

PREFACE

The Thirteenth Edition of the Japanese Pharmacopoeia was promulgated on March 13, 1996 by Ministerial Notification No. 73 of the Ministry of Health and Welfare. To keep pace with progress in medical and pharmaceutical sciences, in November 1996, the Council, at a meeting of the Committee on Japanese Pharmacopoeia (JP) established the principles for the preparation of the JP Fourteenth Edition, setting out the characteristics and roles of the JP, standards for the selection of articles, the items and date of the revision, and the organization of the Subcommittee on JP, as well as agreeing on the publication, if necessary, of a supplement to the current JP.

At the above meeting, the following "five pillars" were established as the basic principles of the JP Fourteenth Edition: 1) making it more substantial by including all drugs which are important from the viewpoint of health care and medical treatment, 2) improving the quality of analytical tests and reducing test items by positively introducing tests using instrumental techniques, 3) ensuring transparency regarding the revision of the JP by opening its draft to the public, 4) taking into consideration its compatibility with equivalent publications in the rest of the world, and 5) setting up a scheme for furnishing information regarding the JP, including drug information. It was decided at the meeting that each panel set up under the Subcommittee on JP should make efforts, on the basis of these principles, to ensure that the JP is used more effectively in the fields of health care and medical treatment by taking appropriate measures, including getting the understanding and cooperation of other parties concerned.

It was agreed that the JP should have the characteristics of an official standard for the description and quality of drugs which are generally recognized to be medically significant from the viewpoint of medical treatment, that its role should be to specify not only the quality standards of drugs which are filed in it, but also the quality level of all drugs in principle, as well as the standard methods of tests, and that at the same time, it should help to ensure international compatibility regarding quality of drugs.

It was also agreed that JP articles should cover drugs which are important from the viewpoint of health care and medical treatment based on demand, frequency of use and clinical results, and which meet the established standards as regards their description and quality, that

especially drugs whose review has been finished or is to be finished before the JP Fourteenth Edition is implemented be filed in it in principle, except those which are not widely used, that opinions from medical treatment-related groups be referred to in selecting articles as occasion may demand, and that the completion of the JP Fourteenth Edition be slated for April 2001.

Under the Subcommittee on JP, the following twelve panels and two provisional panels were established: Panel on the Principles of Revisions; Panel on the Selection of Articles; First Panel on Medicinal Chemicals; Second Panel on Medicinal Chemicals; Panel on Material Sciences; Panel on Biological Tests; Panel on Physico-chemical Tests; Panel on Preparations; Panel on Crude Drugs; Panel on Nomenclature; Panel on Excipients; Panel on Biologically Derived Drugs; Provisional First Panel on Physico-chemical Tests; Provisional First Panel on Crude Drugs. The names of two of the above panels, Panel on Nomenclature and Panel on Excipients, were changed to Subcommittee on Japanese Accepted Names of Drugs and Subcommittee on Pharmaceutical Excipients, respectively, due to the reorganization of the Central Pharmaceutical Affairs Council (CPAC) in November 1999.

In the Committee on Japanese Pharmacopoeia, Mitsuru Uchiyama took the role of chairman from July 1995 to October 1997 and Tadao Terao from November 1997 to December 2000.

With the reform of central government ministries and agencies in January 2001, the Ministry of Health and Welfare became the Ministry of Health, Labour and Welfare, and the Committee on Japanese Pharmacopoeia (CJP) came under the authority of the Minister of Health, Labour and Welfare. At the same time, CPAC became the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) and Mitsuru Uchiyama was nominated as chairman of the CJP.

It was decided that the JP will be revised not only every five years, in line with the revision policy of the JP Eleventh Edition, but also more frequently, if necessary to take account of recent progress of science and in the interests of international harmonization.

In accordance with the revision principles, the panels continued discussions on selection of articles, and revisions for general notices, general rules for preparations, general tests, and monographs on drugs.

Draft revisions covering subjects in the general no-

tices, the general rules for preparations, the general tests, and monographs on drugs, for which discussions were finished between October 1995 and December 1996, were prepared for a supplement to the book. They were examined by the Committee on JP in July 1997, followed by the Executive Committee of the Central Pharmaceutical Affairs Council (CPAC; this became the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) in January 2001), and then submitted to the Minister of Health and Welfare in September 1997, and the supplement was named "Supplement I to the Japanese Pharmacopoeia Thirteenth Edition" and promulgated on December 26, 1997 by Ministerial Notification No.254 of the Ministry of Health and Welfare.

Numbers of discussions in the Panels to prepare supplement drafts were as follows: Panel on the Principles of Revisions, 6 times; First Panel on Medicinal Chemicals, 9 times; Second Panel on Medicinal Chemicals, 8 times; Panel on Material Sciences, 5 times; Panel on Biological Tests, 9 times; Panel on Physico-chemical Tests, 4 times; Panel on Preparations, 5 times; Panel on Crude Drugs, 11 times; Panel on Nomenclature, 6 times; Panel on Excipients, 9 times; Panel on Biologically Derived Drugs, 4 times.

In consequence of this revision, the JP Thirteenth Edition with Supplement I carries 826 articles in Part I owing to the addition of 2 articles; and 469 articles in Part II owing to the addition of one article. It should be noted that in the preparation of the drafts for the revised edition, generous cooperation was given by the Technical Committee of the Pharmaceutical Manufacturer's Association of Tokyo and of Osaka, the Crude Drugs Association of Tokyo, the Japan Pharmaceutical Excipients Council, the Federation of Crude Drugs Associations of Japan, the Japan Flavor and Fragrance Manufacturer's Association, the Japan Medical Plants Federation, the Japan Pharmaceutical Manufacturer's Association, the Japanese Society of Hospital Pharmacists, the Japan Pharmaceutical Association, and the Japan Oilseed Processors Association.

The revision work was continued in the Subcommittee on JP. Draft revisions covering subjects in the general notices, the general rules for preparations, the general tests, and monographs on drugs, for which discussions were finished between January 1997 and December 1998, were prepared for a supplement to the book. They were examined by the Committee on JP in July 1999, followed by the Executive Committee of CPAC, and then submitted to the Minister of Health and Welfare in September 1999, and the supplement was named "Supplement II to the Japanese Phar-

macopoeia Thirteenth Edition" and promulgated on December 21, 1999 by Ministerial Notification No.248 of the Ministry of Health and Welfare.

Numbers of discussions in the Panels to prepare supplement drafts were as follows: Panel on the Principles of Revisions, 8 times; First Panel on Medicinal Chemicals, 17 times; Second Panel on Medicinal Chemicals, 20 times; Panel on Material Sciences, 10 times; Panel on Biological Tests, 9 times; Panel on Physico-chemical Tests, 11 times; Panel on Preparations, 9 times; Panel on Crude Drugs, 9 times; Panel on Nomenclature, 9 times; Panel on Excipients, 11 times; Panel on Biologically Derived Drugs, 12 times; Provisional First Panel on Physico-chemical Tests, 1 time; Provisional First Panel on Crude Drugs, 6 times.

In consequence of this revision, the JP Thirteenth Edition with Supplements I and II carries 839 articles in Part I owing to the addition of 25 articles and the deletion of 12 articles; and 468 articles in Part II owing to the deletion of one article. It should be noted that in the preparation of the drafts for the revised edition, generous cooperation was given by the Technical Committee of the Pharmaceutical Manufacturer's Association of Tokyo and of Osaka, the Crude Drugs Association of Tokyo, the Japan Pharmaceutical Excipients Council, the Federation of Crude Drugs Associations of Japan, the Japan Flavor and Fragrance Manufacturer's Association, the Japan Medical Plants Federation, the Japan Pharmaceutical Manufacturer's Association, the Japanese Society of Hospital Pharmacists, the Japan Pharmaceutical Association, and the Japan Oilseed Processors Association.

The revision work was continued in the Subcommittee on JP. Draft revisions covering subjects in the general notices, the general rules for preparations, the general rules for crude drugs, the general tests, and monographs on drugs, for which discussions were finished between January 1999 and May 2000, were prepared as addition and revision drafts for the Fourteenth Edition of JP. They were examined by the Committee on JP in October 2000, followed by the Executive Committee of CPAC in December 2000, and then submitted to the Minister of Health and Welfare.

Numbers of discussions in the Panels to prepare supplement drafts were as follows: Panel on the Principles of Revisions, 6 times; First Panel on Medicinal Chemicals, 12 times; Second Panel on Medicinal Chemicals, 16 times; Panel on Material Sciences, 7 times; Panel on Biological Tests, 6 times; Panel on Physico-chemical Tests, 8 times; Panel on Preparations, 5 times; Panel on Crude Drugs, 6 times; Panel on Nomenclature, 4 times; Panel on Excipients, 5 times; Panel on Biologically Derived Drugs, 7 times; Provisional First Panel

on Antibiotics, 14 times; Provisional First Panel on Crude Drugs, 6 times. Numbers of additional discussions in the subcommittees for the same purpose were as follows: Subcommittee on Pharmaceutical Nomenclature, 4 times; Subcommittee on Pharmaceutical Excipients, 3 times.

In consequence of this revision, the JP Fourteenth Edition carries 859 articles in Part I owing to the addition of 37 articles and the deletion of 17 articles; and 469 articles in Part II owing to the addition of one article.

It should be noted that in the preparation of the drafts for the new edition, generous cooperation was given by the Technical Committee of the Pharmaceutical Manufacturer's Association of Tokyo and of Osaka, the Crude Drugs Association of Tokyo, the Japan Pharmaceutical Excipients Council, the Federation of Crude Drugs Associations of Japan, the Japan Antibiotics Research Association, the Japan Flavor and Fragrance Manufacturer's Association, the Japan Medical Plants Federation, the Japan Pharmaceutical Manufacturer's Association, the Japanese Society of Hospital Pharmacists, the Japan Pharmaceutical Association, and the Japan Oilseed Processors Association.

The principles of description and the salient points of the revision in this volume are as follows:

1. The JP Fourteenth Edition comprises the following items, in order: Notification of the Ministry of Health and Welfare; Contents; Preface; General Notices; General Rules for Preparations; General Tests, Processes and Apparatus; Monographs on Drugs in Part I, and General Notices; General Rules for Crude Drugs; General Rules for Preparations; General Tests, Processes and Apparatus; Monographs on Drugs in Part II, followed by Infrared Reference Spectra in Part I and Part II; Ultraviolet-visual Reference Spectra in Part I and Part II; General Information, and the Index.

2. The articles in General Rules for Preparations, in General Tests, Processes and Apparatus, Monographs on Drugs, Infrared Reference Spectra and Ultraviolet-visual Reference Spectra are respectively placed in alphabetical order.

3. The following items in each monograph are put in the order shown below, except that unnecessary items are omitted depending on the nature of the drug:

- (1) English title
- (2) Commonly used name(s)
- (3) Latin title (only for Crude Drugs)
- (4) Title in Japanese
- (5) Structural formula or empirical formula

- (6) Molecular formula and molecular mass
- (7) Chemical name
- (8) Origin
- (9) Limits of the content of the ingredient(s) and/or the unit of potency
- (10) Labeling requirements
- (11) Method of preparation
- (12) Description
- (13) Identification tests
- (14) Specific physical and/or chemical values
- (15) Purity tests
- (16) Loss on drying, loss on ignition, and/or water
- (17) Residue on ignition, total ash, and/or acid-insoluble ash
- (18) Special tests
- (19) Isomer ratio
- (20) Assay or the content of the ingredient(s)
- (21) Containers and storage
- (22) Expiration date
- (23) Others

4. In each monograph on a drug, the following physical and chemical values representing the properties and quality of the drug are given in the order indicated below, except that unnecessary items are omitted depending on the nature of the drug:

- (1) Alcohol number
- (2) Absorbance
- (3) Congealing point
- (4) Refractive index
- (5) Osmolarity
- (6) Optical rotation
- (7) Viscosity
- (8) pH
- (9) Specific gravity
- (10) Boiling point
- (11) Melting point
- (12) Acid value
- (13) Saponification value
- (14) Ester value
- (15) Hydroxyl value
- (16) Iodine value

5. Identification tests comprise the following items, which are generally put in the order given below:

- (1) Coloration reactions
- (2) Precipitation reactions
- (3) Decomposition reactions
- (4) Derivative
- (5) Visible, ultraviolet or infrared spectra
- (6) Special reactions
- (7) Cations
- (8) Anions

6. Purity tests comprise the following items, which are generally put in the order given below, except that unnecessary items are omitted depending on the nature of the drug:

- (1) Color
- (2) Odor
- (3) Clarity and/or color of solution
- (4) Acidity or alkalinity
- (5) Acid
- (6) Alkali
- (7) Chloride
- (8) Sulfate
- (9) Sulfite
- (10) Nitrate
- (11) Nitrite
- (12) Carbonate
- (13) Bromide
- (14) Iodide
- (15) Soluble halide
- (16) Thiocyanate
- (17) Selenium
- (18) Cationic salts
- (19) Ammonium
- (20) Heavy metals
- (21) Iron
- (22) Manganese
- (23) Chromium
- (24) Bismuth
- (25) Tin
- (26) Aluminum
- (27) Zinc
- (28) Cadmium
- (29) Mercury
- (30) Copper
- (31) Lead
- (32) Silver
- (33) Alkaline earth metals
- (34) Arsenic
- (35) Foreign matter
- (36) Related substances
- (37) Other mixtures
- (38) Readily carbonizable substances

7. To the General Notices a paragraph explaining the meaning of the statement in a monograph "Being specified separately" is added.

8. Revisions in the General Notices are as follows:

- (1) A part of paragraph 3 was revised owing to the revision in the General Notices for Preparations.
- (2) A part of paragraph 5 was revised as "Atomic masses adopted in JP14 conform to the table of Standard Atomic Weights 1999."

(3) In paragraphs 5, 6 and 26, the word "weight" was changed to "mass".

9. The following items of the General Rules for Preparations are partially revised:

- (1) General Notices for Preparations: Prescribed the conditions that permit omission of the sterility test for the release of the product.
- (2) Injections: Prescribed that principally injections should meet the requirement of the bacterial endotoxins test.

10. The following items of the General Tests, Processes and Apparatus are partially revised:

- (1) Bacterial Endotoxins Test
- (2) Endpoint Detection Method in Titrimetry
- (3) Gas Chromatography
- (4) Infrared Spectrophotometry
- (5) Liquid Chromatography
- (6) pH Determination
- (7) Ultraviolet-visible Spectrophotometry
- (8) Viscosity Determination

11. The following items of the General Tests, Processes and Apparatus are renamed:

- (1) Endpoint Detection Methods in Titrimetry
- (2) Mass Variation Test
- (3) Ultraviolet-visible Spectrophotometry

12. The following tests are added to the General Tests, Processes and Apparatus:

- (1) Microbial Assay for Antibiotics
- (2) Microbial Limit Test for Crude Drugs

13. The following Reference Standards are deleted:
Cyclandelate
G-Strophanthin

14. The following Reference Standards are added:

- Amikacin Sulfate
- Amoxicillin
- Amphotericin B
- Ampicillin
- Aspoxicillin
- Aztreonam
- Bacampicillin Hydrochloride
- Cefadroxil
- Cefalexin
- Cefapirin Sodium
- Cefatrizine Propylene Glycolate
- Cefazolin
- Cefcapene Pivoxil Hydrochloride
- Cefdinir
- Cefditoren Pivoxil
- Cefepime Dihydrochloride
- Cefetamet Pivoxil Hydrochloride

Cefixime
 Cefmetazole
 Cefminox Sodium
 Cefoperazone
 Cefoselis Sulfate
 Cefotiam Hydrochloride
 Cefozopran Hydrochloride
 Cefpirome Sulfate
 Cefradine
 Cefsulodin Sodium
 Ceftazidime
 Ceftibuten Hydrochloride
 Ceftizoxime
 Ceftriaxone Sodium
 Cefuroxime Sodium
 Clarithromycin
 Cloxacillin Sodium
 Colistin Sodium Methanesulfonate
 Cycloserine
 Dicloxacillin Sodium
 Erythromycin
 Faropenem Sodium
 Fosfomycin Phenethylammonium
 Guaifenesin
 Human Insulin
 Idarubicin Hydrochloride
 Isepamicin Sulfate
 Josamycin
 Kitasamycin
 Lithium Clavulanate
 Mecobalamin
 Menatetrenone
 Meropenem Trihydrate
 Midecamycin
 Midecamycin Acetate
 Minocycline Hydrochloride
 Mupirocin Lithium
 Neostigmine Methylsulfate
 Netilmicin Sulfate
 Nystatin
 Panipenem
 Pentobarbital
 Piperacillin
 Rokitamycin
 Roxithromycin
 Sisomicin Sulfate
 Spironolactone
 Sulbactam
 Sultamicillin Tosilate
 Swertiamarin
 Teicoplanin
 Testosterone Propionate
 Tetracycline Hydrochloride

Ticarcillin Sodium
 Zinostatin Stimalamer

15. English and Latin titles of drugs are derived, in principle, from International Nonproprietary Names (INN) for Pharmaceutical Substances recommended by the World Health Organization. Japanese titles are derived from the Japanese version of this book. The chemical names are based on the rules of the International Union of Pure and Applied Chemistry (IUPAC).

16. Molecular formulas of organic compounds begin with C and then H, followed by other involved elements in the alphabetical order of the symbols of the elements.

17. Structural formulas of drugs represent, as far as possible, steric configurations. Molecular masses are calculated based on the table of "Standard Atomic Weights 1999" published by The Chemical Society of Japan.

18. Test procedures in monographs in Part I are, in principle, written in full even in corresponding monographs in Part II, and vice versa. The test procedures in monographs for preparations are also written in full even within the same part, except in the monographs for preparations having a corresponding monograph of their principal material substances.

19. In Official Monographs, names of some of the reagents and the test solutions are changed to the latest names based on the JIS, and the word "weight" is changed to "mass" to adjust to the international metrology.

20. The following articles are deleted from Official Monographs

Part I

Bencyclane Fumarate
 Bencyclane Fumarate Tablets
 Betanidine Sulfate
 Betanidine Sulfate Tablets
 Brovincamine Fumarate
 Cinnarizine
 Cyclandelate
 Dextran 70 Injection
 G-Strophanthin
 G-Strophanthin Injection
 Moxisylyte Hydrochloride
 Pentoxifylline
 Phenoxymethylpenicillin Potassium
 Tetracycline
 Tetracycline Metaphosphate
 Tetragastrin
 Trimetaphan Camsilate

21. The following articles are newly added to Official Monographs:

Part I

Afloqualone
 Alprazolam
 Captopril
 Cefazolin Sodium Hydrate
 Cefcapene Pivoxil Hydrochloride
 Cefdinir
 Cefditoren Pivoxil
 Cefepime Dihydrochloride
 Cefetamet Pivoxil Hydrochloride
 Cefoselis Sulfate
 Cefozopran Hydrochloride
 Cefpiromé Sulfate
 Ceftibuten
 Clarithromycin
 Dopamine Hydrochloride Injection
 Famotidine Powder
 Famotidine Tablets
 Famotidine for Injection
 Faropenem Sodium
 Idarubicin Hydrochloride
 Insulin Human (Genetical Recombination)
 Iopamidol
 Maprotiline Hydrochloride
 Mecobalamin
 Mefruside Tablets
 Menatetrenone
 Mequitazine
 Meropenem Trihydrate
 Mupirocin Calcium Hydrate
 Naloxone Hydrochloride
 Nicardipine Hydrochloride Injection
 Norfloxacin
 Pancuronium Bromide
 Panipenem
 Pentobarbital Calcium
 Teicoplanin
 Zinostatin Stimalamer

Part II

β -Galactosidase (Penicillium)

22. The following monographs are revised by an addition or a change in the Description or other items:

Part I

Acetohexamide
 Acetylcholine Chloride for Injection
 Acetylkitasamycin
 Ambenonium Chloride
 Amikacin Sulfate
 Amoxicillin
 Amphotericin B

Aspoxicillin
 Azathioprine
 Aztreonam
 Bacampicillin Hydrochloride
 Baclofen
 Beclometasone Dipropionate
 Bufexamac Cream
 Bufexamac Ointment
 Camostat Mesilate
d-Camphor
dl-Camphor
 Cefadroxil
 Cefalexin
 Cefapirin Sodium
 Cefatrizine Propylene Glycolate
 Cefazolin Sodium
 Cefixime
 Cefmetazole Sodium
 Cefminox Sodium
 Cefoperazone Sodium
 Cefotiam Hydrochloride
 Cefradine
 Cefsulodin Sodium
 Ceftazidime
 Ceftizoxime Sodium
 Ceftriaxone Sodium
 Cefuroxime Sodium
 Chlorpropamide Tablets
 Cloxacillin Sodium
 Colistin Sodium Methanesulfonate
 Cortisone Acetate
 Cycloserine
 Dextromethorphan Hydrobromide
 Diclofenac Sodium
 Dicloxacillin Sodium
 Distigmine Bromide
 Distigmine Bromide Tablets
 Dopamine Hydrochloride
 Ephedrine Hydrochloride
 Ephedrine Hydrochloride Injection
 10% Ephedrine Hydrochloride Powder
 Ephedrine Hydrochloride Tablets
 Erythromycin Ethylsuccinate
 Erythromycin Stearate
 Famotidine
 Fluocinolone Acetonide
 Fluocinonide
 Fluoxymesterone
 Flurazepam Hydrochloride
 Fosfomycin Calcium
 Fosfomycin Sodium
 Fructose Injection
 Gabexate Mesilate

Glibenclamide
 Glucose Injection
 Guaifenesin
 Hydrocortisone
 Hydrocortisone Succinate
 Ibuprofen
 Indometacin Capsules
 Isepamicin Sulfate
 Kallidinogenase
 Kitasamycin
 Lactulose
 Levallorphan Tartrate Injection
 Lidocaine Injection
 Loxoprofen Sodium
 Magnesium Sulfate
 Magnesium Sulfate Injection
 Mefruside
 Meglumine Amidotrizoate Injection
 Meglumine Iotalamate Injection
 Meglumine Sodium Amidotrizoate Injection
 Midecamycin
 Midecamycin Acetate
 Minocycline Hydrochloride
 Morphine Hydrochloride
 Neostigmine Methylsulfate
 Neostigmine Methylsulfate Injection
 Netilmicin Sulfate
 Nicardipine Hydrochloride
 Niceritrol
 Nicotinic Acid Injection
 Nystatin
 Pethidine Hydrochloride Injection
 Phenolsulfonphthalein
 Phenolsulfonphthalein Injection
 Piperacillin Sodium
 Potassium Clavulanate
 Prednisolone
 Prednisolone Tablets
 Progesterone Injection
 Propantheline Bromide
 Rokitamycin
 Roxithromycin
 Sisomicin Sulfate
 Sodium Iotalamate Injection
 Sodium Salicylate
 Spironolactone
 Sulbactam Sodium
 Sultamicillin Tosilate
 Terbutaline Sulfate
 Testosterone Enanthate Injection
 Testosterone Propionate Injection
 Tetracycline Hydrochloride
 Ticarcillin Sodium

Tipepidine Hibenazate Tablets
 Todralazine Hydrochloride
 Tolazamide
 Triamcinolone Acetonide

Part II

Absorbent Cotton
 Capsicum
 Capsicum Tincture
 Corydalis Tuber
 Diluted Opium Powder
 β -Galactosidase (Aspergillus)
 Magnesium Stearate
 Opium Alkaloids Hydrochlorides
 Opium Alkaloids and Atropine Injection
 Opium Alkaloids and Scopolamine Injection
 Opium Ipecac Powder
 Opium Tincture
 Orange Peel Syrup
 Panax Rhizome
 Powdered Capsicum
 Powdered Opium
 Powdered Swertia Herb
 Propylene Glycol
 Purified Absorbent Cotton
 Sodium Lauryl Sulfate
 Sterile Absorbent Cotton
 Sterile Purified Absorbent Cotton
 Swertia Herb
 Weak Opium Alkaloids and Scopolamine Injection

23. The following monographs are revised in Identification owing to introduction of the Infrared Reference Spectra:

Part I

Alprenolol Hydrochloride
 Amantadine Hydrochloride
 Ambenonium Chloride
 Bamethan Sulfate
 Beclometasone Dipropionate
 Benzbromarone
 Betamethasone
 Betamethasone Dipropionate
 Betamethasone Sodium Phosphate
 Biperiden Hydrochloride
 Bromocriptine Mesilate
 Bucumolol Hydrochloride
 Bufetolol Hydrochloride
 Bufexamac
 Bumetanide
 Bupranolol Hydrochloride
 Calcium Folate
 Calcium Polystyrene Sulfonate
 Carteolol Hydrochloride

Chlormadinone Acetate
Chlorpheniramine Maleate
d-Chlorpheniramine Maleate
Cholecalciferol
Clonidine Hydrochloride
Cloperastine Hydrochloride
Clotrimazole
Cortisone Acetate
Croconazole Hydrochloride
Cyclopentolate Hydrochloride
Deferoxamine Mesilate
Dexamethasone
Diclofenac Sodium
Dihydroergotamine Mesilate
Dilazep Hydrochloride
Dinoprost
Diphenhydramine Hydrochloride
Dipyridamole
Disopyramide
Dopamine Hydrochloride
Drostanolone Propionate
Dydrogesterone
Ephedrine Hydrochloride
Ergocalciferol
Estriol
Fluocinolone Acetonide
Fluoxymesterone
Flurazepam Hydrochloride
Glibenclamide
Guaifenesin
Haloxazolam
Hydrocortisone
Hydrocortisone Butyrate
Hydrocortisone Sodium Phosphate
Hydrocortisone Sodium Succinate
Hydrocortisone Succinate
Hymecromone
Indenolol Hydrochloride
Iodamide
Ipratropium Bromide
Isosorbide
Ketoprofen
Lorazepam
Mefruside
Mepitiostane
Mepivacaine Hydrochloride
Mestranol
Metenolone Acetate
Methotrexate
Metildigoxin
Naproxen
Nicomol
Nifedipine

Norgestrel
Nortriptyline Hydrochloride
Orciprenaline Sulfate
Oxapium Iodide
Oxprenolol Hydrochloride
Oxymetholone
Penbutolol Sulfate
Pentoxyverine Citrate
Pindolol
Pipemidic Acid Trihydrate
Piperazine Adipate
Potassium Canrenoate
Prazepam
Prednisolone
Procaine Hydrochloride
Procarbazine Hydrochloride
Progesterone
Protirelin
Scopolamine Butylbromide
Sodium Picosulfate
Sodium Polystyrene Sulfonate
Sodium Prasterone Sulfate
Sodium Valproate
Sulfadiazine Silver
Sulfinpyrazone
Tegafur
Tetracycline Hydrochloride
Thioridazine Hydrochloride
Tiaramide Hydrochloride
Tinidazole
Tipepidine Hibenazate
Tocopherol
Tocopherol Acetate
Tocopherol Calcium Succinate
Todalazine Hydrochloride
Tolazamide
Tolnaftate
Triamcinolone
Triamcinolone Acetonide
Trimetazidine Hydrochloride
Trimethadione
Trimetoquinol Hydrochloride
Verapamil Hydrochloride
Vinblastine Sulfate
Vincristine Sulfate

24. The following monographs are revised in Identification owing to introduction of the Ultraviolet-visible Reference Spectra:

Part I

Acebutolol Hydrochloride
Acetohexamide
Alimemazine Tartrate
Allopurinol

Alprenolol Hydrochloride
Alprostadil Alfadex
Amibenonium Chloride
Amitriptyline Hydrochloride
Amoxapine
Arotinolol Hydrochloride
Azathioprine
Baclofen
Bamethan Sulfate
Benserazide Hydrochloride
Benzalkonium Chloride
Benzalkonium Chloride Concentrated Solution 50
Benzethonium Chloride
Berberine Chloride
Berberine Tannate
Betahistine Mesilate
Betamethasone
Betamethasone Dipropionate
Bifonazole
Biperiden Hydrochloride
Bisacodyl
Bromazepam
Bromhexine Hydrochloride
Bromocriptine Mesilate
Bucumolol Hydrochloride
Bufetolol Hydrochloride
Bufexamac
Bumetanide
Bupranolol Hydrochloride
Butropium Bromide
Calcium Folate
Camostat Mesilate
Carbamazepine
Carbazochrome Sodium Sulfonate
Carbidopa
Carmofur
Carteolol Hydrochloride
Cetraxate Hydrochloride
Chlordiazepoxide
Chlorphenesin Carbamate
Chlorpropamide
Climofibrate
Clocapramine Hydrochloride
Clofedanol Hydrochloride
Clofibrate
Clomifene Citrate
Clomipramine Hydrochloride
Clonazepam
Clonidine Hydrochloride
Cloperastine Hydrochloride
Clotiazepam
Clotrimazole
Cloxazolam
Cocaine Hydrochloride
Codeine Phosphate
Croconazole Hydrochloride
Cyanocobalamin
Cyproheptadine Hydrochloride
Dantrolene Sodium
Dexamethasone
Dextromethorphan Hydrobromide
Diazepam
Dibucaine Hydrochloride
Diclofenamide
Dihydrocodeine Phosphate
Dihydroergotamine Mesilate
Dilazep Hydrochloride
Diltiazem Hydrochloride
Dimemorfan Phosphate
Dimorpholamine
Dinoprost
Diphenhydramine Hydrochloride
Dipyridamole
Disopyramide
Distigmine Bromide
Disulfiram
Dopamine Hydrochloride
Doxapram Hydrochloride
Droperidol
Dydrogesterone
Edrophonium Chloride
Elcatonin
Enoxacin
Epirizole
Estazolam
Estriol
Etacrynic Acid
Ethosuximide
Ethylmorphine Hydrochloride
Etilefrine Hydrochloride
Famotidine
Fenbufen
Fentanyl Citrate
Flavoxate Hydrochloride
Floctafenine
Flopropione
Flucytosine
Fludiazepam
Flunitrazepam
Fluocinonide
Fluorometholone
Fluorouracil
Fluoxymesterone
Fluphenazine Enanthate
Flurazepam
Flurazepam Hydrochloride

Flurbiprofen
Folic Acid
Formoterol Fumarate
Furosemide
Gabexate Mesilate
Glibenclamide
Guaifenesin
Guanabenz Acetate
Haloperidol
Haloxazolam
Homochlorcyclizine Hydrochloride
Hydralazine Hydrochloride
Hydrochlorothiazide
Hydrocotarnine Hydrochloride
Hydroxocobalamin Acetate
Hydroxyzine Hydrochloride
Hydroxyzine Pamoate
Hymecromone
Ibuprofen
Idoxuridine
Ifenprodil Tartrate
Imipramine Hydrochloride
Indenolol Hydrochloride
Indigocarmine
Indometacin
Ipratropium Bromide
Isoniazid
l-Isoprenaline Hydrochloride
Ketamine Hydrochloride
Ketoprofen
Levallorphan Tartrate
Levodopa
Levothyroxine Sodium
Lidocaine
Liothyronine Sodium
Lorazepam
Loxoprofen Sodium
Meclofenoxate Hydrochloride
Mecobalamin
Medazepam
Mefenamic Acid
Mefruside
Mepenzolate Bromide
Mepivacaine Hydrochloride
Mercaptopurine
Mestranol
Methotrexate
Methotrexate
Methyldopa
Methylergometrine Maleate
Methylprednisolone
Meticrane
Metildigoxin
Metoclopramide
Metronidazole
Metyrapone
Mexiletine Hydrochloride
Miconazole
Miconazole Nitrate
Morphine Hydrochloride
Nadolol
Nalidixic Acid
Naproxen
Nicardipine Hydrochloride
Niceritrol
Nicomol
Nicotinamide
Nicotinic Acid
Nifedipine
Nitrazepam
Nortriptyline Hydrochloride
Noscapine
Orciprenaline Sulfate
Oxazolam
Oxethazaine
Oxybuprocaine Hydrochloride
Oxycodone Hydrochloride
Oxymetholone
Penbutolol Sulfate
Pentazocine
Perphenazine
Perphenazine Maleate
Pethidine Hydrochloride
Phenylbutazone
Phytonadione
Pindolol
Pipemidic Acid Trihydrate
Pirenoxine
Potassium Canrenoate
Potassium Guaiacolsulfonate
Pranoprofen
Prazepam
Probenecid
Procaine Hydrochloride
Procarbazine Hydrochloride
Procaterol Hydrochloride
Promethazine Hydrochloride
Propranolol Hydrochloride
Pyrantel Pamoate
Pyrazinamide
Pyridostigmine Bromide
Quinine Ethyl Carbonate
Quinine Sulfate
Reserpine
Riboflavin
Riboflavin Butyrate

Riboflavin Sodium Phosphate
 Salazosulfapyridine
 Salbutamol Sulfate
 Scopolamine Butylbromide
 Simfibrate
 Sodium Cromoglicate
 Sodium Picosulfate
 Spironolactone
 Sulfinpyrazone
 Sulpiride
 Sultiame
 Tegafur
 Terbutaline Sulfate
 Tetracaine Hydrochloride
 Tetracycline Hydrochloride
 Thiamine Hydrochloride
 Timepidium Bromide
 Tinidazole
 Tipepidine Hibenzate
 Tocopherol Nicotinate
 Todralazine Hydrochloride
 Tofisopam
 Tolazamide
 Tolnaftate
 Trapidil
 Trepibutone
 Triamcinolone Acetonide
 Triamterene
 Trichlormethiazide
 Trimetazidine Hydrochloride
 Trimetoquinol Hydrochloride
 Tubocurarine Chloride
 Tulobuterol Hydrochloride
 Ulinastatin
 Verapamil Hydrochloride
 Vinblastine Sulfate
 Vincristine Sulfate
 Warfarin Potassium

Part II

β -Galactosidase (Aspergillus)

25. The following monograph is revised in origin:
 Prunella Spike

26. The following monographs have a change in their Japanese titles:

Part I

L-Arginine Hydrochloride
 1% Codeine Phosphate Powder
 10% Codeine Phosphate Powder
 1% Dihydrocodeine Phosphate Powder
 10% Dihydrocodeine Phosphate Powder
 10% Ephedrine Hydrochloride Powder
 10% dl-Methylephedrine Hydrochloride Powder

10% Phenobarbital Powder
 0.1% Reserpine Powder
 Ursodeoxycholic Acid

27. In the equation in Monograph, the amount of substance to be titrated equivalent to each mL of the volumetric solution (VS) is expressed as a number of five figures when the number starts with 1, 2 or 3, and is expressed as a number of four figures when the number starts with a figure of 4 or more. The number was obtained from the sum of the atomic masses.

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