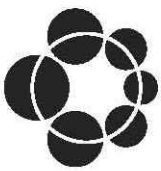
THE KOREAN PHARMACOPOEIA

Tenth Edition

KP X



Ministry of Food and Drug Safety

The Korea Food and Drug Administration* Notification 2012-129

In accordance with the provision of Article 51, paragraph 1 of the Pharmaceutical Affairs Act of Korea, Korean Pharmacopoeia (Korea Food and Drug Administration Notification 2012-9, 2012. 03. 26) is revised as follows.

December 27, 2012

Commissioner of the Korea Food and Drug Administration

Notification of Revision of Korean Pharmacopoeia

Korean Pharmacopoeia is fully revised as follows.

Korean Pharmacopoeia

Article 1 (Purpose) This Notification is intended to describe details regarding the properties, conditions, qualities, storage instructions, and other necessary standards of pharmaceuticals, etc. (hereinafter "Details") in accordance with Article 51, paragraph 1 of the Pharmaceutical Affairs Act of Korea.
Article 2 (Classification of Details) Details shall be described in accordance with the following items.
1. General Notices shall be as set forth in Attachment 1.
2. General Requirements for Pharmaceutical Preparations shall be as set forth in Attachment 2.
3. Monographs Part I shall be as set forth in Attachment 3.
4. Monographs Part II shall be as set forth in Attachment 4.
5. General Tests, Processes and Apparatus shall be as set forth in Attachment 5.
6. General Information shall be as set forth in Attachment 6.
Article 3 (Deadline of Re-review) In accordance with the Regulations on Announcement and Management of Decree and Regulation (President's Decree No. 248), any abolition or revision of this Notification by reviewing changes in legislation or real circumstances that occur after issuance of this Notification shall take place no later than December 27, 2015.

* On March 23, 2013, the Korea Food and Drug Administration (KFDA) was restructured and upgraded to a ministry, changing its name to the Ministry of Food and Drug Safety (MFDS).

Addenda

Article 1 (Effective Date) ① This Notification shall take effect one month after the date of announcement.② Notwithstanding paragraph 1, new monographs in Attachment 3 and Attachment 4 shall be effective as of the date of announcement.

Article 2 (Application) This Notification shall apply starting from the first pharmaceuticals, etc. manufactured by a manufacturer or imported by an importer after the enforcement of this Notification.

Article 3 (Interim Measures) ① In the case of any item, which was previously permitted or declared at the time of enforcement of this Notification, but does not conform to the revised provisions, the item shall be made conforming to the revised provisions within three months of the effective date of this Notification.② Among items that have been permitted or declared as manufactured or imported items in accordance with the Korean Pharmaceutical Codex at the time of enforcement of this Notification, those items included in this Notification shall be regarded as having been permitted or declared in accordance with this Notification.

Article 4 (Relationship to Other Regulations) In the case where another regulation cites the previous Korean Pharmacopoeia or any of its provisions at the time of enforcement of this Notification, and this Notification contains any relevant regulations thereto, it shall be regarded as having cited this Notification or the corresponding provisions of this Notification substituted for the previous regulations.

Foreword

The Korean Pharmacopoeia is a governmental statute on pharmaceuticals established under the Pharmaceutical Affairs Act (Act No. 11421) Article 51 in order to improve public health. The first version was established and proclaimed on October 10, 1958, the second in 1967, and the third in 1976. Since then, revision has been made every 5 years and the 9th Edition was published in 2007.

As test methods have been more diversified and more science-based in the 21st century with new drug development and better instrumental analysis, it is essential to establish standard specifications on pharmaceuticals and implement latest test methods that can ensure safety and efficacy of pharmaceuticals for the public.

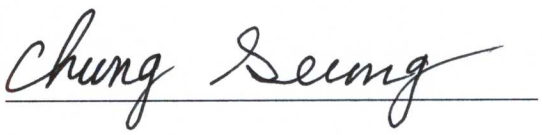
Especially, in an era of globalization, it is becoming critical to harmonize with international specifications and standards. Following the need for international harmonization and advancement, the 10th Edition was published with the cooperation and participation of experts from the Ministry of Food and Drug Safety (MFDS), academia, and pharmaceutical industry.

With the publication of the latest Korean Pharmacopoeia, I would like to express my sincere gratitude to the advisors and staff from the MFDS for their efforts in conducting research and writing manuscript for pharmacopoeia revision, and to the members of the Central Committee for Pharmaceutical Affairs and related subcommittees, including the Committee for Pharmacopoeia and Specifications of Pharmaceuticals, for their dedication in revising pharmacopoeia.

I hope the 10th Edition lays a foundation for the advancement in the field of specifications and standards, and I wish great success and brighter future to the pharmaceutical technology industry and pharmaceutical science field.

Chung Seung

Minister
Ministry of Food and Drug Safety



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Preface

The Korean Pharmacopoeia (KP) is a statute for pharmaceuticals established by the Korean government to contribute to the improvement of public health. It aims to provide safe and efficacious pharmaceuticals of assured quality by prescribing the preparation, properties, performance, quality and storage of pharmaceuticals used for treatment and prevention of diseases.

The first edition of KP was promulgated and published with 635 monographs on October 10, 1958 by Ministry of Health and Welfare Notification No. 25. To keep pace with the development of new drugs and their test methods, the second edition of KP was revised and published as follows: 725 monographs in Monographs Part I on October 10, 1968; 457 monographs in Monographs Part II on July 15, 1968; The Supplement I on August 29, 1968; The Supplement II on May 28, 1969; and Supplement III on January 24, 1972.

Starting from the third edition of KP, promulgated on December 10, 1976, Monographs Part I and Part II were combined in publication. Monographs, Part I was covered with 656 monographs of frequently-used pharmaceuticals and primary preparations, while Monographs Part II, with 357 monographs, mostly consisted of compound preparations, making 1013 monographs in total. This was followed by the publication of 146 monographs in the Supplement I on February 1, 1978 and 72 monographs in the Supplement II on January 13, 1979.

The fourth edition of KP was promulgated on March 1, 1982 with 785 monographs in Monographs Part I and 427 monographs in Monographs Part II, making 1212 monographs in total, and the Supplement I was published on November 24, 1982.

The fifth edition of KP was promulgated on April 22, 1987 with 868 monographs in Monographs Part I and 440 monographs in Monographs Part II, making 1308 monographs in total. The Supplement I, containing 8 monographs and correction tables, was published on March 16, 1988.

The sixth edition of KP was promulgated on April 7, 1992 with 986 monographs in Monographs Part I and 442 monographs in Monographs Part II, making 1428 monographs in total. Supplement I, containing revised test methods and correction tables, was published on March 26, 1993.

The seventh edition of KP was promulgated on December 31, 1997. Monographs, Part I was covered with 1007 monographs of most of single component drugs and Monographs, Part II was covered with 475 monographs of Herbal Drugs, Herbal Drug Preparations, Biological Preparations, Compound Preparations, Pharmaceutical Excipients and Hygienic Products. The Supplement I, containing correction tables and revised test methods, was published on February 19, 2000 following the establishment of the Korea Food and Drug Administration (KFDA) in February 1998 to be in charge of food and drug safety.

The eighth edition of KP was promulgated on December 30, 2002 with 1018 monographs in Monographs Part I and 467 monographs in Monographs Part II, making 1485 monographs in total. The Supplement was published on July 24, 2006, deleting 23 monographs from Monographs Part I by the revision in the Specifications of Antimicrobial Pharmaceuticals and containing correction tables.

The ninth edition of KP was promulgated on December 28, 2007 with 1093 monographs in Monographs Part I and 418 monographs in Monographs Part II, making 1511 monographs in total. The Supplements were revised with correction tables and across eight revisions. On November 1, 2010, the Supplements 1 through 4 were combined to publish Supplements (1~4) for the 9th Edition followed by the Supplements (5~6) on July 29, 2011 and Supplements (7~8) on June 25, 2012.

The supplements from 2009 to 2012, which were published in order to actively respond to the international trend towards the globalization of pharmacopoeia by the international harmonization organization founded by the United States, European Union and Japan, as well as advancements in medical and pharmaceutical sciences, provided the foundation for the tenth revision of the KP.

In July 2011, prior to the final revision of the tenth edition of KP, the KFDA proposed the "Guidelines for Revising the Korean Pharmacopoeia," prescribing specific rules and instructions for revision in order to facilitate systematic and consistent description of information throughout the revised draft. On September 15, 2011, the Committee for Pharmacopoeia and Specifications of Pharmaceuticals and the Subcommittee for Pharmacopoeia and Standards for Pharmaceuticals reviewed and determined the Guidelines along with the revision schedule for the tenth edition, which were used as basic policies and guidelines for the revised draft.

Proposed by the KFDA after reviewing and reflecting the results of data investigations and experiments in response to the international harmonization, the revised draft fully included the opinions generated from experts in the field of the pharmaceutical industry in order to ensure a transparent revision of the KP. Professional opinions were collected from a variety of sectors, including pharmaceutical experts to boost the scientific validity and rationality of the Pharmacopoeia, by providing related Korean organizations with relevant information through a preliminary study of the Society of Korean Official Compendium for Public Health and through the Korean Pharmacopoeial Forum, which has been in publication since 2003. Moreover, key matters of the revision were determined by exchanges of opinion through the KFDA's expert councils in the fields of Drugs, Herbal Drugs, Biological Preparations, and Quasi-drugs, followed by a process of gathering a full range of opinions from academic circles and the pharmaceutical industry.

The five principles for drafting the KP are the same as those from the 9th Edition: 1) to include all drugs which are relevant from the viewpoint of healthcare and medical treatment, 2) to revise in a timely fashion in part, if necessary, for efficient application, 3) to follow international harmonization, 4) to ensure transparency regarding the revision of the KP and render the document publicly available, and 5) to include up-to-date analytical methods in a timely fashion and include reference standards.

The draft for the tenth edition of KP was prepared and reviewed in the meetings of Subcommittee for Pharmacopoeia and Standards of Pharmaceuticals and the Subcommittee for Herbal Drug Preparations and the revised draft was finalized as the 10th edition of KP in the Committee for Pharmacopoeia and Specifications of Pharmaceuticals of the Central Committee for Pharmaceutical Affairs on September 15, 2012. The tenth edition of KP was promulgated on December 27, 2012 by the Notification of the Commissioner of the Korea Food and Drug administration and the summary of the revision in this Edition is as follows.

Summary of the Revision

The principles of description in this edition are as follows.

1. The tenth edition of the Korean Pharmacopoeia, similar to the ninth edition, is divided into Monographs Part I and Monographs Part II. Monographs Part I mainly contains frequently used pharmaceutical ingredients and primary preparations, and Monographs Part II lists: 1) Herbal Drugs and Herbal Drug Preparations, 2) Biological Preparations, etc., 3) Compound Preparations, 4) Excipients and 5) Quasi Drugs.
2. The Pharmacopoeia comprises the following items, in the following order: General Notices, General Requirements for Preparations, Monographs, General Tests, Processes and Apparatus and General Information followed by the Index.
3. The articles in General Requirements for Preparations, in Monographs and in General Tests, Processes and Apparatus are respectively placed in alphabetical order.
4. The following items in each monograph are placed in the order shown below, except that unnecessary items are omitted depending on the nature of the drug.
    1) English title
    2) Structural formula and rational formula
    3) Molecular formula and molecular mass (empirical formula and empirical mass)
    4) Commonly used name(s) or Latin name
    5) Chemical name and Chemical Abstract Service registry number
    6) Origin
    7) Limits of the content of the ingredient(s) or labeling requirements
    8) Method of preparation
    9) Description
    10) Identification
    11) Specific physical and/or chemical values
    12) Purity
    13) Loss on drying, loss on ignition or water
    14) Residue on ignition, ash or acid-insoluble ash
    15) Tests for preparations
    16) Special tests
    17) Other tests (microbial limit for pharmaceutical ingredients, particle size distribution test for pharmaceutical ingredients, isomer ratio, etc.)
    18) Assay
    19) Essential oil content, extract content
    20) Containers and storage
    21) Expiration date
5. The physical and chemical values representing the properties and quality of drugs are given as follows, except that unnecessary items are omitted depending on the nature of the drug.
    1) Refractive index
    2) Saponification value
    3) Unsaponifiable matter
    4) Specific optical rotation
    5) Boiling point
    6) Specific gravity
    7) Acid value
    8) Color, odor, taste, etc.
    9) Hydroxyl value
    10) Thermal stability
    11) Ester value
    12) Iodine value
    13) Solubility
    14) Melting point
    15) Congealing point
    16) Viscosity
    17) Congealing point of fatty acid
    18) pH
    19) Absorbance

6. Identification comprises the following items, which are generally placed in the order given below, except that unnecessary items are omitted depending on the nature of the drug.
    1) Coloration reaction
    2) Precipitation reactions
    3) Decomposition reactions
    4) Derivatization reactions
    5) Ultraviolet, visible or infrared absorption spectra
    6) Nuclear magnetic resonance spectrum
    7) Chromatography
    8) Special reactions
    9) Qualitative reactions for cations and anions
7. Purity comprises the following items, which are generally placed in the order given below, except that unnecessary items are omitted depending on the nature of the drug.
    1) Color, odor, etc.
    2) Clarity and/or color of solution
    3) Acidity or alkalinity
    4) Acid or alkali
    5) Inorganic salts
    6) Ammonium
    7) Heavy metals
    8) Metals
    9) Arsenic
    10) Organic substances
    11) Foreign matter
    12) Residue on evaporation
    13) Related substances
    14) Other impurities
    15) Readily carbonizable substances by sulfuric acid

The summary of the revisions in this edition is as follows.

1. The following revisions, new admissions, or deletions are made in General Notices:
    1) The chemical names of monographs are given in accordance with the International Union of Pure and Applied Chemistry (IUPAC) nomenclature and the Chemical Abstract Service (CAS) registry number is newly admitted (item 2).
    2) Molecular masses are calculated according to the International Atomic Weights 2010 table (item 6).
    3) When an ingredient used in drug preparation is of animal origin, a description specifying that the ingredient must be from healthy animals is newly admitted (item 7).
    4) When the quality of a preparation is affected by light, the product is stored in light-resistant containers (item 13).
    5) Millimole per liter (mmol/L), milli equivalents (mEq), colony forming unit (CFU), microsiemens per centimeter ($\mu S \cdot cm^{-1}$), and degree (°) are added to and pH is deleted from the principal units of measurement of the Pharmacopoeia (item 14).
    6) n monograph tests, allowable ranges for the temperature, pressure, length, and time expressed in single figures are newly admitted (item 17).
    7) Water used in drug tests is clearly described as water suitable for the tests, e.g., not containing any substances that would interfere with the tests (item 23).
    8) The definition of the term "light-resistant" is clarified (item 54).
    9) Descriptions regarding the containers and packaging of preparations are newly admitted (item 55).
2. The following revisions, new admissions, or deletions are made in General Requirements for Preparations:
    1) General rules for dosage forms and information regarding the names of preparations in the monographs are added to the beginning of General Requirements.
    2) Dialysis Solutions·Dialysis Agents, Gargles, Medicated Chewing Gums, and Teabags are newly admitted.
    3) In Granules, Effervescent Granules is added as a subcategory.
    4) Lemonades is deleted as a dosage form and is included under Solutions.
    5) The definition of Aerosols is clarified and a description of metered-dose type preparations is added.
    6) The methods of preparation of Decoctions and Infusions, Fluid Extracts, Spirits, and Tinctures are partially revised.
    7) In Elixirs, Test for Uniformity of Dosage Units is newly admitted for those that are packaged in unit-dose containers.

8) Emulsions and Suspensions are separated into two different dosage forms.
9) In Aerosols, Capsules, Creams, Gels, Granules, Injections, Lotions, Nasal Solutions, Ointments, Ophthalmic Ointments, Ophthalmic Solutions, Otic Solutions, Solutions, and Syrups, the definitions are clarified and the text is revised throughout.
10) In Tablets, the definition and method of preparation are revised and the following subcategories are added: Orally Disintegrating Tablets, Buccal Tablets, Effervescent Tablets, Mucoadhesive Tablets, Dispersible Tablets, Sublingual Tablets, Soluble Tablets, Chewable Tablets, and Vaginal Tablets.

3. The summary of the revisions in the Monographs is as follows.
1) The Korean Pharmacopoeia, 10th Edition, carries a total of 1,559 articles, composed of 1,159 articles in Part I and 400 articles in Part II (179 articles as Herbal Drugs and Herbal Drug Preparations, 46 articles as Biological Preparations, etc., 19 articles as Compound Preparation, 140 articles as Excipients, and 16 articles as Quasi-Drugs).
2) The following articles are newly admitted (see Appendix 1).
A total of 68 articles, with 38 articles in Part I and 30 articles in Part II (29 articles as Biological Preparations, etc., and 1 article as Excipients)
3) The following articles are deleted (see Appendix 2).
A total of 225 articles, with 175 articles in Part I and 50 articles in Part II (3 articles as Herbal Drugs and Herbal Drug Preparations, 23 articles as Biological Preparations, etc., and 24 articles as Compound Preparation).
4) The tests specified in General Requirements for Preparations are described in the Monographs so that they are not omitted from quality control tests. Test items described for each dosage form in the Monographs are as follows (not applicable to test methods that are not specified in General Requirements for Preparations and are applicable in accordance with other notifications):

Emulsions, Suspensions		Uniformity of Dosage Units (divided) (omitted for external preparations for local skin application)
Extracts, Fluid Extracts		Heavy Metals Limit Test
Granules		Particle Size Distribution Test for Preparations, Uniformity of Dosage Units (divided), Disintegration Test/Dissolution Test
Injections		
	suspension	Sterility Test, Pyrogen Test/Bacterial Endotoxins Test (Foreign Insoluble Matter Test and Insoluble Particulate Matter Test are not applicable)
	solution	Sterility Test, Pyrogen Test/Bacterial Endotoxins Test, Foreign Insoluble Matter Test, Insoluble Particulate Matter Test for Injections, Determination of Volume of Injection in Containers
	powder	Sterility Test, Pyrogen Test/Bacterial Endotoxins Test, Foreign Insoluble Matter Test, Insoluble Particulate Matter Test for Injections, Uniformity of Dosage Units
Ophthalmic Ointments		Test for Metal Particles, Sterility Test
Ophthalmic Solutions		Sterility Test, Foreign Insoluble Matter Test (omitted for those that use containers for which testing is difficult), Insoluble Particulate Matter Test for Ophthalmic Solutions
Powders		Particle Size Distribution Test for Preparations, Uniformity of Dosage Units (divided)
Syrups		Uniformity of Dosage Units (divided)
Tablets, Capsules, Suppositories		Disintegration Test/Dissolution Test, Uniformity of Dosage Units

5) The names of the following articles are changed.
(1) The English names of the following articles are changed.

9th Edition	10th Edition
Fusidic Acid	Fusidic Acid Hydrate
Mercaptopurine	Mercaptopurine Hydrate
Thiamine Chloride Hydrochloride Injection	Thiamine Hydrochloride Injection

(2) The commonly used names of the following articles are revised.
Dried Aluminum Potassium Sulfate, Dried Sodium Carbonate, Dried Sodium Sulfite, Guaifenesin

(3) In Monographs Part II, Herbal Drugs and Herbal Drug Preparations:
A. The English names of the following articles are revised.
Alpinia Officinarum Rhizome, Aster Root and Rhizome, Capsicum, Gamisoyosan Extract Granules, Hyeonggaeyeongyotang Extract Granules, Polyporus Sclerotium, Ssanghwatang Extract Granules, Ssanghwatang Solution, Yukmijihwangtang Extract Granules
B. The Latin names of the following articles are revised.
Alpina Katsumadai Seed, Aster Root and Rhizome, Dictamnus Root Bark, Fritillaria Bulb, Gentian Root and Rhizome, Liriope Tuber, Lycium Root Bark, Moutan Root Bark, Mulberry Root Bark, Ostericum Root
C. The common names of the following articles are newly admitted.
Fennel, Saffron, Scopolia Rhizome

6) The chemical names are given in accordance with the International Union of Pure and Applied Chemistry (IUPAC) nomenclature and the Chemical Abstract Service (CAS) registry number is included.

7) The origin, content requirements and labeling requirements are revised for the following articles.
(1) The origin, part of use, and processing method are revised for the following articles.
Amomum Fruit, Asiasarum Root and Rhizome, Aster Root and Rhizome, Corydalis Tuber, Cynomorium Herb, Dioscorea Rhizome, Fritillaria Thunbergii Bulb, Gastrodia Rhizome, Nutmeg, Ostericum Root, Schizonepeta Spike
(2) Content requirements are revised for the following articles.
Methylphenidate Hydrochloride, Anemarrhena Rhizome, Aralia Continentalis Root, Corydalis Tuber, Eucommia Bark, Forsythia Fruit, Gardenia Fruit, Leonurus Herb, Lonicera Leaf and Stem, Polygonum Multiflorum Root, Rhubarb
(3) Labeling requirements are revised for the following articles.
Water

8) Descriptions are newly admitted, revised or deleted for the following articles.
(1) Descriptions are newly admitted for the following articles.
Water for Injection, Sterile Water for Injection
(2) Descriptions are revised for the following articles.
Allopurinol, Bromhexine Hydrochloride, Carvedilol, Ceftibuten Hydrate, Domperidone, Gliclazide, Glycerin, Concentrated Glycerin, Hydroxyprogesterone Caproate, Magnesium Sulfate Injection, Mepivacaine Hydrochloride, Meropenem Hydrate, Nabumetone, Neostigmine Methylsulfate, Pimozide, Pipemidic Acid Hydrate, Ranitidine Hydrochloride, Risperidone, Sodium Aurothiomalate, Sodium Hyaluronate, Tiapride Hydrochloride, Purified Water in Bulk, Sterile Purified Water, Achyranthes Root, Akebia Stem, Alisma Rhizome, Alpinia Officinarum Rhizome, Amomum Fruit, Anemarrhena Rhizome, Angelica Gigas Root, Apricot Kernel, Arctium Fruit, Arisaema Rhizome, Asiasarum Root and Rhizome, Asparagus Tuber, Aster Root and Rhizome, Atractylodes Rhizome White, Bupleurum Root, Capsicum, Cassia Seed, Cattle Gallstone, Cimicifuga Rhizome, Citrus Unshiu Immature Peel, Clove, Cnidium Rhizome, Condurango, Coix Seed, Corydalis Tuber, Croton Seed, Cynomorium Herb, Dictamnus Root Bark, Dioscorea Rhizome, Epimedium Herb, Eucommia Bark, Euryale Seed, Forsythia Fruit, Gambir, Gardenia Fruit, Gastrodia Rhizome, Gentian, Gentian Root and Rhizome, Geranium Herb, Ginger, Ginkgo Leaf, Glehnia Root, Hawthorn Fruit, Imperata Rhizome, Ipecac, Kalopanax Bark, Licorice, Linseed, Liriope Tuber, Lonicera Leaf and Stem, Lycium Root Bark, Mentha Herb, Morinda Root, Moutan Root Bark, Mulberry Root Bark, Mume Fruit, Myrrh, Nelumbo Seed, Nutmeg, Ostericum Root, Oyster Shell, Peach Kernel, Perilla Leaf, Pharbitis Seed, Pinellia Tuber, Plantago Seed, Platycodon Root, Pogostemon Herb, Polygala Root, Polygonum Multiflorum Root, Polyporus Sclerotium, Pueraria Root, Rehmannia Root, Rhubarb, Round Amomum Fruit, Rubus Fruit, Saffron, Safflower, Salvia Miltiorrhiza Root, Saposhnikovia Root, Sappan Wood, Schisandra Fruit, Scutellaria Root, Senega, Sinomenium Stem and Rhizome, Sparganium Rhizome, Thuja Seed, Toad Venom, Tribulus Fruit, Trichosanthes Root, Valerian Root and Rhizome, Zedoary, Zizyphus Seed
(3) Descriptions are deleted for the following articles.
Adsorbed Diphtheria-Tetanus-Acellular Pertussis Combined Vaccine, Freeze-dried Agkistrodon (Salmusa) Antivenom (Equine), Freeze-dried Concentrated Human Antithrombin III, Freeze-dried Concentrated Human Blood Coagulation Factor Ⅷ, Freeze-dried Human Blood Coagulation Factor Ⅸ Complex, Freeze-dried Human Fibrinogen, Freeze-dried Live Attenuated Measles-Mumps-Rubella Combined Vaccine, Human Hepatitis B Immunoglobulin, Human Hepatitis B Immunoglobulin for Intravenous Administration, Human Normal Immunoglobulin, Human Normal Immunoglobulin in Maltose (pH 4.25), Human Serum Albumin, Human Tetanus

Immunoglobulin, Human Varicella Immunoglobulin, Influenza HA Vaccine, Japanese Encephalitis Vaccine, Water

9) In Identification:
   (1) Qualitative tests and other additional test items are newly admitted for the following articles.
   Buspirone Hydrochloride, Clindamycin Hydrochloride, Lidocaine Hydrochloride Hydrate, Risperidone, Tamoxifen Citrate, Kalopanax Bark, Platycodon Root, Sophora Root
   (2) Test items are revised for the following articles.
   Betamethasone Sodium Phosphate, Betahistine Mesilate, Cefaclor Capsules, Diazepam Tablets, Domperidone, Doxycycline Capsules, Gabexate Mesilate, Inositol, Lidocaine Hydrochloride Hydrate, Methylphenidate Hydrochloride, Angelica Dahurica Root, Angelica Gigas Root, Areca, Asparagus Tuber, Cinnamon Bark, Citrus Unshiu Peel, Cnidium Rhizome, Curcuma Longa Rhizome, Cyperus Rhizome, Eucommia Bark, Lonicera Flower, Lonicera Leaf and Stem, Mulberry Root Bark, Pinellia Tuber, Peony Root, Polygonum Multiflorum Root, Raphanus Seed, Saposhnikovia Root, Schizonepeta Spike
   (3) Color reactions and other test items are deleted for the following articles.
   Bupleurum Root, Leonurus Herb, Sappan Wood
10) In specific physical and/or chemical values:
   (1) Specific physical and/or chemical values are newly admitted for the following articles.
   Risperidone, White Beeswax, Yellow Beeswax, Polysorbate 80, Stearic Acid
   (2) Specific physical and/or chemical values are revised for the following articles.
   Beclomethasone Dipropionate, Clobetasol Propionate, Diflucortolone Valerate, Estradiol, Estradiol Valerate, Fructose Injection, Hydrocortisone, Hydrocortisone Butyrate, Mometasone Furoate, Norethisterone Acetate, Testosterone Enanthate, Triamcinolone Acetonide
   (3) Specific physical and/or chemical values are deleted for the following articles.
   Water
11) In Purity:
   (1) Clarity (and color) of solution, water-insoluble substances, chloride, sulfate, and/or heavy metals test are newly admitted for the following articles.
   Aluminum Potassium Sulfate Hydrate, Dried Aluminum Potassium Sulfate, Cefalotin Sodium, Cefepime Dihydrochloride Hydrate, Powdered Cellulose, Clenbuterol Hydrochloride, Clindamycin Hydrochloride, Meropenem Hydrate, Methylcellulose, Potassium Carbonate, Dibasic Sodium Phosphate Hydrate, Dried Sodium Sulfite
   (2) Mercury test is newly admitted for the following articles.
   Acacia, Glacial Acetic Acid, Aluminum Potassium Sulfate Hydrate, Dried Aluminum Potassium Sulfate, White Beeswax, Yellow Beeswax, Anhydrous Dibasic Calcium Phosphate, Dibasic Calcium Phosphate Hydrate, Monobasic Calcium Phosphate Hydrate, Ethylparaben, Glycine, Microcrystalline Cellulose, Powdered Cellulose, Carboxymethylcellulose Sodium, Hypromellose, Lactic Acid, Methylcellulose, Polysorbate 80, Potassium Carbonate, Dried Potassium Hydroxide, Potassium Sulfate, Sodium Acetate Hydrate, Sodium Bisulfite, Sodium Carbonate, Dibasic Sodium Phosphate Hydrate, Dried Sodium Sulfite, Stearic Acid, Tartaric Acid
   (3) Cadmium test is newly admitted for the following articles.
   Acacia, Anhydrous Dibasic Calcium Phosphate, Dibasic Calcium Phosphate Hydrate, Monobasic Calcium Phosphate Hydrate, Carboxymethylcellulose Sodium, Microcrystalline Cellulose, Powdered Cellulose, Hypromellose, Methylcellulose, Polysorbate 80, Dibasic Sodium Phosphate Hydrate
   (4) Lead test is newly admitted for the following articles.
   Acacia, Glacial Acetic Acid, Aluminum Potassium Sulfate Hydrate, Dried Aluminum Potassium Sulfate, White Beeswax, Yellow Beeswax, Calcium Hydroxide, Dibasic Calcium Phosphate Hydrate, Anhydrous Dibasic Calcium Phosphate, Monobasic Calcium Phosphate Hydrate, Carboxymethylcellulose Calcium, Carboxymethylcellulose Sodium, Microcrystalline Cellulose, Powdered Cellulose, Dextrin, Disodium Edetate Hydrate, Ethylparaben, Gelatin, Glycine, Hydroxypropylcellulose, Hypromellose, Lactic Acid, Methylparaben, Methylcellulose, Liquid Paraffin, Potassium Carbonate, Polysorbate 80, Potassium Hydroxide, Potassium Sulfate, Povidone, Propylene Glycol, Saccharin Sodium Hydrate, Purified Shellac, White Shellac, Sodium Acetate Hydrate, Sodium Bisulfite, Dried Sodium Carbonate, Sodium Hydroxide, Dibasic Sodium Phosphate Hydrate, Dried Sodium Sulfite, Stearic Acid, Sucrose, Tartaric Acid
   (5) Selenium and/or chromium tests are newly admitted for the following articles.
   Aluminum Potassium Sulfate Hydrate, Dried Aluminum Potassium Sulfate, Gelatin, Potassium Sulfate, Saccharin Sodium Hydrate, Sodium Bisulfite
   (6) Arsenic test is newly admitted for the following articles.

Acacia, Acetic Acid, Glacial Acetic Acid, White Beeswax, Yellow Beeswax, Carboxymethylcellulose Calcium, Microcrystalline Cellulose, Powdered Cellulose, Ethylparaben, Lactic Acid, Methylcellulose, Methylparaben, Potassium Hydroxide, Saccharin Sodium Hydrate, Sodium Hydroxide, Stearic Acid

(7) Fluoride test is newly admitted for the following articles.
Aluminum Potassium Sulfate Hydrate, Dried Aluminum Potassium Sulfate, Calcium Hydroxide, Dibasic Calcium Phosphate Hydrate, Anhydrous Dibasic Calcium Phosphate, Monobasic Calcium Phosphate Hydrate, Dibasic Sodium Phosphate Hydrate

(8) Reducing sugars, barium, potassium permanganate-reducing substances, sulfur dioxide, peroxide value, phenol, and/or other tests are newly admitted for the following articles.
Acacia, White Beeswax, Yellow Beeswax, Calcium Hydroxide, Microcrystalline Cellulose, Cresol, Dextrin, Hydroxypropylcellulose, Hypromellose, Lactic Acid, Sucrose, Sterile Water for Injection, Sterile Purified Water

(9) Heavy metals, residual pesticides, sulfur dioxide, mycotoxins, and/or other tests are newly admitted for the following articles as Herbal Drugs and Herbal Drug Preparations.
174 articles including Acanthopanax Root Bark

(10) Heavy metals, related substances, phthalic acid, and/or other tests are revised for the following articles.
White Beeswax, Yellow Beeswax, Benzoic Acid, Caffeine And Sodium Benzoate, Carvedilol, Cefaclor Hydrate, Dinoprostone, Domperidone, Doxycycline Hydrate, Famotidine for Injection, Purified Lanolin, Letrozole, Meropenem Hydrate, Nitrogen, Oxaliplatin, Phenobarbital, Polyethylene Glycol 400, Polyethylene Glycol 1500, Polyethylene Glycol 4000, Polyethylene Glycol 6000, Polyethylene Glycol 20000, Sappan Wood, Purified Shellac, White Shellac, Sodium Benzoate, Tamoxifen Citrate, Ursodeoxycholic Acid

(11) Chloride, sulfate, and/or other tests are deleted for the following articles.
Buspirone Hydrochloride, Ephedra Herb, Phenobarbital, Rehmannia Root, Water, Water for Injection, Purified Water in Bulk, Sterile Water for Injection, Zanthoxylum Peel

12) In Loss on drying, loss on ignition, or water:
(1) These tests are newly admitted for the following articles.
Monobasic Calcium Phosphate Hydrate, Cefaclor for Syrup, Ethylparaben, Methylparaben, Stearic Acid
(2) These tests are revised for the following articles.
Azithromycin for Syrup, Repaglinide, Sodium Thiosulfate Hydrate, Torsemide, Rice Starch, Juncus Medulla, Mume Fruit, Ostericum Root

13) Residue on ignition and/or ash are revised for the following articles.
Tamoxifen Citrate, Rice Starch, Akebia Stem, Juncus Medulla, Lycium Fruit, Myrrh, Pogostemon Herb, Salvia Miltiorrhiza Root, Terminalia Fruit

14) Acid-insoluble ash is deleted for the following articles.
Alisma Rhizome, Clove, Dioscorea Rhizome, Gastrodia Rhizome, Nutmeg, Peony Root, Phellodendron Bark, Poncirus Immature Fruit, Sinomenium Stem and Rhizome, Terminalia Fruit

15) Total organic carbon is newly admitted for the following articles.
Water for Injection, Purified Water in Bulk

16) Conductivity is newly admitted or revised for the following articles.
Microcrystalline Cellulose, Water for Injection, Purified Water in Bulk, Sterile Water for Injection, Sterile Purified Water

17) In tests for preparations:
(1) Sterility test is revised for the following articles.
Sterile Purified Water
(2) Bacterial endotoxins is revised for the following articles.
Prednisolone Sodium Succinate for Injection, Water for Injection
(3) Foreign insoluble matter test is newly admitted for the following articles
Sterile Water for Injection
(4) Disintegration test is deleted for the following articles.
Calcium *p*-Aminosalicylate Granules, Doxycycline Hyclate Tablets
(5) Dissolution test is newly admitted or revised for the following articles.
Calcium *p*-Aminosalicylate Granules, Diclofenamide Tablets, Doxycycline Hyclate Tablets, Dydrogesterone Tablets, Metronidazole Tablets, Phenytoin Tablets
(6) Uniformity of dosage units or determination of volume in containers is newly admitted or revised for the following articles.

Diazepam Tablets, Dydrogesterone Tablets, Sterile Water for Injection, Cefaclor for Syrup, Gamisoyosan Extract Granules, Hyeonggaeyeongyotang Extract Granules, Ssanghwatang Extract Granules, Ssanghwatang Solution, Yukmijihwangtang Extract Granules

18) Microbial limit is revised for the following articles.
Aluminum Hydroxide Gel, Calamine, Dextran 40, Dextran 70, Iodixanol, Insulin, Magnesium Carbonate, Medicinal Carbon, Paclitaxel, Sodium Hyaluronate, D-Sorbitol, Acacia, Bentonite, Calcium Stearate, Microcrystalline Cellulose, Powdered Cellulose, Clove Oil, Corn Starch, Gelatin, Purified Gelatin, Honey, Kaolin, Lactose Hydrate, Anhydrous Lactose, Magnesium Stearate, Potato Starch, Rice Starch, Talc, Wheat Starch, Gamisoyosan Extract Granules, Hyeonggaeyeongyotang Extract Granules, Ssanghwatang Extract Granules, Ssanghwatang Solution, Yukmijihwangtang Extract Granules
19) Essential oil content is deleted for the following articles.
Angelica Gigas Root, Codonopsis Pilosula Root, Ostericum Root, Vitex Fruit
20) Assay is newly admitted or revised for the following articles.
Cefaclor Capsules, Cefaclor for Syrup, Cefaclor Hydrate, Cefuroxime Axetil Tablets, Diazepam Tablets, Erythromycin, Letrozole, Magnesium Sulfate Injection, Meropenem Hydrate, Methocarbamol Tablets, Methylphenidate Hydrochloride, Minocycline Hydrochloride, Oxytetracycline Hydrochloride, Prednisolone Sodium Succinate for Injection, Probenecid, Temazepam, Trihexyphenidyl Hydrochloride Tablets, Ursodeoxycholic Acid, Anemarrhena Rhizome, Angelica Gigas Root, Apricot Kernel, Aralia Continentalis Root, Cattle Gallstone, Cinnamon Bark, Citrus Unshiu Peel, Corydalis Tuber, Eucommia Bark, Forsythia Fruit, Gardenia Fruit, Ginger, Leonurus Herb, Lonicera Leaf and Stem, Lycium Fruit, Peach Kernel, Rhubarb, Polygonum Multiflorum Root, Prepared Rehmannia Root, Scutellaria Root
21) Containers and storage is newly admitted, revised, or deleted for the following articles.
Newly admitted in 151 monographs including Acanthopanax Root Bark; revised in Diazepam Tablets, Metronidazole Tablets, Risperidone, Clove, Gentian, and Picrasma Wood; deleted in Water for Injection.

4. In General Tests, Processes and Apparatus:
   1) The following test methods are newly admitted.
   Conductivity Measurement
   2) The following test methods are wholly or partially revised.
   Bacterial Endotoxins Test, Disintegration Test, Dissolution Test, Gas Chromatography, Insoluble Particulate Matter Test for Injections, Insoluble Particulate Matter Test for Ophthalmic Solutions, Liquid Chromatography, Microbial Limit Test, Nitrogen Determination (Semimicro-Kjeldahl Method), pH Determination, Qualitative Tests, Sterility Test, Test for Herbal Drugs, Test for Metal Particles, Test Methods for Plastic Containers, Uniformity of Dosage Units, Water Determination (Karl Fischer Method), X-Ray Powder Diffraction Method, [Reference Standards; Reagents, Test Solutions; Standard Solutions for Volumetric Analysis; Standard Solutions;, Matching Fluids for Color; Optical Filters for Wavelength and Transmission Rate Calibration; Measuring Instruments, Appliances; Sterilization and Aseptic Manipulation]
5. General Information items are as follows.
   Capillary Electrophoresis, Determination of Bulk and Tapped Densities, Disinfection and Sterilization Methods, Guideline for Setting Dissolution Specification of Oral Dosage Forms, Guideline to Pharmaceutical Quality Control Using Near Infrared (NIR) Spectroscopy, Guideline of Limits for Residual Solvents of Pharmaceuticals, Guideline of Validation of Analytical Procedures for Pharmaceuticals, Isoelectric focusing, Particle Size Determination, Powder Particle Density Determination, Preservatives-Effectiveness Tests, Specific Surface Area Determination Method, Terminal Sterilization and Sterilization Indicators (13 items in total)

Appendix 1) 68 articles are newly admitted.

(Part I)

1. Acarbose
2. Almagate
3. Atorvastatin Calcium Hydrate
4. Candesartan Cilexetil
5. Candesartan Cilexetil Tablets
6. Cilostazol
7. Cilostazol Tablets
8. Clopidogrel Bisulfate
9. Doxazosin Mesylate
10. Doxazosin Mesylate Tablets
11. Etizolam
12. Glimepiride
13. Glimepiride Tablets
14. Ketotifen Fumarate
15. Lactitol Hydrate
16. Losartan Potassium
17. Megestrol Acetate
18. Megestrol Acetate Oral Suspension
19. Mosapride Citrate Hydrate
20. Mosapride Citrate Tablets
21. Nicergoline
22. Nicergoline Tablets
23. Nicorandil
24. Norepinephrine Tartrate Hydrate
25. Norepinephrine Tartrate Injection
26. Phloroglucinol Dihydrate
27. Sarpogrelate Hydrochloride
28. Tamsulosin Hydrochloride
29. Telmisartan
30. Terazosin Hydrochloride Hydrate
31. Terazosin Hydrochloride Tablets
32. Trimebutine Maleate
33. Valsartan
34. Voglibose
35. Voglibose Tablets
36. Zaltoprofen
37. Zaltoprofen Tablets
38. Zolpidem Tartrate Tablets

(Part II)

1. Purified Water in Containers
2. Adsorbed Diphtheria-Tetanus-Acellular Pertussis Combined Vaccine
3. Adsorbed Diphtheria-Tetanus Combined Vaccine for Adult
4. Clostridium botulinum Toxin Type A
5. Enhanced Inactivated Poliomyelitis Vaccine
6. Erythropoietin Concentrated Solution (rDNA)
7. Freeze-dried BCG Vaccine for Intradermal Use
8. Freeze-dried BCG Vaccine for Percutaneous Use
9. Freeze-dried Smallpox Vaccine
10. Haemophilus influenzae type b Conjugated to Diphtheria CRM197 Vaccine (Aluminum Adjuvanted)
11. Haemophilus influenzae type b Conjugated to Meningococcal Protein Vaccine
12. Haemophilus influenzae type b Conjugated to Tetanus Toxoid Vaccine
13. Hepatitis A Vaccine (Adsorbed, Inactivated)
14. Hepatitis A Vaccine (Virosome, Inactivated)
15. Hepatitis B Vaccine (rDNA)
16. Human Papillomavirus Vaccine (rDNA)
17. Inactivated Oral Cholera Vaccine
18. Influenza Vaccine (Split Virion, Inactivated)
19. Influenza Vaccine (Surface Antigen, Inactivated)
20. Influenza Vaccine (Surface Antigen-Virosome, Inactivated)
21. Live Attenuated Oral Rotavirus Vaccine
22. Live Attenuated Varicella Vaccine
23. Oral Typhoid Vaccine
24. Pneumococcal Polysaccharide Vaccine
25. Pneumococcus Conjugated to Diphtheria CRM197 Vaccine
26. Purified Vi Polysaccharide Typhoid Vaccine
27. Tetanus Antitoxin (Equine)
28. Somatropin (rDNA)
29. Somatropin Concentrated Solution (rDNA)
30. Somatropin for Injection (rDNA)

Appendix 2) 225 articles are deleted.

(Part I)

1. 10 % dl-Methylephedrine Hydrochloride Powder
2. Acetohexamide
3. Aclarubicin Hydrochloride
4. Ajmaline
5. Ajmaline Tablets
6. Alprenolol Hydrochloride
7. Ambenonium Chloride
8. Amitriptyline Hydrochloride Injection
9. Ampicillin Phthalidyl Hydrochloride
10. Amyl Nitrite
11. Arginine Hydrochloride Injection
12. Bamethan Sulfate
13. Bucumolol Hydrochloride
14. Bufetolol Hydrochloride
15. Buflomedil Hydrochloride
16. Bunazosin Hydrochloride
17. Bupranolol Hydrochloride
18. Ceforanide
19. Chlorpromazine Hydrochloride Syrup
20. Chlorothiazide
21. Chlorothiazide Tablets
22. Chlorzoxazone Tablets
23. Chlorpropamide Tablets
24. Cyanocobalamin Injection
25. Dehydrocholic Acid Injection
26. Deslanoside Injection
27. Dexamethasone Disodium Phosphate Ophthalmic Ointment
28. Dextran 70 Injection
29. Diethylcarbamazine Citrate Tablets
30. Digitoxin Tablets
31. Digitoxin Injection
32. Dimercaprol Injection
33. Dimemorfan Phosphate
34. Dimenhydrinate Injection
35. Dimorpholamine
36. Dimorpholamine Injection
37. Dinoprost
38. Diphenhydramine Tannate
39. Disopyramide
40. Distigmine Bromide
41. Distigmine Bromide Tablets
42. Dried Thyroid
43. Drostanolone Propionate
44. Drostanolone Propionate Injection
45. Ecothiopate Iodide
46. Edrophonium Chloride Injection
47. Emetine Hydrochloride
48. Emetine Hydrochloride Injection
49. Epirizole
50. Ergometrine Maleate
51. Ergometrine Maleate Injection
52. Ergometrine Maleate Tablets
53. Ergotamine Tartrate Injection
54. Estradiol Benzoate Injection
55. Estradiol Benzoate Injection (Aqueous Suspension)
56. Estradiol Cypionate
57. Estradiol Cypionate Injection
58. Estriol Injection (Aqueous Suspension)
59. Etacrynic Acid Tablets
60. Ethionamide Tablets
61. Ethyl Cysteine Hydrochloride
62. Etilefrine Hydrochloride
63. Etilefrine Hydrochloride Tablets
64. Etofenamate
65. Fenbufen
66. Ferrous Fumarate Tablets.
67. Ferrous Sulfate Tablets
68. Floctafenine
69. Flopropione
70. Fluocinolone Acetonide Ointment
71. Folic Acid Injection
72. Fosfestrol
73. Fosfestrol Tablets
74. Gliquidone
75. Haloperidol Oral Solution
76. Homochlorcyclizine Hydrochloride
77. Hydralazine Hydrochloride Powder
78. Hydrocortisone Acetate Injection (Aqueous Suspension)
79. Hydrocortisone Sodium Phosphate
80. Hydroxyzine Pamoate

81. Idoxuridine Ophthalmic Solution
82. Indenolol Hydrochloride
83. Indometacin Suppositories
84. Insulin Zinc Protamine Injection (Aqueous Suspension)
85. Iodamide
86. Iodoform
87. Iopanoic Acid
88. Iopanoic Acid Tablets
89. Iophendylate
90. Iophendylate Injection
91. Isoniazid Injection
92. Josamycin Propionate
93. Lanatoside C
94. Lanatoside C Tablets
95. Levallorphan Tartrate
96. Levallorphan Tartrate Injection
97. Medroxyprogesterone Acetate Injection (Aqueous Suspension)
98. Mefruside
99. Meglumine Amidotrizoate Injection
100. Meglumine Iotalamate Injection
101. Meglumine Sodium Amidotrizoate Injection
102. Meglumine Sodium Iodamide Injection
103. Mepenzolate Bromide
104. Mepitiostane
105. Metenolone Acetate
106. Metenolone Enanthate
107. Metenolone Enanthate Injection
108. Metildigoxin
109. Methylbenactyzium Bromide
110. Metyrapone
111. Naphazoline Nitrate
112. Neutral Insulin Injection
113. Nicomol
114. Nicomol Tablets
115. Nicotinamide Injection
116. Nicotinic Acid Injection
117. Norepinephrine
118. Norepinephrine Injection
119. Paraformaldehyde
120. Pethidine Hydrochloride Tablets
121. Phenolsulfonphthalein Injection
122. Phenovalin
123. Phenoxymethylpenicillin Potassium
124. Phenytoin Powder
125. Piperazine Phosphate Hydrate
126. Piperazine Phosphate Tablets
127. Pirenzepine Hydrochloride Hydrate
128. Potassium Canrenoate
129. Procarbazine Hydrochloride
130. Procainamide Hydrochloride Injection
131. Procainamide Hydrochloride Tablets
132. Prochlorperazine Maleate Tablets
133. Promazine Hydrochloride
134. Promazine Hydrochloride Tablets
135. Propantheline Bromide Tablets
136. Purified Dehydrocholic Acid
137. Physostigmine Salicylate
138. Physostigmine Sulfate
139. Reserpine Injection
140. Reserpine Powder
141. Reserpine Tablets
142. Riboflavin Powder
143. Riboflavin Sodium Phosphate Injection
144. Riboflavin Tablets
145. Simfibrate
146. Sodium Iopodate
147. Sodium Iopodate Capsules
148. Sodium Iotalamate Injection
149. Sodium Prasterone Sulfate Hydrate
150. Sodium Salicylate Tablets
151. Sulfamonomethoxine Hydrate
152. Sulfinpyrazone Tablets
153. Sultiame
154. Terconazole.
155. Testosterone Propionate Injection
156. Testosterone Propionate Injection (Aqueous Suspension)
157. Tetracycline Methylene Lysine
158. Thiamine Hydrochloride Powder
159. Thianthol
160. Tiaramide Hydrochloride
161. Todralazine Hydrochloride Hydrate
162. Tolazamide
163. Tolbutamide Tablets
164. Tolnaftate Topical Solution

165. Trimethadione
166. Trimethadione Tablets
167. Tribenoside
168. Triclofos Sodium
169. Triclofos Sodium Syrup
170. Trioxsalen
171. Tripelennamine Hydrochloride
172. Tubocurarine Chloride Injection
173. Warfarin Potassium
174. Warfarin Potassium Tablets
175. Zinc Undecylenate

(Part II)

1. 10 % Nux Vomica Extract Powder
2. Nux Vomica Tincture
3. Opium Alkaloids Hydrochloride
4. Adsorbed Diphtheria-Tetanus Combined Toxoid
5. Adsorbed Diphtheria Toxoid
6. Adsorbed Tetanus Toxoid
7. Cholera Vaccine
8. Factor VIII:C Monoclonal Antibody-purified, Freeze-dried Human Blood Coagulation Factor VIII: C
9. Factor VIII Inhibitor bypassing Activity Complex
10. Freeze-dried BCG Vaccine
11. Freeze-dried Concentrated Human Blood Coagulation Factor VIII (dry heat treated)
12. Freeze-dried Diphtheria Antitoxin (Equine)
13. Freeze-dried Human Normal Immunoglobulin with Histamin
14. Freeze-dried Live Attenuated Measles-Mumps Combined Vaccine
15. Freeze-dried Live Attenuated Measles Vaccine
16. Freeze-dried Live Attenuated Rubella Vaccine
17. Freeze-dried Live Mumps Vaccine
18. Human Plasma Protein Fraction
19. Ichthammol Ointment
20. Inactivated Hepatitis B Vaccine
21. Inactivated Rabies Vaccine
22. Live Oral Poliomyelitis Vaccine
23. Leptospira Vaccine
24. Monoclonal Antibody-purified, Freeze-dried Human Blood Coagulation Factor VIII:C
25. Pertussis Vaccine
26. Purified Protein Derivative of Tuberculin (PPD)
27. Aromatic Castor Oil
28. Chlorpheniramine and Calcium Powder
29. Compound Salicylic Acid Spirit
30 Compound Thianthol and Salicylic Acid Solution
31. Dental Antiformin
32. Dental Paraformaldehyde Paste
33. Dental Triozinc Paste
34. Formalin Water
35. Glycerin Suppositories
36. Hydrochloric Acid Lemonade
37. Ichthammol Ointment
38. Iodine, Salicylic Acid and Phenol Spirit
39. Mentha Water
40. Naphazoline and Chlorpheniramine Solution
41. Norgestrel and Ethinylestradiol Tablets
42. Phenolated Water for Disinfection
43. Phenovalin and Magnesium Oxide Powder
44. Potash Soap
45. Salicylated Alum Powder
46. Scopolia Extract and Ethyl Aminobenzoate Powder
47. Scopolia Extract, Papaverine and Ethyl Aminobenzoate Powder
48. Wine
49. Zinc Oxide Oil
50. Zinc Sulfate Ophthalmic Solution

Publication History

Date	Details	No. of articles	Remarks
Oct. 10, 1958	KP established and promulgated	635	
Oct. 10, 1967	KP II Part I	725	
Jul. 15, 1968	KP II Part II	457	
Aug. 29, 1968	KP II Supplement I		Revised test methods and correction tables
May 28, 1969	KP II Supplement II	1	2 articles deleted
Jan. 24, 1972	KP II Supplement III	49	
Dec. 10, 1976	KP III Parts I and II	1013	656 articles in Part I, 357 articles in Part II
Feb. 1, 1978	KP III Supplement I	146	
Jan. 13, 1979	KP III Supplement II	72	
Mar. 1, 1982	KP IV Parts I and II	1212	785 articles in Part I, 427 articles in Part II
Nov. 24, 1982	KP IV Supplement I	30	
Apr. 22, 1987	KP V Parts I and II	1308	868 articles in Part I, 440 articles in Part II
Mar. 16, 1988	KP V Supplement I	8	
Apr. 7, 1992	KP VI Parts I and II	1428	986 articles in Part I, 442 articles in Part II
Mar. 26, 1993	KP VI Supplement I		Revised test methods and correction tables
Dec. 31, 1997	KP VII Parts I and II	1482	1007 articles in Part I, 475 articles in Part II
Feb. 19, 2000	KP VII Supplement I		Revised test methods and correction tables
Dec. 30, 2002	KP VIII	1485	1018 articles in Part I, 467 articles in Part II
Jul. 24, 2006	KP VIII Supplement		23 articles deleted, correction tables
Dec. 28, 2007	KP IX	1511	1093 articles in Part I, 418 articles in Part II
Jul. 9, 2009	KP IX Supplement I	1	
Feb. 24, 2010	KP IX Supplement II	76	
May 3, 2010	KP IX Supplement III	109	
May 28, 2010	KP IX Supplement IV	131	
2010. 12. 31	KP IX Supplement V	171	
2011. 3. 14	KP IX Supplement VI	184	
2011. 10. 28	KP IX Supplement VII	298	
2012. 3. 26	KP IX Supplement VIII	176	

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