HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT

VOLUME XI - Part One

Drug Development - Solid Oral Dosage Forms

HANDBOOK OF PHARMACEUTICAL
GENERIC DEVELOPMENT

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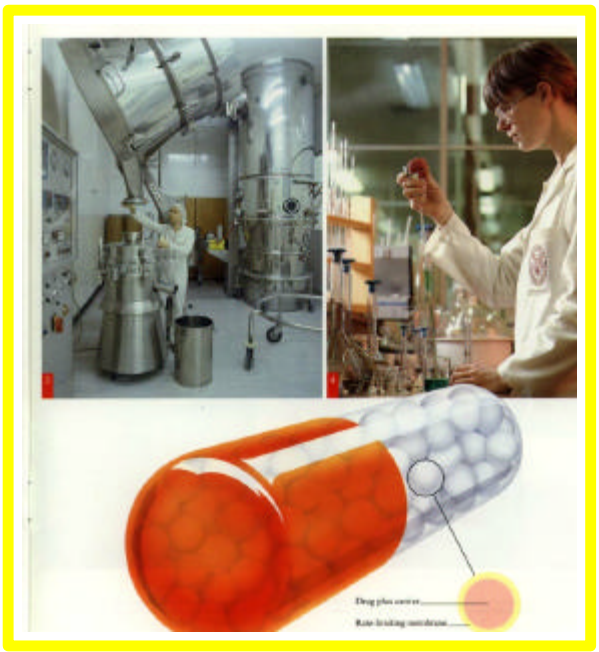

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1995–1997–1999–2001

INTRODUCTION

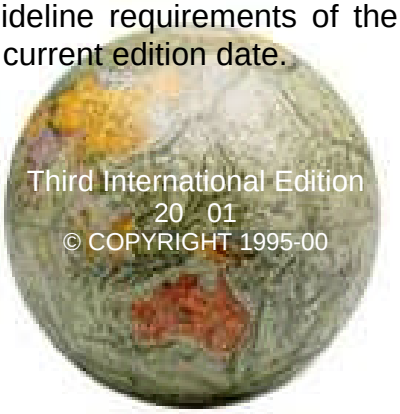
Handbook of Generic Development - Oral Capsule Dosage Form

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 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 application is also available in the EC dossier format with expert report and tabulations.)

This **third** 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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