

Description of content :

The Seventeenth edition of the Japanese Pharmacopoeia (JP17) was partially revised 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)



Tablets

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

List 7 Following monographs of Official Monographs of JP17

- |                                    |  |
|------------------------------------|--|
| (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) Tiperidine Hibenazate Tablets | (18) Teicoplanin   |
| (19) Testosterone Enanthate        | (20) Dehydrocholic Acid                                    |
| (21) Purified Dehydrocholic Acid   | (22) Triamcinolone Acetonide                               |
| (23) Haloperidol                   | (24) Pioglitazone Hydrochloride and<br>Glimepiride Tablets |
| (25) Hydroxypropylcellulose        | (26) Hydrocortisone  |
| (27) Hydrocortisone Acetate        | (28) Hydrocortisone and Diphenhydramine<br>Ointment        |
| (29) Hypromellose                  | (30) Sodium Fusidate                                       |
| (31) Beclometasone Dipropionate    | (32) Betamethasone Dipropionate                            |
| (33) Mestranol                     | (34) Methylcellulose                                       |
| (35) Methylprednisolone            | (36) Anhydrous Dibasic Calcium<br>Phosphate                |

- |  |                                      |
|--|--------------------------------------|
| (37) Artemisia Capillaris Flower           | (38) Otsujito Extract                |
| (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

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

List 9

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

List 10

- |                                      |                                   |
|--------------------------------------|-----------------------------------|
| (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

- (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

- (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

- (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