HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT

VOLUME XI Part ONE

Drug Development - Solid Oral Dosage Forms

Handbook of Pharmaceutical Generic Development *Series*

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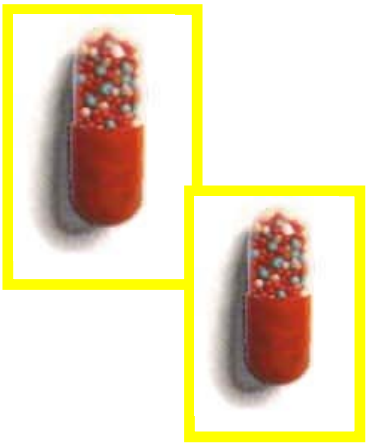

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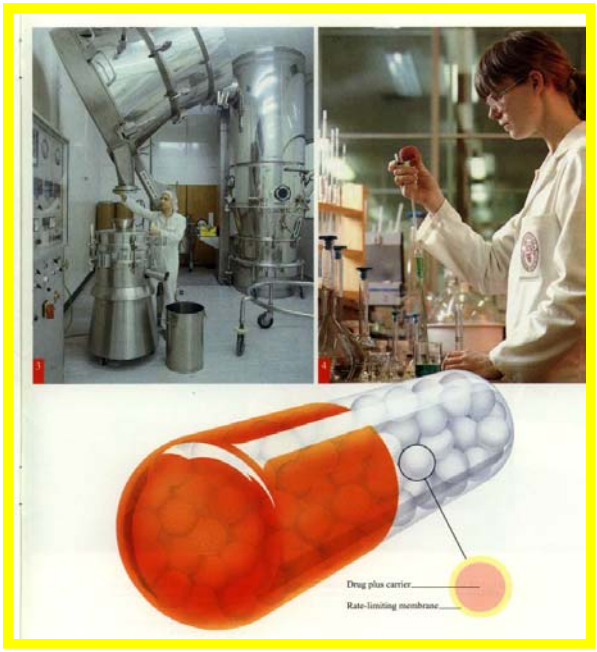

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INTRODUCTION

Handbook of Generic Development - Oral Capsule Dosage Form

This Handbook is the **current** edition of the ongoing 24 volume *series* on the Handbook of Generic Drug Development. It is a hands-on technical presentation that portrays the current drug development requirements at the time of going to print necessary for an Abbreviated New Drug Application for an oral capsule dosage form.

The Handbook is available in PDF electronic format and the **e**-format CD ROM is up-dated annually to association members of IAGIM as required.

The pellet manufacturing method in this application highlights the similarity between the various sphere coating manufacturing processes for pellet encapsulation. Two basic types of dissolution-controlled pulse delivery systems for capsules spheres are common (a) beads/spheres containing the drug with different thickness of dissolving barrier coats (as in this handbook) or (b) pellets of beads/spheres with *alternate* drug and rate controlling barrier layers (i.e. drug / coat / drug / coat / layering etc.). Very soluble active drug materials such as Slow Release Potassium Chloride may be sized and then spray coated with multiple layers of a modern rate controlling barrier coat. The data that changes, for manufacturing procedure is simply the processing, in-process and finished product specifications provided for in Sections 11 and 12 of the **Part Two** of the model Abbreviated New Drug Application.

This 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 *draft* FDA guideline requirements of the Center of Drug Evaluation and Research (CDER) up to current edition date.

Editor-in-Chief.

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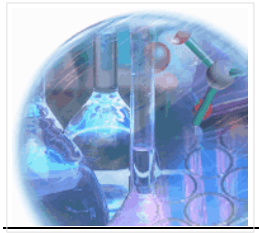

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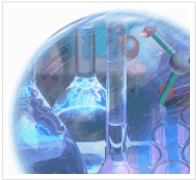

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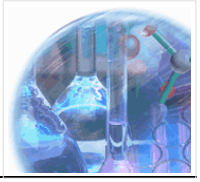

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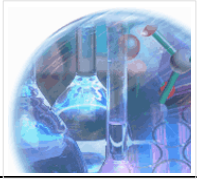

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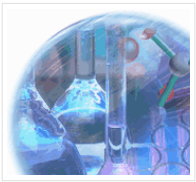

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EDITORIAL PREFACE

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 24 volume series are updated reviewed and expanded annually.

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 **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 updated international edition of the Handbook has been redesigned 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* and final FDA guideline requirements of the Center of Drug Evaluation and Research (CDER).

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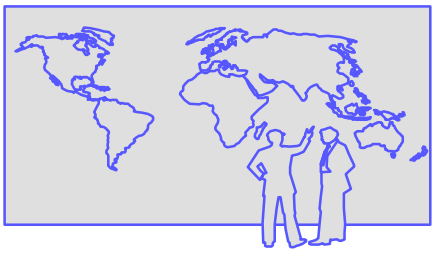

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