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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 International
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 Immediate Release **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, Busprone, Diclofenac, Famotidine, Felodipine, Nabumetone, Naproxin, Piroxicam, Tamoxifen US/EU, Ticlopidine, Trazodone etc.

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ORAL DOSAGE FORMS

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Stability Testing of Drug Substance and Drug Product II

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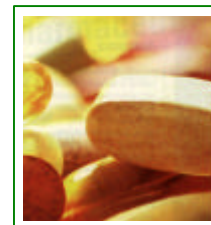
Development SOPs ; Stability SOP Network

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Handbook of Pharmaceutical Generic Development

Controlled Release

Extended Solid Oral Dosage Forms

Part ONE

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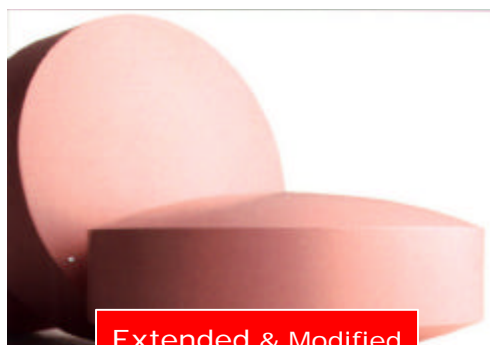
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Part TWO

ANDA Formula & Development Technology

READY-TO-GO™ SERIES

Felodipine ER, Glipizide ER,
Sinemet ER, Naproxen DR,
Carbamazepine ER, Pentoxifyllin ER



Extended & Modified
Release Dosage Forms

Tablets

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 Controlled Release** 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.

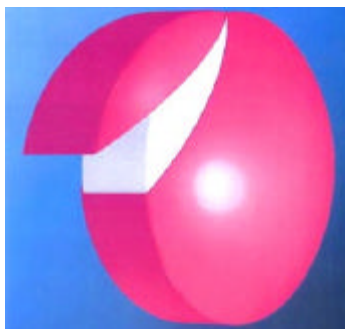
Each and every regulatory guideline is covered in clear detail providing a development protocol for a totally omission-free file submission.

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*.

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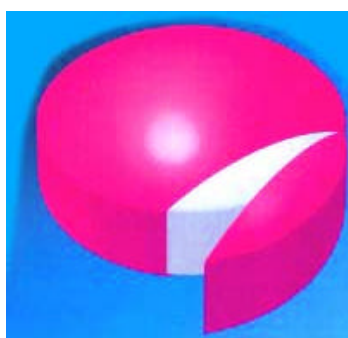


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Part ONE
DRUG DEVELOPMENT KNOW-HOW
&

Part TWO
ANDA DEVELOPMENT & FORMULATIONS

NEW 2001
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ANDA DEVELOPMENT

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Handbook of Pharmaceutical Generic Development Oral DR Tablets

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).

Title:- Handbook of Generic Drug Development
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Part ONE
DRUG DEVELOPMENT

&

Part TWO
Regulatory ANDA Development

[with master formula & commercial processes]

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.



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Handbook of Pharmaceutical Generic Development

Oral IR Capsules

SINGLE ORAL DOSAGE FORM

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.

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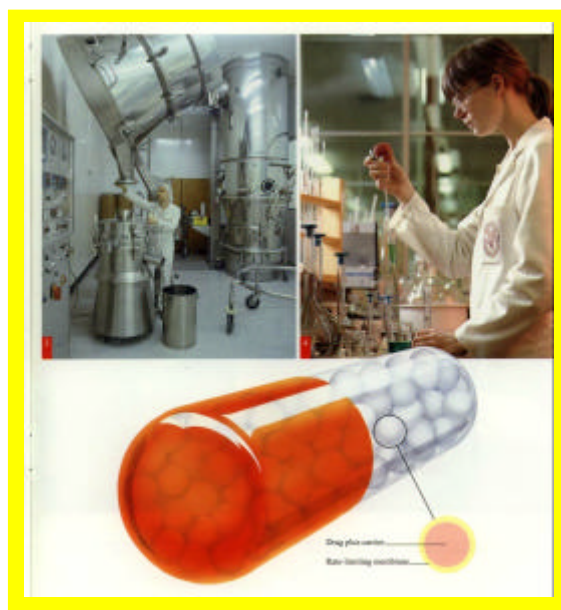
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Part ONE
DRUG DEVELOPMENT

&

Part TWO
Regulatory ANDA Development



Each Volume Includes:

**Development Handbook
ANDA Development**

[with master formula & commercial processes]

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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,

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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.

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Part ONE
DRUG Development Know-how
&

Part TWO
ANDA Development Technology

Drug Development



ANDA Development

Cephalosporins
Synthetic Penicillins
Azithromycin
SMX-TMP
(Cotrimoxazole)

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Handbook of Pharmaceutical Generic Development

ISBN 965 492 004-2

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.

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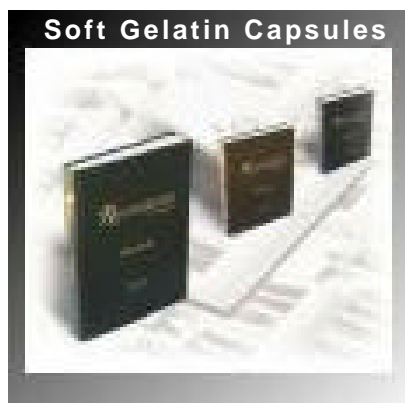
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DRUG DEVELOPMENT

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Handbook of Pharmaceutical Generic Development

Soft Gelatin Capsules

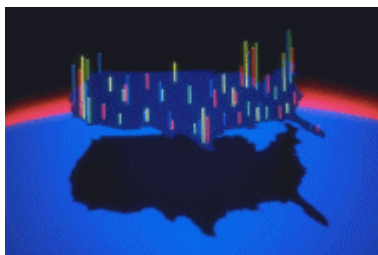
The Handbook of Pharmaceutical Generic Development is an essential workbook covering the full development, CMC and RA sections for a single dose **SG Capsule ANDA** development project.

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.

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Essential Pharmaceutical Generic Drug Development



Pharmaceutical

IQOQ & Analytical

Decision Trees

Bioequivalency

Microbiological

Quality Control

Scale-Up

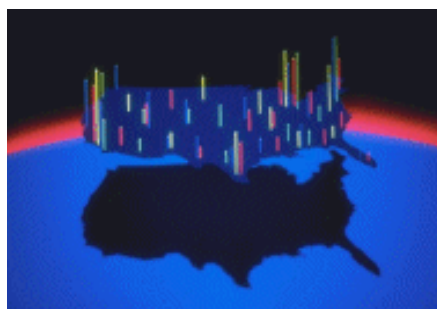
Cleaning Protocols

All Validations

Regulatory

Pre Approvals PAIs

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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.

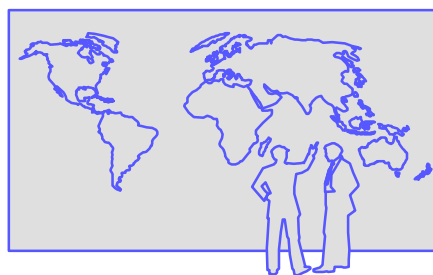
Essential information for Development Pharmacists, R&D Chemists, QA and Regulatory personnel. Allows management to understand the nuts and bolts on Generic ANDA and EC DEVELOPMENT and filing in the most cost effective way.

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

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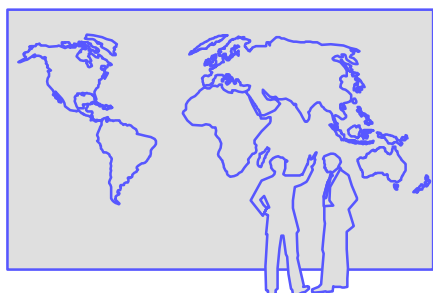
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Handbook Volume Consists of:
Complete Drug Development
Complete ANDA Development

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



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Inhalation Aerosols

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.)

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