

HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT



VOLUME II - Part Two

Drug Development - Solid Oral Dosage Forms

HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT

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Compiled by :

J. D. BLOCK

BSc. MPS. D/PHARM.

Research Director Generic & Innovative Drug Development Division, Locum International Group.
Science Editor - International Journal of Generic Drugs & International Journal of Drug Development
School of Pharmacy University of the Witwatersrand and Witwatersrand Technikon
Johannesburg RSA.

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Part Two
ANDA Development

Oral

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INTRODUCTION

Handbook of Generic Development - Oral Capsule Dosage Form

This Handbook is the **Third** edition (representing the **second** print issue) 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 twice annually to association members of IAGIM as required.

The 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 the **Part Two** of the Abbreviated New Drug Application. (Also available in EC dossier format with expert report and tabulations.)

This **third** international edition of the Handbook has been redesigned and updated to meet the **January 1999** 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 **February 2001**.
Editor-in-Chief.



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