

**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

Noven Pharmaceuticals, Inc.

Contents

Preface v
Contributors xi

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

1. The Modified-Release Drug Delivery Landscape: The Commercial Perspective **1**
Stephen Perrett
2. The Modified-Release Drug Delivery Landscape: Academic Viewpoint **17**
Juergen Siepmann and Florence Siepmann
3. 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
7. 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

PART III: INJECTION AND IMPLANT TECHNOLOGIES

9. Injections and Implants 123
Majella E. Lane, Franklin W. Okumu, and Palani Balasubramanian
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 SABER[™] 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
17. DepoFoam[®] Multivesicular Liposomes for the Sustained Release of Macromolecules 207
William J. Lambert and Kathy Los
18. ALZAMER[®] Depot[™] Bioerodible Polymer Technology 215
Guohua Chen and Gunjan Junnarkar
19. 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

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 PassPort™ 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. DirectHaler™ 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 Respimat[®], a New Soft Mist[™] 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 Jeffrey G. Weers
50. Technosphere[®]/Insulin: Mimicking Endogenous Insulin Release 673
Andrea Leone-Bay and Marshall Grant

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.