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The Third Edition has been extensively updated and describes more than 5300 trade name products and 4000 generic chemicals and materials, available from worldwide manufacturers, that function as pharmaceutical additives. Pharmaceutical additives are defined in this reference as secondary ingredients present in both prescription and over-the-counter drug formulations and contributing in one or more of the following ways: • improving consumption ease of the dosage form by masking unpleasant ...

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A comprehensive, uniform guide to the uses, properties, and safety of pharmaceutical excipients and is an essential reference source for those involved in the development, production, control or regulation of pharmaceutical preparations. Features of this edition: Contains 210 excipient monographs; Collects together essential data of physical properties of excipients; Scanning electron photomicrographs included for many excipients; Contains information from various international sources; Also includes laboratory data determined specifically for the Handbook and personal observations; Contains information on the safe use and potential toxicity of the materials; All monographs in the Handbook are thoroughly cross-referenced and indexed so that excipients may be identified by either chemical, non-proprietary, or trade names; Written by over 120 pharmaceutical scientists expert in pharmaceutical formulation or excipient manufacture.

No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, particularly the new line of small protein products, joining the long list of proven sterile products, the technology of manufacturing ster

The Third Edition presents all pharmaceutical industry personnel and those in academia with critical updates on the recent advances in granulation technology and changes in FDA regulatory guidelines. Addressing precisely how these recent innovations and revisions affect unit operation of particle generation and granulation, this text assists the re

Describes tradename products and generic chemicals and materials, available from worldwide manufacturers, that function as pharmaceutical additives. Entires include chemical description, uses, regulatory, properties, and storage.

An internationally acclaimed reference work recognized as one of the most authoritative and comprehensive sources of information on excipients used in pharmaceutical formulation with this new edition providing 340 excipient monographs. Incorporates information on the uses, and chemical and physical properties of excipients systematically collated from a variety of international sources including: pharmacopeias, patents, primary and secondary literature, websites, and manufacturers' data; extensive data provided on the applications, licensing, and safety of excipients; comprehensively cross-referenced and indexed, with many additional excipients described as related substances and an international supplier's directory and detailed information on trade names and specific grades or types of excipients commercially available.

Provides data on the additives used to convert pharmacologically active compounds into dosage forms suitable for administration to patients. Data includes: nonproprietary names, functional category, synonyms, chemical names and CAS Registry number, empirical formula, molecular weight, structural formula, commercial availability, method of manufacture,description, pharmacopeial specifications, typical properties, stability and storage conditions, incompatibilities, safety, handling precautions, regulatory acceptance, applications in pharmaceutical formulation or technology, use, related substances, comments, and specific references.

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Five, Over-the-Counter Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this fifth volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author ' s own experience, to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. Features: Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines

This practical book provides toxicologists with essential information on the regulations that govern their jobs and products. Regulatory Toxicology, Third Edition is an up-to-date guide to required safety assessment for the entire range of man-made marketed products. Individual chapters written by experts with extensive experience in the field address requirements not only for human pharmaceuticals and medical devices (for which there are available guidances), but for the full range of man-made products. New in this edition are three chapters addressing Safety Data Sheet Preparation, Regulatory Requirements for GMOs, and Regulatory Requirements for Tobacco and Marijuana. The major administrative divisions for regulatory agencies and their main responsibilities are also detailed, as are the basic filing documents the agencies require. Coverage includes food additives, dietary supplements, cosmetics, over-the-counter drugs, personal care and consumer products, agriculture and GMO products, industrial chemicals, air and drinking water regulations and the special cases of California ' s Proposition 65, requirements for safety data sheets, and oversight regulations. Both US and international requirements are clearly presented and referenced. In one volume, those who have regulatory responsibility in companies, lawyers, educators, and those selling these materials in the marketplace can learn about regulatory requirements and how to meet them.

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