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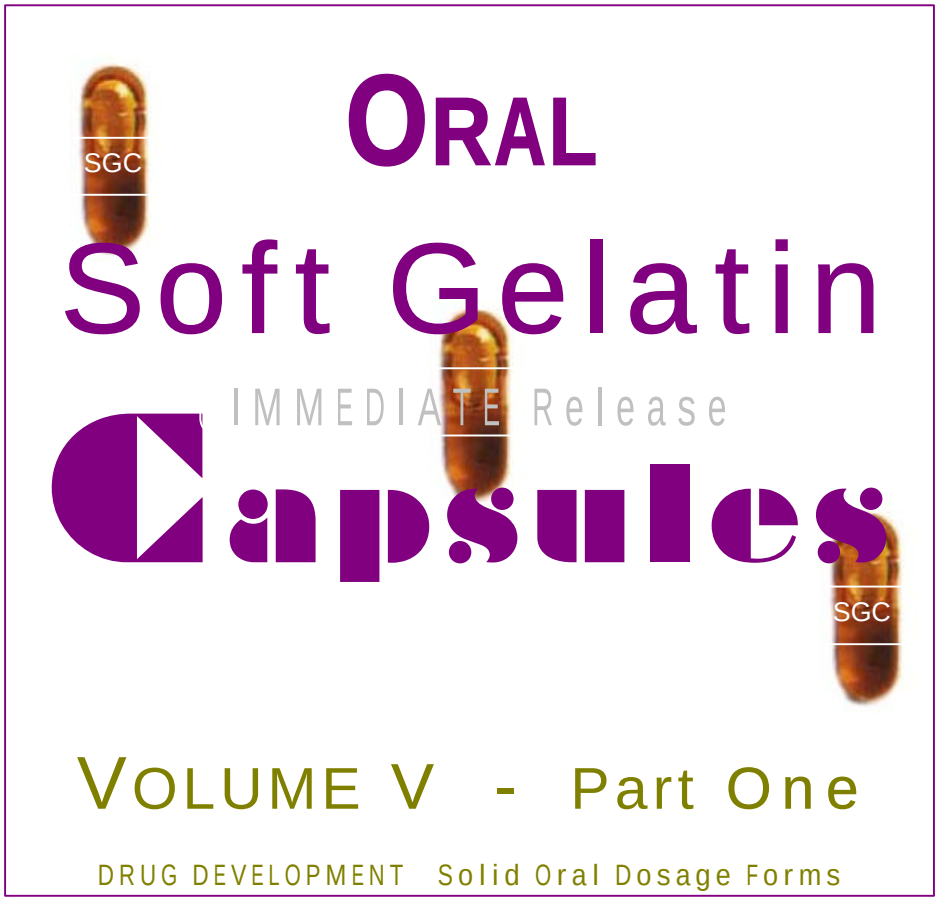

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DRUG DEVELOPMENT Solid Oral Dosage Forms

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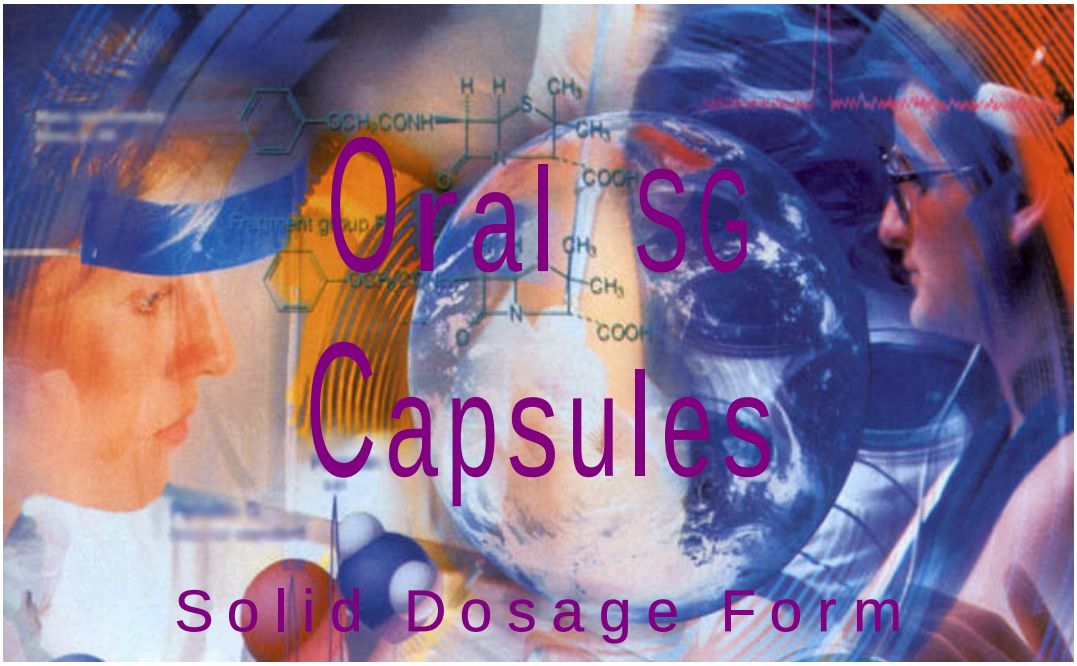

VOLUME V - Part One

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Jeremy **D**. **B**lock
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2000

L O C U M P U B L I S H I N G H O U S E

1995–1996–1997–1998–1999–2000

INTRODUCTION

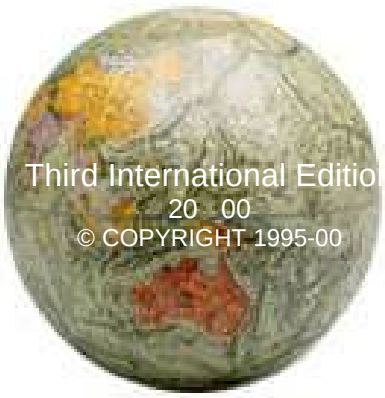
Handbook of Generic Development - Oral Soft Gelatin Capsules

This handbook is the **third** international edition of the ongoing **24** volume *series* under the cumulative title of Handbook of Generic Drug Development. It is a hands-on, technical presentation that portrays the current drug requirement steps necessary at the time of going to print, of the Abbreviated New Drug Application for oral dosage form, namely soft gelatin capsules.
It is written in conjunction with Part Two of the Handbook which models the development requirements of a representative ANDA and as an example of the drug development process required for SGC oral dosage forms. The Handbook is available in electronic format (CD ROM) and e-format (on-line). The Handbook is up-dated to current regulatory requirements once to twice annually. Complete updates are available without charge to Association Members of the Drug Development Association - IAGIM.

This handbook provides a proven pathway to solid oral dosage form development. Modern commercial formulations highlight the common soft gelatin capsule development routes namely the oil and paste filled formulations. Low active dosage (0.25 mcg) and high potency (500 mg) examples are specially chosen to demonstrate and highlight the formulation steps and process stages absolutely necessary as a prerequisite to developing a stable, elegant and rugged formula.

This **third** edition of the Handbook includes additional data on analytical method validation has been redesigned to meet the **January 2000** Guidance for Industry - Organization of an Abbreviated New Drug Application as well as all FDA guideline and requirements of the Center of Drug Evaluation and Research (CDER) up to **current edition date.**

Editor-in-Chief.



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