Modified-Release Drug Delivery Technology Second Edition

Volume 2

edited by

Michael J. Rathbone

InterAg

Hamilton, New Zealand

Jonathan Hadgraft
University of London

London, UK

Michael S. Roberts

University of Queensland

Brisbane, Australia

Majella E. Lane

University of London London, UK

informa

healthcare

New York London



Contents

Preface v
Contributors xi

PART I: USING MODIFIED-RELEASE FORMULATIONS TO MAINTAIN AND DEVELOP MARKETS

- The Modified-Release Drug Delivery Landscape: The Commercial Perspective 1 Stephen Perrett
- The Modified-Release Drug Delivery Landscape: Academic Viewpoint 17 Juergen Siepmann and Florence Siepmann
- The Modified-Release Drug Delivery Landscape: Advantages and Issues for Physicians and Patients 35 Marco M. Anelli
- 4. The Modified-Release Drug Delivery Landscape: Drug Delivery Commercialization Strategies 49

 Fintan Walton

PART II: OCULAR TECHNOLOGIES

- 5. Ophthalmic Drug Delivery 59
 Pascal Furrer, Florence Delie, and Bernard Plazonnet
- 6. Intraocular Implants for Controlled Drug Delivery 85

 Leila Bossy, Signe Erickson, Robert Gurny, and Florence Delie
- Bioadhesive Ophthalmic Drug Inserts (BODI) for Veterinary Use 101 Pascal Furrer, Olivia Felt, and Robert Gurny
- 8. Ion Exchange Resin Technology for Ophthalmic Applications 109
 Rajni Jani and Erin Rhone



viii Contents

PART III: INJECTION AND IMPLANT TECHNOLOGIES

- 9. Injections and Implants 123
 Majella E. Lane, Franklin W. Okumu, and Palani Balausubramanian
- 10. Long-Acting Protein Formulation—PLAD Technology 133
 Franklin W. Okumu
- 11. Long-Term Controlled Delivery of Therapeutic Agents by the Osmotically Driven DUROS® Implant 143

 Jeremy C. Wright and John Culwell
- 12. The SABERTM Delivery System for Parenteral Administration 151 Jeremy C. Wright, A. Neil Verity, and Franklin W. Okumu
- 13. Improving the Delivery of Complex Formulations Using the DepotOne® Needle 159

 Kevin Maynard and Peter Crocker
- 14. ReGel Depot Technology 171
 Ramesh C. Rathi and Kirk D. Fowers
- 15. The Atrigel® Drug Delivery System 183
 Eric J. Dadey
- 16. Enhancing Drug Delivery by Chemical Modification 191
 Mimoun Ayoub, Christina Wedemeyer, and Torsten Wöhr
- DepoFoam[®] Multivesicular Liposomes for the Sustained Release of Macromolecules 207 William J. Lambert and Kathy Los
- 18. ALZAMER® DepotTM Bioerodible Polymer Technology 215
 Guohua Chen and Gunjan Junnarkar
- Pegylated Liposome Delivery of Chemotherapeutic Agents: Rationale and Clinical Benefit 227
 Francis J. Martin

PART IV: DERMAL AND TRANSDERMAL TECHNOLOGIES

- 20. Dermal and Transdermal Drug Delivery 263

 Jonathan Hadgraft, Majella E. Lane, and Adam C. Watkinson
- 21. ALZA Transdermal Drug Delivery Technologies 273
 Rama Padmanabhan, J. Bradley Phipps, Michel Cormier, Janet Tamada,
 Jay Audett, J. Richard Gyory, and Peter E. Daddona



Contents

- 22. Microneedles for Drug Delivery 295

 Mark R. Prausnitz, Harvinder S. Gill, and Jung-Hwan Park
- 23. Transfersome®: Self-Optimizing and Self-Driven Drug-Carrier, for Localized and Transdermal Drug Delivery 311 Gregor Cevc
- 24. Advances in Wound Healing 325

 Michael Walker and Steven Percival
- 25. Ultrasound-Mediated Transdermal Drug Delivery 339
 Samir Mitragotri and Joseph Kost
- 26. Lipid Nanoparticles with Solid Matrix for Dermal Delivery: Solid Lipid Nanoparticles and Nanostructured Lipid Carriers 349

 Eliana B. Souto, Rolf D. Petersen, and Rainer H. Müller
- 27. LidoSite®—Vyteris Iontophoretic Technology 373

 Lakshmi Raghavan and Ashutosh Sharma
- 28. Nail Delivery 383

 Darren M. Green, Keith R. Brain, and Kenneth A. Walters
- 29. Immediate Topical Drug Delivery Using Natural Nano-Injectors 395

 Tamar Lotan
- 30. DOT Matrix® Technology 405

 Juan A. Mantelle
- 31. The PassPortTM System: A New Transdermal Patch for Water-Soluble Drugs, Proteins, and Carbohydrates 417
 Alan Smith and Eric Tomlinson

PART V: NASAL TECHNOLOGIES

- 32. Nasal Drug Delivery 427
 Pradeep K. Karla, Deep Kwatra, Ripal Gaudana, and Ashim K. Mitra
- 33. Controlled Particle Dispersion®: A Twenty-First-Century Nasal Drug Delivery Platform 451

 Marc Giroux, Peter Hwang, and Ajay Prasad
- **34.** DirectHalerTM Nasal: Innovative Device and Delivery Method *469* Troels Keldmann

PART VI: VAGINAL TECHNOLOGIES

35. Intravaginal Drug Delivery Technologies 481



- 36. Vaginal Rings for Controlled-Release Drug Delivery 499

 R. Karl Malcolm
- 37. Phospholipids as Carriers for Vaginal Drug Delivery 511

 Mathew Leigh
- 38. SITE RELEASE®, Vaginal Bioadhesive System 521

 Jennifer Gudeman, Daniel J. Thompson, and R. Saul Levinson
- 39. Clindamycin Vaginal Insert 531

 Janet A. Halliday and Steve Robertson
- **40.** Bioresponsive Vaginal Delivery Systems **539** Patrick F. Kiser

PART VII: PULMONARY TECHNOLOGIES

- 41. Pulmonary Delivery of Drugs by Inhalation 553
 Paul B. Myrdal and B. Steven Angersbach
- **42.** AERx® Pulmonary Drug Delivery Systems 563 David C. Cipolla and Eric Johansson
- 43. Formulation Challenges of Powders for the Delivery of Small Molecular Weight Molecules as Aerosols 573
 Anthony J. Hickey and Heidi M. Mansour
- 44. Adaptive Aerosol Delivery (AAD®) Technology 603

 Kurt Nikander and John Denyer
- 45. Nebulizer Technologies 613

 Martin Knoch and Warren Finlay
- **46.** Formulation Challenges: Protein Powders for Inhalation 623 Hak-Kim Chan
- 47. The Respirat®, a New Soft MistTM Inhaler for Delivering Drugs to the Lungs 637
 Herbert Wachtel and Achim Moser
- **48.** Pressurized Metered Dose Inhalation Technology 647 Ian C. Ashurst
- 49. Dry Powder Inhalation Systems from Nektar Therapeutics 659

 Andrew R. Clark and Jeffry G. Weers
- 50. Technosphere®/Insulin: Mimicking Endogenous Insulin Release 673

 Andrea Leone-Bay and Marshall Grant



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

