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ASSAY -Analytical method validation

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Oona McPolin (BSc MSc CSci CChem MRSC) is the training services manager of Mourn Training Services, a training consultancy which provides training solutions for ...

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This book provides a comprehensive guide on validating analytical methods. Key features: Full review of the available regulatory guidelines on validation and in particular, ICH. Sections of the guideline, Q2(R1), have been reproduced in this book with the kind permission of the ICH Secretariat; Thorough discussion of each of the validation characteristics (Specificity; Linearity; Range; Accuracy; Precision; Detection Limit; Quantitation Limit; Robustness; System Suitability) plus practical tips on how they may be studied; What to include in a validation protocol with advice on the experimental procedure to follow and selection of appropriate acceptance criteria; How to interpret and calculate the results of a validation study including the use of suitable statistical calculations; A fully explained case study demonstrating how to plan a validation study, what to include in the protocol, experiments to perform, setting acceptance criteria, interpretation of the results and reporting the study.

If you are new to HPLC, this book provides an invaluable guide to how HPLC is actually used when analysing pharmaceuticals. It is full of practical advice on the operation of HPLC systems combined with the necessary theoretical knowledge to ensure understanding of the technique. Key features include: A thorough discussion of the stationary phase enabling the reader to make sense of the many parameters used to describe a HPLC column; Practical advice and helpful hints for the preparation and use of mobile phase; A complete overview of each of the different components which together make up a HPLC system; A description of the contents of a typical HPLC analytical method and how to interpret these; A step-by-step guide on how to follow a method and set up a HPLC analysis; A discussion of system suitability criteria and how to interpret the values obtained during an analysis; Explanation of the common methods of calibration and quantification used for pharmaceutical analysis.

Pharmaceutical Medicine and Translational Clinical Research covers clinical testing of medicines and the translation of pharmaceutical drug research into new medicines, also focusing on the need to understand the safety profile of medicine and the benefit-risk balance. Pharmacoeconomics and the social impact of healthcare on patients and public health are also featured. It is written in a clear and straightforward manner to enable rapid review and assimilation of complex information and contains reader-friendly features. As a greater understanding of these aspects is critical for students in the areas of pharmaceutical medicine, clinical research, pharmacology and pharmacy, as well as professionals working in the pharmaceutical industry, this book is an ideal resource. Includes detailed coverage of current trends and key topics in pharmaceutical medicine, including biosimilars, biobetters, super generics, and Provides a comprehensive look at current

and important aspects of the science and regulation of drug and biologics discovery

Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.

This manual and reference work provides a source of analytical data for drugs and related substances. It is aimed at scientists faced with the problem of identifying a drug in a pharmaceutical product, in a sample of tissue or body fluid, from a living patient or in post-mortem material.

An indispensable guide to buffers and to understanding the principles behind their use. Helps the user to avoid common errors in preparing buffers and their solutions. A must for researchers in the biological sciences, this valuable book takes the time to explain something often taken for granted - buffers used in experiments. It answers the common questions such as: which buffer should I choose? What about the temperature effects? What about ionic strength? Why is the buffer with the biggest temperature variation used in PCR? It provides even the most experienced researchers with the means to understand the fundamental principles behind their preparation and use - an indispensable guide essential for everyone using buffers.

During the past two decades, the world scientific community has witnessed major achievements in our understanding of the pathogenesis of HIV infection of the nervous system and HIV-Associated Dementia (HAD). Despite these giant gains, nervous system involvement during AIDS remains a relentlessly progressive disease with a deadly fate in many cases. This book on NeuroAIDS provides a unique resource for both general neurologists as well as basic neuroscientists with profound interests for research on NeuroAIDS. This book has special emphasis on the mechanisms of disease development and progression of HIV-infected patients with NeuroAIDS. The contributors have provided the readers with comprehensive reviews on clinical manifestations of HAD, mechanisms of HIV entry into the central nervous system, the role of cytokines and chemokines in pathogenesis of NeuroAIDS, drug abuse and NeuroAIDS, virus load in HAD, allostasis in HIV and AIDS, stroke in AIDS patients, and neuroimaging of HIV infection of the central nervous system. In addition, there are chapters on Varicella Zoster virus infection of HIV-seropositive and AIDS patients, as well as the molecular basis for opioids and AIDS virus interactions.

A key component of the overall quality of a pharmaceutical is control of impurities, as their presence, even in small amounts, may affect drug safety and efficacy. The identification and quantification of impurities to acceptable standards presents a significant challenge to the analytical chemist. Analytical science is developing rapidly and provides increasing opportunity to identify the structure, and therefore the origin and safety implications of these impurities, and the challenges of their measurement drives the development of modern quantitative methods. Written for both practicing and student analytical chemists, Analysis of Drug Impurities provides a detailed overview of the challenges and the techniques available to permit accurate identification and quantification of drug impurities.

First explaining the basic principles of liquid chromatography and mass spectrometry and then discussing the current applications and practical benefits of LC-MS, along with descriptions of the basic instrumentation, this title will prove to be the indispensable reference source for everyone wishing to use this increasingly important tandem technique. \* First book to concentrate on principles of LC-MS \* Explains principles of mass spectrometry and chromatography before moving on to LC-MS \* Describes instrumental aspects of LC-MS \* Discusses current applications of LC-MS and shows benefits of using this technique in practice

Covering the essential basic science and principles of pharmacology using concise text and diagrams, Dale's Pharmacology Condensed, 3rd Edition, presents the key facts and concepts that are key to understanding how drugs work and their underlying pathophysiological processes. Each of the 50 short chapters provides an organized, consistent approach to efficient learning and retention of complex information. This concise text is an ideal companion volume to Rang and Dale's Pharmacology, as well as a stand-alone condensed textbook or review book for exams. All content has been thoroughly revised and updated, with new coverage of fast-moving therapeutic areas such as cancer treatments, dermatology and immune mediated diseases, and new developments in pharmacological principles such as biased agonism. Each two-page (or less) chapter condenses key information from Rang and Dale's Pharmacology to provide the necessary core knowledge, as well as essential therapeutic information. New editors are experienced teachers who provide a clear focus on what today's students need to know. Ideal for exam preparation with explanatory diagrams throughout, important drugs identified with bold type, and 50 multiple choice questions for self-assessment and review.

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