

Description of content :

The Seventeenth edition of the Japanese Pharmacopoeia (JP17) is to be partially amended as follows:

1. To amend 3 articles under the section of General Notices (List1)
2. To establish 1 article under the section of General Rules of Preparations (List 2)
3. To amend 1 article under the section of General Rules of Preparations (List 3)
4. To establish 4 test methods under the section of General Tests, Processes and Apparatus (List 4)
5. To amend 3 test methods under the section of General Tests, Processes and Apparatus (List 5)
6. To establish 34 monographs under the section of Official Monographs (List 6)
7. To amend 77 monographs under the section of Official Monographs (List 7)
8. To delete 3 monographs under the section of Official Monographs (List 8)
9. To establish 7 spectra under the section of Ultraviolet-visible Reference Spectra (List 9)
10. To establish 9 spectra under the section of Infrared Reference Spectra (List 10)
11. To establish 4 paragraphs under the section of General Information (List 11)
12. To amend 6 paragraphs under the section of General Information (List 12)
13. To delete 3 paragraphs under the section of General Information (List 13)

- Established articles are listed with the planning numbers in Supplement II to the JP seventeenth edition (JP17-2).
- The names of articles in English may change through the process of official English translation of JP17-2.

List 1 Following articles of General Notices of JP17

5, 13, 46

List 2

[3] Monographs for Preparations

3 . 1 . 4. Liposome Injections

List 3 Following articles of General Rules of Preparations of JP17

[3] Monographs for Preparations

3 . 1 . Injections

List 4

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| (1) 2.26 Raman Spectroscopy | (2) 2.66 Elemental Impurities -
Procedures |
| (3) 6.16 Rheological Measurements
for Semi-solid Preparations | (4) 6.17 Insoluble Particulate Matter Test
for Therapeutic Protein Injections |

List 5 Following the methods of General Tests, Process and Apparatus of JP17

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| (1) 2.01 Liquid Chromatography | (2) 2.46 Residual Solvents |
| (3) 2.51 Conductivity Measurement | |

List 6

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| (1) Irinotecan Hydrochloride Hydrate | (2) Ethylcellulose |
| (3) Gatifloxacin Hydrate | (4) Gatifloxacin Ophthalmic Solution |
| (5) Clarithromycin for Syrup | (6) Gentamicin Sulfate Injection |
| (7) Gentamicin Sulfate Ointment | (8) Diclofenac Sodium Suppositories |
| (9) Sitagliptin Phosphate Hydrate | (10) Sitagliptin Phosphate Tablets |
| (11) Cefalotin Sodium for Injection | (12) Cefixime Fine Granules |
| (13) Telmisartan and Hydrochlorothiazide
Tablets | (14) Doripenem Hydrate |

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| (15) Doripenem for Injection | (16) Nortriptyline Hydrochloride Tablets |
| (17) Valsartan and Hydrochlorothiazide Tablets | (18) Sodium Valproate Extended-release Tablets A |
| (19) Sodium Valproate Extended-release Tablets B | (20) Hydroxyethylcellulose |
| (21) Felodipine | (22) Felodipine Tablets |
| (23) Bromfenac Sodium Hydrate | (24) Bromfenac Sodium Ophthalmic Solution |
| (25) Verapamil Hydrochloride Injection | (26) Polaprezinc |
| (27) Polaprezinc Granules | (28) Minocycline Hydrochloride Granules |
| (29) Lanoconazole | (30) Lanoconazole Cutaneous Solution |
| (31) Lanoconazole Ointment | (32) Lanoconazole Cream |
| (33) Ritodrine Hydrochloride Injection | (34) Goshuyuto Extract |

List 7 Following monographs of Official Monographs of JP17

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| (1) Amphotericin B Tablets | (2) Isomalt Hydrate |
| (3) Imipramine Hydrochloride | (4) Imipramine Hydrochloride Tablets |
| (5) Ursodeoxycholic Acid | (6) Estriol |
| (7) Etizolam | (8) Epirubicin Hydrochloride |
| (9) Cloperastine Hydrochloride | (10) Chloramphenicol |
| (11) Chlorpromazine Hydrochloride | (12) Light Anhydrous Silicic Acid |
| (13) Cholesterol | (14) Saccharin |
| (15) Saccharin Sodium Hydrate | (16) Microcrystalline Cellulose |
| (17) Tipepidine Hibenazate Tablets | (18) Teicoplanin |
| (19) Testosterone Enanthate | (20) Dehydrocholic Acid |
| (21) Purified Dehydrocholic Acid | (22) Triamcinolone Acetonide |
| (23) Haloperidol | (24) Pioglitazone Hydrochloride and Glimepiride Tablets |
| (25) Hydroxypropylcellulose | (26) Hydrocortisone |
| (27) Hydrocortisone Acetate | (28) Hydrocortisone and Diphenhydramine Ointment |
| (29) Hypromellose | (30) Sodium Fusidate |
| (31) Beclometasone Dipropionate | (32) Betamethasone Dipropionate |
| (33) Mestranol | (34) Methylcellulose |
| (35) Methylprednisolone | (36) Anhydrous Dibasic Calcium Phosphate |
| (37) Artemisia Capillaris Flower | (38) Otsujito Extract |

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| (39) Polygala Root | (40) Powdered Polygala Root |
| (41) Kakkontokasenkyushin'i Extract | (42) Kamikihito Extract |
| (43) Kamishoyosan Extract | (44) Glycyrrhiza Extract |
| (45) Crude Glycyrrhiza Extract | (46) Platycodon Root |
| (47) Powdered Platycodon Root | (48) Platycodon Fluidextract |
| (49) Chrysanthemum Flower | (50) Bitter Tincture |
| (51) Cassia Seed | (52) Safflower |
| (53) Oriental Bezoar | (54) Calumba |
| (55) Powdered Calumba | (56) Lycium Bark |
| (57) Lithospermum Root | (58) Juzentaihoto Extract |
| (59) Amomum Seed | (60) Toad Cake |
| (61) Swertia Herb | (62) Powdered Swertia Herb |
| (63) Swertia and Sodium Bicarbonate Powder | (64) Gastrodia Tuber |
| (65) Japanese Angelica Root | (66) Powdered Japanese Angelica Root |
| (67) Tokishakuyakusan Extract | (68) Belladonna Root |
| (69) Sinomenium Stem and Rhizome | (70) Boiogito Extract |
| (71) Saposhnikovia Root and Rhizome | (72) Bofutsushosan Extract |
| (73) Hochuekkito Extract | (74) Nux Vomica |
| (75) Eucalyptus Oil | (76) Yokukansan Extract |
| (77) Scopolia Rhizome | |

List 8 Following monographs of Official Monographs of JP17

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| (1) Freeze-dried Tetanus Antitoxin, Equine | (2) Adsorbed Habu-venom Toxoid |
| (3) Compound Vitamin B Powder | |

List 9

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| (1) Irinotecan Hydrochloride Hydrate | (2) Gatifloxacin Hydrate |
| (3) Sitagliptin Phosphate Hydrate | (4) Doripenem Hydrate |
| (5) Felodipine | (6) Bromfenac Sodium Hydrate |
| (7) Lanoconazole | |

List 10

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|--------------------------------------|-----------------------------------|
| (1) Irinotecan Hydrochloride Hydrate | (2) Ethylcellulose |
| (3) Gatifloxacin Hydrate | (4) Sitagliptin Phosphate Hydrate |
| (5) Doripenem Hydrate | (6) Felodipine |
| (7) Bromfenac Sodium Hydrate | (8) Polaprezinc |

(9) Lanoconazole

List 11

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| (1) Control of Elemental Impurities in Drug Products | (2) Host Cell Protein Analysis |
| (3) Concept on Impurities in Chemically synthesized Drug Substances and Drug Products | (4) Glossary for Quality by Design(QbD), Quality Risk Management(QRM) and Pharmaceutical Quality System(PQS) |

List 12 Following paragraphs of General Information of JP17

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|---|---|
| (1) Total Protein Assay | (2) Purity Tests on Crude Drugs using Genetic Information |
| (3) On the Scientific Names of Crude Drugs listed in the JP | (4) Quality Control of Water for Pharmaceutical Use |
| (5) Basic Concepts for Quality Assurance of Drug Substances and Drug Products | (6) International Harmonization Implemented in the Japanese Pharmacopoeia Seventeenth Edition |

List 13

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| (1) Parametric Release of Terminally Sterilized Pharmaceutical Products | (2) Media Fill Test (Process Simulation) |
| (3) Microbiological Environmental Monitoring Methods of Processing Areas for Sterile Pharmaceutical Products | |