazardous, and all can cause cancer. This profile includes: (1) The exam¿n. and interpretation of toxicologic info. and epidemiological eval¿s. on asbestos to ascertain the levels of human exposure for the substance and its health effects; (2) A determination of whether adequate info. on the health effects of asbestos is available or in the process of development to determine levels of exposure that present a significant risk to human health; and (3) Where appropriate, identification of toxicologic testing needed to identify the types or levels of exposure that may present significant risk of adverse health effects in humans. Charts and tables.
Guidelines for Drinking-water Quality - World Health Organization 1993
This volume describes the methods used in the surveillance of drinking water quality in the light of the special problems of small-community supplies, particularly in developing countries, and outlines the strategies necessary to ensure that surveillance is effective.
Poorly Soluble Drugs - Gregory K. Webster 2017-01-06
This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations. Such drug products are, vis-à-vis their physical and chemical properties, inherently incompatible with aqueous dissolution. However, dissolution methods are required for product development

and selection, as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding. The percentage of poorly soluble drugs, defined in classes 2 and 4 of the Biopharmaceutics Classification System (BCS), has significantly increased in the modern pharmaceutical development pipeline. This book provides a thorough exposition of general method development strategies for such drugs, including instrumentation and media selection, the use of compendial and non-compendial techniques in product development, and phase-appropriate approaches to dissolution development. Emerging topics in the field of dissolution are also discussed, including biorelevant and biphasic dissolution, the use on enzymes in dissolution testing, dissolution of suspensions, and drug release of non-oral products. Of particular interest to the industrial pharmaceutical professional, a brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies, including nanosuspensions, lipid-based formulations, and stabilized amorphous drug formulations.

The International Pharmacopoeia - World Health Organization 2006

The International Pharmacopoeia contains a collection of recommended methods for analysis and quality specifications for pharmaceutical substances, excipients and products. This new edition consolidates the texts of the five separate volumes of the third edition and includes new monographs for antiretroviral substances (didanosine, indinavir sulfate, nelfinavir mesilate, nevirapine, ritonavir, saquinovir, and saquinovir mesilate) adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2004. It includes some additions and amendments to the general notices of the Pharmacopoeia, as well as some changes to its layout and format. Volume one contains monographs for pharmaceutical substances A to O and the General Notices; and volume two contains monographs for pharmaceutical substances P to Z, together with those for dosage forms and radiopharmaceutical preparations, the methods of analysis and reagents.

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 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

Mongolia Health System Review - T□S□ilaazhavyn T□S□olmongėrėl 2013

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.

The Selection and Use of Essential Medicines - WHO Expert Committee on the Selection and Use of Essential Medicines 2004

This report presents the recommendations of the WHO Expert Committee responsible for updating the WHO Model List of Essential Medicines. The first part contains a progress report on the new procedures for updating the Model List and the development of the WHO Essential Medicines Library. It continues with a section on changes made in revising the Model List followed by a review of some sections such as hypertensive medicines and fast track procedures for

deleting items. Annexes include the 13th version of the Model List and items on the list sorted according to their 5-level Anatomical Therapeutic Chemical classification codes.