

Description of content :

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

1. To establish 1 item under the section of General Tests, Processes and Apparatus (List 1)
2. To amend 10 items under the section of General Tests, Processes and Apparatus (List 2)
3. To establish 13 monographs under the section of Official Monographs (List 3)
4. To amend 95 monographs under the section of Official Monographs (List 4)
5. To delete 7 monographs under the section of Official Monographs (List 5)
6. To establish 5 spectra under the section of Ultraviolet-visible Reference Spectra (List 6)
7. To establish 7 spectra under the section of Infrared Reference Spectra (List 7)
8. To delete 1 spectra under the section of Infrared Reference Spectra (List 8)
9. To establish 6 paragraphs under the section of General Information (List 9)
10. To amend 5 paragraphs under the section of General Information (List 10)
11. To delete 1 paragraph under the section of General Information (List 11)

- Established articles are listed with the planning numbers in Supplement II to the JP Eighteenth edition (JP18-2).
- Amended or deleted articles are listed with the numbers in the JP (previous Pharmacopoeia).
- The names of articles in English may change through the process of official English translation of JP18-2.

List 1

|     |   |
|-----|---|
| (1) | 3.07 Measurement of the Diameter of Particles Dispersed in Liquid by Dynamic Light Scattering |
|-----|---|

List 2 Following items of General Tests, Processes and Apparatus of previous Pharmacopoeia

|     |  |      |  |
|-----|--|------|--|
| (1) | 2.03 Thin-layer Chromatography                         | (2)  | 2.46 Residual Solvents                 |
| (3) | 2.66 Elemental Impurities                              | (4)  | 3.01 Determination of Bulk Density     |
| (5) | 4.02 Microbial Assay for Antibiotics                   | (6)  | 5.01 Crude Drugs Test                  |
| (7) | 9.01 Reference Standards                               | (8)  | 9.41 Reagents, Test Solutions          |
| (9) | 9.42 Solid Supports/Column Packings for Chromatography | (10) | 9.62 Measuring Instruments, Appliances |

List 3

|      |                        |      |                           |
|------|------------------------|------|---------------------------|
| (1)  | Aripiprazole           | (2)  | Oxaliplatin               |
| (3)  | Oxaliplatin Injection  | (4)  | Gefitinib Tablets         |
| (5)  | Goserelin Acetate      | (6)  | Lithium Carbonate Tablets |
| (7)  | Tolvaptan              | (8)  | Tolvaptan tablets         |
| (9)  | Febuxostat             | (10) | Febuxostat Tablets        |
| (11) | Lornoxicam             | (12) | Lornoxicam Tablets        |
| (13) | Shin'iseihaito Extract |      |                           |

List 4 Following monographs of Official Monographs of previous Pharmacopoeia

|      |                              |      |                         |
|------|------------------------------|------|-------------------------|
| (1)  | Sodium Bisulfite             | (2)  | Dried Sodium Sulfite    |
| (3)  | Disodium Edetate Hydrate     | (4)  | Carmellose Calcium      |
| (5)  | Glycerin                     | (6)  | Concentrated Glycerin   |
| (7)  | Clindamycin Phosphate        | (8)  | Clonidine Hydrochloride |
| (9)  | Light Anhydrous Silicic Acid | (10) | Magnesium Silicate      |
| (11) | Cyclophosphamide Hydrate     | (12) | Citicoline              |

|      |                                      |      |  |
|------|--------------------------------------|------|--|
| (13) | Calcium Stearate                     | (14) | Polyoxyl 40 Stearate                   |
| (15) | Magnesium Stearate                   | (16) | Sorbitan Sesquioleate                  |
| (17) | Talc                                 | (18) | Dried Sodium Carbonate                 |
| (19) | Sodium Carbonate Hydrate             | (20) | Dextran 70                             |
| (21) | Teceleukin (Genetical Recombination) | (22) | White Soft Sugar                       |
| (23) | Paraffin                             | (24) | Liquid Paraffin                        |
| (25) | Light Liquid Paraffin                | (26) | Low Substituted Hydroxypropylcellulose |
| (27) | Hypromellose                         | (28) | Sodium Pyrosulfite                     |
| (29) | Glucose                              | (30) | Propylene Glycol                       |
| (31) | Beclometasone Dipropionate           | (32) | Sodium Polystyrene Sulfonate           |
| (33) | Meglumine                            | (34) | Methylcellulose                        |
| (35) | Aluminum Monostearate                | (36) | Sodium Iodide                          |
| (37) | Loxoprofen Sodium Hydrate            | (38) | Sweet Hydrangea Leaf                   |
| (39) | Artemisia Capillaris Flower          | (40) | Epimedium Herb                         |
| (41) | Lindera Root                         | (42) | Bearberry Leaf                         |
| (43) | Polygonatum Rhizome                  | (44) | Artemisia Leaf                         |
| (45) | Pogostemon Herb                      | (46) | Pueraria Root                          |
| (47) | Chrysanthemum Flower                 | (48) | Lycium Fruit                           |
| (49) | Gentian                              | (50) | Powdered Gentian                       |
| (51) | Goshajinkigan Extract                | (52) | Schisandra Fruit                       |
| (53) | Cornus Fruit                         | (54) | Rehmannia Root                         |
| (55) | Cardamon                             | (56) | Hedysarum Root                         |
| (57) | Shimbuto Extract                     | (58) | Senna Leaf                             |
| (59) | Sappan Wood                          | (60) | Perilla Herb                           |
| (61) | Rhubarb                              | (62) | Powdered Rhubarb                       |
| (63) | Jujube                               | (64) | Salvia Miltiorrhiza Root               |
| (65) | Uncaria Hook                         | (66) | Citrus Unshiu Peel                     |
| (67) | Asparagus Root                       | (68) | Tokishakuyakusan Extract               |
| (69) | Codonopsis Root                      | (70) | Nutmeg                                 |
| (71) | Lonicera Leaf and Stem               | (72) | Ophiopogon Root                        |
| (73) | Hachimijogon Extract                 | (74) | Mentha Herb                            |
| (75) | Loquat Leaf                          | (76) | Processed Aconite Root                 |
| (77) | Belladonna Extract                   | (78) | Boiogito Extract                       |
| (79) | Quercus Bark                         | (80) | Nux Vomica Extract                     |

|      |                                    |      |   |
|------|------------------------------------|------|---|
| (81) | Nux Vomica Extract Powder          | (82) | Nux Vomica Tincture                             |
| (83) | Digenea                            | (84) | Akebia Stem                                     |
| (85) | Leonurus Herb                      | (86) | Coix Seed                                       |
| (87) | Powdered Coix Seed                 | (88) | Yokukansankachimpihange Extract                 |
| (89) | Nelumbo Seed                       | (90) | Scopolia Extract                                |
| (91) | Scopolia Extract Powder            | (92) | Scopolia Extract and Ethyl Aminobenzoate Powder |
| (93) | Scopolia Extract and Carbon Powder | (94) | Compound Scopolia Extract and Diastase Powder   |
| (95) | Royal Jelly                        |      |   |

List 5 Following monographs of Official Monographs of previous Pharmacopoeia

|     |                      |     |                     |
|-----|----------------------|-----|---------------------|
| (1) | Amlexanox            | (2) | Amlexanox Tablets   |
| (3) | Cefadroxil           | (4) | Cefadroxil Capsules |
| (5) | Cefadroxil for Syrup | (6) | Tolbutamide         |
| (7) | Tolbutamide Tablets  |     |                     |

List 6

|     |              |     |             |
|-----|--------------|-----|-------------|
| (1) | Aripiprazole | (2) | Oxaliplatin |
| (3) | Tolvaptan    | (4) | Febuxostat  |
| (5) | Lornoxicam   |     |             |

List 7

|     |              |     |                          |
|-----|--------------|-----|--------------------------|
| (1) | Aripiprazole | (2) | Disodium Edetate Hydrate |
| (3) | Oxaliplatin  | (4) | Cyclophosphamide Hydrate |
| (5) | Tolvaptan    | (6) | Febuxostat               |
| (7) | Lornoxicam   |     |                          |

List 8 Following spectra of Infrared Reference Spectra of previous Pharmacopoeia

|     |                       |
|-----|-----------------------|
| (1) | Clindamycin Phosphate |
|-----|-----------------------|

List 9

|     |  |     |  |
|-----|--|-----|--|
| (1) | Analyses of Size and Morphology of Nanoparticles by Atomic Force Microscope <G1-9-182> | (2) | Concept of Weighing in the Japanese Pharmacopoeia <G1-6-182> |
| (3) | Calibration, Inspection, and Weight of   | (4) | Installation Environment, Basic                              |

|     |   |     |  |
|-----|---|-----|--|
|     | a weighing instrument (balance)<br>〈G1-7-182〉 |     | Handling Method, and Precautions<br>for Weighing of a Balance 〈G1-8-<br>182〉   |
| (5) | Flow Cytometry 〈G3-16-182〉                    | (6) | Evaluation Method of Insoluble<br>Particulate Matter in Biotechnological<br>Products (Biopharmaceuticals) Drug<br>Substances/Drug Products by Flow<br>Imaging Method 〈G3-17-182〉 |

List 10 Following paragraphs of General Information of previous Pharmacopoeia

|     |  |     |   |
|-----|--|-----|---|
| (1) | Solid and Particle Densities 〈G2-1-<br>171〉  | (2) | Powder Flow 〈G2-3-171〉  |
| (3) | Peptide Mapping 〈G3-3-142〉   | (4) | On the Scientific Names of Crude<br>Drugs listed in the JP 〈G5-1-181〉 |
| (5) | Thin-layer Chromatography for<br>Crude Drugs and Crude Drug<br>Preparations 〈G5-3-170〉 |     |   |

List 11 Following paragraph of General Information of previous Pharmacopoeia

|     |  |
|-----|--|
| (1) | Measurement of the Diameter of Particles Dispersed in Liquid by Dynamic Light<br>Scattering 〈G2-4-161〉 |
|-----|--|