

HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT



VOLUME I - Part ONE

Drug Development - Solid Oral Dosage Forms

GENERIC DEVELOPMENT

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Generic Development Series

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Part ONE
Drug Development

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INTRODUCTION

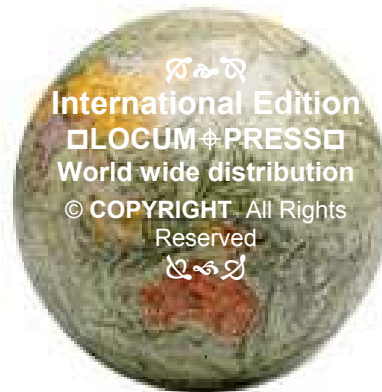
Handbook of Generic Development - Oral Tablet Dosage Form

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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EDITOR'S NOTE

Handbook of Generic Development Series: **ORAL IR TABLETS**

This handbook represents the **current** International Edition of the ongoing 24 volume series of Generic Drug Development and appears under the cumulative title of the Handbook series of Generic Drug Development. The ongoing series is updated annually at the end of each year. This is an ongoing process as new data, specifications and process techniques are added on a continual and expanding basis.

This handbook is fact never fully complete, as each new annual edition brings an enlarged and extended profile in the drug development process, as well as new agency rules, guidelines and guidance to industry which continues year by year as the global product data base expands. Over 150 scientific publications and drug development conferences are annually referenced in the 48 volume Handbook series of Generic Drug Development.

This mammoth task presents a continual ongoing commitment to the improvement of the technical databases and the product specific drug development requirements and know-how through the world wide IAGIM joint ventures and know-how projects currently active in over 15 countries.

The Handbook is available in electronic format (Online and CD ROM) and the **e-**format is up-dated annually to Association Members of IAGIM.

This current international edition of the Handbook has been redesigned and updated to meet the current Guidance for Industry - Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application as well as all current approved and key draft FDA guideline requirements of the Center of Drug Evaluation and Research (CDER) up to current date.

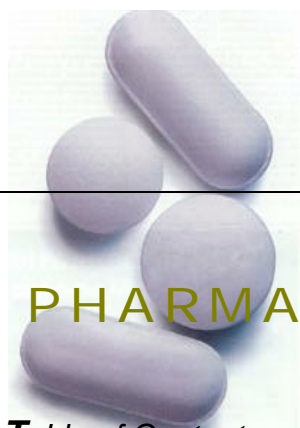
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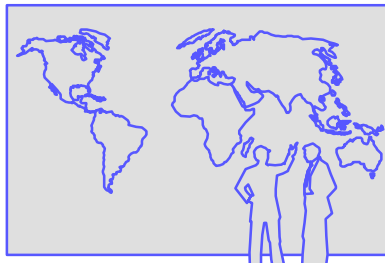
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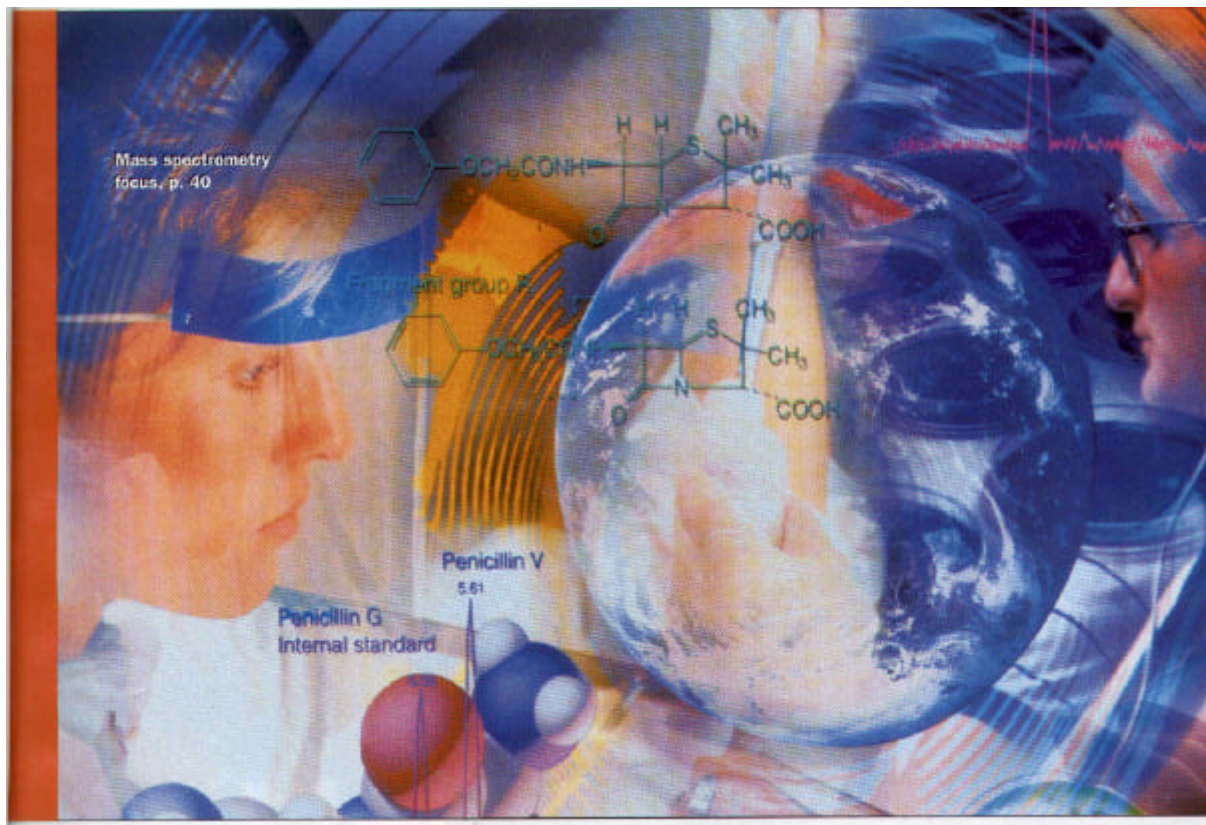
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