HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT

ORAL Soft Gelatin Capsules

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VOLUME V - Part ONE

DRUG DEVELOPMENT SOLID ORAL DOSAGE FORMS

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24 Volume Pharmaceutical Generic Development *Series*

HPGD 24 Vol. *SERIES* ORAL SG CAPSULES - PART I

First and Second International Edition - 01/02 (First & Second Print) Published 1995/6/7/8.
Third International Edition - 03 (First & Second Print) - Published 1999/2000.
Fourth International Edition - 04 (First & Second Print) - Jan 2001 Jan 2002 & Jan 2003
Fifth International Edition - 05 (First Int. Printing) : Publishing Date - January 2004
Sixth International Edition - 05 (Second Int. Printing) : Publishing Date - January 2005
Published and distributed in UK, US, EU, Israel, Asia, and Japan in by Locum International Publishing House (Houston, Israel, South Africa) in Hard Cover; Soft and Spiral Cover; Electronic CD ROM; and Online Editions. All print and electronic editions are identical in content and format.
Sixth International Edition - 05 (Second Int. Printing) : Publishing Date - January 2005
Seventh International Edition - 07 (First Int. Printing) : Publishing Date - January 2006
Eight International Edition - 08 (First Int. Printing) : Publishing Date - January 2007
Ninth International Edition - 09 (First Int. Printing) : Publishing Date - January 2008
Tenth International Edition - 10 (First Int. Printing) : Publishing Date - January 2009

ISBN 0793 **8713.** ISBN 0793 **8721** - Electronic Version (Online and CD ROM version)
Handbook Development 24 Volume Series. General Generic ISSN Series number 0793 7407
General Generic ISSN e-Series number 0793 7792 - Electronic Issue (CD ROM and online editions are identical in size and content to the printed hard or soft cover version).

SERIAL NUMBER - DO NO REMOVE! - REGISTERED WITH
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LOCUM INTERNATIONAL PUBLISHERS REGISTRATION SERVICES
WARNING: THIS ISSUE A IS MULTIPLE PAGE UV ENCODED EDITION.

Current Printing (last digit): 10 9 8 7 6 5 4 3.

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ORAL SOFT GELATIN CAPSULES

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Handbook of Pharmaceutical Generic Development *Series*

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Edited: **I A G I M S c i e n t i f i c C o m m i t t e e**

Locum International Research Center - Basel Switzerland

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Oral
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Part ONE
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ACKNOWLEDGMENTS

I.A.G.I.M. (R&D) Foundation.
I.A.G.I.M. Research Council
Contributions - Generic & Research Firms
Associate Universities, Technicons and Consultan
Handbook *Series* Coordinating Committee.
International Journal of Drug Development.
International Journal of Drug Formulation.
Journal of Pharmaceutical Development.
International Journal of Generic Drugs.
International Journal of Drug R&D
I.A.G.I.M. Drug Development Archives
Locum International Archives.
pFDA/OGD/CDER Maryland
Guides and Guidelines
Library of Congress.
AIC Conferences.
Editorial Board.
Pharm. Eur.
USP/NF.
USPC.
BP.

To Doribelle
for her years of support and help
to Sean for his expert knowledge on computerization
to David and Ari for running the project's computers
and lastly to Pat for his inestimable
contribution.

24 Volume *Series*
Handbook of Pharmaceutical Generic Development
International Edition

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INTRODUCTION

Handbook of Generic Development - Oral Soft Gelatin Capsules

This handbook is the current international edition of the ongoing **24** volume *series* under the cumulative title of Handbook of Pharmaceutical 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 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 new edition of the Handbook includes additional data on analytical method validation has been redesigned to meet the latest 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.

ISSN 0793 8656
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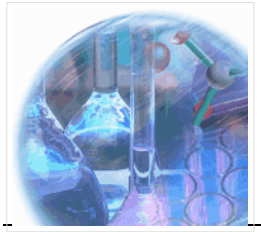

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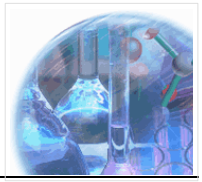

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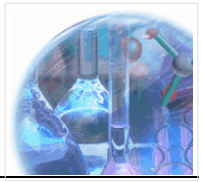

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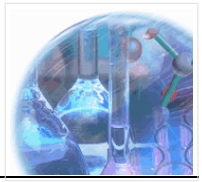

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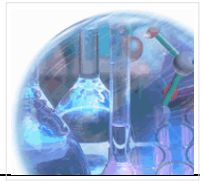

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ISSN 0793 8756
An on-going series
Additional Volumes in Preparation
ISBN 0793 8640 - Electronic Version
Handbook Development 24 Volume *Series*
ISSN Series Number 0793 7792 - Electronic Version

EDITORIAL PREFACE

Handbook of Generic Development - Oral Capsule Dosage Form

This handbook represents the new 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 ongoing 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 continue to be added year by year as the global product data base expands. Currently over 150 scientific publications and drug development conferences are annually referenced in the extended 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 (Online and CD ROM) and the e-format is up-dated annually to association members of IAGIM.

This international edition of the Handbook has been enlarged and updated to meet the latest Guidance for Industry - Organization of an Abbreviated New Drug Application as well as all current approved and key *draft* FDA guideline requirements of the Center of Drug Evaluation and Research (CDER) up to the publishing date.

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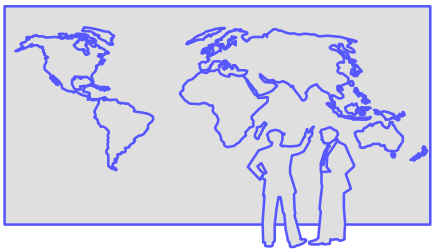

ISSN 0793 8632
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