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Handbook of Pharmaceutical Generic Development

Part TWO
MODEL ANDA

EYE
&
Nose



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EDITORIAL PREFACE

Handbook of Generic Drug Development - Eye & Nose Sterile Forms

This handbook represents the third International Edition for Europe 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 continue 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.

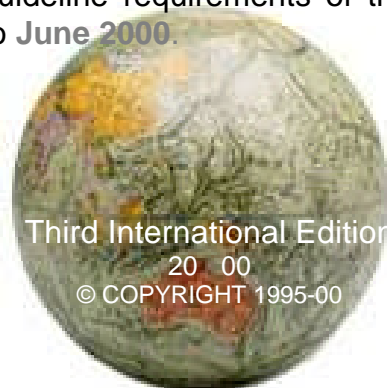
This mammoth task presents a continual ongoing commitment by the scientific review committee to the improvement of the technical databases and the product specific drug development requirements and know-how technology accessed through the world wide IAGIM joint ventures and know-how projects currently 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 **third** international edition of the Handbook has been redesigned and updated to meet the **January 1999** 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 **June 2000**.

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