ISSN 0793 7601 - ISSN 0793 761X
Series Publication in association with:-

The International Association of Generic Drug Manufacturers

Handbook of Pharmaceutical Generic Development

Oral IR Tablets

Part ONE
DRUG DEVELOPMENT KNOW-HOW
&
Part TWO
ANDA DEVELOPMENT & FORMULATIONS

NEW Edition
Year 2001

Handbook Volume in Part I & II
Drug Development

Locum *Publishing* House

Handbook of Pharmaceutical Generic Development a comprehensive and authoritative practical hands-on state-of-the-art handbook covering Generic know-how essential for developing the **21** ANDA Sections of an Immediate Release **Oral Tablet.**

Part One covers Pharmaceutical Drug Development and **Part Two** (ANDA Development) providing know-how for Development, Excipient and specification choice, Formulation, Dissolution, Stability, Scale-up, Process Qualification (Hardness Dissolution & U of C); Pivotal and final **validation** batches; Analytical, Cleaning and Process Validation; Incorporates essential development checklists, flowcharts, tabulations and key SOPs and critical documentation and OGD regulatory know-how for a successful review for a FDA approval, saving queue-time and money.

Essential development and submission know-how on **I**mmediate **R**elease **Oral Tablets** for professional developers to understand the nuts-and-bolts on Generic ANDA DEVELOPMENT with high-tech detailed ANDA Development (new formula & guidelines) for rapid flawless approval of ANDA submissions (Print or CD ROM).

Some Additional Titles:-
Bupropion, Buspirone, Diclofenac, Famotidine, Felodipine, Nabumetone, Naproxin, Piroxicam, Tamoxifen US/EU, Ticlopidine, Trazodone etc.

E-mail: handbooks@locumusa.com
Fax Int.: + 972-97-494-532 Fax US: +(1)-435-408-1665
Fax UK: +(44)-207-900-2096

ORAL DOSAGE FORMS

Table of Content - Summary

PART I - PHARMACEUTICAL DEVELOPMENT

Typical - Oral Tablet or Capsule

ISSN 0793 694X US/Canada **ISSN 0793 7784 Euro** **ISSN 0793 7822 Pacific Rim**

Handbook of
Pharmaceutical Generic Development

Controlled Release

Extended Solid Oral Dosage Forms

Tablets

Part ONE
Complete Drug Development Know-how
&
Part TWO
ANDA Formula & Development Technology

READY-TO-**GO**™ *SERIES*
Felodipine ER, Glipizide ER,
Sinemet ER, Naproxen DR,
Carbamazepine ER, Pentoxiphyllin ER

Extended & Modified
Release Dosage Forms

This Handbook of Pharmaceutical Generic Development is a fully comprehensive practical hands-on workbook covering modern drug development and the full **21** ANDA section interactions of a **Extended** or **Modified** **C**ontrolled **R**elease Oral Tablets or Caplets.

Part One (drug development) and **Part Two** (ANDA Development Know-how) provide Development, Master Drug Formulations, Key Processes, **Scale-up;** Process Optimization & Qualification; Stability; Pivotal and final Process Validation Know-how and Protocols; PAI, Analytical, Cleaning and Process **Validation** Do's & Don'ts. A reference for critical documentation and OGD regulatory know-how that is essential for a successful first time FDA review and approval, saving months of queue-time and market place sales.

Each and every regulatory guideline is covered in clear detail providing a development protocol for a totally omission-free file submission.

Over five years in preparation and claimed as the world's most authoritative and definitive work available on oral dosage form drug development from a generic industry viewpoint.

An Essential Reference for Development Pharmacists, R&D Chemists, QA/QC and Regulatory personnel. Allows management to understand the nuts and bolts on Generic ANDA DEVELOPMENT and filing and how to get to the market place - quickly and *on time*.

Locum *Publishing* House PO Box 16075 Arlington VA 22215 -1075 USA

http://www.locumusa.com **International Journal of Generic Drugs** e-✉ info@locumusa.com
ISSN 0793 694X US/Canada **ISSN 0793 7784 Euro** **ISSN 0793 7822 Pacific Rim**

ISSN 0793 7601 - ISSN 0793 761X
24 Volume *Series* Publication
in association with:-

The International Association of Generic Drug Manufacturers

Handbook of Pharmaceutical Generic Development

Oral DR Tablets

Part ONE
DRUG DEVELOPMENT KNOW-HOW
&
Part TWO
ANDA DEVELOPMENT & FORMULATIONS

NEW 2001 Edition

This Handbook of Pharmaceutical Generic Development is a practical hands-on workbook covering state-of-the-art development for the full **22** ANDA development sections required for a **Oral DR Tablet** (Spay Granulation Enteric Coated Delayed Release). About 450 pages.

Part One covers pharmaceutical drug development and **Part Two** (ANDA Development) provide technical know-how for the Development, Formulation, Dissolution, Stability, Scale-up, Process Qualification; pivotal and final **validation** batches; analytical, cleaning and process validation; essential documentation and OGD regulatory know-how that is essential for a successful first time FDA review and approval, saving months of queue-time and market place sales.

Essential development and submission know-how on Delayed Release **Oral Tablets** for advanced professional developers to understand the nuts-and-bolts on Delayed Release DEVELOPMENT side-by-side with detailed and practical ANDA development technology for rapid approval of ANDA files (Print or CD ROM).

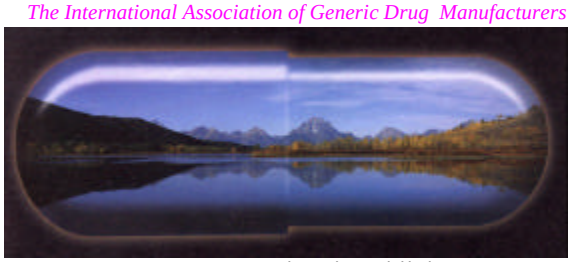
ANDA DEVELOPMENT

Locum *International*
Locum *Publishing* House

Title:- Handbook of Generic Drug Development
Delayed Release Tablets ISSN 0793-7601 / 0793-761X.

E-mail:- **handbooks@locumusa.com**
Fax Int.: + 972-97-494-532 Fax US: +(1)-435-408-1665
Fax UK: +(44)-207-900-2096
handbooks@locumEuro.com

A *Series* Publication in association with
The International Association of Generic Drug Manufacturers



Locum *International* Publishers
ISSN 0793 8659 - ISSN 0793 8667

Handbook of Pharmaceutical Generic Development

Oral IR Capsules

NEW 2001 Edition

SINGLE ORAL DOSAGE FORM

Part ONE
DRUG DEVELOPMENT
&
Part TWO
Regulatory ANDA Development
[with master formula & commercial processes]

The Handbook of Pharmaceutical Generic Development is an essential workbook covering the full development, CMC and RA sections for a single dose **IR Capsule ANDA** development project.

Part One (Drug Development ±500 pages) and **Part Two** (ANDA Development with detailed commercial and state-of-the-art formula ±450 pages) provides essential **IR** capsule technology know-how on all aspects of; Development, Formulation, Scale-up, Process Optimization & Qualification; Pivotal and large scale Validation batches; analytical, cleaning and process validation; detailing crucial documentation and OGD regulatory know-how that is essential for a successful review for FDA approval, saving queue-time and money. Full Review of every CMC/Bio FDA guideline issued.

Essential developmental know-how on **Oral IR Capsules** for professional developers to understand the nuts-and-bolts on Generic ANDA DEVELOPMENT with ***high-tech*** practical ANDA development know-how to produce utterly flawless files. (Print & CD ROM). Technological Level - Advanced.

ADDITIONAL TITLES - in PART II
Amoxicillin 250 / 500mg;Azithromycin 250/600mg Cefaclor 250/500mg
Clomipramine 25/50/75mg
Etodolac 200/300 mg; Fluoxetine 10/20mg
Gabapentin 100/200/300mg
Piroxicam 10/20mg; Tolmetin 600 mg.

Locum *International*
Locum *Publishing* House
Fax + 972-97-494 532

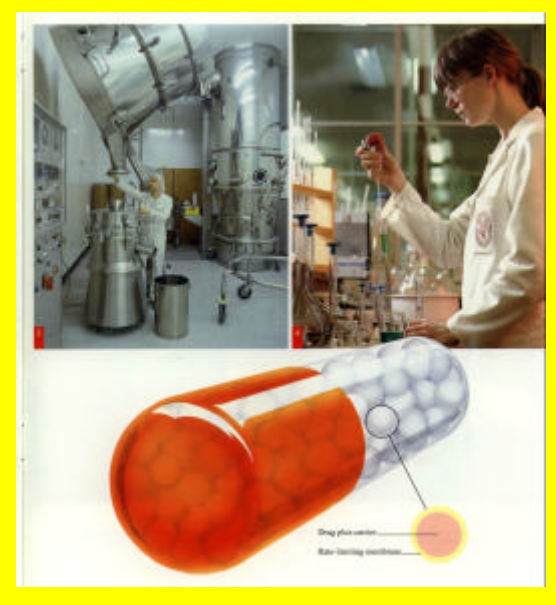
e-mail:- handbooks@locum**usa**.com

For Complete Table of Contents
(Go to Web Site - www.iagim.org)

Locum *International* Publishers
ISSN 0793 7407 - ISSN 0793 8756 - ISSN 0793 8764
A *Series* Publication in association with
The International Association of Generic Drug Manufacturers.

NEW Advanced 2000-Edition

Part ONE
DRUG DEVELOPMENT
&
Part TWO
Regulatory ANDA Development



Each Volume Includes:
Development Handbook
ANDA Development
[with master formula & commercial processes]

ADVANCED ER & SR [MR]
Formula & Manufacturing Details for Coated Sugar Spherical (bead) Technology Coated Pellets and Coating Highly Soluble Crystals (SR KCL 1200 mg, 20-40 mesh)

Coating materials include Ethocel 100 HPMC; Methocel; Dibutyl Sebacate; DEP etc,

Locum *International*
Locum *Publishing* House

Handbook of Pharmaceutical Generic Development

Oral ER CAPSULES

The Handbook of Pharmaceutical Generic Development is an essential workbook covering the Full Development, CMC and QA/RA sections for a **ER & SR [MR] CAPSULE** development program.

Part One (**ER** Development ±450 pages) and **Part Two** (ANDA Development with detailed commercial and state-of-the-art **MR** formulae and manufacturing processes ±350 pages) provides essential ER Capsule Technology know-how on all aspects of; Development, Formulation, Scale-up, Process Optimization & Qualification; Pivotal and Large Scale Validation batches using both pan and Wurster Spray Granulators (GPCG 60/120); ER analytical methodology; Dissolution, cleaning and process validation; essential documentation and OGD Regulatory / R&D know-how, essential for a successful review & FDA approval, saving queue-time and money.

Essential development know-how on **Oral ER/SR Capsule** for advanced developers to understand the nuts-and-bolts on Generic MODIFIED RELEASE DEVELOPMENT with a ***high-tech*** detailed ANDA development to produce flawless files. (Print & CD ROM). Presented at an Advanced Technological Level.

E-mail: handbooks@locumusa.com

See Web Book shop or Fax+972-97-494 532

handbooks@locumUSA.com

Locum *International* Publishers
ISSN 0793 8713 - ISSN 0793 8721
A *Series* Publication in association with
The International Association of Generic Drug Manufacturers.

NEW Edition 2001

Handbook of Pharmaceutical Generic Development

ISBN 965 492 004-2

Part ONE
DRUG Development Know-how
&
Part TWO
ANDA Development Technology

Oral Suspensions

The Handbook of Pharmaceutical Generic Development is an essential workbook covering the full CMC & Bio and RA sections of normal **Oral Suspension** ANDA / AADA and a **Suspension for Reconstitution.**

Part One (Development ISBN 965 492 004-2) and **Part Two** (ANDA Development - ISBN 965492005-0 with detailed commercial and state-of-the-art formula) provides essential know-how technology on all aspects of; Development, Formulation, Scale-up, Process Optimization & Qualification; Pivotal and large scale Validation batches; analytical, cleaning and process validation; essential documentation and OGD regulatory know-how that is essential for a successful review for a FDA approval, saving queue-time and money.

Essential development know-how on **Oral Suspensions and Suspensions for Reconstitution** professional developers to understand the nuts-and-bolts on Generic MODIFIED RELEASE DEVELOPMENT with a ***high-tech*** detailed ANDA development to produce flawless files. (Print & CD ROM). Presented at an Advanced Technological Level.

*See Web Secure Book Shop or Fax+972-9**7**-494 532*

Drug Development

ANDA Development

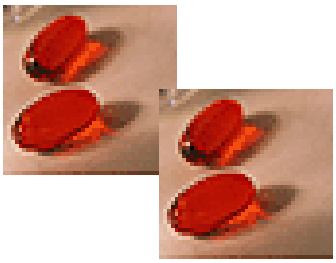
Cephalosporins
Synthetic Penicillins
Azithromycin
SMX-TMP
(Cotrimoxazole)

handbooks@locumUSA.com

Locum *International Press*
Locum *Publishing* House

A Locum House Publication

A *Series* Publication in association with
The International Association of Generic Drug Manufacturers



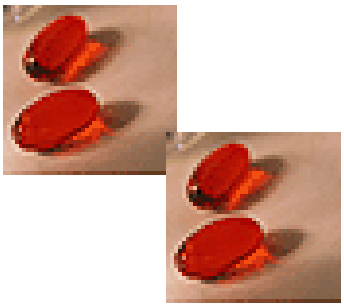
Locum *International* Publishers
ISSN 0793 8659 - ISSN 0793 8667

Handbook of Pharmaceutical Generic Development

Soft Gelatin Capsules

NEW 2001 Edition

Part ONE
DRUG DEVELOPMENT
&
Part TWO
Regulatory ANDA Development
[with master formula & commercial processes]



Locum *Publishing* House
Fax US +435-808-1891
Global Fax +972-97-494 532
Fax UK +44-207-900-2096

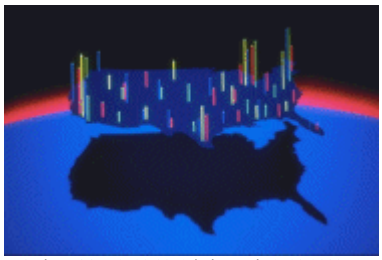
***T**he Handbook of Pharmaceutical Generic Development* is an essential workbook covering the full development, CMC and RA sections for a single dose **SG Capsule ANDA** development project.

Part One (Drug Development ±500 pages) and **Part Two** (ANDA Development with detailed commercial and state-of-the-art formula ±450 pages) provides essential **SG** capsule technology know-how on all aspects of; Development, Formulation, Scale-up, Process Optimization & Qualification; Pivotal and large scale Validation batches; analytical, cleaning and process validation; detailing crucial documentation and OGD regulatory know-how that is essential for a successful review for FDA approval, saving queue-time and money. Full Review of every CMC/Bio FDA guideline issued.

Essential developmental know-how on **Oral SG Capsules** for professional developers to understand the nuts-and-bolts on Generic ANDA DEVELOPMENT with ***high-tech*** practical ANDA development know-how to produce utterly flawless files. (Print & CD ROM). Technological Level - Advanced.

e-mail:- handbooks@locum**usa**.com

For Complete Table of Contents
(Go to Web Site - www.iagim.org)



Series ISSN 0793 8810 / Electronic 0793 8828
A *Series* Publication in association with
The International Association of Generic & Innovative Drug Manufacturers.

☑ **Pharmaceutical**

☑ **IQOQ & Analytical**

☑ **Decision Trees**

☑ **Bioequivalency**

☑ **Microbiological**

☑ **Quality Control**

☑ **Scale-Up**

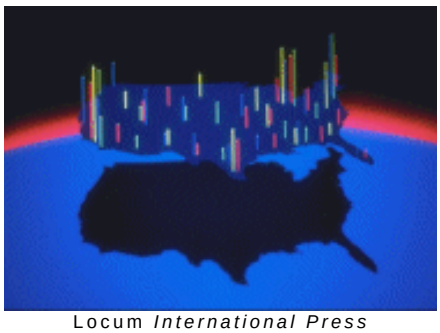
☑ **Cleaning Protocols**

☑ **All Validations**

☑ **Regulatory**

☑ **Pre Approvals-PAIs**

☑ **Annual Reports**



Locum *International Press*
Locum *Publishing* House

handbooks@locum**euro**.com

Essential Pharmaceutical Generic Drug Development

e-SOPs

Electronic Standard Operating Procedures.

Available as Electronic SOPs on CD ROM *for immediate in-house use.* Guidelines provided on how to convert development SOPs into your own customized research-based-development system that meet all international regulatory guides, guidelines and regulatory requirements. e-SOPs can be edited to meet your development units own in-house needs. Designed for Generic and NDA Drug Development use.

Electronic SOPs provide a complete electronic Drug Development System, including Decision Trees, Formulation, Scale-up, Process Optimization & Qualification; pivotal and final large scale validation batches; IQOQ, Analytical, Cleaning and Process Validation. Essential technical documentation and OGD regulatory know-how that is essential for a successful product development and a speedy FDA approval, saving queue-time and development dollars.

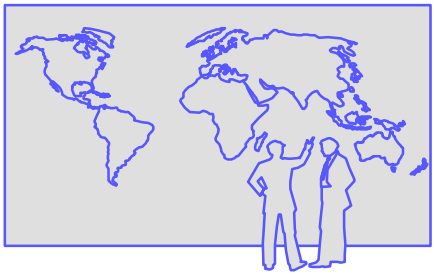
Essential information for Development Pharmacists, R&D Chemists, QA and Regulatory personnel. Allows management to understand the nuts and bolts on Generic ANDA and EC DEVELOPMENT and filing in the most cost effective way.

CD ROM or PRINT available at: **$289**

In association with the
International Association of Generic Drug Manufacturers

A Locum House Publication

handbooks@locumusa.com



Handbook of Pharmaceutical Generic Development

ISSN 0793 7601 - ISSN 0793 761X

Inhalation Aerosols

Handbook Volume Consists of:
Complete Drug Development
Complete ANDA Development

Part ONE
DRUG Development Know-how
&
Part TWO
ANDA Development Technology

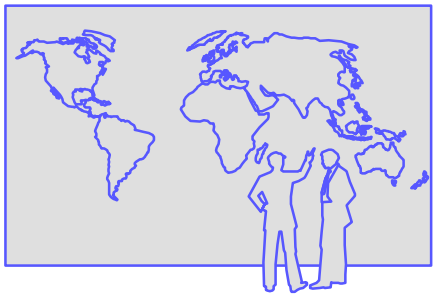
The *Handbook of Pharmaceutical Generic Development* is a practical hand-on workbook covering the full **22** ANDA sections of ORAL & NASAL **Inhalation Aerosol (MDI** Aerosol solutions and suspensions).

Part One (Full Development ISBN 0793 7601) **and Part Two** (Detailed ANDA Development covering all 22 Sections - ISSN 0793-761X) provide Development, Formulation, Scale-up Process Qualification; pivotal and final validation batches; analytical, cleaning and process validation; essential documentation and OGD regulatory know-how that is essential for a successful review for a FDA approval, saving queue-time and money.

Essential development know-how on **Oral & Nasal Inhalation Aerosols for** professional developers to understand the nuts-and-bolts on Generic Dosage Form DEVELOPMENT with ***high-tech*** detailed ANDA development know-how to produce flawless files. (Print & CD ROM). Presented at an Advanced Technological Level.)

E-mail:- **handbooks@locumusa.com**

A Locum House Publication



Locum *Internationa*
Publishing House