HANDBOOK of Pharmaceutical Generic Development

e-SOPs

DRUG DEVELOPMENT

The Complete Handbook Series of Pharmaceutical Drug Development

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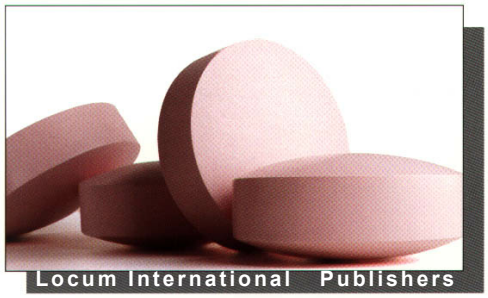

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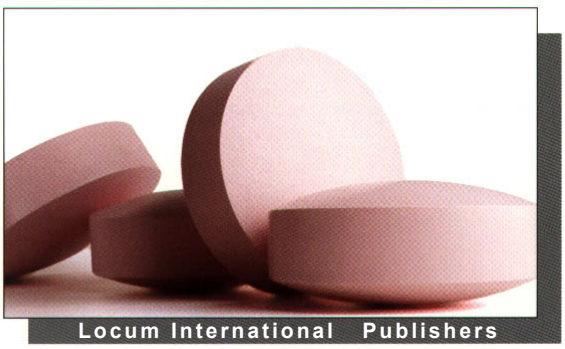

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EDITORIAL PREFACE

Handbook of Generic Drug Development – e-SOPs

This handbook represents the current International Edition of the ongoing 24 volume series of Generic Drug Development and appears under the cumulative title of the Handbook series of Generic Drug Development. The ongoing series is updated annually at the end of each year. This is an ongoing process as new data, specifications and process techniques are added on a continual and expanding basis. This handbook is fact, never fully complete, as each new annual edition brings an enlarged and extended profile in the drug development process, as well as new agency rules, guidelines and guidance to industry which continues to be added year by year as the global product data base expands. Currently over 150 scientific publications and drug development conferences are annually referenced in the 24 volume Handbook series of Generic Drug Development.

This mammoth task presents a continual ongoing commitment by the scientific review committee to the improvement of the technical databases and the product specific drug development requirements and know-how technology accessed through the world wide IAGIM joint ventures and know-how projects currently active in over 15 countries.

The Handbook is available in electronic format (Online and CD ROM) and the e-format is up-dated annually to association members of IAGIM.

This revised international edition of the Handbook has been redesigned and updated to meet the current Guidance for Industry - Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application as well as all current approved and draft FDA guideline requirements of the Center of Drug Evaluation and Research (CDER) up to date of publishing

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