HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT

VOLUME I - Part ONE

Drug Development - Solid Oral Dosage Forms

GENERIC DEVELOPMENT
Handbook of Pharmaceutical
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L O C U M P U B L I S H I N G H O U S E

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INTRODUCTION

Handbook of Generic Development - Oral Tablet Dosage Form

This handbook is the **new expanded** international edition of the ongoing **24** Volume *Series* under the cumulative title of Handbook of Generic Drug Development. It is a hands-on, technical presentation that portrays the current drug requirement steps necessary at the time of going to print, of the Abbreviated New Drug Application for oral tablet dosage form, namely tablets and caplets. It is written in conjunction with Part Two of the Handbook which models as a representative ANDA and as an example of the drug development process required for solid oral dosage forms. The Handbook is available in electronic format (CD ROM) and e-format (on-line). The Handbook is up-dated to current regulatory requirements once or occasionally under exceptional circumstances twice annually. Complete updates are available without charge to Association Members of the Drug Development Association - IAGIM.

This handbook provides a proven pathway to solid oral dosage form development. Modern commercial formulations highlight the common tablet/caplet development routes namely the classical wet granulation, spray granulation, dry granulation and finally slugging with direct compression. Low active dosage (<10mg) and high potency (>50%) examples are specially chosen to demonstrate the formulation steps and process stages as a prerequisite to developing stable, elegant and rugged formulas.

This Handbook edition includes additional data on analytical method validation has been redesigned to meet the Guidance for Industry - Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application as well as all FDA guideline and requirements of the Center of Drug Evaluation and Research (CDER) to date of publishing.

Editor-in-Chief.

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