

HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT



HANDBOOK OF PHARMACEUTICAL
GENERIC DEVELOPMENT

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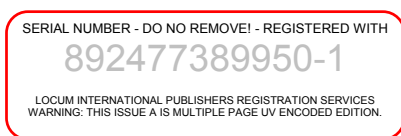
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ORAL SOFT GELATIN CAPSULES

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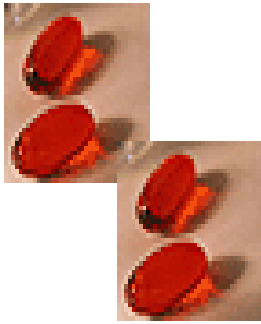
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To Doribelle
for her years of support and help
to Sean for his expert knowledge on computerization
to David and Ari for running the project's computers
and lastly to Pat for his inestimable
contribution.

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INTRODUCTION

Handbook of Generic Development - Oral Soft Gelatin Capsules

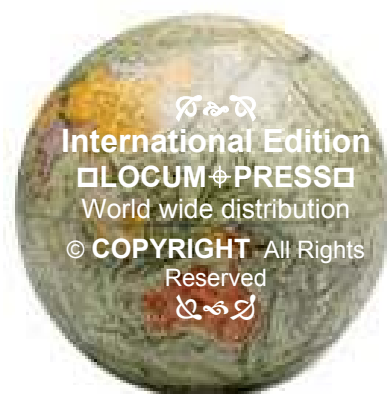
This handbook is the current international edition of the ongoing **24** volume *series* under the cumulative title of Handbook of Pharmaceutical Generic Drug Development. It is a hands-on, technical presentation that portrays the current drug requirement steps necessary at the time of going to print, of the Abbreviated New Drug Application for oral dosage form, namely soft gelatin capsules.

It is written in conjunction with Part Two of the Handbook which models the development requirements of a representative ANDA and as an example of the drug development process required for SGC oral dosage forms. The Handbook is available in electronic format (CD ROM) and e-format (on-line). The Handbook is updated to current regulatory requirements once 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 soft gelatin capsule development routes namely the oil and paste filled formulations. Low active dosage (0.25 mcg) and high potency (500 mg) examples are specially chosen to demonstrate and highlight the formulation steps and process stages absolutely necessary as a prerequisite to developing a stable, elegant and rugged formula.

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

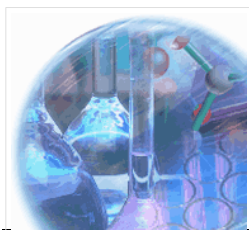
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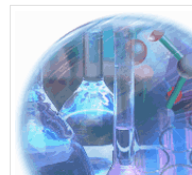
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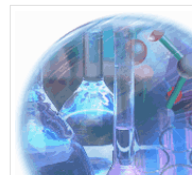
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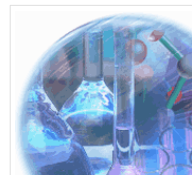
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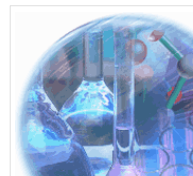
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EDITORIAL PREFACE

Handbook of Generic Development - Oral Capsule Dosage Form

This handbook represents the **new** 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 continue to be added year by year as the global product data base expands. Currently over 150 scientific publications and drug development conferences are annually referenced in the extended **24** volume Handbook *series* of Generic Drug Development.

This mammoth task presents a continual ongoing commitment by the scientific review committee to the improvement of the technical databases and the product specific drug development requirements and know-how technology accessed 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 international edition of the Handbook has been enlarged and updated to meet the latest Guidance for Industry - Organization of an Abbreviated New Drug Application as well as all current approved and key *draft* FDA guideline requirements of the Center of Drug Evaluation and Research (CDER) up to the publishing date.

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