HANDBOOK of Pharmaceutical

Generic Development



Pharmaceutical Drug Development

VOLUME 10 - Part One

DRUG Development - Solid CR Oral Dosage Forms

DRUG DEVELOPMENT

The Complete Handbook Series of Pharmaceutical Drug Development

ISBN 0793 **8632** - Electronic Version Handbook Development 24 Volume *Series* ISSN Series Number 0793 761X - Electronic Version

Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development

Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Development) & Part II (Development ANDA or EU Dossier)
Handbook of Pharmaceutical Generic Development Part I (Method Validation) & Part II (Analytical Methods 1994-2003)

Handbook of Pharmaceutical Innovative Development Handbook of Pharmaceutical Innovative Development

Handbook of Pharmaceutical Innovative Development

Handbook of Pharmaceutical Drug Development (Master Formula & Manufacturing Instructions Parts 1 - 5)

Handbook of Pharmaceutical Drug Development (Master Formula & Manufacturing Instructions Parts 6 -10)

Handbook of Pharmaceutical Innovative Development Part I, II & III (Development, Manufacturing & Engineering)

Handbook of Pharmaceutical Drug Development Part I (Development) & Part II (Development ANDA or EU Dossier)

Vol. 1 - Tablets Oral

Vol. 2 - Capsules Oral

Vol. 3 - Semisolids

Vol. 4 - Liquids Oral

Vol. 5 - SG Capsules

Vol. 6 - e-SOPs / SOPs

Vol. 7 - Suspensions

Vol. 8 - Eye & Nose

Vol. 9 - Aerosols MDI

Vol. 10 -Tablets CR/MR

Vol. 11 - Capsules ER

Vol. 12 - Tablets Oral DR

Vol. 13 - Analytical (Top 50 Generic Assay Methods)

Vol. 14 - Tablets Oral

Vol. 15 - Capsules Oral

Vol.16 Suspensions Oral

Vol. 17 - MF and MMI

Vol. 18 - MF and MMI

Vol. 19-SOPs/PAI-Checklist

Vol. 20 - Sterile Injections

Available as Print, Online, CD ROM or electronic mail attachment. Additional Drug Specific Volumes in Preparation. Pentoxifylline ER; Gabapentin ER, Glipizide ER; Felodipine ER; Naproxen DR; Sinemet ER. An on-going electronic and print series. Available either as Hard Bound, Soft Bound or Soft Spiral Cover (for Updating).

For Drug Specific Handbooks refer to the 120+ Drug Development Series titled READY-TO-GO™ DRUG DEVELOPMENT SERIES

http://www.locumusa.com/2go

□ http://www.iagim.org □ □

氲



Handbook of Pharmaceutical Generic Development







Neither this book nor any part may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, microfilming and recording, or by any information storage and retrieval system, without the permission of the publishers.

Copyright © 1995-2001 Locum Publishing House Inc. All Rights Reserved.

A Locum House Publication

HPGD Series CR Tablets Oral - Part I.

First International Edition - 01. First published and distributed in United Kingdom, European Union, RSA, Israel and Japan in January 1995 by Locum International Publishing House (Houston, Israel, South Africa).

Second International Edition - 02.

Published and distributed in United Kingdom, United States, European Union, Israel, Asia and Japan in June 1998 by Locum International Publishing House (Houston, Israel, South Africa).

Third International Edition - 03. Published in March 2001 and distributed in United Kingdom, United States, European Union, Israel, Asia and Japan by Locum International Publishing House (Houston, Israel, South Africa).

Copyright © 1995 -2001 Handbook of Pharmaceutical Generic Development
Text Copyright © 1994 - Handbook of Pharmaceutical Generic Development
Illustration copyright © 1994 - Handbook of Pharmaceutical Generic Development
Locum International Publishing House PO Box 874, 50 Gilad Street Kochav Yair 44864 Israel.
All right reserved.

ISSN Series 0793 8772 - Part One ISSN Series 0793 8780 - Part Two

GENERAL Drug Development Series ISSN 0793 7601

GENERAL Generic Series ISSN 0793 7407

GENERAL Generic e-Series ISSN 0793 7792 - Electronic Disc / CD ROM Version

GENERAL ISSN Drug Development e-Series 0793 761X - Electronic Disc Version

General ISSN Series number 0793 7792 - Electronic Issue (Diskette and e-mail attachment version are identical in size and content to the printed hard or soft cover version.)

Duplication: No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, mechanical, photocopying, microfilming, recording or otherwise, without the prior written permission of the copyright owner or subject to the following conditions:

Authorization to photocopy items for internal or personal use or internal or personal use of specific company personnel, is granted by Locum International Publishing House, provided that the base fee of \$2 per page is paid directly to the Copyright Clearance Center (CCC) 222 Rosewood Drive, Danvers, MA 01923 USA.

For organizations that have been granted a photocopy license by CCC, a separate system of payment has been arranged.

For additional information, contact the Publications Department Locum International Publishing House; PO Box 874, 50 Gilad Street, Kochav Yair, 44864 Israel.



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

SERIAL NUMBER - DO NO REMOVE! - REGISTERED WITH

LOCUM INTERNATIONAL PUBLISHERS REGISTRATION SERVICES
WARNING: THIS ISSUE A IS MULTIPLE PAGE UV ENCODED EDITION.

UK Fax: +(44) 207-900 2096
US Fax: +(1) 435-408 1665
Fax: +972-97-494 532
E-mail: info@locum.co.il
http://www.locum.co.il
http://www.locumeuro.com
http://www.locumusa.com
handbooks@locumusa.com
sales@locumusa.com

PRINTED IN USA
PRINTED IN ISRAEL
PRINTED IN IRELAND
PRINTED IN REPUBLIC OF SOUTH AFRICA

Acknowledgments

I.A.G.I.M. (R&D) Foundation.
I.A.G.I.M. Members (1994 - 2001).
Contributions - Generic & Research Firms
Associate Universities, Technicons 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
o Sean for his expert knowledge on computerizati
o David and Ari for running the project's compule
and lastly to Pat for his inestimable
contribution.

Third International Edition. **2001**



 LOCUM
 PUBLISHING
 HOUSE

 は申数
 株

 は1995-1996-1997-1998-1999-2001 まます。

 は申数