# Pharmaceutical Manufacturing Formulations

Uncompressed Solid Products

VOLUME 2

Sarfaraz K. Niazi



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K. Niazi,2014-10-29 As the generic pharmaceutical industry continues to grow and thrive so does the need to conduct adequate efficient bioequivalence studies In recent years there have been significant changes to the statistical models for evaluating bioequivalence In addition advances in the analytical technology used to detect drug and metabolite levels have m

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understanding of the U S statutory requirements vis a vis the regulatory guidelines Provides model CQA and Analytical Similarity testing protocols for cytokines and monoclonal antibodies Allow creation of a fast to market pathway to develop biosimilars Handbook of Pharmaceutical Manufacturing Formulations Sarfaraz K. Niazi, 2016-04-19 Providing methodologies that can serve as a reference point for new formulations the second volume covers uncompressed solids which include formulations of powders capsules powders ready for reconstitution and other similar products Highlights from Uncompressed Solid Products Volume Two include the fundamental issues of good manufacturin Handbook of Pharmaceutical Manufacturing Formulations, Third American Book Publishing Record, 2005 ,1981 Edition Sarfaraz K. Niazi, 2019-12-05 The Handbook of Pharmaceutical Manufacturing Formulations Third Edition Volume Three Liquid 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 third 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 Handbook of Pharmaceutical Manufacturing Formulations Sarfaraz K. Niazi, 2016-04-19 While liquid drugs do not share the compression problems of solid dosage forms the filling problems of powder dosage forms or the consistency problems of semisolid dosage forms they do have their own set of considerations in the formulation and manufacturing stages Highlights from Liquid Products Volume Three include practical details invo Handbook of Pharmaceutical Manufacturing Formulations Sarfaraz K. Niazi, 2004-04-27 The fourth volume in the six volume Handbook of Pharmaceutical Manufacturing Formulations this book covers semi solid drugs It includes ointments lotions gels and suppositories from publicly available but widely dispersed information from FDA New Drug Applications NDA patent applications and the BASF book of generic formulations Each entry begins with a fully validated scaleable manufacturing formula that includes compendial specification requirement for each ingredient in process controls for manufacturing and release of product a summary of manufacturing process and details of packaging **Handbook of Pharmaceutical** Manufacturing Formulations, Third Edition Sarfaraz K. Niazi, 2019-11-25 The Handbook of Pharmaceutical

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around the world identification and inclusion of the most often approved capsules and powders in the US <u>Handbook of Pharmaceutical Manufacturing Formulations</u> Sarfaraz K. Niazi,2004-04-27 The fifth volume in the series this book covers over the counter products which include formulations of products classified by the US FDA under the OTC category Each entry begins with a fully validated scaleable manufacturing formula and a summary of manufacturing process The book provides a detailed discussion on the difficulties encountered in formulating and manufacturing OTC products The section on regulatory and manufacturing guidance deals with the topics of cGMP practices for the OTC drug products formulations of solid oral dosage forms oral solutions and suspensions validation of cleaning process in addition to providing quick tips on resolving the common problems in formulating OTC drugs

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