

HANDBOOK OF
Pharmaceutical
Manufacturing
Formulations

Over-the-Counter Products

VOLUME 5

Sarfaraz K. Niazi



CRC PRESS

Table of Contents

Part I

Regulatory Guidance.....	1
Chapter 1	
Good Manufacturing Practices in Over-the-Counter Drug Product Manufacturing.....	3
I. Introduction.....	3
II. Buildings and Facilities (21 CFR 211, Subpart C)	3
III. Equipment (21 CFR 211, Subpart D)	3
IV. Components and Product Containers (21 CFR 211, Subpart E).....	4
V. Production and Process Controls (21 CFR 211, Subpart F).....	4
A. Critical Manufacturing Steps (21 CFR 211.101).....	4
B. Equipment Identification (21 CFR 211.105).....	5
C. In-Line and Bulk Testing (21 CFR 211.110).....	5
D. Actual Yield (21 CFR 211.103).....	5
E. Personnel Habits	5
F. Tablet and Capsule Products.....	5
G. Sterile Products	5
1. Personnel	6
2. Buildings.....	6
3. Air.....	6
4. Environmental Controls.....	6
5. Equipment.....	6
6. Water for Injection	6
7. Containers and Closures.....	6
H. Sterilization	6
1. Methods	6
2. Indicators	7
3. Filled Containers	7
4. Personnel Practices.....	8
I. Laboratory Controls	8
1. Retesting for Sterility	8
2. Retesting for Pyrogens	8
3. Particulate Matter Testing	8
J. Production Records	8
K. Ointments, Liquids, and Lotions	8
VI. Packaging and Labeling (21 CFR, Subpart G).....	8
VII. Holding and Distribution (21 CFR, Subpart H)	10
VIII. Laboratory Controls (21 CFR, Subpart I).....	10
A. Sterility Testing Procedures	10
IX. Control Records (21 CFR 211, Subpart J)	11
A. Master Production and Control Records (21 CFR 211.186)	11
B. Batch Production and Control Records (21 CFR 211.188).....	11
C. Distribution (21 CFR 211.196).....	11
D. Complaint Files (21 CFR 211.198).....	11

X. Returned Drug Products (21 CFR 211, Subpart K)	11
Appendix	12
1 Personnel	12
2 Hygiene	12
3 Warehouse	13
4 Dispensing/Assembling	15
5 Solids Manufacturing	15
6 Liquids Manufacturing	18
7 Packaging	23
8 Documentation	25
9 Quality Control	28
10 Complaints and Product Recalls	31
11 Self Inspection	31
12 Contract Manufacture and Analysis	32
13 Audit of Suppliers	33
 Chapter 2	
Solid Oral Dosage Forms	35
I. Introduction	35
II. Background	35
III. Product Development	35
A. Product Development Reports	35
1. Drug Substance Characterization	36
2. Manufacturing Procedures	37
3. In-Process Testing	37
4. Finished Product Testing	37
5. Dissolution Profile	37
6. Stability	37
B. Pre-Approval Inspections	37
1. Master Formula	38
2. History Section of the Application	38
3. Development Data (Product Development Report)	38
4. Inspection of the Facilities	38
5. Raw Materials	38
6. Laboratory	38
7. Equipment	39
IV. Validation Protocols	39
V. Demonstration Runs (Validation of the Process)	39
A. Test Batch Relationships	39
B. Post-Approval Prospective Validation Inspections	39
1. Raw Materials	39
2. Manufacturing Procedures and Equipment	39
3. Granulation/Mix Analysis	42
4. In-Process Testing	43
5. Test Results	43
6. Investigations and Product Failures	43
7. Site Review	44

Chapter 3

Oral Solutions and Suspensions	45
I. Introduction	45
II. Facilities	45
III. Equipment	45
IV. Raw Materials	45

V. Compounding.....	46
VI. Microbiological Quality	46
VII. Oral Suspension Uniformity	46
VIII. Product Specifications	47
IX. Process Validation.....	47
X. Stability	47
XI. Packaging	47

Chapter 4

Validation of Cleaning Process	49
I. Introduction.....	49
II. Background	49
III. General Requirements	49
IV. Evaluation of Cleaning Validation	50
A. Equipment Design.....	50
B. Cleaning Process, Written Procedure, and Documentation	51
C. Analytical Methods	51
D. Sampling.....	51
1. Direct Surface Sampling	51
2. Rinse Samples	51
3. Routine Production In-Process Control Monitoring.....	51
V. Establishment of Limits.....	51
VI. Other Issues	52
A. Placebo Product.....	52
B. Detergent	52
C. Test Until Clean	52

Part II

Over-the-Counter Product Formulations.....53

Acetaminophen and Caffeine Tablets	55
Acetaminophen and Caffeine Tablets	55
Acetaminophen and Diphenhydramine Hydrochloride Hot Therapy Sachets	56
Acetaminophen and Pseudoephedrine Hydrochloride Hot Therapy Sachets	56
Acetaminophen and Diphenhydramine Hydrochloride Tablets	57
Acetaminophen and Pseudoephedrine Hydrochloride Tablets	58
Acetaminophen Chewable Tablets	58
Acetaminophen, Chlorpheniramine, and Pseudoephedrine Syrup	59
Acetaminophen, Chlorpheniramine Maleate, and Pseudoephedrine Caplets	60
Acetaminophen, Dextromethorphan, and Pseudoephedrine Caplets	61
Acetaminophen, Doxylamine, and Caffeine Effervescent Granules	61
Acetaminophen Drops	62
Acetaminophen Effervescent Tablets	62
Acetaminophen, Ibuprofen, and Orphenadine Hydrochloride Tablets	63
Acetaminophen Instant Granules	63
Acetaminophen Instant Granules	64
Acetaminophen Instant Granules	64
Acetaminophen, Norephedrine, and Phenyltoloxamine Tablets	65
Acetaminophen Oral Suspension	66
Acetaminophen, Phenylpropanoamine, Dextromethorphan, and Chlorpheniramine Tablets	67
Acetaminophen, Propoxyphenazone, and Caffeine Tablets	68
Acetaminophen, Pseudoephedrine Hydrochloride, and Chlorpheniramine Hot Therapy Sachet	69
Acetaminophen Suppositories	69
Acetaminophen Suppositories	69

Acetaminophen Suppositories.....	70
Acetaminophen Suppositories.....	70
Acetaminophen Suppositories	70
Acetaminophen Suspension	71
Acetaminophen Syrup	71
Acetaminophen Syrup	72
Acetaminophen Syrup for Children.....	72
Acetaminophen Tablets	73
Acetaminophen Tablets	73
Acetaminophen Tablets	74
Acetaminophen Tablets	74
Acetaminophen Tablets for Children.....	74
Acetylcysteine Sachets	75
Acetylsalicylic Acid, Acetaminophen, and Caffeine Tablets	75
Acetylsalicylic Acid, Acetaminophen, and Caffeine Tablets (Direct Compression)	76
Acetylsalicylic Acid and Acetaminophen Tablets	76
Acetylsalicylic Acid and Acetaminophen Tablets	76
Acetylsalicylic Acid and Ascorbic Acid Tablets	77
Acetylsalicylic Acid and Ascorbic Acid Tablets	77
Acetylsalicylic Acid Suppositories	77
Acetylsalicylic Acid Tablets, Buffered	78
Acetylsalicylic Acid Tablets (Direct Compression)	78
Acetylsalicylic Acid Tablets (Direct Compression)	79
Acetylsalicylic Acid Tablets (Direct Compression)	79
Acne Cover Cream.....	80
Acne Scrub	80
Acne Treatment Cream	81
Aloe Vera Gel.....	81
alpha-Bisabolol Aqueous Mouthwash Solution.....	82
alpha-Bisabolol Buccal or Topical Solution	82
alpha-Bisabolol Ethanolic Mouthwash Solution	82
alpha-Bisabolol Mouthwash Solution	83
Aluminum Hydroxide and Magnesium Carbonate Dry Syrup	83
Aluminum Acetylsalicylate Tablets	84
Aluminum Hydroxide and Magnesium Hydroxide Chewable Tablets	84
Aluminum Hydroxide and Magnesium Hydroxide Chewable Tablets	85
Aluminum Hydroxide and Magnesium Hydroxide Antacid Suspension.....	85
Aluminum Hydroxide and Magnesium Hydroxide Antacid Suspension.....	86
Aluminum Hydroxide and Magnesium Hydroxide Suspension	87
Aluminum Hydroxide and Magnesium Hydroxide Suspension	88
Aluminum Hydroxide and Magnesium Hydroxide Suspension	88
Aluminum Hydroxide and Magnesium Hydroxide Tablets	89
Aluminum Hydroxide and Magnesium Silicate Chewable Tablets	89
Aluminum Hydroxide, Magnesium Carbonate (or Oxide), and Simethicone Tablets	90
Aluminum Hydroxide, Magnesium Hydroxide, and Simethicone Suspension	90
Aluminum Hydroxide, Magnesium Hydroxide, and Simethicone Suspension	91
Aluminum Hydroxide, Magnesium Hydroxide, and Simethicone Tablets	92
Analgesic Clear Gel	93
Analgesic Cream	93
Analgesic Lotion	94
Anise Oil Solution.....	94
Antazoline and Xylometazoline Eye Drops	95
Anti-Acne Gel	95
Antifungal Foot Powder	96
Antiseptic Cream	96

Antiseptic Lotion.....	96
Antiseptic Lotion.....	97
Antiseptic Wet Wipes.....	97
Aspartame Granules in Sachets.....	98
Aspartame Powder in Sachets.....	98
Aspartame Tablets	99
Aspartame Tablets	99
Aspartame Tablets	100
Aspartame Tablets, Effervescent.....	100
Aspirin, Acetaminophen, and Caffeine Tablets	100
Aspirin, Acetaminophen, Caffeine, and Salicylamide Tablets	101
Attapulgite Tablets	102
Baby Cream, Benzalkonium Chloride and Zinc Oxide	103
Baby Lotion.....	104
Baby Shampoo	104
Basic Cream for Varioius Active Ingredients	105
Benzalkonium Chloride Contraceptive Gel.....	105
Benzyl Benzoate Solution.....	105
Benzoyl Peroxide and α -Bisabolol Gel.....	106
Benzoyl Peroxide Anti-Acne Cream.....	106
Benzoyl Peroxide Anti-Acne Gel	107
Benzoyl Peroxide Anti-Acne Lotion.....	107
Benzoyl Peroxide Anti-Acne Microemulsion.....	108
Berberine Tablets.....	108
Beta-Carotene Effervescent Tablets	108
Beta-Carotene Tablets	109
Beta-Carotene Tablets	109
Beta-Carotene Tablets	109
Beta-Carotene, Vitamin C, and Vitamin E Chewable Tablets.....	110
Beta-Carotene, Vitamin C, and Vitamin E Tablets	110
Beta-Carotene, Vitamin C, and Vitamin E Tablets	111
Beta-Carotene, Vitamin C, and Vitamin E Tablets	111
Beta-Carotene, Vitamin C, and Vitamin E Tablets	111
Betamethasone and Neomycin Gel-Cream.....	112
Betamethasone Cream.....	112
Betamethasone Gel.....	112
Betamethasone Valerate Cream.....	113
Betamethasone Valerate Ointment	114
Bisacodyl Delayed-Release Tablets	114
Bisacodyl Suppositories	115
Bismuth Carbonate Suspension	115
Bismuth Subsalicylate Suspension	116
Bran Tablets.....	116
Breast Care Cream	116
Bromhexine Hydrochloride Syrup	117
Bromhexine Hydrochloride Syrup, Alcohol Free	118
Bromhexine Hydrochloride Tablets	119
Burn Cream	119
Burn Cream	120
Caffeine Tablets	120
Calamine Cream	121
Calamine Cream	121
Calamine Lotion	122
Calcium and Vitamin D Tablets	122
Calcium Carbonate and Glycine Tablets	123

Calcium Carbonate and Vitamin D Tablets	123
Calcium Carbonate Tablets	124
Calcium D-Pantothenate Chewable Tablets	124
Calcium D-Pantothenate Tablets	124
Calcium D-Pantothenate Tablets	125
Calcium Effervescent Tablets	125
Calcium Gluconate Tablets	126
Calcium Glycerophosphate Tablets	126
Calcium Glycerophosphate Tablets	126
Calcium Iodide and Ascorbic Acid Syrup	127
Calcium Phosphate Tablets for Cats and Dogs (Direct Compression)	127
Calcium Phosphate Tablets for Cats and Dogs	128
Carbinoxamine Maleate, Phenylpropanolamine, and Acetaminophen Sustained-Release Tablets	128
Carbonyl Iron, Copper Sulfate, and Manganese Sulfate Tablets	129
Carnitine and Coenzyme Q Solution	129
Cetrimide Antiseptic Cream	129
Charcoal Tablets	130
Chlophedianol, Ipecac, Ephedrine, Ammonium Chloride, Carbinoxamine, and Balsam Tolu Syrup	131
Chlorhexidine Gel	131
Chlorhexidine Lozenges	132
Chlorpheniramine Maleate Syrup	132
Chymotrypsine Tablets	133
Citrate Effervescent Powder	133
Crospovidone Effervescent Tablets	134
Crospovidone Water Dispersible Tablets	134
Cyanocobalamin Tablets	135
Dexpanthenol Gel-Cream	135
Dextromethorphan, Pseudoephedrine, and Chlorpheniramine Maleate Syrup	136
Dihydroxyaluminum Sodium Carbonate Tablets	136
Dimenhydrinate Tablets	137
Dimenhydrinate Tablets	137
Dimenhydrinate Tablets	137
Diphenhydramine Hydrochloride Tablets	138
Econazole Nitrate and Benzoyl Peroxide Anti-Acne Cream	138
Econazole Nitrate and Benzoyl Peroxide Anti-Acne Lotion	139
Eucalyptol Solution	139
Eucalyptus and Mint Emulsion	139
Eucalyptus and Mint Ointment	140
Ferrous Fumarate Tablets	140
Ferrous Sulfate, Manganese Sulfate, and Copper Sulfate Tablets	140
Ferrous Sulfate Oral Solution	141
Ferrous Sulfate Oral Syrup	141
Ferrous Sulfate Tablets	142
Fir Needle Oil Solution	142
Folic Acid Tablets	143
Folic Acid Tablets	143
Foot Bath	144
Foot Freshener Cream	144
Foot Mousse	145
Garlic Tablets	145
Glycerin Suppositories	146
Glycerin Suppositories for Children	146
Glycol Foam, Nonaqueous	146
Guaiifenesin Pseudoephedrine, Carbinoxamine, and Chlophedianol Drops	147
Hemorrhoid Cream	148

Horsetail Extract Tablets	148
Hydrocortisone Aqueous Gel	149
Hydrocortisone Aqueous Gel	149
Hydrocortisone Cream	150
Hydrocortisone Cream	150
Hydrocortisone Ethanolic Gel	151
Hydrocortisone Ointment	151
Ibuprofen Pediatric Suspension	152
Ibuprofen Tablets	153
Inosin Tablets	154
Insect Bite Cream	155
Iron (Polymer Coated Particle) Tablets	155
Iron Infant Drops	156
Iron Polystyrene and Vitamin C Syrup	157
Kaolin-Pectin Suspension	158
Kaolin-Pectin Tablets	159
Keratolytic Cream	160
Khellin Tablets	160
Lidocaine Gel	161
Lidocaine Gel-Cream	161
Lidocaine Ointment	162
Lidocaine, Eugenol, and Menthol Dental Ointment	162
Loratadine Tablets	163
Loratadine Fastab	163
Magaldrate Chewable Tablets	164
Magaldrate Dispersible Tablets	164
Magaldrate Instant Powder or Dry Syrup	165
Magaldrate Suspension	165
Magaldrate Tablets	166
Magaldrate with Simethicone Suspension	167
Magaldrate with Simethicone Tablet	168
Magnesium Carbonate Tablets	169
Medicated Foot Cream	169
Methyl Salicylate Heat Rub Lotion	170
Methyl Salicylate Analgesic Cream	170
Methyl Salicylate Analgesic Cream	171
Methyl Salicylate and Menthol Gel	171
Metoclopramide Tablets	172
Miconazole Nitrate Cream	172
Mineral and Multivitamin Syrup	173
Mint-Menthol Mouthwash	174
Menthol Mouthwash	175
Mini Oil Solution	175
Multivitamin, Calcium, and Iron Tablets	176
Multivitamin and Calcium Syrup	176
Multivitamin and Carbonyl Iron Tablets	177
Multivitamin and Mineral Tablets with Beta Carotene	177
Multivitamin and Mineral Syrup	178
Multivitamin and Mineral Tablets	180
Multivitamin Chewable Tablets for Children	181
Multivitamin Drops	181
Multivitamin Effervescent Granules	182
Multivitamin Effervescent Tablets with Beta Carotene	183
Multivitamin Effervescent Tablets	184
Multivitamin Effervescent Tablets	185

Multivitamin Infant Drops	186
Multivitamin Infant Drops	187
Multivitamin Instant Granules	188
Multivitamin Mineral Syrup	189
Multivitamin Oral Gel with Linoleic and Linolenic Acid	190
Multivitamin Oral Gel Veterinary	191
Multivitamin Syrup	192
Multivitamin Syrup	192
Multivitamin with Beta-Carotene Tablets	193
Multivitamin Tablets with Beta-Carotene	193
Multivitamin and Beta-Carotene Tablets	194
Multivitamin Tablets	195
Multivitamin Tablets	196
Multivitamin Tablets	197
Multivitamin Tablets	198
Multivitamin Tablets	198
Multivitamin Tablets for Dogs	199
Multivitamin and Fluoride Chewable Tablets	200
Multivitamin with Fluoride Infant Drops	201
Multivitamin with Zinc Tablets	202
Naphazoline Eye Drops	203
Neomycin Gel	203
Nicotinamide Tablets	204
Nicotinic Acid (Niacin) Tablets	204
Nondetergent Neutral Dry Skin Cream	204
Norephedrine Syrup	205
Nystatin Cream	206
Nystatin Ointment	207
Nystatin, Neomycin Sulfate, Gramicidin, and Triamcinolone Acetonide Cream	208
Nystatin, Neomycin Sulfate, Gramicidin, and Triamcinolone Acetonide Ointment	209
Omega Fatty Acids Tablets	209
Oral Rehydration Salt (45 mEq)	210
Pancreatin Tablets	210
Pancreatin Tablets	211
Pancreatin and Cholic Acid Tablets	211
Panthenol Lotion	212
Panthenol Ointment	213
Peppermint Rub Cream	213
Phenindion Tablets	214
Phenolphthalein Tablets	214
Phenolphthalein Tablets	214
Phenylpropanolamine Hydrochloride Tablets	215
Phenylpropanolamine, Chlorpheniramine, Dextromethorphan, Vitamin C Syrup	216
Placebo Tablets	217
Polidocanol Wound Spray	217
Polyvinylpyrrolidone-Iodine Mouthwash	217
Povidone-Iodine and Lidocaine Gel	218
Povidone-Iodine Bar Soap	218
Povidone-Iodine Bar Soap	218
Povidone-Iodine Bar Soap	219
Povidone-Iodine Concentrates for Broilers and Cattle	219
Povidone-Iodine Cream	219
Povidone-Iodine Effervescent Vaginal Tablets	220
Povidone-Iodine Foam Spray	220
Povidone-Iodine Gargle	220

Povidone-Iodine Gargle Solution Concentrate	221
Povidone-Iodine Gel-Cream	221
Povidone-Iodine Gels	221
Povidone-Iodine Glucose Ointment	222
Povidone-Iodine Liquid Spray	222
Povidone-Iodine Lozenges	222
Povidone-Iodine Mastitis Cream for Cattle	223
Povidone-Iodine Mouthwash and Gargle Solution Concentrate	223
Povidone-Iodine Powder Spray	223
Povidone-Iodine Pump Spray	224
Povidone-Iodine Shampoo	224
Povidone-Iodine Soft Gel	224
Povidone-Iodine Solution	225
Povidone-Iodine Solution	225
Povidone-Iodine Solution	226
Povidone-Iodine Solution	226
Povidone-Iodine Solution	226
Povidone-Iodine Scrub	227
Povidone-Iodine Surgical Scrub	227
Povidone-Iodine Surgical Scrub	228
Povidone-Iodine Transparent Ointment	228
Povidone-Iodine Vaginal Douche Concentrate	228
Povidone-Iodine Vaginal Ovule	229
Povidone-Iodine Vaginal Ovule	229
Povidone-Iodine Viscous Solution	229
Promethazine Hydrochloride Syrup	230
Promethazine Hydrochloride Tablets	231
Pseudoephedrine Hydrochloride Capsules	232
Pseudoephedrine Hydrochloride Syrup	232
Pseudoephedrine Hydrochloride Tablets	233
Pseudoephedrine Tablets	233
Pseudoephedrine Hydrochloride, Carbinoxamine Maleate Oral Drops	234
Psoriasis Cream	234
Psoriasis Cream	235
Pyridoxine Tablets	235
Pyridoxine Tablets	235
Pyridoxine Tablets	236
Pyridoxine Tablets	236
Pyridoxine Tablets	236
Pyridoxine Tablets	237
Ranitidine Tablets	237
Ranitidine Hydrochloride Tablets	238
Riboflavin Tablets	238
Riboflavin Tablets	238
Riboflavin Tablets	239
Riboflavin Tablets	239
Riboflavin Tablets	239
Rubefacient Analgesic Ointment	240
Saccharin Effervescent Tablets	240
Saccharin Tablets	241
Saccharin Tablets	241
Salicylic Acid Cream	242
Selegiline Tablets	242
Selenium Sulfide Shampoo with Conditioner	243
Serratio Peptidase Tablets	243

Silicone Protective Cream.....	244
Silimarin Tablets.....	244
Simethicone Chewable Tablets	244
Simethicone Chewable Tablets	245
Simethicone Tablets	245
Sodium Fluoride Tablets	246
Sodium Fluoride Tablets	246
Spirulina Extract Chewable Tablets	246
Sucralfate and Sodium Alginate Tablets	247
Sulfur Antiseptic Ointment	247
Tannin-Crospovidone Complex Tablets	248
Tetrahydrozoline Eye Drops	248
Thiamine and Caffeine Tablets	249
Thiamine Hydrochloride Tablets.....	249
Thiamine Hydrochloride Tablets, Sugar-Coated	250
Thiamine, Pyridoxine, and Cyanocobalamin Tablets	251
Thiamine, Pyridoxine, and Cyanocobalamin Tablets	252
Thiamine, Pyridoxine, and Cyanocobalamin Tablets	252
Thiamine, Pyridoxine, and Cyanocobalamin Tablets	253
Thiamine, Pyridoxine, and Cyanocobalamin Tablets	253
Thiamine Tablets	253
Thiamine Tablets	254
Thiamine Tablets	254
Thiamine Tablets	254
Tolnaftate and Undecylanate Foot Care Cream.....	255
Tolnaftate Foot Care Microemulsion	256
Tolu Balsam Cough Syrup	257
Triclosan and Zinc Foot Deodorant Powder.....	258
Triclosan Foot Care Cream	258
Triprolidine and Pseudoephedrine Hydrochloride Syrup	259
Triprolidine and Pseudoephedrine Hydrochloride Tablets	260
Trolamine Salicylate Cream.....	260
Ultrasonic Adhesive Gel	261
Urea Peroxide Ear Drops	261
Valeriana and Passiflora Extract Tablets	262
Vitamin A and Vitamin D Infant Drops	263
Vitamin A and Vitamin D3 Drops	264
Vitamin A and Vitamin D3 Oral Solution	264
Vitamin A and Vitamin D3 Syrup	264
Vitamin A and Vitamin E Drops	265
Vitamin A and Vitamin E Drops (25,000 IU/50 mg/mL)	265
Vitamin A and Vitamin E Tablets	265
Vitamin A Chewable Tablets	266
Vitamin A Concentrate, Water-Miscible	266
Vitamin A Drops	266
Vitamin A Suppositories	267
Vitamin A Tablets	267
Vitamin A Tablets	267
Vitamin A Tablets	268
Vitamin A Tablets	268
Vitamin A Tablets	268
Vitamin A, Vitamin B6, and Vitamin E Tablets	269
Vitamin A, Vitamin C, and Vitamin D3 Chewable Tablets	269
Vitamin A, Vitamin C, and Vitamin E Tablets (1200 IU/60 mg/30 mg)	270

Vitamin B-Complex, Amino Acids, and Magnesium Effervescent Granules (Sugar-Free)	270
Vitamin B-Complex and Carnitine Tablets.....	271
Vitamin B-Complex and Folic Acid Dragees.....	272
Vitamin B-Complex and Iron Syrup.....	273
Vitamin B-Complex and Vitamin C Effervescent Tablets.....	274
Vitamin B-Complex and Vitamin C Instant Granules.....	275
Vitamin B-Complex and Vitamin C Syrup.....	275
Vitamin B-Complex and Vitamin C Syrup.....	276
Vitamin B-Complex and Vitamin C Tablets.....	276
Vitamin B-Complex and Vitamin C Tablets.....	277
Vitamin B-Complex, Choline, and Bile Tablets.....	277
Vitamin B-Complex Syrup.....	278
Vitamin B-Complex Syrup.....	279
Vitamin B-Complex Syrup (without B12).....	280
Vitamin B-Complex Tablets.....	281
Vitamin B-Complex Tablets.....	281
Vitamin B-Complex Tablets.....	282
Vitamin B-Complex, Vitamin A, Vitamin C, and Vitamin D Syrup.....	283
Vitamin B-Complex, Vitamin A, Vitamin C, and Vitamin D Tablets.....	284
Vitamin B-Complex, Vitamin A, Vitamin C, Vitamin D, and Calcium Drops.....	285
Vitamin B-Complex, Vitamin A, Vitamin C, Vitamin D, and Mineral Tablets.....	286
Vitamin B-Complex, Vitamin A, Vitamin C, Vitamin D, and Vitamin E Pediatric Drops.....	287
Vitamin B-Complex, Vitamin C, and Calcium Effervescent Tablets.....	288
Vitamin B-Complex, Vitamin C, and Ferrous Sulfate Tablets.....	288
Vitamin B-Complex, Vitamin C, and Iron Syrup.....	289
Vitamin B-Complex, Vitamin C, and Iron Syrup.....	290
Vitamin B-Complex, Vitamin C, and Vitamin E Tablets	291
Vitamin C and Calcium Carbonate Effervescent Tablets (500 mg/300 mg)	292
Vitamin C and Vitamin E Lozenges	292
Vitamin C Chewable Tablets.....	293
Vitamin C Chewable Tablets.....	293
Vitamin C Chewable Tablets.....	294
Vitamin C Chewable Tablets.....	294
Vitamin C Chewable Tablets.....	295
Vitamin C Chewable Tablets with Dextrose.....	295
Vitamin C Chewable Tablets with Fructose.....	296
Vitamin C Chewable Tablets with Sucrose	296
Vitamin C Drops	296
Vitamin C Effervescent Tablets	297
Vitamin C Effervescent Tablets	298
Vitamin C Effervescent Tablets	298
Vitamin C Effervescent Tablets	299
Vitamin C Tablets.....	299
Vitamin C Tablets.....	300
Vitamin C Tablets.....	300
Vitamin E and Benzocaine Solution.....	300
Vitamin E Chewable Tablets.....	301
Vitamin E Chewable Tablets.....	301
Vitamin E Chewable Tablets.....	301
Vitamin E Concentrate, Water-Miscible	302
Vitamin E Drops.....	302
Vitamin E Gel-Cream.....	302
Vitamin E Softgel Capsules	303
Vitamin E Solution with Ethanol.....	303
Vitamin E Tablets	303

Vitamin E Tablets.....	304
Zinc Oxide Lotion.....	304
Zinc Oxide Ointment	305
Zinc Pyrithione Shampoo	305
Zinc Undecylenate Cream.....	306
Zirconium Oxide Lotion.....	306

Part III

Appendix	307
I. Introduction.....	309
II. Hydroxypropyl Methylcellulose (Methocel, HPMC) Aqueous Coatings.....	310
A. Brite Rose.....	310
B. Cherry Red.....	310
C. Geranium Rose.....	310
D. Gloss.....	311
E. Red	311
F. Moderate Red	311
G. Clear	312
H. Green.....	312
I. Holberry Red	312
J. Sun Orange.....	313
K. Opadry Yellow	313
L. Opadry Yellow.....	313
M. Opadry Red	314
N. Opadry Green	314
O. White Coating	315
III. Hydroxypropyl Methylcellulose Opaque Organic Coating	315
A. Brite Green.....	315
B. Red Mahogany	316
C. Sun Orange	316
D. Dark Red	316
E. Deep Yellow	316
F. Pale Yellow.....	317
G. Scarlet Red	317
IV. Hydroxypropyl Methyl Cellulose/Hydroxypropyl Cellulose (<i>Klucel®</i>) Coating	317
A. White	317
V. Hydroxypropyl Methyl Cellulose/Ethyl Cellulose Coating	318
A. Reddish Orange Opaque	318
B. Subcoating Solution	318
VI. Hydroxy Methyl Cellulose/Hydroxy Cellulose Coating	319
A. Blue	319
B. Clear (50:50)	319
VII. Hydroxy Methyl Cellulose/Ethyl Cellulose Coating	320
A. Clear	320
VIII. Polyvinylpyrrolidone (PVP) Coatings.....	320
A. Subcoating	320
B. Kollidon® VA 64 (Polyvinylpyrrolidone/Vinylacetate Copolymer, BASF)	321
C. Kollidon® VA 64 and Polyvinyl Alcohol	322
D. Kollidon® 30 and Shellac	322
E. Kollidon® VA 64 and Hydroxypropyl Methyl Cellulose	323
F. Povidone, Ethyl Cellulose, and Talc	323

IX.	Cellulose Acetate Phthalate and Carbowax Coatings	324
A.	Brite Green	324
B.	Cherry Red	324
C.	Clear	324
D.	Orange	324
E.	Red Mahogany	324
F.	Orange	324
X.	Sugar Coatings	325
A.	Basic	325
B.	Automatic	326
C.	Manual, White	326
XI.	Enteric Coatings	327
A.	Kollicoat® and Kollidon® Enteric Film Coating	327
XII.	Eudragit® Enteric Aqueous	328
A.	Brick Red	328
B.	Yellow	328
C.	Brown	328
D.	Dark Orange	329
E.	Orange	329
F.	Dispersed Orange	329
XIII.	Hydroxypropyl Methyl Cellulose Phthalate Enteric Coating	330
A.	Clear Enteric	330
B.	Orchid Pink Opaque	330
C.	Light Apricot Orange	330
	Index	331