



Handbook of Pharmaceutical Generic Development

Controlled Release

Extended Solid Oral Dosage Forms

Part ONE

Complete Drug Development Know-how

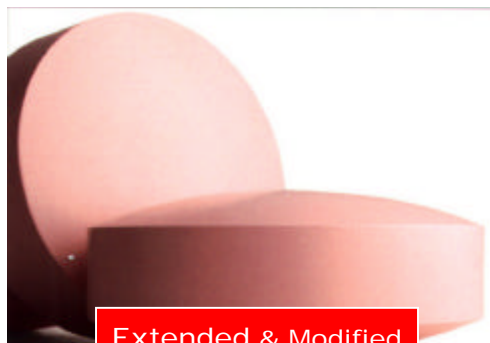
&

Part TWO

ANDA Formula & Development Technology

READY-TO-GO™ SERIES

Felodipine ER, Glipizide ER,
Sinemet ER, Naproxen DR,
Carbamazepine ER, 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 22 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.

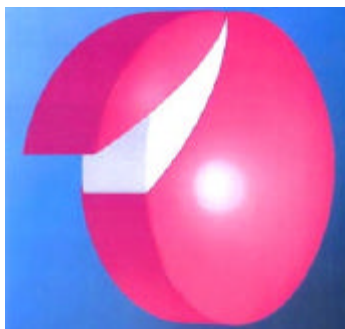
Each and every regulatory guideline is covered in clear detail providing a development protocol for a totally omission-free file submission.

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*.

Locum Publishing House Arlington VA 22215 -1075 USA
A Locum House Publication - ©Copyright LOCUM 1996-2000

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

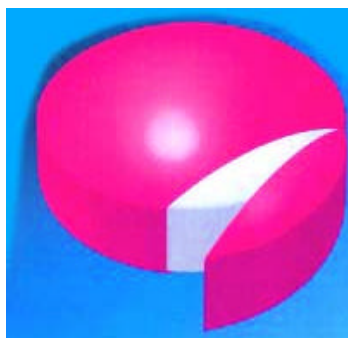


The International Association of
Generic Drug Manufacturers

Part ONE
DRUG DEVELOPMENT KNOW-HOW
&

Part TWO
ANDA DEVELOPMENT & FORMULATIONS

Updated & Revised
2001 Edition



ANDA DEVELOPMENT

Locum International
Locum Publishing House

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
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 Locum House Publication - ©Copyright LOCUM 1996-2001