

Contents

<i>Foreword</i>	<i>vii</i>
<i>Preface</i>	<i>xi</i>

1. CAPSULES

Introduction	1
Hard gelatin capsules	2
Raw materials used	3
Angle of repose	6
Capsule filling devices	13
Liquids in hard gelatin capsules	15
Difficulties in filling capsules	16
Soft-gelatin capsules	17
Materials to be filled	20
Large-scale manufacture	23
Seamless gelatin capsules	23
Ingredients used in formulation of soft-gelatin capsules	24
Quality control of capsules	25

2. MICROENCAPSULATION

Definition	44
Core material	44
Coating material	44
Application of microencapsulation in pharmacy	45
Microencapsulation techniques	46
Chemical methods	47
Physicochemical methods	49
Mechanism of microcapsule formation	49
Complex coacervation—general outline	55

3. TABLETS

Advantages of the tablet	72
Disadvantages of tablet	72
Different types of tablets	73
Tablets ingested orally	73
Tablets used in oral cavity	74
Tablets administered by other route	75
Tablets used to prepare solution	76
Tablet excipients	77
Diluents	77
Classification of diluents	79
Binders	81
Disintegrant	85
Miscellaneous excipients	92
Tablet manufacturing	97
Tablet manufacturing methods	102
Slugging process	108
Roller compaction	109
Formulation for dry granulation	109
Direct compression	109
Manufacturing steps for direct compression	111
Advancement in granulations	114
Steam granulation	114
Melt granulation (thermoplastic granulation)	114

- Moisture activated dry granulation (MADG) 114
- Thermal adhesion granulation process (TAGP) 115
- Foam granulation 115
- Problems in tablet manufacturing 115
- Tablet testing 123
- General appearance 124
- Size and shape 124
- Organoleptic properties 125
- Assay 125
- Content uniformity test 125
- Hardness or crushing strength 127
- Tablet disintegration 127
- Friability test 130
- Dissolution 132
- Procedure 134

4. TABLET COATING

144

- Advantages of tablet coating 144
- Type of tablet coating process 145
 1. Sugar coating 145
 2. Film coating 147
- Materials used in film coating 148
- Solvents 151
- Plasticizers 151
- Colourants 152
- Opacifier 152
- Miscellaneous coating solution component 153
 3. Enteric coating 153
 4. Specialized coating 155
- Factors affecting coating 156
- Conventional pan system 157
- Immersion sword 158
- Immersion tube 158
- Accela-cota and driacoater systems 159
- Fluidized bed dryer (FBD) 160
- Principle of operation 160
- Bottom spray coating (continuous fluid bed) 162
- Tangential spray coating (rotor pellet coating) 162
- Problems in tablet coating 163
- Evaluation of coated tablets 168
- Isolated key points 169
- Coating problems and remedy 170

5. SUSTAINED AND CONTROLLED RELEASE DOSAGE FORMS

174

- Definition 174
- Classification 174
- Physicochemical properties of drug 177
- Biological properties 182
- Pharmacokinetics 182
- Pharmacodynamic characteristics 182
- Oral controlled release systems 185
- Dissolution controlled release systems 186
- Matrix dissolution controlled systems 186
- Coating dissolution controlled systems 187
- Diffusion controlled release systems 187
- Matrix diffusion controlled systems 187
- Dissolution and diffusion controlled release systems 189
- Ion exchange resin-drug complexes 189

6. OPHTHALMIC PRODUCTS**220**

Physiology of eye 221
 Ideal ophthalmic formulations 222
 Important characteristics required for ophthalmic preparation 222
 Various types of ophthalmic products 224
 Eye drops 224
 Formulation of eye drops 224
 Excipients used in eye drops 225
 Precaution used in handling eye drops 226
 Eye-lotions 226
 Formulation of eye-lotion 226
 Eye ointments 227
 Formulation of eye ointments 227
 Contact lens solutions 228

Soft contact lens liquid 229
 Enhancement in controlled drug-delivery 231
 1. In situ forming gels 231
 2. Oil in water emulsions 232
 3. Colloidal particles 232
 4. Liposomes 232
 5. Nanoparticles 234
 6. Micro particulates 234
 7. Inserts 235
 8. Implantable systems 235
 9. Minidisc 236
 10. Soft contact lenses 236
 11. Niosomes 236
 12. Pharmacosomes 236
 13. Collagen shields 236
 Recent advances 237

7. NASAL PRODUCTS**250**

Advantages 250
 Disadvantages 251
 Limitations 251
 Drug concentration, dose and dose volume 254

Formulation pH 255
 Buffer capacity 255
 Osmolarity 255
 Formulation ingredients 256

8. OTIC (EAR) PRODUCTS**279**

Anatomy of ear 279
 External or outer ear 279
 Middle ear (tympanic cavity) 280
 Inner ear 280
 Applications 284
 Drawbacks 284
 Microcatheter injection 284

Osmotic pump 287
 Reciprocating perfusion system 287
 Drawbacks 287
 Evaluation of otic products 287
 Particle size determination 287

9. PARENTERAL PRODUCTS**298**

Definition 289
 Classifications 299
 Classification of injections on the basis of injection volumes 303
 Preformulation studies of parenteral formulation 304

Components of parenteral formulation 306
 Vehicles 306
 Container types 316
 Plastic 316
 Glass 317

Closure	319	Method 1	330
Rubber closure	319	Method 2	330
Criteria for selecting closure	320	Important unit operations	
Rubber closures compendial		involved during parenteral	
test series	327	preparation	331
Elastomeric closure/plunger test		Ampoule filling	335
series	327	Features of ampoule filling	
Compendial drug product		machines	335
testing	322	Sealing	335
Plastics test series	323	Sealing of vials and bottles	337
Pharmaceutical container		Lyophilization	340
testing	323	Methods of sample frozen	341
Container closure integrity		Characteristics of the finished	
testing methodologies	324	product	346
Helium leak testing	324	Contamination of the	
Method of preparing parenteral		lyophilizer	346
suspension and solution	329	Clean room area for sterile	
		products	349

10. PACKAGING OF PHARMACEUTICALS

362

Packaging types	362	Glass	366
Functions of packaging	363	Types of glass used for pharma-	
Desirable qualities of good		ceutical packaging	370
containers	365	Paper and board	375
Types of containers	365	Package validation	376
Materials used for containers	366		

Appendices

<i>Appendix 1: List of some commonly used additives</i>	383
<i>Appendix 2: Units and conversion factors</i>	388
<i>Glossary</i>	391
<i>Index</i>	403