Encyclopedia of Pharmaceutical Technology

Volume 13

Editors

James Swarbrick

James C. Boylan

ENCYCLOPEDIA OF PHARMACEUTICAL TECHNOLOGY

Editors



JAMES SWARBRICK

Vice President Research and Development AAI, Inc. Wilmington, North Carolina

JAMES C. BOYLAN

Director Pharmaceutical Technology Hospital Products Division Abbott Laboratories Abbott Park, Illinois



VOLUME 13

PRESERVATION OF PHARMACEUTICAL PRODUCTS TO SALT FORMS OF DRUGS AND ABSORPTION

MARCEL DEKKER, INC., NEW YORK • BASEL • HONG KONG

TR 460.6-61

523

Library of Congress Cataloging in Publication Data

Main entry under title:

Encyclopedia of Pharmaceutical Technology. editors: James Swarbrick, James C. Boylan.

Includes index.

1. Pharmaceutical technology—Dictionaries. I. Swarbrick, James. II. Boylan, James C. [DNLM: 1. Chemistry, Pharmaceutical-encyclopedias. 2. Drugs—encyclopedias. 3. Technology, Pharmaceutical-encyclopedias. QV 13 E565]. RS192.E53 1988 615'.1'0321-dc19

COPYRIGHT © 1996 BY MARCEL DEKKER, INC. ALL RIGHTS RESERVED.

Neither this book nor any part may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, microfilming, and recording, or by any information storage and retrieval system, without permission in writing from the publisher.

MARCEL DEKKER, INC. 270 Madison Avenue, New York, New York 10016

LIBRARY OF CONGRESS CATALOG CARD NUMBER 88-25664 ISBN: 0-8247-2812-2

Current printing (last digit): 10 9 8 7 6 5 4 3 2 1

PRINTED IN THE UNITED STATES OF AMERICA

ENCYCLOPEDIA OF PHARMACEUTICAL TECHNOLOGY

VOLUME 13

CONTRIBUTORS TO VOLUME 13

Phillip M. Achey Department of Microbiology, University of Florida, Gainesville, Florida: *Radiation Sterilization of Drugs*

Stephen M. Berge, Ph.D. Manager, Transdermal Drug Delivery, 3M Pharmaceuticals, St. Paul, Minnesota: *Salt Forms of Drugs and Absorption*

Kumaril Bhargava, Ph.D. Research Pharmacist, Hospital Products Division, Abbott Laboratories, Abbott Park, Illinois: *Radiochemical Methods of Analysis*

Lyle D. Bighley, Ph.D. President, L.D. Bighley Associates, Lenexa, Kansas: *Salt Forms of Drugs and Absorption*

Sally F. Bloomfield, Ph.D. Senior Lecturer, Department of Pharmacy, King's College London, London, England: *Preservation of Pharmaceutical Products*

Lona L. Christrup, Ph.D. Associate Professor, Department of Pharmaceutics, The Royal Danish School of Pharmacy, Copenhagen, Denmark: *Prodrugs*

Richard W. J. Currie Political Consultant, London, England: Registration of Drugs

William J. C. Currie Executive Director, Clinical and Regulatory Development, Merck Research Laboratories, Merck & Company, Inc., Rahway, New Jersey: Registration of Drugs

Stephen P. Denyer Professor of Pharmaceutical and Applied Microbiology and Head of Department of Pharmacy, University of Brighton, Sussex, England: *Preservative Testing*

Jie Du, Ph.D. Research Pharmacist, Hospital Products Division, Abbott Laboratories, Abbott Park, Illinois: *Radiochemical Methods of Analysis*

Joseph A. Fix, Ph.D. ALZA Corporation, Palo Alto, California: Rectal Administration and Absorption of Drugs

Jerome J. Groen Hospital Products Division, Abbott Laboratories, Abbott Park, Illinois: *Project Management*

Jeffrey M. Herz, Ph.D. Senior Scientist, Drug Discovery Services, Panlabs, Inc., Bothell, Washington: *Receptors for Drugs*

Norman A. Hodges Principal Lecturer in Microbiology, Department of Pharmacy, University of Brighton, Sussex, England: *Preservative Testing*

Jose Joseph, Ph.D. Manager, Scientific Services, Hospital Products Division, Abbott Laboratories, Abbott Park, Illinois: *Radiochemical Methods of Analysis*

Richard Kaplan, Ph.D. Group Director, Quality Assurance and Responsible Head, Ortho Biotech, Raritan, New Jersey: *Quality Assurance of Drug Products*

James G. Kenimer, Ph.D. President, Kenimer Associates, Alexandria, Virginia: Product License Applications (PLAs) and Establishment License Applications (ELAs) for Biological Products

Sylvie Laganière, Ph.D. Research Scientist, Biopharmaceutics & Pharmacodynamics Division, Bureau of Drug Research, Drugs Directorate, Health Canada, Ottawa, Ontario, Canada: *Protein Binding of Drugs*

lain J. McGilveray, Ph.D. Division Chief, Biopharmaceutics & Pharmacodynamics Division, Bureau of Drug Research, Drugs Directorate, Health Canada, Ottawa, Ontario, Canada: *Protein Binding of Drugs*

Richard Mitchell, Ph.D. Director of Pharmacology, U.S. Laboratory, Panlabs, Inc., Bothell, Washington: *Receptors for Drugs*

Donald C. Monkhouse, Ph.D. Drug Development Consultant, Radnor, Pennsylvania: *Salt Forms of Drugs and Absorption*

Judi Moss, Ph.D. Assistant Professor, Department of Analytical and Pharmaceutical Chemistry, The Royal Danish School of Pharmacy, Copenhagen, Denmark: *Prodrugs*

Rajagopalan Raghavan, Ph.D. Research Investigator, Hospital Products Division, Abbott Laboratories, Abbott Park, Illinois: *Radiochemical Methods of Analysis*

J. Howard Rytting Pharmaceutical Chemistry Department, The University of Kansas, Lawrence, Kansas: Rectal Administration and Absorption of Drugs

Stephen G. Schulman, Ph.D. Professor of Medicinal Chemistry, Department of Medicinal Chemistry, College of Pharmacy, University of Florida, Gainesville, Florida: *Radiation Sterilization of Drugs*

Dhiren N. Shah, Ph.D. Director, Global Regulatory CMC, Regulatory Affairs, Marion Merrell Dow Inc., Kansas City, Missouri: *Product License Applications (PLAs) and Establishment License Applications (ELAs) for Biological Products*

Fiona C. Sheppard, B.Pharm. Department of Pharmacy, King's College London, London, England: *Preservation of Pharmaceutical Products*

Bente Steffansen, Ph.D. Associate Professor, Department of Pharmaceutics, The Royal Danish School of Pharmacy, Copenhagen, Denmark: *Prodrugs*

William J. Thomsen, Ph.D. Director of Research, Lasure and Crawford, Inc., Seattle, Washington: *Receptors for Drugs*

Brian Warburton, Ph.D. Senior Lecturer in Pharmaceutics, Centre for Material Science, The School of Pharmacy, London, England: *Rheology of Pharmaceutical Systems*

Marlys E. Weary, Ph.D. President, MERIT Consulting Services, Mount Prospect, Illinois: Pyrogens and Pyrogen Testing

J. Wieling, Ph.D. Senior Research Scientist Bioanalysis, Pharma Bio-Research Laboratories B.V., Zuidlaren, The Netherlands: *Robotics in the Pharmaceutical and Biomedical Laboratory*

George G. Yarbrough, Ph.D. Director, Pharmacology Services, Panlabs, Inc., Bothell, Washington: *Receptors for Drugs*

Contributors to Volume 13	V
Contents of Other Volumes	vii
Preservation of Pharmaceutical Products Sally F. Bloomfield and Fiona C. Sheppard	1
Preservative Testing Norman A. Hodges and Stephen P. Denyer	21
Prodrugs Lona L. Christrup, Judi Moss, and Bente Steffansen	39
Product License Applications (PLAs) and Establishment License Applications (ELAs) for Biological Products Dhiren N. Shah and James G. Kenimer	71
Project Management Jerome J. Groen	121
Protein Binding of Drugs Sylvie Laganière and Iain J. McGilveray	151
Pyrogens and Pyrogen Testing Marlys E. Weary	179
Quality Assurance of Drug Products Richard Kaplan	207
Radiation Sterilization of Drugs Stephen G. Schulman and Phillip M. Achey	233
Radiochemical Methods of Analysis Kumaril Bhargava, Jie Du, Rajagopalan Raghavan, and Jose Joseph	255
Receptors for Drugs Jeffrey M. Herz, William J. Thomsen, Richard Mitchell, and George G. Yarbrough	283
Rectal Administration and Absorption of Drugs Joseph A. Fix and J. Howard Rytting	335

Index to Volume 13

Contents of Volume 13

501

CONTENTS OF OTHER VOLUMES

Contributors to Volume 1		v
Preface		vii
Absorption of Drugs Peter G. Welling		1 1 m
Abuse of Drugs Ahmad Rezvani and E. Leong Way		33
Adsorption at Solid Surfaces Herbert Rupprecht and Geoffrey Lee		73
Adulteration of Drugs and Drug Products Raymond E. Hamilton		115
Adverse Drug Reactions Therese I. Poirier		121
Advertising and Promotion of Prescription Drug Pr Lloyd G. Millstein	oducts	147
Air Suspension Coating David M. Jones		189
Analysis and Assay of Drugs Robert V. Smith		217
Analysis of Biologic Fluids Stephen G. Schulman and Stephen H. Curry		233
Analysis of Recombinant Biologicals Robert L. Garnick, Michael J. Ross, and Charles P. of	du Mée	253
Animals in Drug Development Farrel L. Fort		315

James A. Seitz	337
Aseptic Processing Operations, Validation of William R. Frieben	351
Atomic Absorption Spectrophotometry John P. Oberdier	371
Auditing of Pharmaceutical Processing William J. Mead	383
Autoclaves and Autoclaving Edward J. Leuthner	393
Autoxidation and Antioxidants David M. Johnson and Leo C. Gu	415
Binders Henning G. Kristensen	451
Bioabsorbable Polymers Shalaby W. Shalaby	465
Bioavailability of Drugs and Bioequivalence Marvin C. Meyer	477
CONTENTS OF VOLUME 2	
Contributors to Volume 2	v
Biodegradable Polyester Polymers as Drug Carriers M. Regina Brophy and Patrick B. Deasy	
Biological Indicators Peter Lancy and Karl Kereluk	27
Biopharmaceutics Leon Shargel	33
Biopolymers for Controlled Drug Delivery Avinash G. Thombre and John R. Cardinal	61

CONTENTS OF OTHER VOLUMES	ix
Biosynthesis of Drugs Christopher W. W. Beecher and Geoffrey A. Cordell	89
Biotechnology and Biologic Preparations Hollis G. Schoepke	117
Biotransformation of Drugs L. F. Chasseaud and D. R. Hawkins	129
Blenders and Blending Operations M. S. Spring	159
Buccal Absorption of Drugs James C. McElnay	189
Buffers and Buffering Agents Lydia C. Kaus	213
Calorimetry in Pharmaceutical Research and Development Siegfried Lindenbaum	233
Capsules, Hard Brian E. Jones	251
Capsules, Soft Robert F. Jimerson and F. S. Hom	269
Carcinogenicity Testing Joseph L. Ciminera and Henry L. Allen	285
Cellulose Derivatives and Natural Products Utilized in Pharmaceutics Jesse W. Wallace	319
Centrifugation Graham C. Cole	339
Chemical Kinetics and Drug Stability Jens T. Carstensen	355
Chewable Tablets Robert W. Mendes and Aloysius O. Anaebonam	
Chromatographic Analysis Gary M. Pollack	419
Cleaning of Equipment Samuel W. Harder	447

Clinical Evaluation of Drugs Allen Cato, Allen Lai, and Robert Sutton	457
Clinical Pharmacokinetics and Pharmacodynamics Margareta Hammarlund-Udenaes and Leslie Z. Benet	483

Contributors to Volume 3	V
Clinical Supplies Michael McNear and Robert E. Shaffer	1
Coacervation/Phase Separation Joseph A. Bakan and Anil M. Doshi	21
Colloids and Colloid Drug Delvery Systems Diane J. Burgess	31
Coloring Agents for Use in Pharmaceuticals Edward J. Woznicki and David R. Schoneker	65
Comminution Eugene L. Parrott	101
Compendial Specifications Lee T. Grady	123
Compression of Solids and Compressed Dosage Forms Edward G. Rippie	149
Computer-Aided Drug Design J. Phillip Bowen and Michael Cory	167
Computers in Pharmaceutical Technology Onkaram Basavapathruni	201
Contamination Control Richard G. Johnson	237
Continuous Processing of Pharmaceuticals Kunio Kawamura	253

CONTENTS OF OTHER VOLUMES		xi
Controlled- and Modulated-Release Drug-Delivery System Yie W. Chien	ems	281
Cooling Processes and Congealing James W. McGinity and Mark D. Coffin		315
Coprecipitates and Melts Madhu K. Vadnere		337
Corrosion in Pharmaceutical Processing Arvind N. Narurkar and Pai-Chang Sheen		353
Cosmetics and Their Relation to Drugs Martin M. Rieger		361
Cosolvents and Cosolvency Joseph T. Rubino		375
Crystallization and the Properties of Crystals Nair Rodríguez-Hornedo		399
Dental Products Sebastian G. Ciancio		435
Dermal Diffusion and Delivery Principles Gordon L. Flynn		457
CONTENTS OF VOLUME 4		
Contributors to Volume 4		v
Design of Drugs: Basic Concepts and Applications Jacques H. Poupaert		1
Diffuse Reflectance Spectroscopy Michael Bornstein		23
Diluents Jeffrey L. Czeisler and Karl P. Perlman		37
Direct Compression Tabletting Ralph F. Shangraw		85

J. Graham Nairn	107
Dissolution and Dissolution Testing James L. Ford	121
Dissolution of Pharmaceutical Suspensions Paula Jo Stout, Stephen A. Howard, and John W. Mauger	
Dosage Form Design: A Physicochemical Approach Michael B. Maurin, Anwar A. Hussain, and Lewis W. Dittert	193
Dosage Forms: Non-Parenteral Paul Zanowiak	209
Dosage Forms: Parenteral Salvatore J. Turco	231
Dosing of Drugs: Dosage Regimens and Dose-Response Chyung S. Cook and Aziz Karim	249
Dressings in Wound Management Terence D. Turner	283
Drug Delivery and Therapeutic Systems Felix Theeuwes, Patrick S. L. Wong, and Su Il Yum	303
Drug Information Systems John M. Fischer	349
Drug Interactions Daniel A. Hussar	357
Drug Product Selection by the Pharmacist Robert P. Rapp	377
Drug Safety Evaluation Farrel L. Fort	389
Dry Granulation Kozo Kurihara	423
Dry Heat Sterilization and Depyrogenation Frances M. Groves and Michael J. Groves	447
Drying and Driers Kurt G. Van Scoik, Michael A. Zoglio, and Jens T. Carstensen	485

Contributors to Volume 5	V
Contents of Other Volumes	vii
Economic Characteristics of the R&D-Intensive Pharmaceutical Inc Douglas L. Cocks	lustry 1
Effervescent Pharmaceuticals Nils-Olof Lindberg, Hans Engfors, and Thomas Ericsson	45
Elastomeric Parenteral Closures Kenneth E. Avis and Edward J. Smith	73
Electrochemical Methods of Analysis Barbara J. Norris	89
Electron Beam Sterilization Marshall R. Cleland and Jeffrey A. Beck	105
Emulsions Gillian M. Eccleston	137
Enteric Coatings Walter G. Chambliss	189
Enzyme Immunoassay Hsin-Hsiung Tai	201
Enzymes Ingrid M. A. Verhamme and Albert R. Lauwers	235
Equipment Selection and Evaluation Bhoghi B. Sheth and Fred J. Bandelin	263
Ethics of Drug Making Michael Montagne	301
Ethylene Oxide Sterilization Robert R. Reich and Daniel J. Burgess	315
Evaporation and Evaporators David P. Kessler	337

171

197

Expert Systems as Applied to Pharmaceutical Technology Felix Lai	361
Expiration Dating Mark VanArendonk and G. R. Dukes	379
Extrusion and Extruders K. E. Fielden and J. M. Newton	395
Fermentation Processes Peter F. Stanbury	443
Cumulative Index to Volumes 1–5	475
CONTENTS OF VOLUME 6	
Contributors to Volume 6	v
Contents of Other Volumes	vii
Film Coatings and Film-Forming Materials: Evaluation Galen W. Radebaugh	1
Films and Sheets for Packaging Shalaby W. Shalaby and Bernard L. Williams	29
Filters and Filtration Theodore H. Meltzer	51
Flame Photometry Thomas M. Nowak	93
Flavors and Flavor Modifiers Akwete L. Adjei, Richard Doyle, and Thomas Reiland	101
Flow Properties of Solids Stephen A. Howard and Jin-Wang Lai	141

Fluid-Bed Dryers, Granulators, and Coaters

Victoria Saldajeno de Leon and Stephen G. Schulman

Leo K. Mathur

Fluorescence Spectroscopy

CONTENTS OF OTHER VOLUMES	xv
Food and Drug Administration: Role in Drug Regulation James C. Morrison	231
Foods and "Health Foods" as Drugs Ara H. DerMarderosian	251
Freeze Drying Michael J. Pikal	275
Gamma Radiation Sterilization Geoffrey P. Jacobs	305
Gas Chromatography Isadore Kanfer	333
Gastrointestinal Absorption of Drugs Alice E. Loper and Colin R. Gardner	385
Gels and Jellies Cathy M. Klech	415
Generic Drugs and Generic Equivalency Arthur H. Kibbe and Lawrence C. Weaver	441
Index to Volume 6	469
CONTENTS OF VOLUME 7	
Contributors to Volume 7	v
Contents of Other Volumes	vii
Genetic Engineering Donald E. Frail	1
Genetic Factors in Drug Use David W. J. Clark	37
Geriatric Drug Use Sandra Knowles and Susan K. Bowles	55
Glass as a Packaging Material for Pharmaceuticals R. Paul Abendroth	79