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An Introduction to HPLC for Pharmaceutical Analysis 2009-03-01 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

Validation of Analytical Methods for Pharmaceutical Analysis 2009-05-01 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 Pharmaceutical Analysis 1961 handbook of modern pharmaceutical analysis second edition synthesizes the complex research and recent changes in the field while covering the techniques and technology required for today s laboratories the work integrates strategy case studies methodologies and implications of new regulatory structures providing complete coverage of quality assurance from the point of discovery to the point of use treats pharmaceutical analysis pa as an integral partner to the drug development process rather than as a service to it covers method development validation selection testing modeling and simulation studies combined with advanced exploration of assays impurity testing biomolecules and chiral separations features detailed coverage of qa ethics and regulatory guidance quality by design good manufacturing practice as well as high tech methodologies and technologies from lab on a chip to lc ms lc nmr and lc nmr ms

Pharmaceutical Analysis 1984-01-01 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

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