Contents

Part I  Percutaneous Absorption

1  Percutaneous Absorption ................................................................. 3
   Michael S. Leo and Howard I. Maibach

2  Animal Models for Percutaneous Absorption ................................. 21
   Eui Chang Jung and Howard I. Maibach

3  Mitigating Dermal Exposure to Agrochemicals ............................... 41
   Robert P. Chilcott

Part II  In Vitro Drug Release

4  Importance of In Vitro Drug Release .............................................. 61
   Vinod P. Shah and Roger L. Williams

5  Diffusion Cell Design ........................................................................ 79
   Jon R. Heylings

6  In Vitro Product Quality Tests and Product Performance
   Tests for Topical and Transdermal Drug Products ........................... 81
   Avraham Yacobi, Clarence T. Ueda and Vinod P. Shah

7  Safety and Efficacy Testing of Topical Products; Practical
   Considerations................................................................................... 91
   Rashmikant Mohile
Part III  Bioequivalence of Topical Drug Products

8 Challenges in Evaluating Bioequivalence of Topical Dermatological Drug Products ................................................................. 101
Vinod P. Shah and Roger L. Williams

9 Methods for the Assessment of Bioequivalence of Topical Dosage Forms: Correlations, Optimization Strategies, and Innovative Approaches ................................................................. 113
Isadore Kanfer

10 Application of Microdialysis in Assessing Cutaneous Bioavailability ................................................................. 153
Eva Benfeldt

Part IV  Bioequivalence: Targeted Drug Delivery

11 Follicular Drug Penetration ................................................................. 169
Jürgen Lademann and Alexa Patzelt

12 Development of Pilosebaceous Unit-Targeted Drug Products ........ 181
Guang Wei Lu, Kevin S. Warner and Fangjing Wang

13 Deep Percutaneous Penetration into Muscles and Joints: Update .... 217
Vladyslava Doktor, Christine M. Lee and Howard I. Maibach

14 Efficacy and Toxicity of Microneedle-Based Devices .................. 237
Michael S. Leo, Hadar A. Lev-Tov, Faranak Kamangar, Howard I. Maibach and Raja K. Sivamani

Part V  Transdermal Drugs and Modelling

15 Mathematical Models for Topical and Transdermal Drug Products ................................................................. 249
Yuri G. Anissimov and Michael S. Roberts

16 Transdermal Patches: An Industrial Perspective on the Relevance of In Vitro Skin Permeation Studies and Approaches on Design of Manufacturing Processes .................. 299
Björn Schurad and Marieke Gosau

17 Transdermal Drug Delivery Systems ................................................................. 319
Vinod P. Shah and Roger L. Williams
Part VI  Clinical Studies and Bioequivalence

18 Dermal Estradiol and Testosterone Transfer in Man: Existence, Models, and Strategies for Prevention ........................................ 331
   Aaron Gandhi, K. L. Busse and Howard I. Maibach

19 Effects of Occlusion on Dermal Drug Delivery: Implications for Bioequivalence Measurement .......................................................... 351
   Nilab Osman and Howard I. Maibach

20 Challenges with Clinical Endpoints—Bioequivalence .......................... 361
   Garrett Coman, Nicholas Blickenstaff and Howard I. Maibach

21 Clinical Considerations of Bioequivalence for Topical Dermatologic Drugs ................................................................. 371
   Jessica Schweitzer and Howard I. Maibach

Part VII  Guidelines and Workshop Report

22 OECD Test Guideline 428—A Method for In Vitro Percutaneous Absorption Measurement? .................................................. 381
   John Jenner

23 Bioequivalence, Quality, and Novel Assessment Technologies for Topical Products: Current Challenges and Future Prospects ........ 389
   Vinod P. Shah, Avraham Yacobi and Majella E. Lane

Index .................................................................................................................. 399
Topical Drug Bioavailability, Bioequivalence, and Penetration
Shah, V.; Maibach, H.I.; Jenner, J. (Eds.)
2014, XIII, 402 p. 64 illus., 16 illus. in color., Hardcover
ISBN: 978-1-4939-1288-9