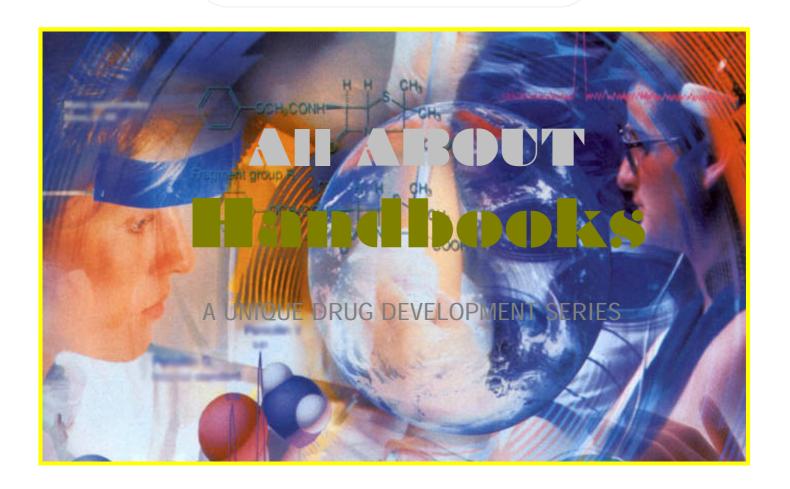
DRUG DEVELOPMENT

Hand 20 Books

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 Generic Drug Manufacturers

Handbook of Pharmaceutical Generic Development

Oral IIITablets

Part ONE
DRUG DEVELOPMENT KNOW-HOW

Part TWO
ANDA DEVELOPMENT & FORMULATIONS

NEW Edition Year 2002





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 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 knowhow 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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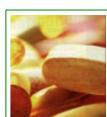
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Pharmaceutical Generic Development

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Extended Solid Oral Dosage Forms

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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.

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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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&

Part TWO
ANDA DEVELOPMENT & FORMULATIONS

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ANDA DEVELOPMENT

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Pharmaceutical Generic Development 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.

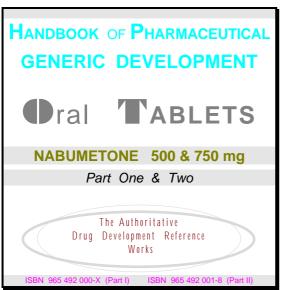
Part One covers pharmaceutical drug development and Part Two (ANDA Development) provide technical know-how for the Development, Formulation, Dissolution, Stability, Scale-up, Process Qualification; pivotal and final validation batches; analytical, cleaning and process validation; essential documentation 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 Delayed Release Tablets ISSN 0793-7601 / 0793-761X.

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The Development Handbook NABUMETONE



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Part Two

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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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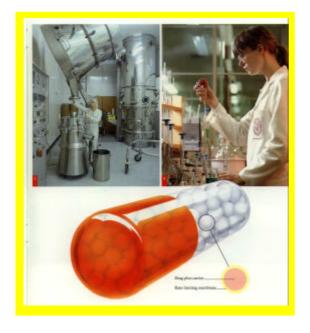
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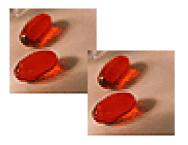
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Soft Gelatin Capsules

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Oral LIOUIDS

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Part ONE
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Drug Development



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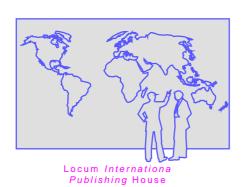
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Handbook Volume Consists of: Complete Drug Development Complete ANDA Development

Part ONE
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Part TWO
ANDA Development Technology



Inhalation Acrosols

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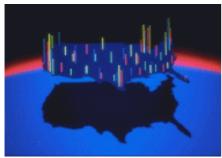
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