

# Contents

<b>Preface to the First Edition</b> .....	vii
<b>Preface to the Second Edition</b> .....	ix
<b>Editor</b> .....	xi
<b>Contributors</b> .....	xiii
<b>Chapter 1</b> Introduction .....	1
<i>Rong (Ron) Liu</i>	
<b>Chapter 2</b> Solubility Theories .....	5
<i>Steven H. Neau</i>	
<b>Chapter 3</b> Prediction of Solubility .....	23
<i>Yisheng Chen, Xiaohong Qi, and Rong (Ron) Liu</i>	
<b>Chapter 4</b> Preformulation Aspects of Insoluble Compounds .....	61
<i>Wei-Qin (Tony) Tong and Hong Wen</i>	
<b>Chapter 5</b> Water-Insoluble Drugs and Their Pharmacokinetic Behaviors .....	91
<i>Honghui Zhou</i>	
<b>Chapter 6</b> Regulatory Aspects of Dissolution for Low Solubility Drug Products .....	101
<i>Pradeep Sathe, Robert A. Lionberger, Sau Lawrence Lee, and Lawrence X. Yu</i>	
<b>Chapter 7</b> Formulation Strategies and Practice Used for Drug Candidates with Water-Insoluble Properties for Toxicology, Biology, and Pharmacology Studies in Discovery Support .....	113
<i>Lian-Feng Huang, Shyam B. Karki, Örn Almarsson, and Jinquan Dong</i>	
<b>Chapter 8</b> Applications of Complexation in the Formulation of Insoluble Compounds .....	133
<i>Wei-Qin (Tony) Tong and Hong Wen</i>	
<b>Chapter 9</b> Solubilization Using Cosolvent Approach .....	161
<i>Jay S. Trivedi</i>	
<b>Chapter 10</b> Emulsions, Microemulsions, and Lipid-Based Drug Delivery Systems for Drug Solubilization and Delivery—Part I: Parenteral Applications .....	195
<i>John B. Cannon, Yi Shi, and Pramod Gupta</i>	
<b>Chapter 11</b> Emulsions, Microemulsions, and Lipid-Based Drug Delivery Systems for Drug Solubilization and Delivery—Part II: Oral Applications .....	227
<i>John B. Cannon and Michelle A. Long</i>	
<b>Chapter 12</b> Micellization and Drug Solubility Enhancement .....	255
<i>Rong (Ron) Liu, Rose-Marie Dannenfelser, and Shoufeng Li</i>	

<b>Chapter 13</b> Micellization and Drug Solubility Enhancement Part II: Polymeric Micelles ....	307
<i>Rong (Ron) Liu, M. Laird Forrest, and Glen S. Kwon</i>	
<b>Chapter 14</b> Liposomes in Solubilization .....	375
<i>Rong (Ron) Liu, John B. Cannon, and Sophia Y.L. Paspal</i>	
<b>Chapter 15</b> Pharmaceutical Salts .....	417
<i>Steven H. Neau</i>	
<b>Chapter 16</b> Prodrugs for Improved Aqueous Solubility.....	437
<i>Steven H. Neau</i>	
<b>Chapter 17</b> Particle Size Reduction .....	467
<i>Robert W. Lee, James McShane, J. Michael Shaw, Ray W. Wood, and Dinesh B. Shenoy</i>	
<b>Chapter 18</b> Development of Solid Dispersion for Poorly Water-Soluble Drugs .....	499
<i>Madhav Vasanthavada, Wei-Qin (Tony) Tong, and Abu T.M. Serajuddin</i>	
<b>Chapter 19</b> Alteration of the Solid State of the Drug Substances: Polymorphs, Solvates, and Amorphous Forms .....	531
<i>Paul B. Myrdal and Michael J. Jozwiakowski</i>	
<b>Chapter 20</b> Pharmaceutical Powder Technology—Building the Pyramid of Knowledge and the Challenge of FDA’s PAT Initiative .....	567
<i>Hans Leuenberger, Silvia Kocova El-Arini, and Gabriele Betz</i>	
<b>Chapter 21</b> Soft Gelatin Capsules Development .....	589
<i>S. Esmail Tabibi and Shanker L. Gupta</i>	
<b>Chapter 22</b> Oral Modified-Release Drug Delivery for Water-Insoluble Drugs .....	609
<i>Shaoling Li, Nuo (Nolan) Wang, and Rong (Ron) Liu</i>	
<b>Chapter 23</b> Scalable Manufacturing of Water-Insoluble Drug Products .....	637
<i>Nitin P. Pathak and Richard (Ruey-ching) Hwang</i>	
<b>Index</b> .....	663