

Japanese Pharmacopoeial Forum

Vol. 23 No. 3

September 2014

Contents

Revision Drafts	
Revision Drafts on Dissolution for JP 17	
1. Official Monographs	
(1) Addition	
Miglitol Tablets	525
Montelkast Sodium Tablets	526
Pioglitazone Hydrochloride and Glimepiride Tablets	526
Drafts for JP 17	
1. General Rules for Preparations	528
2. General Tests, Processes and Apparatus	
(1) Revision	
6.06 Foreign Insoluble Matter Test for Injections	528
9.01 Reference Standards	528
3. Official Monographs	
(1) Addition	
Ampicillin Sodium-Sulbactam Sodium for Injection	528
Cefalexin Combination Granules	530
Felbinac Cataplasm	532
Levofloxacin Injection	533
Mitiglinide Calcium Hydrate	534
Mitiglinide Calcium Tablets	536
Montelukast Sodium	538
Ozagrel Sodium Injection	541
Ribavirin	542
Ribavirin Capsules	544
Silodosin	545
(2) Revision	
Benserazide Hydrochloride	548
Cefroxadine Hydrate	548
Gabexate Mesilate	549
Gelatin	549
Ozagrel Sodium for Injection	550
Progesterone Injection	550
Spectinomycin Hydrochloride Hydrate	550
Thiamine Chloride Hydrochloride	551
Tulobuterol Hydrochloride	552
(3) On Unified Revision of the Uniformity of dosage units in Drug Monographs	552
Alacepril Tablets	553
Aldioxa Tablets	553
Alendronate Sodium Tablets	553
Allopurinol Tablets	553
Amiodarone Hydrochloride Tablets	553
Amlexanox Tablets	553
Azathioprine Tablets	553
Bucillamine Tablets	553
Buformin Hydrochloride Tablets	553
Cefalexin Capsules	553
Cefcapene Pivoxil Hydrochloride Tablets	553
Cefditoren Pivoxil Tablets	553
Cefixime Capsules	553
Cefpodoxime Proxetil Tablets	553
Cefteram Pivoxil Tablets	553
Chlorphenesin Carbamate Tablets	553
Cibenzoline Succinate Tablets	553
Cilostazol Tablets	553
Clarithromycin Tablets	553
Clopidogrel Sulfate Tablets	553
Diethylcarbamazine Citrate Tablets	553
Droxidopa Capsules	553
Epalrestat Tablets	553
Faropenem Sodium Tablets	553
Fexofenadine Hydrochloride Tablets	553
Flecainide Acetate Tablets	553
Fluconazole Capsules	553
Fluvoxamine Maleate Tablets	553
Furosemide Tablets	553
Labetalol Hydrochloride Tablets	553
Levofloxacin Tablets	553
Losartan Potassium Tablets	553
Losartan Potassium and Hydrochlorothiazide Tablets	553
Loxoprofen Sodium Tablets	553
Metoprolol Tartrate Tablets	553
Minocycline Hydrochloride Tablets	553
Mizoribine Tablets	553
Naftopidil Orally Disintegrating Tablets	553

Nateglinide Tablets	553	Lithospermum Root	560
Nizatidine Capsules	553	Loquat Leaf	560
Phenytoin Tablets	553	Lycium Fruit	560
Pilsicainide Hydrochloride Capsules	553	Magnolia Flower	560
Pioglitazone Hydrochloride Tablets	553	Notopterygium	561
Propafenone Hydrochloride Tablets	553	Peach Kernel	561
Propylthiouracil Tablets	553	Powdered Peach Kernel	561
Quetiapine Fumarate Tablets	553	Peony Root	561
Rebamipide Tablets	553	Powdered Peony Root	562
Roxatidine Acetate Hydrochloride Extended-release Capsules	553	Phellodendron Bark	562
Sarpogrelate Hydrochloride Tablets	553	Powdered Phellodendron Bark	562
Sodium Risedronate Tablets	553	Compound Phellodendron Powder for Cata-plasm	562
Sodium Valproate Tablets	553	Phellodendron, Albumin Tannate and Bis-muth Subnitrate Powder	563
Spironolactone Tablets	553	Pueraria Root	563
Sulpiride Capsules	553	Rikkunshito Extract	563
Sulpiride Tablets	553	Saibokuto Extract	563
Tiapride Hydrochloride Tablets	553	Saikokeishito Extract	564
Tosufloxacin Tosilate Tablets	553	Saireito Extract	564
Tranilast Capsules	553	Scopolia Extract and Ethyl Aminobenzoate Powder	564
Troxipide Tablets	553	Scopolia Rhizome	565
Ursodeoxycholic Acid Tablets	553	Scutellaria Root	565
Valsartan Tablets	553	Powdered Scutellaria Root	565
Zaltoprofen Tablets	553	Senna Leaf	565
(4) Deletion		Powdered Senna Leaf	566
Serum Gonadotrophin	554	Shakuyakukanzoto Extract	566
Serum Gonadotrophin for Injection	554	Shimbuto Extract	566
4 . Official Monographs – Crude Drugs		Shosaikoto Extract	567
(1) Revision		Shoseiryuto Extract	567
Artemisia Capillaris Flower	554	Swertia Herb	567
Bakumondoto Extract	554	Powdered Swertia Herb	567
Belladonna Root	554	Swertia and Sodium Bicarbonate Powder	567
Burdock Fruit	554	Tokishakuyakusan Extract	568
Chotosan Extract	555	Tribulus Fruit	568
Cinnamon Bark	555	5 . Infrared Reference Spectra	
Powdered Cinnamon Bark	555	Benserazide Hydrochloride	568
Coptis Rhizome	555	Cefroxadine Hydrate	569
Powdered Coptis Rhizome	556	Mitiglinide Calcium Hydrate	569
Daisaikoto Extract	556	Montelukast Sodium	569
Fennel	557	Ribavirin	570
Powdered Fennel	557	Silodosin	570
Fennel Oil	557	Thiamine Chloride Hydrochloride	570
Fritillaria Bulb	557	6 . Ultraviolet-visible Reference Spectra	
Gastrodia Tuber	557	Mitiglinide Calcium Hydrate	571
Glycyrrhiza	558	Montelukast Sodium	571
Powdered Glycyrrhiza	558	Ribavirin	572
Hangeshashinto Extract	558	Silodosin	572
Hochuekkito Extract	558	7 . General Information	
Juzentaihoto Extract	559	(1) Addition	
Kakkonto Extract	559	Surface Plasmon Resonance	573
Kakkontokasenyushin'i Extract	559		
Lilium Bulb	560		

Additional Revision of the Revision Drafts for JP 17

1. Official Monographs	
(1) Addition	
Diltiazem Hydrochloride Extended-release Capsules	577
Ethyl Icosapentate Capsules	577
Interferon Alfa (NAMALWA)	578
2. Official Monographs – Crude Drugs	
Additional Expression for Water Determination of	
Reference Standard used in Assay of Crude Drugs	579

Pharmacopoeial Harmonization

1. Harmonized Document	
(1) General Tests	
1) Addition	
① Thermal Analysis (Sign-off document)	423
2) Revision, Correction	

① Polyacrylamide Gel Electrophoresis (Rev. 1)	430
(2) Monographs	
1) Addition	
① Glucose Anhydrous/Monohydrate	443
2) Revision, Correction	
① Ethanol (Rev. 2, corr. 2)	454
② Ethanol Anhydrous (Rev. 2, corr. 2)	455
③ Gelatin, Gelling grade (Corr. 2) (差し替え)	456
④ Gelatin, Non-gelling grade (Corr. 2) (差し替え)	462
⑤ Mannitol, (Corr. 1)	469
⑥ Hypromellose (Rev. 1, Corr. 1)	470
⑦ Methylcellulose (Rev. 2, Corr. 1)	477

Useful Information

PMRJ Reference Standards Ordering Information for Foreign	
Users	580

Publishing Schedule (Vol.23, No.4): December 2014
