

Partial revision of the Japanese Pharmacopoeia, Seventeenth edition

Description of content :

The Seventeenth edition of the Japanese Pharmacopoeia (JP) is to be partially amended as follows:

1. To establish 2 article under the section of General Rules of Preparations (List 1)
2. To amend 6 article under the section of General Rules of Preparations (List 2)
3. To establish 3 test methods under the section of General Tests, Process and Apparatus (List 3)
4. To amend 9 test methods under the section of General Tests, Process and Apparatus (List 4)
5. To establish 32 monographs under the section of Official Monographs (List 5)
6. To amend 114 monographs under the section of Official Monographs (List 6)
7. To delete 17 monographs under the section of Official Monographs (List 7)
8. To establish 10 spectra under the section of Ultraviolet-visible Reference Spectra (List 8)
9. To delete 5 spectra under the section of Ultraviolet-visible Reference Spectra (List 9)
10. To establish 10 spectra under the section of Infrared Reference Spectra (List 10)
11. To delete 5 spectra under the section of Infrared Reference Spectra (List 11)
12. To establish 6 paragraphs under the section of General Information (List 12)
13. To amend 8 paragraphs under the section of General Information (List 13)
14. To delete 1 paragraphs under the section of General Information (List 14)

List 1

- [2] Monographs for Preparations
 - 1. 8. Films for Oral Administration
 - 1. 8. 1 Orally Disintegrating Films/Orodispersible Films

List 2

- [1] General Notices for Preparations
- [2] Monographs for Preparations
 - 5. 1. 1 Dry Powder Inhalers
 - 5. 1. 3 Metered-Dose Inhalers
 - 9. 1. Suppositories for Rectal Application
 - 10. 2. Suppositories for Vaginal Use
 - 11. 2. Liquids and Solutions for Cutaneous Application

List 3

- (1) 3.06 Laser Diffraction (2) 6.14 Uniformity of Delivered Dose for Measurement of Particle Size Inhalations
- (3) 6.15 Aerodynamic Particle Size Measurement for Inhalations

List 4

- (1) 2.24 Ultraviolet-visible Spectrophotometry (2) 2.46 Residual Solvents
- (3) 4.03 Digestion Test (4) 6.02 Uniformity of Dosage Units
- (5) 6.04 Test for Acid-neutralizing Capacity of Gastrointestinal Medicines (6) 9.01 Reference Standards
- (7) 9.21 Standard Solutions for Volumetric Analysis (8) 9.41 Reagents, Test Solutions
- (9) 9.42 Solid Supports/Column Packings for Chromatography

List 5

- (1) Azosemide (2) Azosemide Tablets
- (3) Irbesartan Tablets (4) Irbesartan and Amlodipine Besilate Tablets
- (5) Isophane Insulin Human (Genetical (6) Biphasic Isophane Insulin Human

	Recombination) Injectable Aqueous Suspension	(Genetical Recombination) Injectable Aqueous Suspension
(7)	Insulin Aspart (Genetical Recombination)	(8) Entacapone
(9)	Entacapone Tablets	(10) Clotiazepam Tablets
(11)	Clomipramine Hydrochloride Tablets	(12) Chloramphenicol and Colistin Sodium Methanesulfonate Ophthalmic Solution
(13)	Magnesium Aluminosilicate	(14) Magnesium Aluminometasilicate
(15)	Cefoperazone Sodium for Injection	(16) Zonisamide
(17)	Zonisamide Tablets	(18) Tramadol Hydrochloride
(19)	Pazufloxacin Mesilate	(20) Pazufloxacin Mesilate Injection
(21)	Pyridoxal Phosphate Hydrate	(22) Purified Glucose
(23)	Glucose Hydrate	(24) Pentobarbital Calcium Tablets
(25)	Voriconazole for Injection	(26) Mesalazine
(27)	Mesalazine Extended-release Tablets	(28) Methotrexate Tablets
(29)	Montelukast Sodium Granules	(30) Calcium Levofolinate Hydrate
(31)	Roxithromycin Tablets	(32) Goreisan Extract

List 6

(1)	Amoxicillin Hydrate	(2)	Ampicillin Hydrate
(3)	Iohexol Injection	(4)	Isosorbide Mononitrate 70%/Lactose 30%
(5)	Ethanol	(6)	Anhydrous Ethanol
(7)	Edaravone Injection	(8)	Epalrestat
(9)	Erythromycin	(10)	Oxytetracycline Hydrochloride
(11)	Clarithromycin	(12)	Cloxacillin Sodium Hydrate
(13)	Chloramphenicol Sodium Succinate	(14)	Gentamicin Sulfate
(15)	Colistin Sodium Methanesulfonate	(16)	Saccharin Sodium Hydrate
(17)	Digoxin	(18)	Suxamethonium Chloride Injection
(19)	Spiramycin Acetate	(20)	Sultamicillin Tosilate Hydrate
(21)	Sulbactam Sodium	(22)	Cefixime Hydrate
(23)	Ceftizoxime Sodium	(24)	Cellacefate
(25)	Teicoplanin	(26)	Dextran 40
(27)	Tetracycline Hydrochloride	(28)	Demethylchlortetracycline Hydrochloride
(29)	Doxycycline Hydrochloride Hydrate	(30)	Doxorubicin Hydrochloride
(31)	Tobramycin	(32)	Thrombin

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| (33) Anhydrous Lactose | (34) Lactose Hydrate |
| (35) Noradrenaline | (36) Bacitracin |
| (37) Vasopressin Injection | (38) Hydroxypropylcellulose |
| (39) Low Substituted
Hydroxypropylcellulose | (40) Hydroxocobalamin Acetate |
| (41) Hydrocortisone Acetate | (42) Hydrocortisone Butyrate |
| (43) Hypromellose | (44) Vincristine Sulfate |
| (45) Vinblastine Sulfate | (46) Glucose Injection |
| (47) Heparin Calcium | (48) Heparin Sodium |
| (49) Verapamil Hydrochloride | (50) Verapamil Hydrochloride Tablets |
| (51) Benzylpenicillin Potassium | (52) Pentobarbital Calcium |
| (53) Fosfomycin Calcium Hydrate | (54) Fosfomycin Sodium |
| (55) Povidone | (56) Polysorbate 80 |
| (57) Polymixin B Sulfate | (58) D-Mannitol |
| (59) Methylcellulose | (60) Folic Acid |
| (61) Sodium Lauryl Sulfate | (62) Powdered Sweet Hydrangea Leaf |
| (63) Artemisia Capillaris Flower | (64) Turmeric |
| (65) Powdered Turmeri | (66) Orengedokuto Extract |
| (67) Otsujito Extract | (68) Curcuma Rhizome |
| (69) Kakkonto Extract | (70) Kakkontokasenkyushin'i Extract |
| (71) Kamikihito Extract | (72) Kamishoyosan Extract |
| (73) Trichosanthes Root | (74) Glycyrrhiza Extract |
| (75) Crude Glycyrrhiza Extract | (76) Platycodon Root |
| (77) Keishibukuryogan Extract | (78) Cyperus Rhizome |
| (79) Powdered Cyperus Rhizome | (80) Oriental Bezoar |
| (81) Goshajinkigan Extract | (82) Euodia Fruit |
| (83) Saikoikeishito Extract | (84) Saibokuto Extract |
| (85) Saireito Extract | (86) Gardenia Fruit |
| (87) Cornus Fruit | (88) Jujube Seed |
| (89) Shakuyakukanzoto Extract | (90) Juzentaihoto Extract |
| (91) Shosaikoto Extract | (92) Shoseiryuto Extract |
| (93) Shimbuto Extract | (94) Daiokanzoto Extract |
| (95) Mukoi-Daikenchuto Extract | (96) Daisaikoto Extract |
| (97) Jujube | (98) Powdered Alisma Tuber |
| (99) Chotosan Extract | (100) Tokakujokito Extract |
| (101) Tokishakuyakusan Extract | (102) Rape Seed Oil |
| (103) Bakumondoto Extract | (104) Hachimijiogan Extract |

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| (105) Hangekobokuto Extract | (106) Hangeshashinto Extract |
| (107) Boigito Extract | (108) Saponnikovia Root and Rhizome |
| (109) Bofutsushosan Extract | (110) Hochuekkito Extract |
| (111) Maoto Extract | (112) Yokukansan Extract |
| (113) Rikkunshito Extract | (114) Ryokeijutsukanto Extract |

List 7

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| (1) Aceglutamide Aluminum | (2) Gramicidin |
| (3) Digitoxin | (4) Digitoxin Tablets |
| (5) Diclofenamide | (6) Diclofenamide Tablets |
| (7) Zinostatin Stimalamer | (8) Serrapeptase |
| (9) Tolazamide | (10) Fluoxymesterone |
| (11) Mercurochrome | (12) Mercurochrome Solution |
| (13) Lanatoside C | (14) Lanatoside C Tablets |
| (15) Rokitamycin | (16) Rokitamycin Tablets |
| (17) Scopolia Extract, Papaverine and
Ethyl Aminobenzoate Powder | |

List 8

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| (1) Azosemide | (2) Entacapone |
| (3) Sultamicillin Tosilate Hydrate | (4) Zonisamide |
| (5) Doxycycline Hydrochloride Hydrate | (6) Tramadol Hydrochloride |
| (7) Pazufloxacin Mesilate | (8) Pyridoxal Phosphate Hydrate |
| (9) Mesalazine | (10) Calcium Levofolinate Hydrate |

List 9

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|-----------------|---------------------|
| (1) Gramicidin | (2) Diclofenamide |
| (3) Tolazamide | (4) Fluoxymesterone |
| (5) Rokitamycin | |

List 10

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|---|-----------------------------------|
| (1) Azosemide | (2) Entacapone |
| (3) Oxytetracycline Hydrochloride | (4) Zonisamide |
| (5) Tramadol Hydrochloride | (6) Pazufloxacin Mesilate |
| (7) Low Substituted
Hydroxypropylcellulose | (8) Pyridoxal Phosphate Hydrate |
| (9) Mesalazine | (10) Calcium Levofolinate Hydrate |

List 11 Following spectra of Infrared Reference Spectra of JP17

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|---------------------------------|------------------------|
| (1) Saccharin Sodium Hydrate | (2) Diclofenamide |
| (3) Tolazamide | (4) Fluoxymesterone |
| (5) Rokitamycin | |

List 12

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| (1) Enzyme-linked immunosorbent assay
(ELISA) | (2) Aerodynamic Assessment of Fine
Particles for Inhalations by Glass
Impingers |
| (3) Glass Containers for Pharmaceutical
Products | (4) Moisture Permeability Test for Blister
Packaging of Solid Preparations |
| (5) Stability Testing of Drug Substance
and Product | (6) Criteria for Content Uniformity in Real
Time Release Testing by Process
Analytical Technology |

List 13

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| (1) Solid and Particle Densities | (2) Powder Fineness |
| (3) Powder Flow | (4) Amino Acid Analysis |
| (5) Purity Tests on Crude Drugs using
Genetic Information | (6) On the Scientific Names of Crude Drugs
listed in the JP |
| (7) Basic Concepts for Quality Assurance
of Drug Substances and Drug
Products | (8) International Harmonization
Implemented in the Japanese
Pharmacopoeia Seventeenth Edition |

List 14 Following paragraphs of General Information of JP17

- (1) Laser Diffraction Measurement of
Particle Size