HANDBOOK of Pharmaceutical Generic Development

Controlled Release Oral Tablets

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
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.

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

HANDBOOK OF GENERIC DRUG DEVELOPMENT
DRUG DEVELOPMENT
Oral

Part ONE

DRUG DEVELOPMENT

Handbook of Pharmaceutical
Generic Development

Tablets

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.


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

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.
Acknowledgments

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.

2001

LOCUM PUBLISHING HOUSE