



Handbook of Pharmaceutical Generic Development

Controlled Release

Extended Solid Oral Dosage Forms

Part ONE

Complete Drug Development Know-how

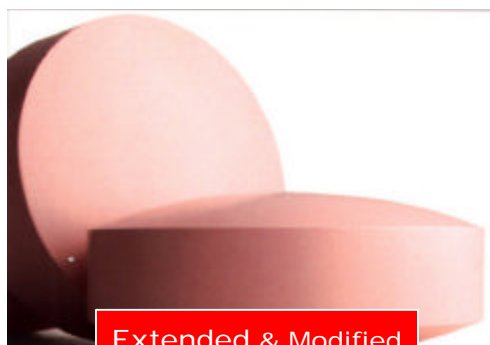
&

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 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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