

Description of content :

The Eighteenth edition of the Japanese Pharmacopoeia (JP) shall be established as follows:

1. To establish 1 paragraph under the section of General Notices (List 1)
2. To amend 1 paragraph under the section of General Notices (List 2)
3. To establish 1 item under the section of General Tests, Processes and Apparatus (List 3)
4. To amend 11 items under the section of General Tests, Processes and Apparatus (List 4)
5. To establish 33 monographs under the section of Official Monographs (List 5)
6. To amend 168 monographs under the section of Official Monographs (List 6)
7. To delete 8 monographs under the section of Official Monographs (List 7)
8. To establish 11 spectra under the section of Ultraviolet-visible Reference Spectra (List 8)
9. To establish 13 spectra under the section of Infrared Reference Spectra (List 9)
10. To establish 7 paragraphs under the section of General Information (List 10)
11. To amend 3 paragraphs under the section of General Information (List 11)
12. To delete 1 paragraph under the section of General Information (List 12)

- Established articles are listed with the planning numbers in the JP Eighteenth edition (JP18).
- Amended or deleted articles are listed with the numbers in the JP Seventeenth edition (JP17).
- The names of articles in English may change through the process of official English translation of JP18.

List 1 34 Paragraph of elemental impurities

List 2 Following paragraphs of General Notices of JP17
8

List 3
2.05 Size Exclusion Chromatography

List 4 Following items of General Tests, Processes and Apparatus of JP17

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|----------------------------------------------------|------------------------------------|
| (1) Preface | (2) 2.46 Residual Solvents |
| (3) 2.48 Water Determination (Karl Fischer Method) | (4) 2.51 Conductivity Measurement |
| (5) 2.52 Thermal Analysis | (6) 2.66 Elemental Impurities |
| (7) 4.06 Sterility Test | (8) 5.01 Crude Drugs Test |
| (9) 9.01 Reference Standards | (10) 9.41 Reagents, Test Solutions |
| (11) 9.62 Measuring Instruments, Appliances | |

List 5

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|--------------------------------------------------|----------------------------------------|
| (1) Irinotecan Hydrochloride Injection | (2) Eribulin Mesilate |
| (3) Cabergoline | (4) Glucagon (Genetical Recombination) |
| (5) Cloperastine Fendizoate | (6) Cloperastine Fendizoate Tablets |
| (7) Gefitinib | (8) Copovidone |
| (9) Silodosin Orally Disintegrating Tablets | (10) Celecoxib |
| (11) Zopiclone | (12) Zopiclone Tablets |
| (13) Telmisartan and Amlodipine Besilate Tablets | (14) Triazolam |

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|---------------------------------------------------------------------------|-------------------------------------------|
| (15) Dorzolamide Hydrochloride and
Timolol Maleate Ophthalmic Solution | (16) Bicalutamide |
| (17) Pitavastatin Calcium Orally
Disintegrating Tablets | (18) Phenobarbital Tablets |
| (19) Fenofibrate | (20) Fenofibrate Tablets |
| (21) Fludiazepam Tablets | (22) Heparin Sodium Solution for Dialysis |
| (23) Heparin Sodium Lock Solution | (24) Miglitol Tablets |
| (25) Methotrexate for Injection | (26) Rilmazafone Hydrochloride Hydrate |
| (27) Rilmazafone Hydrochloride Tablets | (28) Rosuvastatin Calcium |
| (29) Rosuvastatin Calcium Tablets | (30) Ethyl Loflazepate |
| (31) Ethyl Loflazepate Tablets | (32) Unseiin Extract |
| (33) Byakkokaninjinto Extract | |

List 6 Following monographs of Official Monographs of JP17

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|-------------------------------------------------|---------------------------------------------------|
| (1) Azathioprine Tablets | (2) Aprindine Hydrochloride |
| (3) Ethyl Aminobenzoate | (4) Insulin Human
(Genetical Recombination) |
| (5) Insulin Aspart
(Genetical Recombination) | (6) Insulin Glargine
(Genetical Recombination) |
| (7) Ethambutol Hydrochloride | (8) Epoetin Alfa
(Genetical Recombination) |
| (9) Epoetin Beta
(Genetical Recombination) | (10) Ergometrine Maleate |
| (11) Enviomycin Sulfate | (12) Oxytocin |
| (13) Oxybuprocaine Hydrochloride | (14) Olmesartan Medoxomil |
| (15) Kallidinogenase | (16) Calcitonin Salmon |
| (17) Carmellose Calcium | (18) Carmellose Sodium |
| (19) Croscarmellose Sodium | (20) Kitasamycin Acetate |
| (21) Kitasamycin Tartrate | (22) Clinofibrate |
| (23) Clopidogrel Sulfate | (24) Gentamicin Sulfate |
| (25) Colistin Sodium Methanesulfonate | (26) Saccharin |
| (27) Saccharin Sodium Hydrate | (28) Oxygen |
| (29) Distigmine Bromide | (30) Dihydroergotoxine Mesilate |
| (31) Diphenhydramine | (32) Diphenhydramine Hydrochloride |
| (33) Dimorpholamine | (34) Silodosin |

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| (35) Silodosin Tablets | (36) Scopolamine Hydrobromide Hydrate |
| (37) HumanMenopausal Gonadotrophin | (38) Cefoperazone Sodium |
| (39) Gelatin | (40) Purified Gelatin |
| (41) Purified Shellac | (42) White Shellac |
| (43) Celmoleukin (Genetical Recombination) | (44) Teceleukin (Genetical Recombination) |
| (45) Tetracaine Hydrochloride | (46) Wheat Starch |
| (47) Dorzolamide Hydrochloride | (48) Nafamostat Mesilate |
| (49) Nartograstim (Genetical Recombination) | (50) Anhydrous Lactose |
| (51) Lactose Hydrate | (52) Norgestrel and Ethinylestradiol Tablets |
| (53) Sucrose | (54) Vasopressin Injection |
| (55) Calcium Paraaminosalicylate Hydrate | (56) Valaciclovir Hydrochloride |
| (57) Valsartan | (58) Paroxetine Hydrochloride Hydrate |
| (59) Pitavastatin Calcium Hydrate | (60) Pitavastatin Calcium Tablets |
| (61) Low Substituted Hydroxypropylcellulose | (62) Hypromellose |
| (63) Filgrastim (Genetical Recombination) | (64) Scopolamine Butylbromide |
| (65) Glucose Injection | (66) Fradiomycin Sulfate |
| (67) Pullulan | (68) Bleomycin Hydrochloride |
| (69) Bleomycin Sulfate | (70) Protamine Sulfate |
| (71) Heparin Calcium | (72) Heparin Sodium |
| (73) Bepotastine Besilate | (74) Povidone |
| (75) Povidone-Iodine | (76) Voriconazole |
| (77) Voriconazole for Injection | (78) Calcium Folate |
| (79) Polymixin B Sulfate | (80) Mexiletine Hydrochloride |
| (81) Methylergometrine Maleate | (82) Methylcellulose |
| (83) Montelukast Sodium | (84) Sodium Lauryl Sulfate |
| (85) Lauromacrogol | (86) Lysozyme Hydrochloride |
| (87) Lenograstim (Genetical Recombination) | (88) Levofloxacin Hydrate |
| (89) Levofloxacin Tablets | (90) Levofloxacin Fine Granules |
| (91) Levofloxacin Injection | (92) Bearberry Leaf |

- (93) Phellodendron Bark
(94) Powdered Phellodendron Bark
(95) Coptis Rhizome
(96) Powdered Coptis Rhizome
(97) Orengekuto Extract
(98) Zedoary
(99) Pogostemon Herb
(100) Pueraria Root
(101) Kamikihito Extract
(102) Kamishoyosan Extract
(103) Trichosanthes Root
(104) Glycyrrhiza
(105) Notopterygium
(106) Lycium Fruit
(107) Sophora Root
(108) Powdered Sophora Root
(109) Keishibukuryogan Extract
(110) Cinnamon Bark
(111) Cinnamon Oil
(112) Magnolia Bark
(113) Powdered Magnolia Bark
(114) Euodia Fruit
(115) Goshuyuto Extract
(116) Goreisan Extract
(117) Bupleurum Root
(118) Asiasarum Root
(119) Saffron
(120) Gardenia Fruit
(121) Powdered Gardenia Fruit
(122) Cornus Fruit
(123) Japanese Zanthoxylum Peel
(124) Powdered Japanese Zanthoxylum Peel
(125) Jujube Seed
(126) Dioscorea Rhizome
(127) Plantago Seed
(128) Plantago Herb
(129) Houttuynia Herb
(130) Cardamon
(131) Cnidium Rhizome
(132) Powdered Cnidium Rhizome
(133) Peucedanum Root
(134) Nuphar Rhizome
(135) Toad Cake
(136) Atractylodes Lancea Rhizome
(137) Sappan Wood
(138) Perilla Herb
(139) Salvia Miltiorrhiza Root
(140) Clove
(141) Powdered Clove
(142) Uncaria Hook
(143) Polyporus Sclerotium
(144) Powdered Polyporus Sclerotium
(145) Asparagus Root
(146) Tokakujokito Extract
(147) Ipecac Syrup
(148) Nutmeg
(149) Mentha Oil
(150) Hangekobokuto Extract
(151) Lilium Bulb
(152) Poria Sclerotium
(153) Powdered Poria Sclerotium
(154) Belladonna Root
(155) Imperata Rhizome
(156) Quercus Bark
(157) Moutan Bark
(158) Powdered Moutan Bark
(159) Nux Vomica
(160) Nux Vomica Extract Powder
(161) Ephedra Herb
(162) Powdered Japanese Gentian
(163) Alpinia Officinarum Rhizome
(164) Ryokeijutsukanto Extract

(165) Nelumbo Seed

(167) Scopolia Extract Powder

(166) Scopolia Rhizome

(168) Scopolia Extract and Ethyl
Aminobenzoate Powder

List 7 Following monographs of Official Monographs of JP17

(1) Gas Gangrene Antitoxin, Equine

(3) Diphtheria-Tetanus Combined
Toxoid

(5) Freeze-dried Japanese Encephalitis
Vaccine

(7) Methylrosanilinium Chloride

(2) Cholera Vaccine

(4) Japanese Encephalitis Vaccine

(6) Live Oral Poliomyelitis Vaccine

(8) Weil's Disease and Akiyami
Combined Vaccine

List 8

(1) Cabergoline

(3) Gefitinib

(5) Zopiclone

(7) Bicalutamide

(9) Rilmazafone Hydrochloride Hydrate

(11) Ethyl Loflazepate

(2) Cloperastine Fendizoate

(4) Celecoxib

(6) Triazolam

(8) Fenofibrate

(10) Rosuvastatin Calcium

List 9

(1) Cabergoline

(3) Gefitinib

(5) Celecoxib

(7) Triazolam

(9) Fenofibrate

(11) Rilmazafone Hydrochloride Hydrate

(13) Ethyl Loflazepate

(2) Cloperastine Fendizoate

(4) Copovidone

(6) Zopiclone

(8) Bicalutamide

(10) Sodium Lauryl Sulfate

(12) Rosuvastatin Calcium

List 10

(1) A Basic Concept of the Quality
Assurance on Biotechnological
Products (Biopharmaceuticals) 〈G3-
1-180〉

(3) Bacterial Endotoxins Test and
Alternative Methods Using

(2) Control of Culture Media and Strains
of Microorganisms Used for Microbial
Test Methods 〈G4-2-180〉

(4) Radioactivity Measurements Method
for Crude Drugs 〈G5-8-180〉

Recombinant Protein-Reagents for
Endotoxin Assay 〈G4-4-180〉

- (5) Tablet Hardness Determinations 〈G6-4-180〉
- (6) Packaging Integrity Evaluation of Sterile Products 〈G7-4-180〉
- (7) Leak Tests for Packaging of Sterile Products 〈G7-5-180〉

List 11 Following paragraphs of General Information of JP17

- (1) Capillary Electrophoresis 〈G3-7-180〉
- (2) On the Scientific Names of Crude Drugs listed in the JP 〈G5-1-180〉
- (3) International Harmonization Implemented in the Japanese Pharmacopoeia Seventeenth Edition 〈GZ-3-180〉

List 12 Following paragraphs of General Information of JP17

- (1) Control of Elemental Impurities in Drug Products