

## Partial revision of the Japanese Pharmacopoeia, Sixteenth Edition

The Japanese Pharmacopoeia, Sixteenth Edition is to be partially amended as follows :

1. To amend article 23 under the section of General Notice
2. To amend article 1 under the section of General Rules for Crude Drugs
3. To amend article 2 under the section of General Rules of Preparation
4. To add 2.61 Turbidimetric Test under the section of General Tests, Process and Apparatus
5. To amend 7 test methods under the section of General Tests, Process and Apparatus  
(For details to Annex 1)
6. To add 60 monographs under the section of Monographs (For details to Annex 2)
7. To amend 173 monographs under the section of Monographs (For details to Annex 3)
8. To delete the provision of Thiotepa under the section of Monographs
9. To add the provision of Basic Requirements for Plastic Containers for Pharmaceutical Use and Rubber Closures for Containers for Aqueous Infusions under the section of General Information
10. To amend 4 paragraphs under the section of General Information (For details to Annex 4)
11. To delete the provision of Plastic Containers for Pharmaceutical Products under the section of General Information

Annex 1

(1)	1.11 Arsenic Limit Test	(2)	2.25 Infrared Spectrophotometry
(3)	5.01 Crude Drugs Test	(4)	6.02 Uniformity of Dosage Units
(5)	6.06 Foreign Insoluble Matter Test for Injections	(6)	7.02 Test Methods for Plastic Containers
(7)	7.03 Test for Rubber Closure for Aqueous Infusions		

Annex 2

(1)	Aciclovir Granules	(2)	Aciclovir Ophthalmic Ointment
(3)	Aciclovir Tablets	(4)	Azelnidipine Tablets
(5)	Iopamidol Injection	(6)	Ifenprodil Tartrate Fine Granules
(7)	Ifenprodil Tartrate Tablets	(8)	Insulin Human (Genetical Recombination) Injection
(9)	Insulin Glargine (Genetical Recombination)	(10)	Insulin Glargine (Genetical Recombination) Injection
(11)	Calcium Sodium Edetate Hydrate	(12)	Olmесartan Medoxomil
(13)	Olmесartan Medoxomil Tablets	(14)	Olopatadine Hydrochloride
(15)	Olopatadine Hydrochloride Tablets	(16)	Candesartan Cilexetil and Amlodipine Besylate Tablets
(17)	Clonazepam Fine Granules	(18)	Clonazepam Tablets
(19)	Clopidogrel Sulfate	(20)	Clopidogrel Sulfate Tablets
(21)	Colestimide Granules	(22)	Cyclophosphamide Tablets
(23)	Sivelestat Sodium Hydrate	(24)	Sivelestat Sodium for Injection
(25)	Tacalcitol Ointment	(26)	Tazobactam and Piperacillin for Injection
(27)	Telmisartan	(28)	Telmisartan Tablets
(29)	Docetaxel Hydrate	(30)	Docetaxel Injection
(31)	Docetaxel for Injection	(32)	Naftopidil
(33)	Naftopidil Tablets	(34)	Naftopidil Orally Disintegrating Tablets
(35)	Paroxetine Hydrochloride Hydrate	(36)	Paroxetine Hydrochloride Tablets
(37)	Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets	(38)	Pitavastatin Calcium Hydrate
(39)	Pitavastatin Calcium Tablets	(40)	Pilsicainide Hydrochloride Hydrate

(41)	Pilsicainide Hydrochloride Capsules	(42)	Fudosteine
(43)	Fudosteine Tablets	(44)	Pranlukast Hydrate
(45)	Fluconazole Capsules	(46)	Brotizolam Tablets
(47)	Bepotastine Besilate	(48)	Bepotastine Besilate Tablets
(49)	Mequitazine Tablets	(50)	Mecobalamin Tablets
(51)	Leuprorelin Acetate	(52)	Loxoprofen Sodium Tablets
(53)	Losartan Potassium and Hydrochlorothiazide Tablets	(54)	Otsujito Extract
(55)	Kakkontokasenkyushin'i Extract	(56)	Prepared Glycyrrhiza
(57)	Daisaikoto Extract	(58)	Cistanche Herb
(59)	Belladonna Total Alkaloids	(60)	Maoto Extract

### Annex 3

(1)	Alprostadil Alfadex	(2)	Iohexol Injection
(3)	Irsogladine Maleate Fine Granules	(4)	Insulin Human (Genetical Recombination)
(5)	Indometacin	(6)	Ethanol
(7)	Anhydrous Ethanol	(8)	Etizolam Fine Granules
(9)	Etizolam Tablets	(10)	Epoetin Alfa (Genetical Recombination)
(11)	Calcitonin (Salmon)	(12)	Carmellose
(13)	Glycine	(14)	Glycerin
(15)	Concentrated Glycerin	(16)	L-Glutamic Acid
(17)	Chlordiazepoxide Powder	(18)	Cortisone Acetate
(19)	Zaltoprofen Tablets	(20)	Sarpogrelate Hydrochloride Fine Granules
(21)	Zidovudine	(22)	Sterile Water for Injection in Containers
(23)	Dried Aluminum Hydroxide Gel Fine Granules	(24)	Stearic Acid
(25)	Spiramycin Acetate	(26)	Spirolactone
(27)	Cefaclor Fine Granules	(28)	Cefotaxime Sodium
(29)	Cefcapene Pivoxil Hydrochloride Fine Granules	(30)	Cefditoren Pivoxil Fine Granules
(31)	Cefdinir	(32)	Cefdinir Fine Granules
(33)	Ceftazidime Hydrate	(34)	Cefteram Pivoxil

(35)	Cefteram Pivoxil Fine Granules	(36)	Cefpodoxime Proxetil
(37)	Cefmetazole Sodium	(38)	Cefuroxime Axetil
(39)	Celmoleukin (Genetical Recombination)	(40)	Daunorubicin Hydrochloride
(41)	Precipitated Calcium Carbonate Fine Granules	(42)	Thiamine Chloride Hydrochloride
(43)	Tegafur	(44)	Dexamethasone
(45)	Wheat Starch	(46)	Rice Starch
(47)	Corn Starch	(48)	Potato Starch
(49)	Donepezil Hydrochloride Fine Granules	(50)	Dobutamine Hydrochloride
(51)	Triamcinolone	(52)	Triamcinolone Acetonide
(53)	Droxidopa Fine Granules	(54)	Troxipide Fine Granules
(55)	Droperidol	(56)	Nartograstim (Genetical Recombination)
(57)	Panipenem	(58)	Haloperidol Fine Granules
(59)	Calcium Pantothenate	(60)	Purified Sodium Hyaluronate
(61)	Bisacodyl Suppositories	(62)	L-Histidine
(63)	Hydrocortisone	(64)	Hydrocortisone Succinate
(65)	Hydrocortisone Sodium Succinate	(66)	Hydrocortisone Acetate
(67)	Hydrocortisone Sodium Phosphate	(68)	Hypromellose
(69)	Piroxicam	(70)	Filgrastim (Genetical Recombination)
(71)	Pravastatin Sodium Fine Granules	(72)	Fluoxymesterone
(73)	Fluocinonide	(74)	Fluocinolone Acetonide
(75)	Fursultiamine Hydrochloride	(76)	Prednisolone
(77)	Prednisolone Acetate	(78)	Progesterone
(79)	Propylene Glycol	(80)	Probucol Fine Granules
(81)	Flomoxef Sodium	(82)	Beclometasone Dipropionate
(83)	Betamethasone	(84)	Heparin Calcium
(85)	Heparin Sodium	(86)	Heparin Sodium Injection
(87)	Peplomycin Sulfate	(88)	Polysorbate 80
(89)	Maprotiline Hydrochloride	(90)	D-Mannitol
(91)	D-Mannitol Injection	(92)	Mexiletine Hydrochloride
(93)	Mecobalamin	(94)	Metildigoxin
(95)	Methylcellulose	(96)	Methylprednisolone Succinate
(97)	Metoprolol Tartrate	(98)	Meropenem for Injection

(99)	Morphine Hydrochloride Hydrate	(100)	Iodamide
(101)	L-Lysine Hydrochloride	(102)	Risperidone Fine Granules
(103)	Roxithromycin	(104)	Mallotus Bark
(105)	Acacia	(106)	Powdered Acacia
(107)	Scutellaria Root	(108)	Powdered Scutellaria Root
(109)	Phellodendron Bark	(110)	Coptis Rhizome
(111)	Powdered Coptis Rhizome	(112)	Orengedokuto Extract
(113)	Orange Oil	(114)	Pogostemon Herb
(115)	Kakkonto Extract	(116)	Kamishoyosan Extract
(117)	Glycyrrhiza	(118)	Powdered Glycyrrhiza
(119)	Chrysanthemum Flower	(120)	Apricot Kernel
(121)	Gentian	(122)	Powdered Gentian
(123)	Koi	(124)	Brown Rice
(125)	Magnolia Bark	(126)	Powdered Magnolia Bark
(127)	Sesame	(128)	Schisandra Fruit
(129)	Saikokeishito Extract	(130)	Saibokuto Extract
(131)	Saireito Extract	(132)	Crataegus Fruit
(133)	Gardenia Fruit	(134)	Powdered Gardenia Fruit
(135)	Cornus Fruit	(136)	Jujube Seed
(137)	Peony Root	(138)	Powdered Peony Root
(139)	Shosaikoto Extract	(140)	Shoseiryuto Extract
(141)	Exsiccated Gypsum	(142)	Peucedanum Root
(143)	Toad Cake	(144)	Senna Leaf
(145)	Powdered Senna Leaf	(146)	Swertia Herb
(147)	Powdered Swertia Herb	(148)	Atractylodes Lancea Rhizome
(149)	Powdered Atractylodes Lancea Rhizome	(150)	Perilla Herb
(151)	Rhubarb	(152)	Powdered Rhubarb
(153)	Daiokanzoto Extract	(154)	Clove Oil
(155)	Benincasa Seed	(156)	Peach Kernel
(157)	Nutmeg	(158)	Lonicera Leaf and Stem
(159)	Mentha Herb	(160)	Mentha Oil
(161)	Hangekobokuto Extract	(162)	Atractylodes Rhizome
(163)	Powdered Atractylodes Rhizome	(164)	Areca
(165)	Processed Aconite Root	(166)	Powdered Processed Aconite Root

(167)	Moutan Bark	(168)	Powdered Moutan Bark
(169)	Hochuekkito Extract	(170)	Ephedra Herb
(171)	Wood Creosote	(172)	Japanese Gentian
(173)	Royal Jelly		

Annex 4

(1)	Terminal Sterilization and Sterilization Indicators	(2)	Media Fill Test (Process Simulation)
(3)	Quantitative Analytical Technique Utilizing Nuclear Magnetic Resonance (NMR) Spectroscopy and Its Application to Reagents in the Japanese Pharmacopoeia	(4)	International Harmonization Implemented in the Japanese Pharmacopoeia Sixteenth Edition