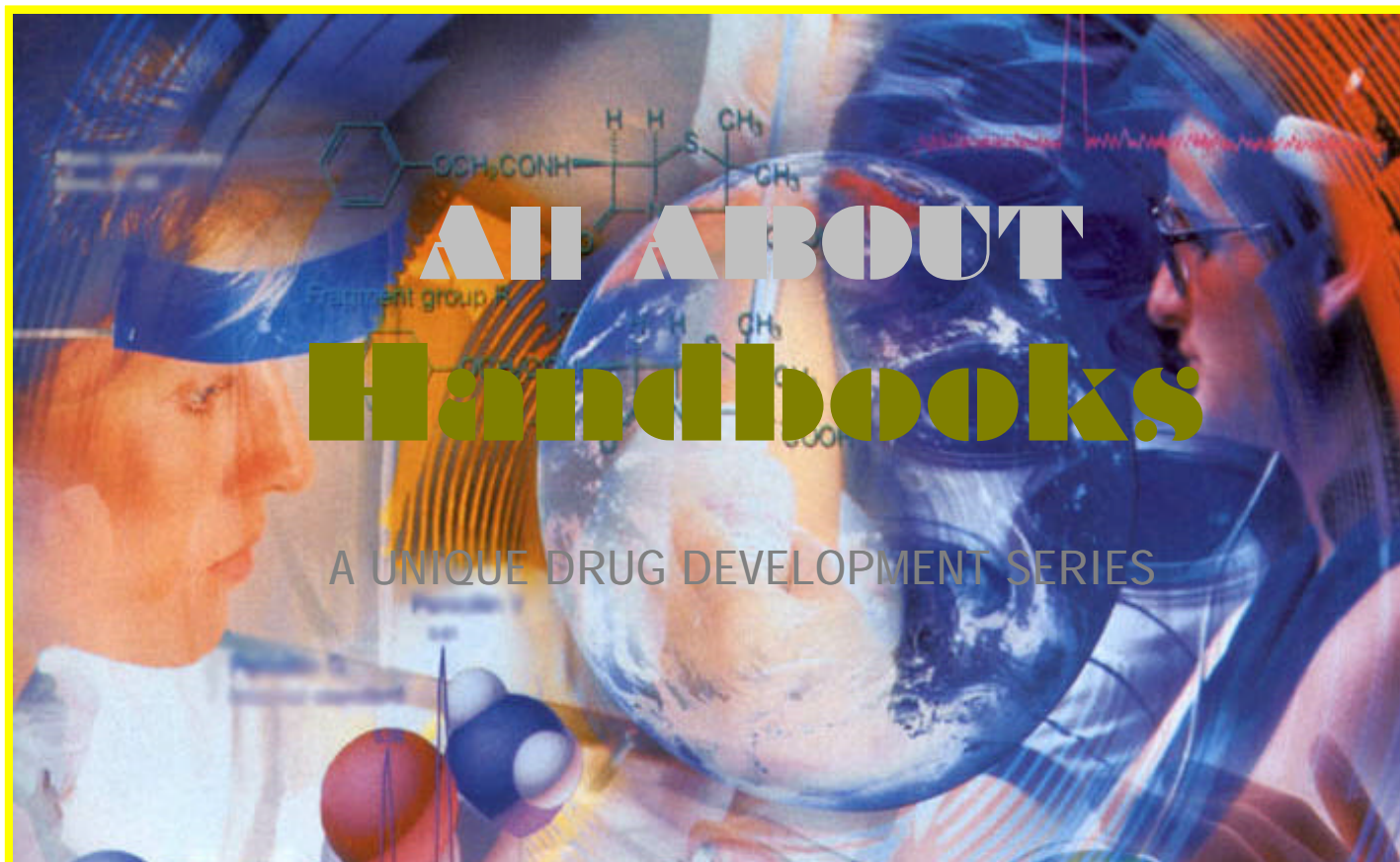


DRUG DEVELOPMENT

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GENERIC DRUGS

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 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.

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## ORAL DOSAGE FORMS

### Table of Content - Summary

#### PART I - PHARMACEUTICAL DEVELOPMENT

#### Typical - Oral Tablet or Capsule

##### Acronyms - Abbreviations

Introduction, Preface & Forward

##### Chapter 1

##### Regulatory

- Pre-formulation Checklist

##### Documentation

- SOP Control Checklist

##### Development Notebooks

- Development Notebooks Checklist

- SOP Control and Development Notebooks SOPs

##### Chapter 2

##### Developing the Formula -an Overview

- Formulation Checklist

- Key Generic Development formulations

##### Drug Development Checklist (Top Generics )

Development Formula for today's top Generics

##### Developing the generic Formula

Product Development Flow Chart

Product Development Guide - Tips & Traps

Purified Water - an essential ingredient

Do and Don'ts in Development

Purified Water - Checklist

##### Chapter 3

##### Active Ingredients

-Do's and Don'ts

-Active development Checklist

-Approved Suppliers Checklist

-Standard Operating Procedures, Actives

##### Chapter 4

##### Semi active ingredients

-Validating the Semi-active ingredients, Checklist

Qualifying the Antioxidant - Protocol & Procedure

Antioxidant Tabulations & Documentation

##### Chapter 5

##### Non active materials (excipients)

-Checklist non active ingredient & FDA IIG list

-Standard Operating Procedures, Non actives

##### Chapter 6

##### Container closure systems

-Container-liner-closure systems, Checklist

-Container-liner-closure systems, Key SOPs

-Packaging Components - rules & regulations

-Packaging Components Documentation Requirements SOP

##### Chapter 7

##### Manufacturing Process & Instructions from A to Z

- Wet, Dry, Spray Granulation

- Aqueous & alcoholic granulation

- Dry Mixing and Slugging

- Manufacturing Instructions; Checklist

- The manufacturing Instructions and Controls

- Manufacturing Flow Charts and Diagrams

- Large scale manufacturing Instructions

- Large scale Master Formula and Processes -key generics

- Large scale Manufacturing Instructions

##### Chapter 8

##### In-process Quality Controls

-Manufacturing in-process controls; Checklist

-In-process Quality Controls; SOPs

##### Chapter 9

##### Finished Product Specifications

- Finished Product Specifications example and Checklist

- Release & Check Specifications

- Finished Product Specifications; Required SOPs

##### Chapter

Qualification of Antioxidant and Lubricant

Process Optimization and Procedures

Qualification of Loss on Drying Limits

##### Chapter 11

##### Scale-up Procedures know-how

- Scale-up procedures; checklist

- Scale-up procedures; SOPs



##### Chapter 12

Cleaning Procedures, guidelines & Limits

Cleaning Limits Procedures; Checklist

Cleaning Validation Requirements; SOPs

##### Chapter 13

Analytical Validation Requirements

-Analytical Testing Out of Specification

-Analytical Testing Do's and Don'ts

-Ruggedness and Robustness

-Impurities in Drug Substances

-Impurities Do's and Don'ts

-Impurities Glossary of Terms

-Impurities Decision Trees

Analytical Post approval Changes -PAC-ALTS

PAC-ALTS Checklist

##### Chapter 14

Process Qualification Batch Know-how

-Process Qualification Batch; Checklist

-Process Qualification Batch; SOPs

-Process Qualification Blend Analysis and - Do's and Don'ts

-Process Qualification **Content Uniformity or Tablet Hardness**

**Content Uniformity or Tablet Hardness Protocol**

##### Chapter 15

Pivotal batch Operation & Process from A to Z

-The Pivotal Batch regulatory requirements

-Pivotal batch Checklist & Do's and don'ts

-Pivotal batch Critical SOPs, Tips & Traps

-Sampling and Testing the Pivotal Batch

-Auditing the Pivotal batch - Tabulations

-Auditing the Pivotal batch - Checklist

##### Chapter 16

Bioequivalence vs. RLD

Test Designs - Overview

Statistical Bioequivalence

IBE Equation explained

IBE Big Picture (Pros and Cons)

Comparing IBE and ABE

Typical IVIVC Models

Choosing IVIVC levels

Dissolution Testing in IR Dosage Forms

Similarity Factor in dissolution testing

**BSC and Biowaivers**

Overall Dissolution Picture

Biopharmaceutics Classification System

Performance Verification in Dissolution testing

Food-Effects in BA-BE Studies

Similarity Testing - Chow, Pitt and Others

##### Chapter 17

Technical Transfer Documentation

-Technical Transfer Documentation; Checklist

-Technical Transfer Documentation; Pharmaceutical Part

-Technical Transfer Documentation; Analytical Part

##### Chapter 18

The Process Validation Batch - Tips & Traps

-The Process Validation Batches; Checklist

-Process Validation Requirements; SOPs

-Process Validation Master Plan & Protocols

##### Chapter 19

Pre--Approval Inspections

**PAI Summary**

Pre--Approval Inspection Audit - Team Set Up

Pre--Approval Inspection Audit - Team Activities

##### Chapter 20

Stability Testing of Drug Substance and Drug Product I

Stability Testing of Drug Substance and Drug Product II

Stability Testing of Drug Substance and Drug Product II

Stability Testing Significant Change

Storage Conditions

Setting up a functional Stability Unit

Stability SOPs Development

##### Chapter 21

**Standard Operational Procedures**

Development SOPs ; Stability SOP Network

Index of Pharmaceutical Standard Operating Procedures

Index of Analytical Standard Operating Procedures

Index of Microbiological Standard Operating Procedures

Index of Stability Standard Operating Procedures.





# Handbook of Pharmaceutical Generic Development

## Controlled Release

Extended Solid Oral Dosage Forms

### Part ONE

Complete Drug Development Know-how

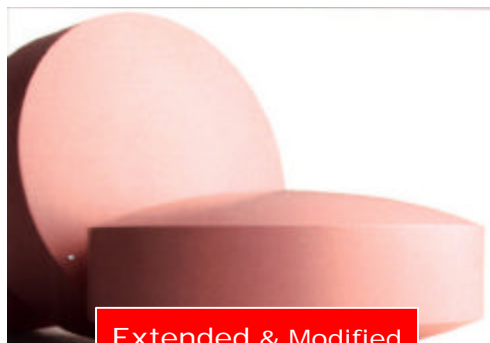
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Sinemet ER, Naproxen DR,  
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Extended & Modified  
Release Dosage Forms

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**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.

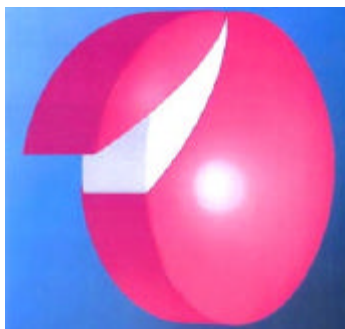
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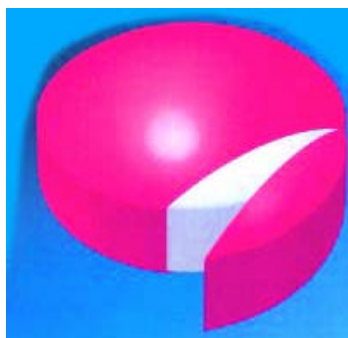


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DRUG DEVELOPMENT KNOW-HOW  
&

**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.

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**Title:-** Handbook of Generic Drug Development  
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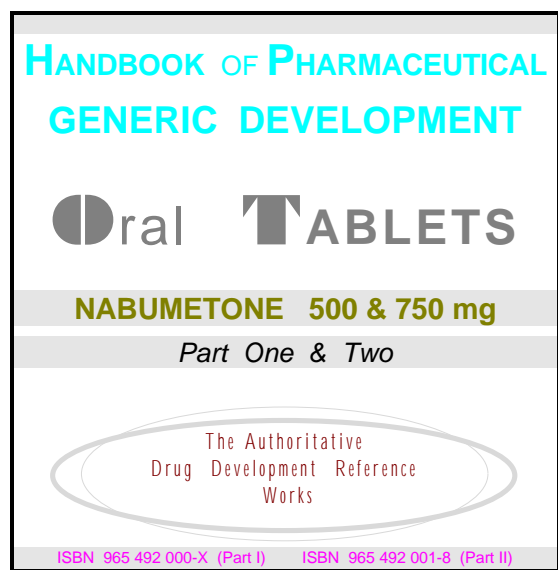
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**Part Two** covers the full ANDA development steps with substantial explanation notes and dovetails side-by-side with part one.

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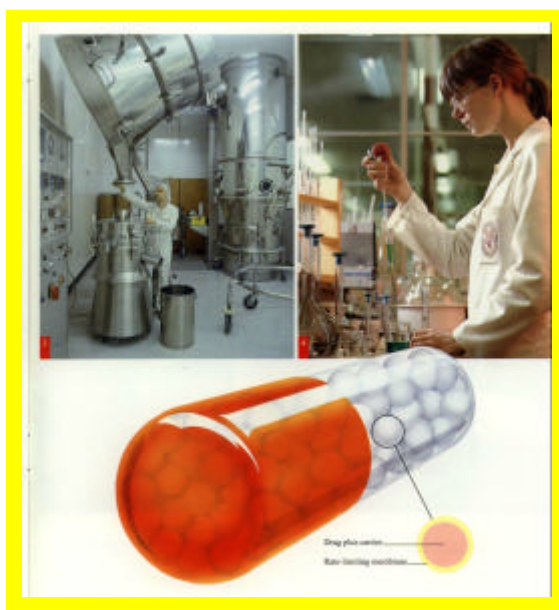
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LIQUID DOSAGE FORMS

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Part ONE  
DRUG Development Know-how  
&

Part TWO  
ANDA Development Technology

### Drug Development



### ANDA Development

Cephalosporins  
Synthetic Penicillins  
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# Handbook of Pharmaceutical Generic Development

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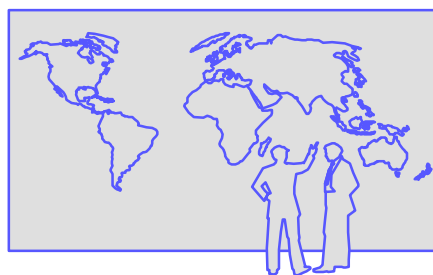
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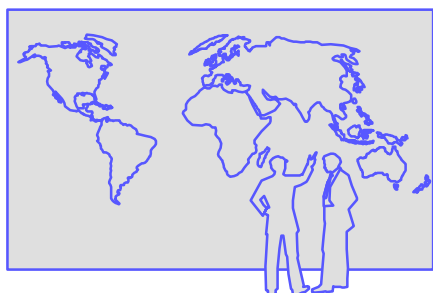
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ISSN 0793 7601 - ISSN 0793 761X



Handbook Volume Consists of:  
Complete Drug Development  
Complete ANDA Development

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## Inhalation Aerosols

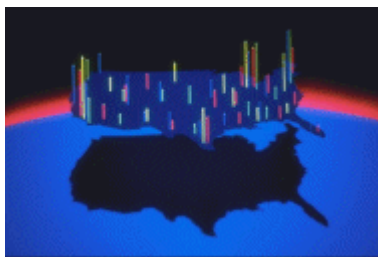
The *Handbook of Pharmaceutical Generic Development* is a practical hand-on workbook covering the full 22 ANDA sections of ORAL & NASAL **Inhalation Aerosol** (MDI Aerosol solutions and suspensions).

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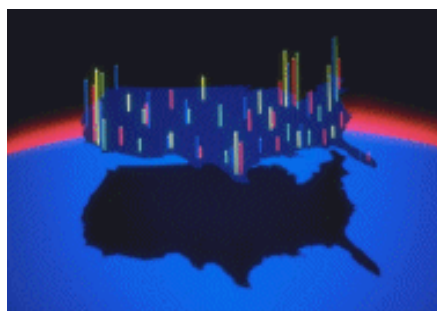
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