

HANDBOOK OF  
Pharmaceutical  
Manufacturing  
Formulations

*Compressed Solid Products*

VOLUME 1

Sarfaraz K. Niazi



CRC PRESS

---

# Table of Contents

## Part I

### Regulatory and Manufacturing Requirements in Compressed Solid Dosage Forms .....

#### Chapter 1

Bioavailability and Bioequivalence Studies for Orally Administered Drug Products.....	3
I.      Introduction .....	3
II.     Background .....	3
A.    General .....	3
B.    Bioavailability .....	4
C.    Bioequivalence .....	4
1.    INDs/NDAs.....	4
2.    ANDAs.....	5
3.    Postapproval Changes.....	5
III.    Methods to Document BA and BE.....	5
A.    Pharmacokinetic Studies.....	5
1.    General Considerations.....	5
2.    Pilot Study .....	6
3.    Pivotal Bioequivalence Studies .....	6
4.    Study Designs .....	6
5.    Study Population.....	6
6.    Single-Dose/Multiple-Dose Studies .....	6
7.    Bioanalytical Methodology .....	6
8.    Pharmacokinetic Measures of Systemic Exposure .....	7
B.    Pharmacodynamic Studies.....	7
C.    Comparative Clinical Studies .....	7
D. <i>In Vitro</i> Studies .....	7
IV.     Comparison of BA Measures in BE Studies.....	8
V.      Documentation of BA and BE.....	8
A.    Solutions.....	9
B.    Suspensions.....	9
C.    Immediate-Release Products: Capsules and Tablets .....	9
1.    General Recommendations.....	9
2.    Waivers of <i>In Vivo</i> BE Studies (Biowaivers) .....	9
D.    Modified-Release Products .....	10
1.    NDAs: BA and BE Studies .....	10
2.    ANDAs: BE Studies .....	10
3.    Waivers of <i>In Vivo</i> BE Studies (Biowaivers); NDAs and ANDAs .....	11
4.    Postapproval Changes.....	11
E.    Miscellaneous Dosage Forms .....	11
VI.     Special Topics.....	11
A.    Food-Effect Studies.....	11
B.    Moieties to Be Measured .....	11
1.    Parent Drug vs. Metabolites .....	11
2.    Enantiomers vs. Racemates .....	12
3.    Drug Products with Complex Mixtures as the Active Ingredients.....	12

C.	Long Half-Life Drugs .....	12
D.	First Point C <sub>max</sub> .....	13
E.	Orally Administered Drugs Intended for Local Action .....	13
F.	Narrow Therapeutic Range Drugs .....	13
Appendix 1A — General Pharmacokinetic Study Design and Data Handling.....		15
<b>Chapter 2</b>		
Guidance on Formulating Compressed Solids .....		17
I.	Abbreviated Directions .....	17
II.	API.....	17
III.	Bio vs. Production Batches .....	17
IV.	Cleaning Validation .....	17
V.	Coatings.....	17
VI.	Compliance with Regulatory Requirements .....	18
VII.	Compression Process Control.....	18
VIII.	Content Uniformity .....	18
IX.	Cross-Contamination.....	18
X.	Desegregation of Powders.....	18
XI.	Disintegration Test .....	19
	A. Uncoated Tablets .....	19
	B. Plain Coated Tablets .....	19
	C. Delayed-Release (Enteric-Coated) Tablets .....	19
	D. Buccal Tablets .....	19
	E. Sublingual Tablets .....	19
XII.	Dissolution.....	19
XIII.	Disintegration and Dissolution .....	20
XIV.	Drug Substance Characterization.....	20
XV.	Drying Process .....	20
XVI.	Dyes in Formulations .....	20
XVII.	Equipment .....	20
	A. Blenders .....	20
	1. Pony Pan .....	21
	2. Ribbon .....	21
	3. Tumbler .....	21
	4. High-Shear (High-Energy) .....	21
	5. Plastic Bag .....	22
	B. Dryers .....	22
	C. Tablet Compression Equipment .....	22
	D. Coating Equipment .....	22
XVIII.	Excipients .....	23
	A. Coating Agent .....	23
	B. Glidant.....	23
	C. Tablet Binder.....	23
	D. Diluent.....	23
	E. Disintegrant .....	23
	F. Lubricant .....	23
XIX.	Fill Weights .....	24
XX.	Final Packaging .....	24
XXI.	Final Testing .....	25
XXII.	Fines .....	25
XXIII.	Formula Excesses .....	25
XXIV.	Geometric Dilution .....	25
XXV.	Granulation/Mix Analysis .....	25
XXVI.	Ingredient Warning .....	26

XXVII.	In-Process Testing .....	26
XXVIII.	Loss on Drying (LOD) .....	26
XXIX.	Manufacturing Yields .....	27
XXX.	Master Formula .....	27
XXXI.	Multiple-Item Entries .....	27
XXXII.	Multiple Strengths of Formulations .....	27
XXXIII.	Novel Drug Delivery Systems .....	27
XXXIV.	Particle Coating .....	28
XXXV.	Preservatives in Compressed Solid Dosage Formulations .....	28
XXXVI.	Punch Size and Shape .....	28
XXXVII.	Reworking Culls .....	28
XXXVIII.	Scale-Up .....	28
XXXIX.	Segregation .....	29
XXXV.	Sifting Ingredients and Granules .....	29
XXXVI.	Specifications .....	29
XXXVII.	Stability Testing .....	29
XXXVIII.	Storage of In-Process Material .....	30
XXXIX.	Tablet Friability .....	30
XL.	Tablet Manufacturing .....	30
XLI.	Tablets .....	30
XLII.	Water-Purified USP .....	31
XLIII.	Weight Variation and Content Uniformity .....	31
XLIV.	Wet Granulation vs. Dry Granulation or Direct Compression .....	32

## Part II

### Compressed Solid Formulations..... 33

Acetaminophen, Ibuprofen, and Orphenadrine Tablets (250 mg/200 mg/200 mg) .....	35
Acetaminophen, Norephedrine, and Phenyltoloxamine Tablets (300 mg/25 mg/22 mg) .....	35
Acetaminophen and Phenprobamat Tablets (200 mg/200 mg) .....	36
Acetaminophen and Orphenadrine Citrate Tablets (450 mg/35 mg) .....	37
Acetaminophen Tablets, Chewable .....	38
Acetaminophen, Dextropropoxyphen Hydrochloride Tablets (325 mg/32 mg) .....	39
Acetaminophen and Codeine Tablets [34] .....	40
Acetaminophen, Salicylamide, Caffeine, and Codeine Tablets (150 mg/200 mg/50 mg/10 mg) .....	41
Acyclovir Tablets [162] .....	42
Acyclovir Water-Dispersible Tablets (800 mg) .....	42
Albendazole Tablets (200 mg) .....	43
Alendronate Tablets [38] .....	44
Alendronate Tablets, Effervescent (10 mg) .....	44
Alendronate Sodium Tablets (50 mg) .....	44
Allopurinol Tablets (100 mg) [84] .....	45
Allopurinol Tablets (300 mg) .....	46
Alprazolam Tablets (0.25 mg/0.50 mg/1.0 mg) .....	47
4-Amino-1-hydroxybutylidene-1,1-bisphosphonic Acid Tablets (5 mg) .....	48
Aminophylline Tablets (100 mg) .....	48
Amiodarone Tablets (200 mg) .....	49
Amlodipine Besylate Tablets [9] .....	50
Amitriptyline Tablets (50 mg) [42] .....	51
Amoxicillin Tablets (250 mg/500 mg/1 g) .....	52
Amoxicillin Trihydrate and Clavulanate Potassium Tablets (500 mg/125 mg) .....	53
Amoxicillin and Potassium Clavulanate Tablets (250 mg/62.5 mg) .....	54
Amphetamine Salts Tablets .....	54
Atenolol Tablets (50 mg/100 mg) .....	55

Atorvastatin Tablets (10 mg/20 mg).....	57
Azithromycin Tablets (250 mg).....	58
Benzafibrate Tablets (200 mg).....	59
Benzepril Hydrochloride Tablets.....	60
Betamethasone Tablets (0.50 mg).....	61
BIRB 796 Tablets (100 mg).....	61
Bisoprolol Fumarate and Hydrochlorothiazide Tablets.....	62
Bromazepam Tablets (3 mg).....	62
Bromhexine Tablets (8 mg).....	63
Bromocriptine Tablets.....	63
Buflomedil Hydrochloride Tablets (150 mg/300 mg).....	64
Buflomedil Hydrochloride Tablets (600 mg).....	65
Bupropion Hydrochloride Tablets.....	66
Buspirone Hydrochloride Tablets.....	67
Buspirone Hydrochloride Tablets, Controlled-Release (30 mg).....	67
Captopril Tablets (25 mg).....	68
Carbamazepine Tablets (200 mg).....	69
Carbamazepine Tablets (200 mg).....	70
Carbidopa and Levodopa Tablets.....	70
Carisoprodol Tablets.....	71
Carvedilol Tablets.....	71
Cefadroxil Dispersible Tablets (250 mg).....	72
Cefdinir Tablets (300 mg).....	72
Cefixime Tablets (400 mg).....	73
Cefprozil Tablets (250 mg).....	73
Celecoxib Tablets .....	74
Cephalexin Tablets .....	74
Cetirizine and Pseudoephedrine Delayed-Release Tablets (5 mg/120 mg).....	74
Cetirizine Hydrochloride Tablets (10 mg).....	75
Chlorcyclizine Hydrochloride Tablets (50 mg).....	75
Chlordiazepoxide and Clonidium Bromide Tablets (5 mg/2.5 mg).....	76
Chlordiazepoxide Tablets (10 mg).....	76
Chloroquine Tablets (250 mg).....	77
Choline Theophyllinate Tablets (100 mg).....	77
Chymotrypsine Tablets (25 mg).....	77
Cilazapril Tablets (2.5 mg) .....	78
Cimetidine Tablets (200 mg) .....	79
Ciprofloxacin Tablets (500 mg) .....	80
Ciprofloxacin Tablets (750 mg) .....	81
Cisapride Tablets (5 mg) .....	82
Citalopram Hydrobromide Tablets .....	82
Clarithromycin Tablets (250 mg/500 mg) .....	83
Clenbuterol Tablets (20 mcg).....	84
Clindamycin Tablets (20 mg).....	84
Clobazam Tablets (10 mg).....	85
Clomifen Citrate Tablets (50 mg) .....	85
Clomipramine Hydrochloride Tablets, Effervescent (300 mg) .....	85
Clomipramine Hydrochloride Tablets, Buccal (10 mg) .....	86
Clonazepam Tablets (1 mg/2 mg) .....	86
Clonidine Tablets (0.1 mg/0.2 mg/0.3 mg) .....	86
Clopidogrel Bisulfate Tablets (75 mg) .....	87
Codeine, Acetaminophen, and Pentobarbital Tablets (15 mg/300 mg/30 mg) .....	87
Conjugated Estrogens (0.3–2.50 mg) .....	88
Conjugated Estrogens and Medroxyprogesterone Tablets .....	89
Coumadin Tablets.....	89

Cyclobenzaprine Hydrochloride Tablets (10 mg) [64].....	90
Cyproheptadine Tablets (4 mg).....	90
Dapsone Tablets (50 mg) .....	91
Desloratadine Tablets (5 mg).....	91
Desogestrel and Ethynodiol Diacetate Tablets (0.15 mg/0.03 mg) .....	91
Diazepam Tablets (2 mg/5 mg/10 mg) .....	92
Diclofenac Sodium Tablets (25 mg).....	93
Diclofenac Sodium Tablets (50 mg).....	94
Diclofenac Sodium Tablets (100 mg).....	94
Didanosine Tablets (50 mg).....	95
Diethylcarbamazine Tablets (100 mg).....	95
Difenoxin and Atropine Tablets (0.5 mg/0.025 mg) .....	96
Digoxin Tablets (0.125 mg/0.25 mg) [92].....	96
Diltiazem Hydrochloride Tablets (60 mg).....	97
Diltiazem Tablets 60 mg [95] .....	98
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets (2.5 mg/0.025 mg).....	98
Divalproate Sodium Tablets (125 mg) [121] .....	99
Divalproex Sodium Tablets (400 mg).....	100
Doxazosin Mesylate Tablets (1 mg/2 mg/4 mg/8 mg) [112].....	100
Doxycycline Hydrochloride Tablets (100 mg) [91] .....	101
Enalapril Maleate Tablets (2.5 mg/5 mg/10 mg/20 mg) [66] .....	102
Enalapril Maleate Tablets (10 mg) .....	102
Enoxacin Tablets (400 mg) .....	103
Erythromycin Ethylsuccinate Tablets (400 mg) .....	104
Erythromycin Particle-Coated Tablets (150 mg) .....	105
Erythromycin Tablets (100 mg).....	106
Erythromycin Tablets (100 mg).....	106
Erythromycin Tablets (500 mg).....	107
Estazolam Tablets (1 mg).....	109
Estazolam Tablets (2 mg).....	109
Estradiol Tablets (0.5 mg/1 mg/2 mg) [85] .....	110
Estropipate Tablets (0.626 mg/1.25 mg/2.25 mg/5 mg) .....	110
Ethambutol Tablets (400 mg).....	111
Ethambutol Tablets (800 mg).....	112
Etophylline and Theophylline Tablets (100 mg/22 mg).....	113
Etophylline and Theophylline Tablets (100 mg/22 mg).....	113
Famiciclovir Tablets (125 mg/250 mg) .....	114
Famotidine Tablets (20 mg) [146] .....	115
Famotidine Tablets (40 mg) .....	116
Fexofenadine Tablets (30 mg/60 mg/180 mg) [26] .....	116
Fexofenadine and Pseudoephedrine Tablets (10 mg/240 mg) [111] .....	117
Finasteride Tablets (5 mg) .....	118
Fluconazole Tablets (50 mg/100 mg/200 mg) [75] .....	118
Fluvoxamine Maleate Tablets (50 mg) .....	119
Fluoxetine Hydrochloride Tablets (10 mg/20 mg/40 mg) [33] .....	120
Fluoxetine Hydrochloride Tablets (12.5 mg/25.0 mg) Controlled-Release Bilayer .....	121
Fosinopril Tablets (20 mg) [133] .....	122
Fucidine Tablets (125 mg) .....	122
Furazolidone Tablets (100 mg) .....	123
Furosemide Tablets (40 mg) [7] .....	123
Furosemide Tablets (40 mg) .....	124
Furosemide Tablets (200 mg) .....	125
Gabapentin Tablets (600 mg) .....	125
Glanthamine Hydrobromide Tablets (1 mg) .....	126
Gemfibrozil Tablets (600 mg) [114] .....	127

Glibenclamide Tablets (2.5 mg).....	128
Glibenclamide Tablets (5 mg).....	129
Gliclazide Tablets (80 mg).....	130
Glimepiride Tablets (1 mg/2 mg) [129] .....	131
Glipizide Tablets (5 mg) [71] .....	132
Glipizide Tablets CR (5 mg).....	133
Glyburide and Metformin Tablets (250 mg/500 mg; 1.25 mg/2.50 mg) [124].....	134
Glyburide Tablets (5 mg) [81] .....	135
Griseofulvin Tablets (125 mg).....	136
Griseofulvin Tablets (500 mg).....	136
Hydrochlorothiazide and Potassium Chloride (50 mg/300 mg).....	137
Hydrochlorothiazide Tablets (50 mg) [10].....	137
Hydrochlorothiazide Tablets (50 mg).....	138
Hydrocodone and Acetaminophen Tablets (5.0 mg/500 mg; 7.50 mg/750 mg).....	139
Hydrocodone and Ibuprofen Tablets.....	140
Hydroxyzine Tablets [132].....	140
Hyoscine Butyl Bromide Tablets (10 mg).....	141
Ibuprofen Tablets (400 mg) [19].....	142
Ibuprofen Tablets (400 mg).....	143
Ibuprofen Tablets (600 mg).....	144
Imipramine Tablets (25 mg).....	144
Irbesartan Tablets (75 mg/150 mg/300 mg) [149] .....	145
Isoniazid Tablets (100 mg).....	146
Isosorbide Dinitrate Tablets (5 mg) [68] .....	147
Isosorbide Dinitrate Tablets (10 mg) .....	147
Ketotifen Tablets (1 mg) .....	148
Lamotrigine Tablets (100 mg) .....	148
Lansoprazole Tablets (10 mg or 20 mg) .....	149
Lansoprazole Tablets (10 mg or 20 mg) .....	149
Lansoprazole Tablets Chewable (10 mg/20 mg) .....	149
Lansoprazole Tablets, Rapid Dissolution (20 mg) .....	150
Levamisole Hydrochloride Tablets (40 mg) .....	150
Levamisole Tablets (150 mg).....	151
Levofoxacin Tablets (250 mg) [69] .....	151
Levothyroxine Tablets [4] .....	151
Levothyroxine Tablets (50 mcg) [25] .....	152
Levothyroxine Tablets (0.025 mg) .....	152
Linezolid Tablets (400 mg) .....	153
Lisinopril Tablets (10 mg) [52].....	153
Lomefloxacin Hydrochloride Tablets (400 mg) .....	154
Loperamide Hydrochloride Tablets (2 mg) .....	154
Loratadine and Pseudoephedrine Sulfate Tablets (10 mg/240 mg) [127] .....	155
Loratadine Tablets (10 mg) [32] .....	156
Lorazepam Tablets (0.50 mg/1 mg/2 mg) [37] .....	157
Losartan and Hydrochlorothiazide Tablets (50 mg/12.5 mg) [118] .....	157
Losartan Potassium Tablets (50 mg) [93] .....	158
Mebendazole Tablets (100 mg) .....	159
Meclizine Hydrochloride Tablets (25 mg) [135] .....	159
Medroxyprogesterone Acetate Tablets (2.5 mg/5 mg/10 mg) [89] .....	159
Mefenamic Acid and Dicyclomine Hydrochloride Tablets (250 mg/10 mg) .....	160
Mefenamic Acid Tablets (250 mg) .....	160
Mefloquine Hydrochloride Tablets (250 mg) .....	161
Meprobamate and Phenobarbital Tablets (400 mg/30 mg) .....	161
Meprobamate and Phenobarbital Tablets (400 mg/30 mg) .....	162
Meprobamate Tablets (400 mg) .....	162

Meprobamate Tablets (400 mg).....	163
Metamizol Tablets (500 mg).....	163
Metamizol Tablets (500 mg).....	164
Metformin Hydrochloride Tablets, Extended Release (500 mg) .....	165
Metformin Tablets (500 mg) [40].....	166
Metformin Tablets, Extended Release (500 mg).....	167
Methenamine Tablets (500 mg).....	167
Methyclothiazide and Deserpidine Tablets (5 mg/0.25 mg) .....	168
Methyclothiazide Tablets (5 mg) .....	169
Methylergotamine Malate Tablets (0.5 mg) .....	170
Methylphenidate Hydrochloride Tablets Extended Release (18 mg/36 mg) [122] .....	170
Methylprednisolone Tablets (2 mg/4 mg/8 mg/16 mg/24 mg/32 mg) [99].....	171
Metoclopramide Tablets (10 mg) [138].....	171
Metoclopramide Tablets (20 mg).....	172
Metoprolol Succinate Tablets (95 mg) [21] .....	173
Metoprolol Tartrate Tablets [36] .....	173
Metronidazole Effervescent Vaginal Tablets (500 mg) .....	174
Metronidazole, Furazolidone, and Loperamide Tablets (200 mg/25 mg/2 mg) .....	174
Metronidazole Tablets (200 mg).....	175
Metronidazole Tablets (200 mg/400 mg) .....	176
Metronidazole Tablets (400 mg) [147] .....	177
Metronidazole Tablets (500 mg).....	177
Mirtazapine Tablets [145] .....	178
Montelukast Sodium Tablets (5 mg) [54] .....	178
Nalidixic Acid Tablets (500 mg).....	179
Nalidixic Acid Tablets (500 mg).....	179
Naproxen Tablets (250 mg) [58].....	180
Naproxen Tablets (250 mg/500 mg) .....	181
Naproxen Tablets (450 mg) .....	182
Neomycin Tablets (250 mg).....	182
Nifedipine Tablets (5 mg).....	183
Nifedipine Tablets (10 mg).....	183
Nimesulide Dispersible Tablets (100 mg) .....	184
Nitrendipine Tablets (25 mg).....	184
Nitrofurantoin Tablets (100 mg) .....	185
Nitrofurantoin Tablets (100 mg) .....	185
Nitroglycerine Tablets (0.3 mg) .....	186
Noramidopyrine Methansulfonate and Dicyclomine Hydrochloride Tablets (500 mg/10 mg).....	187
Norethindrone and Ethinyl Estradiol Tablets (0.75 mg/0.035 mg; 0.50 mg/0.035 mg; 1.0 mg/0.035 mg) [131] .....	188
Norfloxacin Tablets (400 mg) .....	189
Norgestimate and Ethinyl Estradiol Tablets (0.18 mg/0.035 mg; 0.215 mg/0.035; 0.25 mg/0.035 mg) [27].....	190
Nystatin Tablets (50 mg).....	190
Nystatin Tablets (200 mg).....	191
Olanzapine Tablets [110] .....	191
Omeprazole and Ibuprofen Tablets (10 mg/400 mg) .....	192
Omeprazole Tablets (10 mg/20 mg) .....	192
Omeprazole Tablets (10 mg/20 mg) .....	193
Omeprazole Tablets, Chewable (10 mg/20 mg) .....	193
Omeprazole Tablets, Rapid Dissolution (20 mg) .....	193
Oxybutynin Chloride Tablets (5 mg/10 mg) [194] .....	194
Oxycodone Hydrochloride and Acetaminophen Tablets (5 mg/325 mg) [90] .....	195
Oxycodone Hydrochloride Tablets (5 mg) [119] .....	196
Oxytetracycline Tablets (250 mg) .....	196
Pantoprazole Tablets [77].....	196
Pantoprazole Tablets (10 mg/20 mg) .....	197

Pantoprazole Tablets, Chewable (10 mg/20 mg).....	197
Pantoprazole Tablets, Rapid Dissolution (20 mg).....	198
Para Amino Salicylic Acid Tablets (500 mg).....	199
Paroxetine Hydrochloride Tablets (10 mg/20 mg/30 mg/40 mg) [15] .....	200
Penicillin Chewable Tablets (125 mg) [103].....	201
Perfloxacin Tablets (400 mg).....	202
Phendimetrazine Tablets (35 mg).....	202
Phenindion Tablets (50 mg).....	203
Phenoxy methyl Penicillin Potassium Tablets (250 mg).....	204
Phenylbutazone Tablets (100 mg).....	205
Phenylpropanolamine Hydrochloride Tablets (60 mg).....	206
Phenytoin Sodium Tablets (100 mg).....	206
Phenytoin Sodium Tablets (100 mg).....	207
Phenytoin Tablets (100 mg).....	207
Pioglitazone Hydrochloride Tablets (15 mg/30 mg/45 mg) [87].....	208
Pipemidic Acid Tablets (200 mg).....	209
Pipobroman Tablets (25 mg).....	210
Potassium Chloride Tablets (30 mg) [56, 137].....	211
Pravastatin Sodium Tablets (10 to 40 mg) [48] .....	212
Prazosin Tablets (5 mg) .....	212
Prednisolone Tablets (5 mg).....	213
Prednisolone Tablets (10 mg).....	214
Prednisolone Tablets (20 mg) .....	214
Prednisolone Tablets (20 mg).....	214
Prednisone Tablets (10 mg) .....	215
Probenecid Tablets (500 mg) .....	215
Promethazine Hydrochloride Tablets (10 mg) [107].....	216
Promethazine Hydrochloride Tablets (25 mg).....	217
Propranolol Hydrochloride Tablets (10 mg).....	217
Propranolol Tablets (40 mg) .....	217
Propranolol Hydrochloride Tablets (10 mg) [141].....	218
Pyrazinamide Tablets (500 mg) .....	219
Pyrazinamide Tablets (500 mg) .....	219
Pyrazinamide Tablets (500 mg) .....	220
Pyridostigmine Bromide Tablets (10 mg).....	221
Quetiapine Fumarate Tablets (25 mg/100 mg/200 mg) [161] .....	221
Quinapril Hydrochloride Tablets (5 mg/10 mg/20 mg/40 mg) [51] .....	222
Quinine Sulfate Tablets (300 mg).....	223
Quinolone Antibiotic Tablets (100 mg) .....	223
Rabeprazole Sodium Tablets (20 mg) [109].....	224
Raloxifene Tablets (60 mg) [100].....	225
Ranitidine Hydrochloride Tablets (150 mg) .....	226
Ranitidine Tablets (75 mg).....	226
Ranitidine Tablets (150 mg) [41].....	227
Ranitidine Tablets (300 mg) .....	228
Rifampicin, Isoniazid, Ethambutol, and Pyridoxine Tablets (300 mg/200 mg/25 mg) .....	229
Rifampicin Tablets (300 mg) .....	231
Rifampicin Tablets (450 mg) .....	232
Risedronate Sodium Tablets (5 mg/30 mg) [188] .....	233
Risperidone Tablets (4 mg) [1050] .....	234
Rofecoxib Tablets (12.5 mg/25 mg/50 mg) [31] .....	234
Rosiglitazone Maleate Tablets (2 mg/4 mg/8 mg) [86] .....	235
Roxithromycin Dispersible Tablets (200 mg).....	235
Salbutamol Tablets (2 mg) .....	236
Salbutamol Tablets (4 mg) .....	237

Serratiopeptidase Tablets (10 mg) .....	237
Serratiopeptidase Tablets (10 mg) .....	238
Sertraline Hydrochloride Tablets (25 mg/50 mg/100 mg) [14] .....	238
Sildenafil Tablets (25 mg/50 mg/100 mg) [43] .....	239
Silimaric Tablets (35 mg) .....	240
Simvastatin Tablets (10 mg) [17] .....	241
Simvastatin Tablets (20 mg) .....	242
Spironolactone Tablets (25 mg/50 mg/100 mg) [130] .....	242
Stalol Hydrochloride Tablets (500 mg) .....	243
Sulfadimidine Tablets (500 mg) .....	243
Sulfamethoxazole and Trimethoprim Tablets (400 mg/80 mg; 800 mg/160 mg; 100 mg/20 mg) ) [106] .....	244
Sulfamethoxazole and Trimethoprim Tablets (400 mg/80 mg) .....	245
Sulfamethoxazole and Trimethoprim Tablets (800 mg/160 mg; 400 mg/80 mg) .....	245
Sulfamethoxazole and Trimethoprim Tablets, Dispersible (800 mg/160 mg) .....	246
Sulfathiazole Tablets (250 mg) .....	247
Sumatriptan Succinate Tablets (25 mg/50 mg) [125] .....	247
Tamoxifen Tablets (10 mg/20 mg) [191] .....	248
Tenaxofloxacin Hydrochloride Tablets (200 mg/300 mg) .....	249
Tenoxicam Tablets (20 mg) .....	250
Terazosin Tablets (1 mg–10 mg) [126] .....	250
Terazosin Tablets (1 mg) .....	251
Terbinafine Tablets (250 mg) .....	252
Terfenadine Tablets (60 mg) .....	252
Tetracycline Tablets (125 mg) .....	253
Tetracycline Tablets (250 mg) .....	253
Tetrazepam Tablets (50 mg) .....	254
Theophylline and Ephedrine Tablets (130 mg/15 mg) .....	254
Theophylline Tablets (100 mg) .....	254
Theophylline Tablets (100 mg) .....	255
Theophylline Tablets CR (200 mg) .....	255
Tibolone Tablets (0.3 mg) .....	256
Ticlopidine Hydrochloride Tablets (250 mg) .....	256
Tolterodine Tablets (1 mg/2 mg) [171] .....	257
Topiramate Tablets (100 mg/200 mg) [189] .....	257
Tosufloxacin Tosylate Tablets (75 mg) .....	257
Trazodone Hydrochloride Tablets (100 mg) [61] .....	258
Triamcinolone Tablets (4 mg) .....	258
Trifluoperazine Tablets (5 mg) .....	258
Tulobuterol Hydrochloride Tablets (1 mg) .....	259
Valacyclovir Hydrochloride Tablets (500 mg/1 g) [144] .....	259
Valdecoxib Tablets (10 mg/20 mg) [148] .....	260
Valproate Sodium Tablets (500 mg) [121] .....	260
Valsartan and Hydrochlorothiazide Tablets (80 mg/12.5 mg; 160 mg/25 mg) [108] .....	261
Venlafaxine Hydrochloride Tablets (25 mg/37.5 mg/50 mg) [53] .....	262
Verapamil Tablets (120 mg) [65] .....	263
Warfarin Tablets (1, 2, 2.5, 3, 4, 5, 6, 7.5, and 10 mg) [59] .....	264
Zolpidem Tartrate Tablets (5 mg/10 mg) [35] .....	265

## Appendix

Coating Solutions .....	267
I.      Introduction .....	267
II.     Hydroxypropyl Methylcellulose (Methocel, HPMC) Aqueous Coatings .....	268
A.    Brite Rose .....	268
B.    Cherry Red .....	268

C.	Geranium Rose .....	269
D.	Gloss.....	269
E.	Red .....	269
F.	Moderate Red.....	269
G.	Clear .....	270
H.	Green .....	270
I.	Holberry Red.....	271
J.	Sun Orange .....	271
K.	Opadry Yellow (Caplets).....	271
L.	Opadry Yellow (Tabs) .....	272
M.	Opadry Red .....	272
N.	Opadry Green.....	272
O.	White Coating .....	273
III.	Hydroxypropyl Methylcellulose Opaque Organic Coating.....	273
A.	Brite Green.....	273
B.	Red Mahogany .....	274
C.	Sun Orange .....	274
D.	Dark Red .....	275
E.	Deep Yellow .....	275
F.	Pale Yellow.....	275
G.	Scarlet Red .....	275
IV.	Hydroxypropyl Methyl Cellulose-Hydroxypropyl Cellulose (Klucel) Coating.....	276
A.	White .....	276
V.	Hydroxypropyl Methylcellulose-Ethylcellulose Coating.....	276
A.	Reddish Orange Opaque .....	276
B.	Subcoating Solution .....	277
VI.	Hydroxymethyl Cellulose and Hydroxy Cellulose Coating.....	277
A.	Blue .....	277
B.	Clear (50:50) .....	277
VII.	Hydroxymethyl Cellulose and Ethyl Cellulose Coating.....	278
A.	Clear .....	278
VIII.	Polyvinylpyrrolidone Coatings .....	278
A.	Subcoating .....	278
B.	Kollidon VA 64 .....	279
C.	Kollidon VA 64 and Polyvinyl Alcohol .....	279
D.	Kollidon 30 and Shellac .....	280
E.	Kollidon VA 64 and Hydroxypropylmethyl Cellulose .....	280
F.	Povidone, Ethylcellulose, and Talc .....	281
IX.	Cellulose-Acetate Phthalate and Carbowax Coatings .....	281
A.	Brite Green .....	281
B.	Cherry Red .....	281
C.	Clear .....	282
D.	Orange .....	282
E.	Red Mahogany .....	282
F.	Orange .....	282
X.	Sugar Coatings .....	282
A.	Basic .....	282
B.	Automatic .....	283
C.	Manual White .....	283
XI.	Enteric Coatings .....	284
A.	Kollicoat and Kollidon Enteric Film Coating .....	284
B.	Eudragit Enteric Aqueous .....	284
1.	Brick Red .....	284
2.	Yellow .....	285
3.	Brown .....	285

4.	<b>Dark Orange</b>	285
5.	<b>Orange</b>	286
6.	<b>Dispersed Orange</b>	286
C.	<b>Hydroxypropyl Methylcellulose Phthalate Enteric Coating</b>	286
1.	<b>Clear Enteric</b>	286
2.	<b>Orchid Pink Opaque</b>	287
3.	<b>Light Apricot Orange</b>	287

<b>Index</b>	289
--------------	-----