

HANDBOOK of
Pharmaceutical
Generic Development



Pharmaceutical Drug Development

VOLUME 10 - Part ONE

DRUG Development - Solid CR Oral Dosage Forms

DRUG DEVELOPMENT

The Complete Handbook Series of Pharmaceutical Drug Development

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Handbook of Pharmaceutical Generic Development

Oral

PART ONE
DRUG DEVELOPMENT

CR

Tablets



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EDITORIAL PREFACE

Handbook of Generic Drug Development - **ORAL CR 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 full reference 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 to be added year by year as the global product data base expands. Currently over 350 scientific publications and tens of 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 (CD ROM) and the **e-format** is up-dated annually to association members of IAGIM – Drug Development Association.

This revised 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 date of publishing

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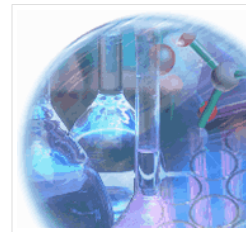
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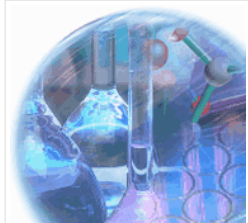
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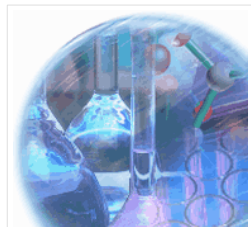
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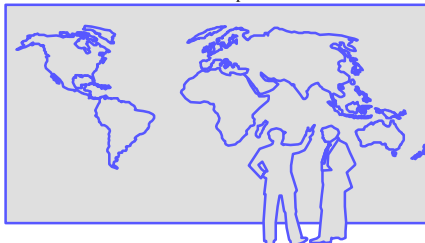
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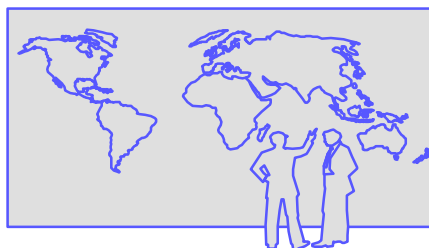
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