HANDBOOK OF PHARMACEUTICAL GENERIC DEVELOPMENT

VOLUME VII - Part One

Drug Development - Oral Suspension Dosage Forms

BLOCK J. D. & **BELLE** D.

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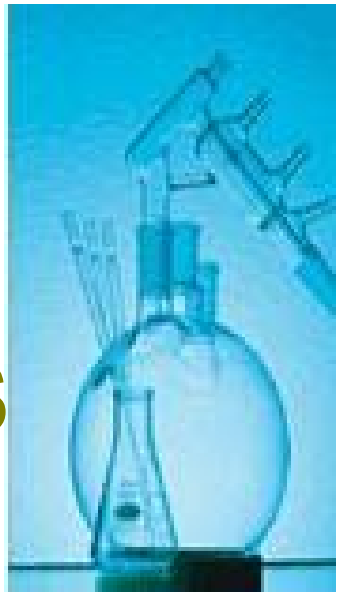
Oral
Part One
Suspensions



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INTRODUCTION

Handbook of Generic Drug Development - Oral Suspension Dosage Forms

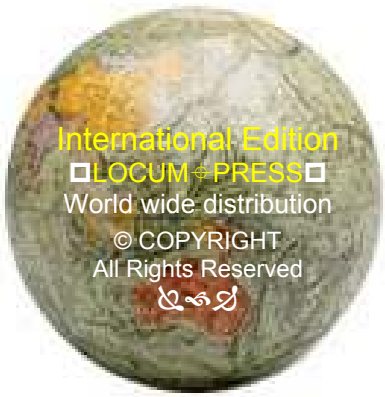
This handbook is the newest updated and expanded international edition of the ongoing 24 volume *series* under the cumulative title of Handbook of Generic Drug Development. It is a hands-on, technical presentation that portrays the current drug requirement steps necessary at the time of going to print, of the Abbreviated New Drug Application for oral suspensions dosage forms. It is written in conjunction with Part Two of the Handbook which covers commercial development formulations and a development ANDA presentation as an example of the drug development process required for modern suspended oral dosage form.

The Handbook is available in print and electronic formats namely CD ROM and online **e-**format. The Handbook's know-how technology is written by industrial, agency and academic authorities and the full set of regulatory requirements are up-dated once annually in order to keep them current.

This handbook provides a proven pathway to suspended oral dosage form technology and development. Modern commercial formulations highlight the common development pathways to produce an appropriate granule for reconstitution. Examples are specially chosen to demonstrate the formulation steps and process stages as a prerequisite to developing stable, elegant, robust and rugged formulas.

This expanded current edition of the Handbook includes additional data on process and analytical method validation has been redesigned to meet the current Guidance for Industry - Organization of an Abbreviated New Drug Application as well as all FDA key draft and final guidelines and requirements of the Center of Drug Evaluation and Research (CDER) until current print date.

Editor-in-Chief.



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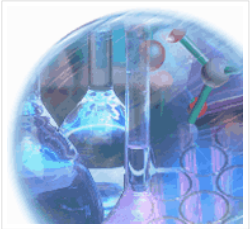

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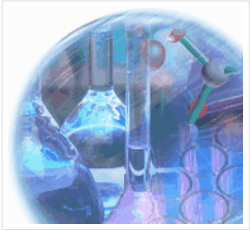

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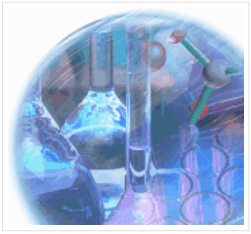

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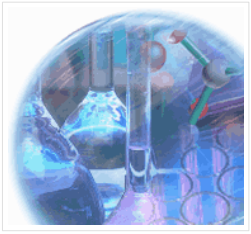

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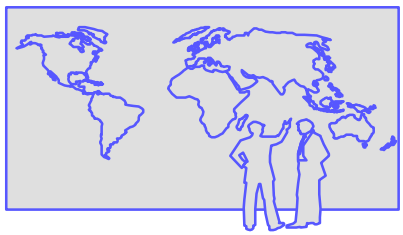

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