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In order to learn from foreign pharmaceutical quality control and production management experience, in this paper, the concept of PAT was introduced, the background of drug pro- ...

The definitive textbook on the chemical analysis of pharmaceutical drugs – fully revised and updated Introduction to Pharmaceutical Analytical Chemistry enables students to gain fundamental knowledge of the vital concepts, techniques and applications of the chemical analysis of pharmaceutical ingredients, final pharmaceutical products and drug substances in biological fluids. A unique emphasis on pharmaceutical laboratory practices, such as sample preparation and separation techniques, provides an efficient and practical educational framework for undergraduate studies in areas such as pharmaceutical sciences, analytical chemistry and forensic analysis. Suitable for foundational courses, this essential undergraduate text introduces the common analytical methods used in quantitative and qualitative chemical analysis of pharmaceuticals. This extensively revised second edition includes a new chapter on chemical analysis of biopharmaceuticals, which includes discussions on identification, purity testing and assay of peptide and protein-based formulations. Also new to this edition are improved colour illustrations and tables, a streamlined chapter structure and text revised for increased clarity and comprehension. Introduces the fundamental concepts of pharmaceutical analytical chemistry and statistics Presents a systematic investigation of pharmaceutical applications absent from other textbooks on the subject Examines various analytical techniques commonly used in pharmaceutical laboratories Provides practice problems, up-to-date practical examples and detailed illustrations Includes updated content aligned with the current European and United States Pharmacopeia regulations and guidelines Covering the analytical techniques and concepts necessary for pharmaceutical analytical chemistry, Introduction to Pharmaceutical Analytical Chemistry is ideally suited for students of chemical and pharmaceutical sciences as well as analytical chemists transitioning into the field of pharmaceutical analytical chemistry.

Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

This textbook is the first to present a systematic introduction to chemical analysis of pharmaceutical raw materials, finished pharmaceutical products, and of drugs in biological fluids, which are carried out in pharmaceutical laboratories worldwide. In addition, this textbook teaches the fundamentals of all the major analytical techniques used in the pharmaceutical laboratory, and teaches the international pharmacopoeias and guidelines of importance for the field. It is primarily intended for the pharmacy student, to teach the requirements in “analytical chemistry” for the 5 years pharmacy curriculum, but the textbook is also intended for analytical chemists moving into the field of pharmaceutical analysis. Addresses the basic concepts, then establishes the foundations for the common analytical methods that are currently used in the quantitative and qualitative chemical analysis of pharmaceutical drugs Provides an understanding of common analytical techniques used in all areas of pharmaceutical development Suitable for a foundation course in chemical and pharmaceutical sciences Aimed at undergraduate students of degrees in Pharmaceutical Science/Chemistry Analytical Science/Chemistry, Forensic analysis Includes many illustrative examples

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.

This open access book presents a unique collection of practical examples from the field of pharma business management and research. It covers a wide range of topics such as: 'Brexit and its Impact on pharmaceutical Law - Implications for Global Pharma Companies', 'Implementation of Measures and Sustainable Actions to Improve Employee's Engagement', 'Global Medical Clinical and Regulatory Affairs (GMCRA)', and 'A Quality Management System for R & D Project and Portfolio Management in a Pharmaceutical Company'. The chapters are summaries of masters theses by "high potential" Pharma MBA students from the Goethe Business School, Frankfurt/Main, Germany, with 8-10 years of work experience and are based on scientific know-how and real-world experience. The authors applied their interdisciplinary knowledge gained in 22 months of studies in the MBA program to selected practical themes drawn from their daily business.

This portrait of the global debate over patent law and access to essential medicines focuses on public health concerns about HIV/AIDS, malaria, tuberculosis, the SARS virus, influenza, and diseases of poverty. The essays explore the diplomatic negotiations and disputes in key international fora, such as the World Trade Organization, the World Health Organization and the World Intellectual Property Organization. Drawing upon international trade law, innovation policy, intellectual property law, health law, human rights and philosophy, the authors seek to canvass policy solutions which encourage and reward worthwhile pharmaceutical innovation while ensuring affordable access to advanced medicines. A number of creative policy options are critically assessed, including the development of a Health Impact Fund, prizes for medical innovation, the use of patent pools, open-source drug development and forms of 'creative capitalism'.