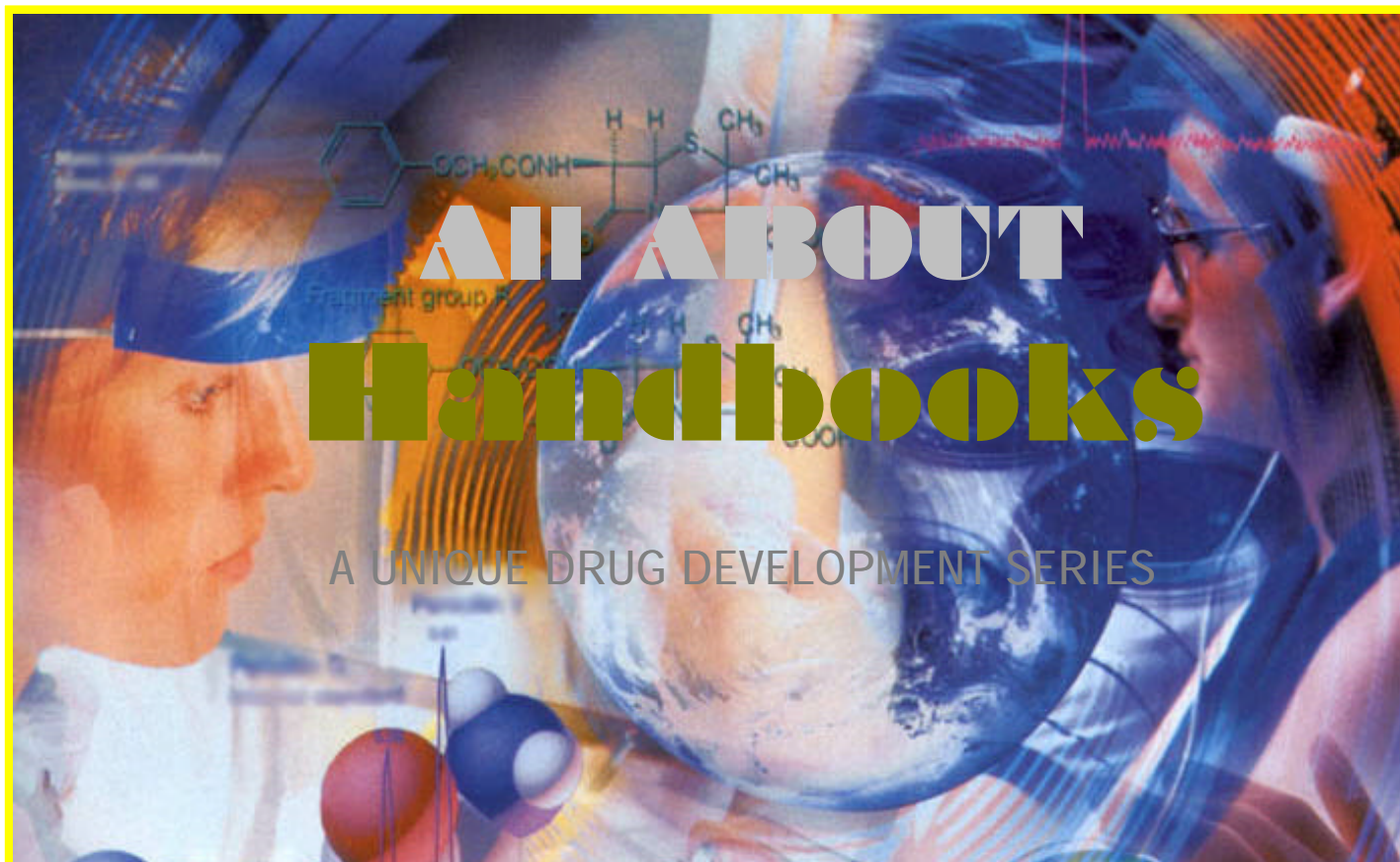


DRUG DEVELOPMENT

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Drug Development & Manufacture for Pharmaceutical Technology Professions



FOR THE

DEVELOPMENTAL KNOW HOW  
OF THE WORLDS TOP

GENERIC DRUGS

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



The International Association of  
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# Handbook of Pharmaceutical Generic Development

# Oral IR Tablets

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

NEW Edition  
Year 2000



Handbook Volume in Part I & II  
Drug Development



*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).

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## ORAL DOSAGE FORMS

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# Handbook of Pharmaceutical Generic Development

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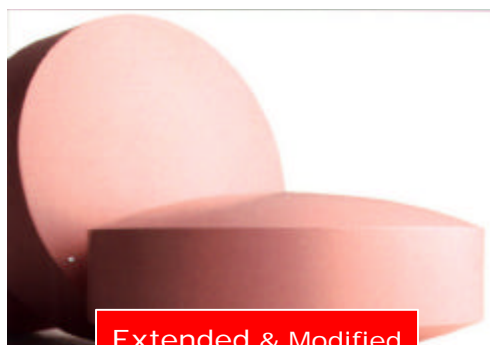
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### Part TWO

ANDA Formula & Development Technology

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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.

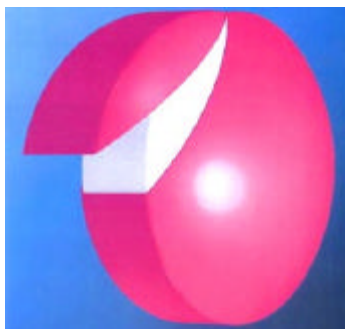
Over five years in preparation and claimed as the world's most authoritative and definitive work available on oral dosage form drug development from a generic industry viewpoint.

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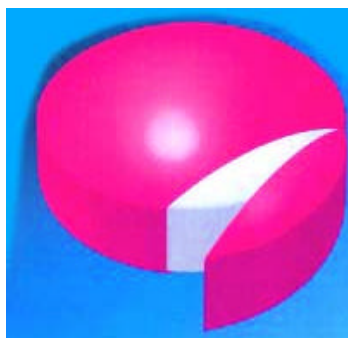
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DRUG DEVELOPMENT KNOW-HOW

&

**Part TWO**  
ANDA DEVELOPMENT & FORMULATIONS

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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.

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**Title:-** Handbook of Generic Drug Development  
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## The Development Handbook NABUMETONE



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**Part Two** covers the full ANDA development steps with substantial explanation notes and dovetails side-by-side with part one.

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Volumes consists of Part One & Two  
Who this book is for:

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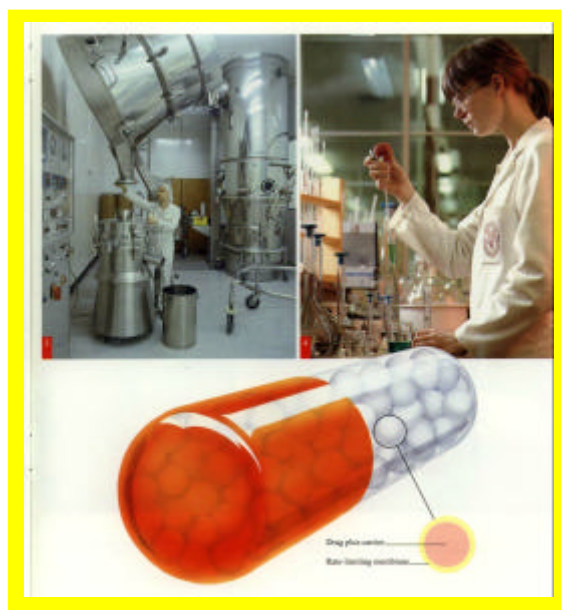
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# Handbook of Pharmaceutical Generic Development

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**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.

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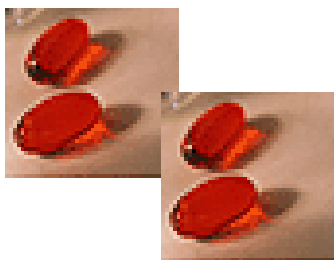
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Part ONE  
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&

Part TWO  
ANDA Development Technology

Drug Development



ANDA Development

Cephalosporins  
Synthetic Penicillins  
Azithromycin  
SMX-TMP  
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# Handbook of Pharmaceutical Generic Development

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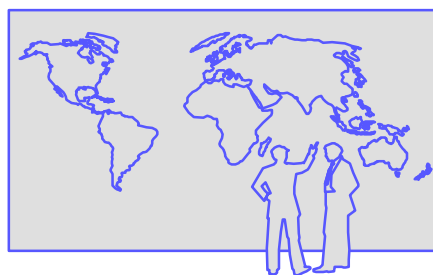
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# Handbook of Pharmaceutical Generic Development

ISSN 0793 7601 - ISSN 0793 761X



## Inhalation Aerosols

Handbook Volume Consists of:  
Complete Drug Development  
Complete ANDA Development

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).

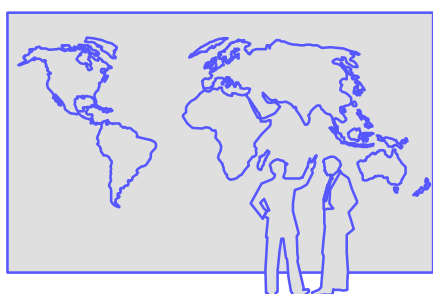
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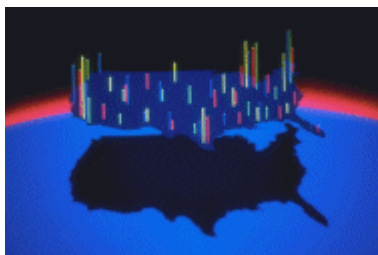
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**Decision Trees**

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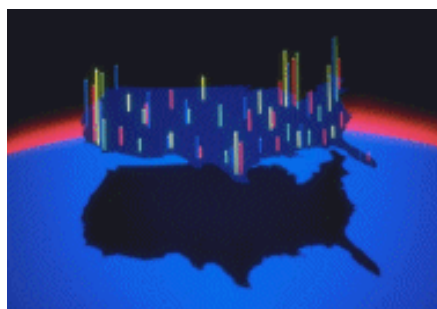
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