

# Japanese Pharmacopoeial Forum

Vol. 28 No. 4

December 2019

## Contents

<b>Revision Drafts</b>	
<b>Revision Drafts for First Supplement to JP 18</b>	
1. Official Monographs – Crude Drugs	
(1) Revision	
Achyranthes Root	766
Glehnia Root and Rhizome	766
Magnolia Bark	766
Sinomenium Stem and Rhizome	766
2. General Information	
(1) Revision	
On the Scientific Names of Crude Drugs listed in the JP	767
<b>Drafts for JP 18</b>	
1. General Notices	768
2. General Tests, Processes and Apparatus	
(1) Revision	
2.48 Water Determination (Karl Fischer Method)	768
5.01 Crude Drugs Test	772
9.41 Reagents, Test Solutions	774
3. Official Monographs	
(1) Addition	
Cloperastine Fendizoate	778
Cloperastine Fendizoate Tablets	779
Eribulin Mesilate	781
Phenobarbital Tablets	785
Pitavastatin Calcium Orally Disintegrating Tablets	786
Silodosin Orally Disintegrating Tablets	788
(2) Revision	
Calcium Folate Hydrate	791
Croscarmellose Sodium	791
Low Substituted Hydroxypropylcellulose	793
Purified Gelatin	794
Hypromellose	794
Anhydrous Lactose	795
Lactose Hydrate	795
Methylcellulose	796
Oxygen	797
White Petrolatum	798
Yellow Petrolatum	799
Sucrose	800
Sodium Lauryl Sulfate	800
4. Official Monographs – Crude Drugs	
(1) Revision	
Bupleurum Root	801
Glycyrrhiza	802
Goshuyuto Extract	802
5. General Information	
(1) Addition	
Bacterial Endotoxins Test and alternative methods using recombinant protein-reagents for endotoxin assay	803
Biorisk Management of the Handling of Microorganisms in Microbial Tests	805
Radioactivity Measurements Method for Crude Drugs	810
6. Infrared Reference Spectra	
Cloperastine Fendizoate	818
Sodium Lauryl Sulfate	818
White Petrolatum	819
Yellow Petrolatum	819
7. Ultraviolet-visible Reference Spectra	
Cloperastine Fendizoate	820
<b>Additional Revision of Drafts for JP 18</b>	
1. Official Monographs	
(1) Revision	
Saccharin	820
Saccharin Sodium Hydrate	821
<b>Drafts for JP 18</b>	
1. General Tests, Processes and Apparatus	
(1) Revision	
2.52 Thermal Analysis	822
4.06 Sterility Test	823

**Revision of the term “ internal reference compound” for listed articles (9.41 Reagent, Test Solutions) ..... 824**

**Deletion of “assay 1” for listed articles (9.41 Reagent, Test Solutions)..... 825**

**Revision of the description of optical isomer for listed articles (official monographs)**

Bepotastine Besilate .....	827
Clopidogrel Sulfate .....	827
Dorzolamide Hydrochloride .....	828
Levofloxacin Hydrate .....	829
Levofloxacin Fine Granules .....	829
Levofloxacin Injection .....	830
Levofloxacin Tablets .....	830
Montelukast Sodium .....	831
Paroxetine Hydrochloride Hydrate .....	831
Valaciclovir Hydrochloride .....	832
Valsartan .....	832
Voriconazole .....	833
Voriconazole for Injection .....	833

---

***Authority Announcements***

Briefing on Proposed Draft Official Monograph “Eribulin Mesilate” .....	834
---	-----

---

***Useful Information***

PMRJ Reference Standards Ordering Information for Foreign Users .....	835
---	-----

---

***Pharmacopoeial Harmonization***

1. Official Inquiry Stage Draft	
(1) Monographs	
1) Revision	
① Croscarmellose Sodium .....	718
2. Sign-off Cover Sheet of Harmonized Document	
(1) General Tests	
1) Revision • Correction • Revision of Cover Sheet	
① Conductivity (Corr. 1) .....	720
② Dissolution (Rev. 3, Correction of the Sign-off Cover Sheet) .....	723
(2) Monographs	
1) Revision • Correction • Revision of Cover Sheet	
① Gelatin (Rev. 3) .....	725
② Sodium Laurylsulfate (Rev. 1) .....	726
③ Lactose, Anhydrous (Rev. 4, Corr. 1) .....	727
④ Lactose, Monohydrate (Rev. 2, Corr. 1) .....	729
⑤ Copovidone (Corr. 1) .....	731

---

***Cumulative Contents***

Vol. 28 Cumulative Contents .....	846
-----------------------------------	-----

Publishing Schedule (Vol.29, No.1): March 2020