

Volume 072002EUROEdition



THE INTERNATIONAL JOURNAL OF

International Journal of Generic Drugs

Development and Manufacture of

Generics and NDA CMC sections for the Pharmaceutical

Scientist

neric

rugs

Features reviews and articles on Drug Development for the Pharmaceutical RA, R&D and Manufacturing Scientist.

- Generic & Innovative Drug Development.
- Generic Drug Manufacturing.
- Quality Control /Assurance
- PAI Know How
 - Microbiology Control
- BA/BE Food-Effect Studies
 - Pharmaceutical Stability

• Regulatory Affairs

- Global Product Registration
- Bulk Pharmaceutical Chemical GMP/validation
- Features the *Ins-and-Outs* of **NDA CMC** sections.
- Dissolution Similarity Testing
- IVIVC Development
- New Assays & Impurity Profiles
- Innovative Drug Development

LOCUM Int. Publishing House

International Journal of Generic Drugs ISSN 0793-7784 Euro GENERIC DRUGS

Drug Development & Manufacture for Pharmaceutical Technology Profession:

International Journal of Generic Drugs Electronic < Journal on Disk

Journal on : the Web

e-- Journal

T A B L E O F C O N T E N T S 2 0 0 1 - 2 0 0 2 I s s u e s

(Representative list of the current 2001/2002 Table of Contents in Summary Form)

Material Selection

- Choosing the right active
- ♦ Choosing the right excipient
- ♦ Choosing the right dyes and colors
- ♦ DMF's Do's and Don'ts
- ♦ The Development Notebook

♦ Generic Drug Manufacture

- ♦ Preparing the *right* documentation
- Manufacturing Instructions Do's and Don'ts
- ♦ Developing the Formula from A Z
- Developing CR / MR/ ER and DR forms
- ♦ Development Checklist Step by Step.
- ♦ Individual and Population Bioequivalence
- ♦ Bioequivalence and IVIVC, & CDP's

• Setting the correct specifications

- ♦ In-process, Release and Check Specifications
- ♦ Decision trees (Polymorphism, Impurities etc.)
- ♦ 10 key Decision Trees in SOPs

Process validation and protocols

- ♦ *Scale-up* for specific dosage forms
- ♦ Cleaning *validation* requirements
- ♦ PAIs and Post approval Inspections
- ♦ Tablet Hardness Qualification / LOD
- ♦ Sampling and Testing the Pivotal Batch

Container-closure Systems

- ♦ Closure DMF's vendors obligations
- ♦ ANDA container-closure requirements
- ♦ EC and ANDA comparisons
- ♦ Getting the *paper work* right-first time
- New guidelines / New DMF obligations
- VSP / 21 CFR / Indirect Food Regulations

♦ Biostudies

- ♦ Food/Fasting Studies, BCS, Waivers
- ABE, IBE, IVIVC, CDP Bio Conferences

◆ Quality Control and Assurance

- Audits and vendor inspections
- ♦ Vendor audits by mail/fax

Microbiological Controls

- ◊ Purified Water USP when to use it
- ♦ Topicals and their controls
- ♦ Cleaning Limits

Pharmaceutical Stability

- Auditing your Stability Department
- ♦ Time limitations in the stability protocols
- ♦ Checking the Reference Listed Drug
- Reduced Testing Plans Bracketing / Matrixing

Analytical Aspects

- Auditing Raw Data / Impurities / Limits
- ◊ Handling graphs and print-outs
- ♦ High Speed stability assay validations
- Model validation protocols /Assay /Dissolution
- Residual Solvents, OVI's & Limits/Regulations
- Ruggedness and Robustness / FDA vs.ICH

Auditing your firm

- ◊ Spotting Deficiencies before PAI inspections
- ◊ Building in success for PAIs & File Reviews

Regulatory Affairs

- ANDA & Global Generic Development
- ♦ Global Product Registration made simple
- ◊ ANDA Templates for any Documentation System
- All ANDAs made simple / EU interfacing

Regulatory Do's and Don'ts

- ♦ Tips and traps to consider
- ♦ Annual Reports made simple

• Bulk Pharmaceutical Chemicals

- ♦ Actives for Generic Drugs
- Orug Master Files Actives
- $\diamond~$ How and What to Validate

New Regulations

- ◊ Bioequivalent Food/Fasting Studies, BCS, Waivers
- ♦ How to handle *New OGD's Regulations*.
- OGD Regulations Made Simple
- ◊ Converting FDA speak into Plain English

Current Checklists

- Generic Development Checklists
- Analytical checklists, Protocols, Validation
- ◊ Stability Indicating System checklists
- $\diamond~$ PAI Approvals All that's necessary
- $\Diamond\,$ Drug Development Checklist Solid Oral Dosages
- Orug Development Checklist Liquid & Suspensions

ISSN 0793-7822 Pacific Rim

SOPs of the Month

- ♦ New SOPs for generic firms
- ♦ Ten Major Decision Trees
- $\diamond~$ Current SOPs you should have
- \diamond SOPs for your firms security.

• Regulatory and Patents Info

- ♦ The Generic Drug Enforcement Act
- ♦ Seminar/Conference Summaries
- ♦ Drugs Off-Patents to the year 2016
- ♦ Drugs coming Off-Patent (annually).

International Journal of Generic Drugs

ISSN 0793-7784 Euro

ISSN 0793 694X US/Canada