

# HANDBOOK OF PHARMACEUTICAL **GENERIC DEVELOPMENT**



## VOLUME **II** - PART **ONE**

Drug Development - Solid Oral Dosage Forms

Handbook of Pharmaceutical  
Generic Development *Series*

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# Handbook of Pharmaceutical Generic Development

**Part One**  
Drug Development

# ORAL CAPSULES

**BLOCK J. D. & BELLE D.**



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# INTRODUCTION

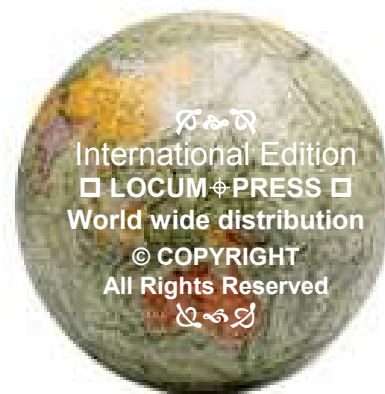
## Handbook of Generic Development - Oral Capsule Dosage Form

**T**his handbook is the new **expanded** international edition of the ongoing **24** Volume under the cumulative title of Handbook of Pharmaceutical 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 presented in two parts and is available in print, PDF electronic format. The **e**-format CD ROM is up-dated annually to association members of IAGIM as required.

**T**he alternative manufacturing methods in this application highlight the similarity of the wet granulation manufacturing process for encapsulation or dry granulation encapsulation (blending, slugging or roller compaction). The data that changes, for alternative processing procedures is simply the manufacturing, in-process and finished product specifications provided for in Sections 11 and 12 of **Part Two** of the Abbreviated New Drug Application. (Also available in EC dossier format with expert report and tabulations.)

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

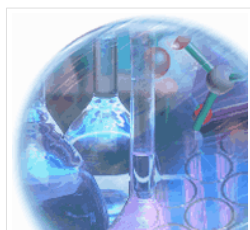
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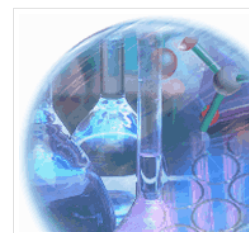
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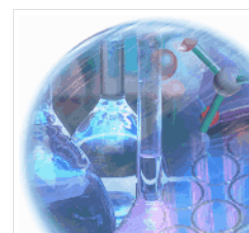
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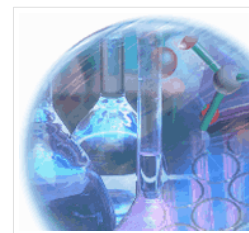
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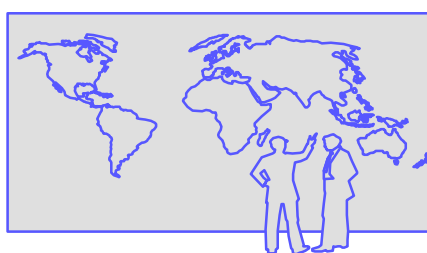
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