

HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT

SEMISOLIDS



HANDBOOK OF PHARMACEUTICAL
GENERIC DEVELOPMENT

Handbook of Pharmaceutical
Generic Development 24 Volume Series

Handbook of Pharmaceutical Generic Development Series

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.

Edited:

IAGIM Scientific Committee

Review Process :

Generic & Innovative Drug Development Division
Research Center
Locum International Research

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ISSN Series Number 0793 761X - Electronic Version

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VOLUME III - Part ONE
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Jeremy D. Block
B.Sc. MPS. D/Pharm.

International Euro Edition.

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Locum Publishing House - Israel Locum Pharmaceutical Publishers - USA Locum International Publishers - Cape Town



Handbook of Pharmaceutical Generic Development

Part One

DRUG Development

Semi Solids



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A Locum House Publication

HPDD Innovative Series - Semisolid Dosage Forms

First and Second International Edition - 01/02.

First and Second edition published and distributed in UK, US, EU, RSA, Israel and Japan in November 1996-9: by Locum International Publishing House (Houston, Israel, South Africa).

Third International Edition - 03 (First Print).

Second printing published and distributed in UK, US, EU, Israel, Asia, and Japan in February 2000 by Locum International Publishing House (Houston, Israel, South Africa) in Hard Cover; Soft and Spiral Cover; Electronic Diskette; and e-mail attachment versions. All print and electronic versions identical in content and format.

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ISBN 0793 873X

ISBN 0793 8748 - Electronic Version (Diskette, CD ROM, and Online version)
Handbook Development 24 volume series.

General ISSN Series number **0793 7407**

General ISSN Series number **0793 7792** - Electronic Issue (Diskette, CD ROM and Online version are identical in size and content to the printed hard or soft cover version.)

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LOCUM INTERNATIONAL PUBLISHERS REGISTRATION SERVICES
WARNING: THIS ISSUE IS A MULTIPLE PAGE UV CODED PUBLICATION.

PRINTED IN USA

PRINTED IN ISRAEL

PRINTED IN IRELAND

PRINTED IN REPUBLIC OF SOUTH AFRICA

EDITORIAL PREFACE

Handbook of Generic Drug Development - Semisolid Dosage Forms

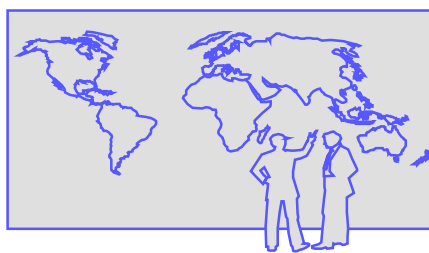
This handbook represents the third International Edition for Europe of the ongoing 24 volume series of Generic Drug Development and appears under the cumulative title of the Handbook series of Generic Drug Development. The ongoing series is updated annually at the end of each year. This is an ongoing 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 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 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 June 2001.

Editor-in-Chief.



ISSN 0793 873X

*An on-going series
Additional Volumes in Preparation*

General Series ISSN 0793 7407
Electronic Series ISSN 0793 7792

0793 7407
International Print Edition
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Acknowledgments

I.A.G.I.M. (R&D) Foundation.
 I.A.G.I.M. Members (1994 - 2000).
 Contributions - Generic & Research Firms
 Associate Universities, Technicians and Consultants.
 Handbook *Series* Coordinating Committee.
 International Journal of Drug Development.
 Journal of Pharmaceutical Development.
 International Journal of Generic Drugs.
 I.A.G.I.M. Drug Development Archives
 Locum International Archives.
 FDA/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.*



**Third International Edition.
 2000**

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1995-1996-1997-1998-1999-2000