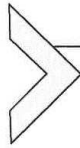


Profiles of
**Drug Substances,
Excipients, and
Related Methodology**
Volume 46





VOLUME FORTY SIX

**PROFILES OF
DRUG SUBSTANCES,
EXCIPIENTS, AND RELATED
METHODOLOGY**

Contents

| | |
|---|------------|
| <i>Contributors</i> | <i>vii</i> |
| <i>Preface</i> | <i>ix</i> |
| 1. Darunavir: A comprehensive profile | 1 |
| Ibrahim A. Darwish, Abdulrahman A. Al-Majed, Nawaf A. Alsaif, Ahmed H. Bakheit, Rashed N. Herqash, and Abdullah Alzaid | |
| 1. Description | 2 |
| 2. Uses and applications | 4 |
| 3. Methods of preparation | 4 |
| 4. Physical characteristics | 11 |
| 5. Methods of analysis | 19 |
| 6. Pharmacological properties | 38 |
| 7. Dosing information | 40 |
| References | 43 |
| 2. Bisoprolol: A comprehensive profile | 51 |
| Ahmed H. Bakheit, Raisuddin Ali, Ali D. Alshahrani, and Adel S. El-Azab | |
| 1. Description | 52 |
| 2. Methods of preparation of bisoprolol | 53 |
| 3. Physical characteristics | 55 |
| 4. Method of analysis | 62 |
| 5. Stability | 83 |
| 6. Clinical applications | 83 |
| References | 85 |
| 3. Betaxolol: A comprehensive profile | 91 |
| Majed J. Al-wadei, Ahmed H. Bakheit, Alaa A.-M. Abdel-Aziz, and Tanveer A. Wani | |
| 1. Description | 92 |
| 2. Method of preparation | 95 |
| 3. Physical characteristics | 98 |
| 4. Method of analysis | 104 |
| 5. Stability | 125 |
| 6. Pharmacology | 128 |
| References | 133 |

| | |
|---|------------|
| 4. Rabeprazole: A comprehensive profile | 137 |
| Ahmed H. Bakheit, Hamad M. Al-Kahtani, and Salem Albraiki | |
| 1. Description | 138 |
| 2. Methods of preparation | 140 |
| 3. Physical characteristics | 144 |
| 4. Characterization and identification | 145 |
| 5. Methods of analysis | 154 |
| 6. Stability | 166 |
| 7. Uses | 168 |
| 8. Pharmacology | 169 |
| References | 177 |
| 5. Irbesartan (a comprehensive profile) | 185 |
| Ibrahim A. Darwish, Hany W. Darwish, Ahmed H. Bakheit, Hamad M. Al-Kahtani, and Zahi Alanazi | |
| 1. Description | 186 |
| 2. Methods of synthesis | 188 |
| 3. Physical characteristics | 192 |
| 4. Thermal analysis | 195 |
| 5. Spectroscopic analysis | 196 |
| 6. Methods of analysis | 201 |
| 7. Stability and impurity profiling | 254 |
| 8. Pharmacological properties | 256 |
| 9. Dosing information | 258 |
| 10. Toxicology | 260 |
| References | 262 |
| 6. Validation of <i>in-vitro</i> bioassay methods: Application in herbal drug research | 273 |
| Gunawan Indrayanto, Galih Satrio Putra, and Farida Suhud | |
| 1. Introduction | 273 |
| 2. Definition, principle and objective of the bioassay | 276 |
| 3. Strategy for developing a bioassay and its validation | 278 |
| 4. <i>In-vitro</i> toxicity testing | 290 |
| 5. Determination the relative potency of sample using authentic standard | 291 |
| 6. Summary and recommendations | 298 |
| Acknowledgments | 299 |
| References | 301 |
| <i>Cumulative index</i> | 309 |
