

Japanese Pharmacopoeial Forum

Vol. 24 No. 1

March 2015

Contents

Revision Drafts

Drafts for JP 17

1. General Tests, Processes and Apparatus

(1) Revision

- 2.21 Nuclear Magnetic Resonance Spectroscopy
..... 156

2. Official Monographs

(1) Addition

- Diflorasone Diacetate 159
Haloperidol Injection 160
Irbesartan 161
Isomalt Hydrate 162
Medroxyprogesterone Acetate 165
Purified Sodium Hyaluronate Ophthalmic Solution
..... 166
Sodium L-Lactate Ringer's Solution 168
Terbinafine Hydrochloride Tablets 171
Valaciclovir Hydrochloride 172
Valaciclovir Hydrochloride Tablets 175

(2) Revision

- Aminophylline Hydrate 176
Aminophylline Injection 176
Ampicillin Sodium 176
Calcium Folate 178
Chloramphenicol Sodium Succinate 178
Cloxacillin Sodium Hydrate 178
Enviomycin Sulfate 179
Epoetin Alfa (Genetical Recombination) 179
Epoetin Beta (Genetical Recombination) 181
Ethambutol Hydrochloride 181
Ethanol 181
Anhydrous Ethanol 182
Ethanol for Disinfection 182
Filgrastim (Genetical Recombination) 182
Filgrastim (Genetical Recombination) Injection 184
Hydroxyzine Pamoate 184
Kitasamycin Tartrate 184
Lenograstim (Genetical Recombination) 185
Nartograstim (Genetical Recombination) 186

- Nartograstim for Injection (Genetical Recombination)
..... 186
Pyrantel Pamoate 186
Rice Starch 186
Roxithromycin 187
Saccharin 188
Sodium Aurothiomalate 188
Sodium Chloride 188
Purified Sodium Hyaluronate 189
Sodium Prasterone Sulfate Hydrate 190
Sodium Starch Glycolate 190
Teceleukin for Injection (Genetical Recombination)
..... 190
Wine 191

3. Official Monographs—Crude Drugs

(1) Addition

- Codonopsis Root 191
Hedysarum Root 192
Kamikihito Extract 192
Salvia Miltiorrhiza Root 197

(2) Revision

- Daisaikoto Extract 197
Hochuekkito Extract 198
Orengedokuto Extract 198
Otsujito Extract 199
Peucedanum Root 202
Prepared Glycyrrhiza 202
Saibokuto Extract 203
Saikokeishito Extract 203
Saireito Extract 204
Shosaikoto Extract 204
Shoseiryuto Extract 205

4. Infrared Reference Spectra

- Diflorasone Diacetate 206
Eplerenone 206
Hydroxypropylcellulose 206
Irbesartan 207
Lansoprazole 207
Medroxyprogesterone Acetate 207
Miglitol 208

Valaciclovir Hydrochloride	208
Voriconazole	208
5 . Ultraviolet-visible Reference Spectra	
Eplerenone	209
Irbesartan	209
Lansoprazole	209
Medroxyprogesterone Acetate	210
Valaciclovir Hydrochloride	210
Voriconazole	210
6 . General Information	
(1) Addition	
Analytical methods for aflatoxins in crude drug and its product	211
Notification for the quantitative marker constituents of crude drugs and crude drug preparations	212
(2) Revision	
Disinfection and Sterilization Methods	214
Quantitative Analytical Technique Utilizing Nuclear Magnetic Resonance (NMR) Spectroscopy and Its Application to Reagents in the Japanese Pharmacopoeia	217

Additional Revision of the Revision Drafts for JP 17

1 . Official Monographs

(1) Revision	
Doxycycline Hydrochloride Tablets	219
Lansoprazole	220
Purified Sodium Hyaluronate Injection	220
2 . Official Monographs—Crude drugs	
(1) Revision	
Coptis Rhizome	223
Powdered Coptis Rhizome	223

Pharmacopoeial Harmonization

1 . Official Inquiry Stage Draft	
(1) Monographs	
1) Addition	
① Propylene Glycol	113
2 . Harmonized Document	
(1) Monographs	
1) Revision • Correction	
① Glucose Monohydrate (Corr.1)	121

Useful Information

PMRJ Reference Standards Ordering Information for Foreign Users	224
---	-----

Publishing Schedule (Vol.24, No.2): June 2015
