Regulations on the Approval, Notification, and Evaluation of Quasi-Drugs

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Chapter 1 General Provisions

Article 1 (Purpose)

The purpose of this Notice is to provide detailed procedures and requirements for manufacturing or importing approval (notification) of quasi-drugs, and products subject to the safety and efficacy evaluation and scientific review of specifications and testing methods for quasi-drugs, data requirements (scope, description and waiver), and relevant criteria and management of data pursuant to Articles 31, 42, and 76 of the Pharmaceutical Affairs Act and Articles 4, 5, 8 to 13, 39, 40, and 57 to 59 of the Rules on the Safety of Drugs, etc.

Article 2 (Definitions)

The terms used in this Notice shall be defined as follows:

1. "Active ingredient" means a substance or a group of substances (including herbal medicines, of which pharmacologically active ingredient, etc. have not been identified yet) expected to manifest, directly or indirectly, the indications of quasi-drugs.
2. "New material" means a substance or a group of substances that have not been used domestically as an active ingredient of drugs or quasi-drugs; however, for quasi-drugs falling under subparagraph 7 (a) of Article 2 of the Pharmaceutical Affairs Act, it also means a substance or a group of substances that have not been used domestically as an excipient of quasi-drugs.
3. "Herbal medicinal product", as seen from the western medicine point of view, means a preparation made with raw materials or substances derived from natural materials that is not used for treatment purposes in the oriental medicine. However, a preparation, though originated from a natural material, made by extracting and refining a particular ingredient, shall not be considered as herbal medicinal product.
4. "Combination products" means quasi-drugs containing two or more active ingredients including extracts (such as

herbal medicinal products) from two or more plants and extracts from two or more organs of the same animal (e.g.: an extract from liver and stomach of a pig), etc. Synthetic materials that are difficult to separate or refine individual ingredient, or unnecessary to process such operations (e.g.: o-, m-, or p-Cresol), or an extract from the same plant (provided, that even if extracted from the same plant, if the active ingredients extracted from different parts are noticeably different, as Scopoliae Rhozoma extract, it shall be excluded.) and an extract from the same organ of the same animal (e.g.: gastric mucous membrane extract of a pig) shall be considered as a single-component product.

5. "Sample" means materials collected in a reasonable manner, such as random sampling.
6. "Actual value" means a value obtained from actual measurement to be used for actual statistical analysis with outliers excluded.
7. "Actual statistical value" means a value obtained from statistical analysis of actual values
8. " Disinfectants and insecticides for preventing infectious disease" means one of the following products:

(a) Products used for the purpose of expelling or controlling harmful pathogen carrying insects (including larva and imago of mosquitoes, ants, flies, fleas, lice, and cockroaches) causing diseases and sanitary hazards for people.

(b) Products used for the purpose of sterilization and disinfection, not directly applied to people, animals or medical devices.

(c) "Rodenticides" means products used for the purpose of controlling pathogen carrying rodents causing diseases in people.

9. "Booster" means a substance or a group of substances that enhances the action of active ingredients, though it does not have inherently sterilizing, insecticidal and rodenticidal effects.
10. "Inhalable products" means products, such as cigarette-type products specified in subparagraph 2 (e) of the Designation of the Scope of Quasi-Drugs (MFDS Notice), that are used through repeated and direct inhalation or products specified in subparagraph 2 (j) of the Designation of the Scope of Quasi-Drugs that may be used through prolonged or repeated and indirect inhalation.

Chapter 2 Application for Approval or Notification of Quasi-drugs and Data Requirements

Article 3 (Approval or Notification Process)

(1) Quasi-drugs that are subject to notification pursuant to Articles 31 (4) and 42 (1) of the Pharmaceutical Affairs Act shall be as follows; however products subject to safety and efficacy evaluation pursuant to Articles 21 and 44 shall be excluded:

1. Products listed in the Korean Pharmacopoeia (Notice of MFDS), compendia or drug formularies recognized by the Minister of Ministry of Food and Drug Safety (hereinafter referred to as the Minister of MFDS); however, products that have not been approved domestically shall be excluded.
2. Products for which specifications and test methods are notified by the Minister of MFDS.
3. Products that comply with the manufacturing standards notified by the Minister of MFDS.

(2) Manufacturers or importers who filed for approval (notification) of quasi-drugs shall be approved or declare as specified below:

1. For products with the same specifications and quantities of active ingredient(s), dosage form, and route of administration (or application), they shall be regarded as, and approved (notified) as one product; however, it is

not applied, if the unique nature of a product is recognized within a scope of the same specifications or if a product is intended for export only. Also, approval (notification) for manufacture and import shall be regarded as separate cases and, thus, shall be applied with different product names.

2. Notwithstanding subparagraph 1, for products to be mixed up prior to use (e.g.: a double batch of a developer and dye for hair coloring products) or when a mix-based manufacturing is justifiable, they may be approved (or notified) as a package. If only the taste (flavor), color, or shape differ, they may be approved (or notified) as one product with one certificate of approval (notification).
3. Notwithstanding subparagraphs 1 and 2, quasi-drugs falling under subparagraphs 1 and 2 (a), (b), (f), and (i) of the Designation of the Scope of Quasi-Drugs (MFDS Notice) may be approved (notified) as a package with different product names, even if they have the same active ingredient. However, in such a case, if the type, quantities and dosage form of the active ingredient are the same, even though the rest of the ingredients are different, they may be approved (or notified) with one certificate of approval (notification).

(3) For quasi-drugs intended for export only, the application for product approval (notification) may be submitted only with specifications, etc. required by the importer of the product, instead of information on safety and efficacy, specifications, and test methods pursuant to Article 4 (1) 1 and 2 of the Rules on the Safety of Drugs, etc. In such a case, the Minister of MFDS may grant approval (or accept notification) on the basis of those documents etc.

(4) Quasi-drugs falling under subparagraph 7 (c) of Article 2 of the Pharmaceutical Affairs Act shall comply with Chapter 5 Approval, Notification and Review of Disinfectants and Insecticides, etc for preventing Infectious Diseases

Article 4 (Processing of Changes to Approval or Notification of Quasi-Drugs)

(1) If approved or notified quasi-drugs specified in Article 3 are intended to be changed in accordance with Article 8 (1) of the Rules on the Safety of Drugs, etc., such changes shall comply with provisions of Articles 7 to 18 of the Rules.

(2) Notwithstanding paragraph (1), for the following minor changes, dossiers (including electronic documents) describing such changes may be provided for approval or notification pursuant to Article 8 (4) of the Rules on the Safety of Drugs, etc:

1. Changes to the product name (applicable only for single-component products, for which the active ingredient or prescription information is used as the product name), drug substances and their quantities, or terms used in specifications and test methods, etc. in accordance with changes to terms of substances or preparations listed in the Korean Pharmacopoeia, Korean Pharmaceutical Codex, Specifications and Test Methods for Quasi-Drugs and others as notified by the Minister of MFDS, and foreign compendia as listed in the Designation of Compendia and Monographs (MFDS Notice);
2. In the section of manufacturing method, changes to the containers or packaging (except for immediate container or packaging) that do not affect the stability;
3. In the section of manufacturing method, changes to the manufacturer’s address due to change of administrative district.
4. In the section of indications (efficacy and effects), dosage and administration and precautions, use of easy terms designated and notified by the Minister of MFDS.
5. In the section of drug substances and their quantities, changes to the type of tar colorant

6. Change to the specifications of additives within the scope of the standards and compendia notified by the Minister of MFDS pursuant to subparagraph 1.

(3) For changes pursuant to each subparagraph of paragraph (2), the manufacturer or importer of the quasi-drug shall specify the date and changes in "Changes and Regulatory Actions, etc." on the back side of the approval (or notification) certificate..

(4) For changes as listed in the above paragraph (2), the quasi-drug manufacturer or importer shall submit to the Minister of MFDS or the Commissioner of the competent Regional Office of MFDS the application of changes in accordance with Article 5 (1), together with the electronic media containing the information by the end date of the month where the approval or notification date belongs, on changes occurred for the past 1 year from the end date of the month prior to the month where the initial approval or notification date belongs.

Article 5 (Preparation of Application for Product Approval or Notification)

(1) The application for manufacture and import, or notification of quasi-drugs shall be prepared in an appropriate manner on the basis of attached documents specified in this Notice, and contain information as specified in Articles 7 to 18. When submitting attached documents, they shall be electronically prepared using a software program designated by the Minister of MFDS and the electronic media containing those files (such as CD, disk) shall be provided.

(2) Supporting data (including domestic and overseas approval information, data requirements pursuant to the Manufacturing Standards for Drugs, etc. (MFDS Notice)) on the prescription, indications, dosage and administration, precautions shall be attached. For products subject to notification pursuant to Article 3 (1), supporting data on the active ingredient and their quantities, dosage form, and specifications and test methods verifying that they correspond to one of the subparagraphs in Article 3 (1) shall be attached; however, for solid and liquid preparations among quasi-drugs that comply with the Manufacturing Standards for Drugs, etc., documents on the standards and test methods are not required.

(3) Notwithstanding paragraph (1), if one intends to apply for approval of (or declare) manufacturing or importing of products, for which data submission have been modified (harmonized) pursuant to Article 50, application shall be prepared according to such modification; however, it is not applied when one intends to request review and attach safety and efficacy data or submit the "results of safety and efficacy evaluation."

(4) For imported products, the following documents on the manufacture and sale of the product shall be submitted; however, if it is difficult to submit such documents at the time of the application, the applicants may indicate the expected due date for submission within the period for processing of the application and submit them by the due date. The certificates on the manufacture and sale shall be issued within two years prior to the application date (Certificates issued before may be acceptable, depending on the issuance system of the manufacturing or registering country, or public agency that are responsible directly or indirectly for approval or management of the product).

1. Quasi-drugs falling under subparagraph 1, 2 (a) and 2 (b) of the of the Designation of the Scope of Quasi-Drugs (MFDS Notice)

(a) A certificate of marketing authorization describing the product name, drug substances and their quantities, indications, etc. demonstrating that the product is marketed in or outside of the manufacturing country, signed by the responsible person of the manufacturer and officially notarized by a competent authority (a public agency in

the country responsible directly or indirectly for approval or management of the product)

2. Quasi-drugs not covered by subparagraph 1

(a) A certificate of manufacture describing the product name, drug substances and their quantities (active ingredient and its specifications, and excipients such as diluents and colorants shall be described. However, omission may be allowed if such information is contained in the certificate of marketing as specified in the below clause (b)), the name and address of the manufacturer which demonstrates the product is legitimately manufactured in the country of production.

(b) A certificate of marketing authorization describing the product name, drug substances and their quantities (active ingredient and its specifications, and excipents such as diluents and colorants. However, omission may be allowed if such information is contained in the certificate of manufacture as specified in the above clause (a)), the name and address of the manufacturer issued by the government or a public agency that granted approval or registered the product (a competent authority responsible directly or indirectly for approval and management of the product in the country of sale)

(5) When applying for the initial approval of sanitary masks, the results of leakage rate testing shall also be provided as supporting data. The leakage rates shall be no greater than 25.0% for the KF80 rating, no greater than 11.0% for the KF94 rating, and no greater than 5.0% for the KF99 rating.

Article 6 (Data Requirements for Approval and Notification)

(1) The following information shall be described in the approval or notification certificates of manufacture and sale or import of quasi-drugs in accordance with Article 12, 13, or 59 of the Rules on the Safety of Drugs, etc:

1. Product Name
2. Code Number and class
3. Drug substances and their quantities
4. Appearance
5. Manufacturing methods (addresses of manufacturing sites for active ingredients and all manufacturing processes shall be specified; however, the manufacturer of active ingredients may not be specified for subparagraph 2 (a) and (b) of the Designation of the Scope of Quasi-Drugs (MFDS Notice))
6. Indications (efficacy and effects)
7. Dosage and administration
8. Precautions in use
9. Packing units
10. Storage and expiry date (shelf-life)
11. Specifications and test methods
12. Manufacturer (including the contract manufacturer when applicable) and importer (including the original manufacturer)
13. Approval conditions

(2) For changes to the appearance only (external shape or color, etc.) according to paragraph (1), specifications and test methods may not be revised.

Article 7 (Product Name)

(1) The product name identical to the one already approved or notified for other medicinal products or quasi-drugs shall not be used. However, if different importers import the same product from the same manufacturer, the names of importers shall be indicated respectively for easy discrimination..

(2) In principle, the product name shall be indicated as follows:

1. If the brand name is intended to be indicated, the name of quasi-drug manufacturer or importer in accordance with Articles 31 (4) and 42 (1) (including a unique abbreviations or symbolic representation hereinafter referred to as the "name of business"), the brand name and dosage form shall be indicated. However, name of business may be omitted. Further, the name of the active ingredient of a single-component product, the names as listed in the relevant notice for products notified by the Minister of MFDS, and prescription information for products made using prescription listed in the herbal medicines codex shall be described in the parenthesis. In addition, for quasi-drugs falling under subparagraphs 1 and 2 (a), (b), (f), and (i), dosage form may be omitted.
2. If the brand name is not indicated, "the name of business, the name of the active ingredient (for a single-component product) or the prescription name, and dosage form shall be indicated."
3. The ratings for sanitary masks (e.g.: KF80, KF90, K99) shall be indicated in the parenthesis.

(3) If one intends to use a product name that are amended by simply adding or replacing a letter, word or number, etc. (e.g.: ㅿㅿ-A, ㅿㅿ—F, composite OOO, etc.) of the product name already approved or notified, such name may be used only for the product having similar indications as the one approved or notified..

(4) For dosage form, the term specified in the General Rules for Preparations in the Korean Pharmacopoeia shall be used. However, if it is recognized that it is a new dosage form such as jelly or that it is a required to separately managed such as the enteric granules, sustained-release tablet, effervescent tablets, sugar-coated tablets, film-coated tablets, soft capsule, hard capsule, and emulsion, etc., such name may be indicated..

(5) If it is necessary to indicate the quantities of the active ingredient (mass, volume, potency) of a single-component product, it shall be stated with the dosage form and the unit (e.g.; OO sodium fluoride solution 0.2 mg). And for combination products, the administration time (morning or evening), taste (flavor), intended use (bleaching or dye remover), etc. shall be indicated, and if necessary, indicated by prescription.

(6) The name used for export shall be indicated in the product standards (4.1 Product Standards under Drug GMP in Appendix 1 of the Rules on the Safety of Drugs, etc. or standards equivalent to this) to be regarded as "name for export" approved or notified in accordance with this Notice.

(7) If one intends to amend the product name, such amendment shall be appropriate in accordance with Article 11 (2) of the Rules on the Safety of Drugs, etc.

Article 8 (Code Number and Class)

(1) Code number shall comply with the Regulations on Codes for Classification of Quasi-Drugs (MFDS Internal Rules).

(2) Class shall be indicated as quasi-drugs.

Article 9 (Composition)

(1) Dosage form shall be selected to maximize the efficacy of the active ingredient and ensure the stability and safety.

The composition (drug substances and their quantities) shall be reasonable and justifiable. Dosage shall be consistent with indications, dosage and administration, etc. Considering the nature of the product, intended use, names, specifications of substances, and their quantities (mass, volume, potency, or amount used) shall be specified for individual ingredient according to the guidance defined in paragraph (2). However, when extracts or derivatives are used, the names (specifications) of the extracts or derivatives may be stated. In addition, the contents of the active ingredient shall be reasonable and justifiable on the basis of the pharmacological data, clinical trial results, etc. For combination products, intended use shall be valid for individual ingredient.

(2) The intended use of substances such as active ingredient and diluents shall be specified by product or preparation, and the active ingredient and additives (according to the amount of administration or order of administration used in the manufacturing process) shall be indicated as follows:

1. For divided power, divided granules or divided pills, content "in one pouch (mass or number of pills) or "per one serving (mass or number of pills)."
2. For tablets, capsules, pills (divided pills are excluded), or troches content "in a unit preparation [tablets, capsules, pills, etc.] (mass)."
3. For powders, liquids, ointments, creams, lotions, gels, pastes and emulsions, etc. content "in 100 mL" or "in 100 g" (v/v, w/v,/ w/w); however, for powder-type syrups content "in 100 g" (including the amount of solvent), and for disposable preparations "in a unit container [1bottle, ample, etc.] (dose)."
4. For products directly attached to the skin, content "in 1 sheet (the area and mass)" or "in a unit area (e.g.: 1 cm^2)"; however, for content indicated in a unit area, the size of each sheet (2x2 cm^2, 4x2 cm^2, etc.)
5. For aerosols, content "in 100 g" (separately indicating the amounts of the original solution and the propellant).
6. For other preparations that do not correspond to the above-mentioned items, but required to be stated in an individual unit, content "in a unit dosage form [one item, one piece, etc.] (mass or volume)."

(3) The names and specifications of individual substance shall comply with the following:

1. For subparagraphs 2 (a) to (e), the names listed in the relevant monographs shall be indicated in Korean. For those, for which attached specifications are used, common names or other appropriate name showing the nature of the substances shall be indicated in Korean.
2. Specifications shall be described according to one of the following:

(a) Substances listed in the Korean Pharmacopoeia: "Pharmacopoeia" or "KP"

(b) Substances listed in compendia: title (or acronym) of the relevant compendium

(c) Substances listed in the Korean Herbal (Herbal Medicines) Pharmacopoeia (MFDS Notice): "Herbal Medicine Specifications"

(d) Substances listed in the Korean Quasi-Drug Codex (MFDS Notice): "KQC"

(e) Substances listed as excipients in the Standards and Specifications for Food Additives (MFDS Notice): "Food Additives"

(f) Raw materials listed as excipients (products for internal use only are excluded) in the Japanese Quasi-Drug Raw Material Codex: "JQRC"

(g) Drug substances listed as excipients (products for internal use only are excluded) in the Japanese Drug Additive Codex: "JDAC"

(h) Specifications of substances that do not correspond to the items (a) to (g), and are prepared by the business who

filed for approval or notification: “Enclosed Specifications” or “Enc. Spec”

(i) Notwithstanding subparagraphs (a) to (h), herbal medicines that are dried, cut or refined in their original form, and of which the quality has not been verified, may be indicated as the “original herbal medicine.” For substances that are specified as drug additives in subparagraphs 1, 2 (a), (b), (c), (f), (g), (i), and 3 of the Designation of the Scope of Quasi-Drugs (MFDS Notice), and whose specifications are defined in Part 4 Additives for quasi-drugs of the Korean Quasi-Drug Codex (MFDS Notice), the appropriate specifications may be stated respectively.

(j) Among drug substances of fiber, rubber or papers used for sanitary purposes, the substances whose specifications are listed in the Korean Industrial Standards (KS) may be indicated as “KS.”

(k) Substances listed in the Korean Pharmaceutical Codex (MFDS Notice): KPC

(4) Active ingredient and its quantity (mass, volume, potency, or amount used) shall be safe and effective on the basis of the toxicity test data, pharmacological action data, clinical trial data, and data on the use (other literatures, etc.) and shall comply with the following:

1. Criteria for fluorine contents in toothpastes shall be as follows:

(a) Criteria for individual substance

Sodium monofluorophosphate: ≤1.14% (1,500 ppm as fluorine)

Sodium fluoride: ≤0.33% (1,500 ppm as fluorine)

Stannous fluoride: ≤ 0.6% (1,500 ppm as fluorine)

N,N,N'-tris-(2-hydroxyethyl)-N'-octadecyl-1,3-diaminopropane dihydrofluoride: ≤1.97% (1,500 ppm as fluorine)

(b) When the above substances are mixed up, the total content of fluorine shall be no greater than 1,500 ppm.

2. If an extracted herbal material is used as an active ingredient, the name of the raw herbal material and its quantity (amount used), the type of the extracted liquid (it may be omitted for purified water) and yield rate (e.g.: ginseng 50% ethanol extract: 10→1) shall be stated. If the raw herbal material is pulverized, the quantity of the raw herbal material shall be clearly stated (e.g.: licorice powder: 100→65).

(5) Additives and their quantities shall comply with the following:

1. In principle, the quantities of all additives used shall be stated; however, the amount of the main diluent may be indicated in a certain range, if justifiable (e.g.: difference in amounts administered in the summer or winter season), or if additives that comply with the Korean Pharmacopoeia or compendia are used for creams, ointments, and lotions. For additives used in minor volume as follows, amount may be indicated as “optimum dose.”

(a) Coating agent, pills, enteric coating capsules, slip modifiers, polishing agent

(b) Sweetening agent, coloring agent, flavoring agent

(c) Suspending agents, emulsifier, dissolution supplements

(d) Stabilizer, isotonic solution, pH regulator, viscosity regulator

(e) Solvent, base compound (including capsules)

2. For excipients other than drug substance, those listed in the Korean Pharmacopoeia or compendia, specified in the Appendix 7 of the Regulations on the Approval, Notification, and Review of Quasi-Drugs (MFDS Notice), or other excipients whose functions par pharmaceutically appropriate when considering reliable data on their use in

Korea or foreign countries, that do not have direct pharmacological effects, and that do not compromise the efficacy or quality control of the product shall be used.. However, if an active ingredient is used as an excipient, daily dose of the excipient shall not exceed 1/5 of the minimum daily dose for the same route of administration. If exceeded, pharmaceutically appropriate data on such formulation and references published in Korea or foreign countries shall be provided.

3. Types and contents of preservatives shall meet the requirements specified in Appendix 1 "Preservatives for Quasi-Drugs and their Range of Use.. <Proviso Deleted.>
4. Tar colorants used in quasi-drugs shall comply with the requirements specified in the Designation, Specifications and Test Methods for Tar Colorants for Drugs, etc. (MFDS Notice); however, it is not applied when tar colorants are used in certain parts of a repellant (band-type) that are not in a direct contact with the human body as specified in subparagraphs 1 (a) 1), (b), (c) 1) and 8), and 2 (c) in the Designation of the Scope of Quasi-Drugs (MFDS Notice); or in products that are filled in a container to reduce the risks of accidental intake by people or animals, such as extirpators, inhibitors, and insect-attracting pesticides as specified in subparagraph 2 (c); and in products that are not directly applied to the human body as specified in subparagraph 3 (a) 2) .

Article 10 (Appearance)

(1) The characteristic appearance and shape of the product shall be described in accordance with the Korean Pharmacopoeia and the provisions mentioned below. The color, shape, material type, and dosage form (e.g egg-shape cotton sanitary pad) shall be specified. However, the material of the product may not be specified if it is unnecessary (e.g.: insecticides, hair dye product).

1. In principle, for dosage form, the term specified in the General Provisions for Preparations of the Korean Pharmacopoeia shall be used. However, if the dosage form is not listed in the Korean Pharmacopoeia (e.g.: fiber, rubber or papers used for sanitary purpose, anti-smoking aid, etc.), or if it is needed to be separately managed (e.g.: enteric granules, sustained-release tablet, effervescent tablets, sugar-coated tablets, film-coated tablets, soft capsule, hard capsule, emulsion, etc.), such name may be indicated.
2. For capsules the appearance of the enclosed substances shall be specified (e.g.: transparent soft capsule containing yellow liquid, hard capsule containing white powders with blue on the top and yellow, on the bottom green soft capsule containing brown semi-solid material, hard capsule containing brown powder with blue on the top and white on the bottom)
3. For plated pills, the appearance of the enclosed materials shall be indicated (e.g.: brown pills plated with gold).
4. For fiber, rubber or papers, etc. (e.g.: band-aids) that are used for sanitary purposes, and whose material type affects the indications and dosage and administration, and for which the shape of the container need to be indicated (e.g.: yellow suspending agent contained in a container to be sprayed in particular amounts, etc.), the appearance shall be described in detail (e.g.: sponge pressed with a white porous synthetic resin, disposable polyurethane film covered with an adhesive material on one side). And if it deems necessary, a structural diagram including the shape and size (e.g.: external photo, floor plan, etc.) shall be described. .

(2) For products manufactured in different appearances, the appearance shall be indicated for each purpose as follows: "for medical insurance," "for export," or "for military supply", etc.

Article 11 (Manufacturing Method)

(1) The manufacturing method shall be reasonable and justifiable from physicochemical, biological, bioengineering, and pharmaceutical perspectives on the basis of the contemporary scientific knowledge and technologies.

(2) For preparations, the flow chart showing the whole production process and step-by-step description shall be provided in detail pursuant to Appendix 2 of the Guidelines for Description of Manufacturing Methods, and shall be in compliance with subparagraphs 1 to 3. And supporting data shall be provided in accordance with subparagraph 4.

1. If organic solvents are used in the manufacturing process:

(a) It shall be justifiable from the pharmaceutical perspective.

(b) It shall not exercise direct pharmacological effects and be used in safe dosage.

(c) It shall not compromise the safety or quality control of the product.

(d) Intended use, name, specifications and quantities, etc. of the solvent shall be indicated.

2. If the whole or part of the manufacturing process or testing is commissioned to other drug manufacturers and conducted using their facilities and equipments pursuant to the Standards for Facilities of Manufacturers, Importers and Sales Business of Pharmacy and Drugs, etc. (Presidential Decree), the name and address of contract manufacturer, etc. shall be clearly indicated.

3. If the finished product contains animals-derived substances or such substances are used in the manufacturing process, information on the animal and its parts used shall be specified. If a substance of ruminant origin is used, information on the selection of the substance (the country of origin, age of the ruminant, etc.), or the processing method to prevent the infection of the Transmissible Spongiform Encephalopathy (TSE) shall be additionally provided as mentioned in the below:

(a) [A substance of animal origin] derived from [the part used] of [the name of the animal] is contained or used.

(b) In order to prevent the infection of the Transmissible Spongiform Encephalopathy (TSE), [the name of the substance of animal origin] obtained by collecting [the part used] from healthy [the name of the ruminant] of [age of the ruminant] from [the country of origin] that is processed by [the processing method] is used.

4. If necessary due to the nature of the product, a separate sub-section for product design may be added to describe the reason for selection of the dosage form, drug substances and their quantities.

(a) If any special process method is adopted, data justifying selection of the drug substances and their quantities used, such as the reason for selection of excipients and mixing ratio, and if necessary, the biological evaluation data and justification of product design shall be provided.

(3) Paragraphs (1) and (2) shall apply for dispensing of finished quasi-drugs products..

(4) If necessary, the order of administration of each drug substance shall be indicated. And, if the comparability of the finished products is demonstrated, more than 2 manufacturing methods may be used. In this case, the method shall be indicated as <Method 1>, <Method 2>, and so on.

(5) If a special container is used for insecticides to reduce the risks of accidental poisoning, the material and structure of such a container shall be specified.

(6) Paragraphs (1) to (5) shall apply for imported products.

(7) If it is necessary to irradiate finished products for sterilization, operating parameters (irradiation dose, time, and others) shall be specified and stability data (three lots), including comparative data on degradation products detected in irradiated or non-irradiated products, shall be provided.

Article 12 (Indications)

Information on indications shall be described as follows:

1. Information on indications shall be provided in medical terms and on the basis of obvious and clear supporting data on pharmaceutical activity of the product.
2. Terms that are vague and indefinite, are redundant or exaggerated, or may lead to misunderstanding, misuse, or abuse shall not be used.
3. For quasi-drugs that are subject to notification pursuant to Article 3 (1), indications shall comply with those already approved or notified. For products that comply with the Manufacturing Standards for Drugs, etc. indications shall meet the manufacturing standards, and in other cases, shall comply with regulations prescribed by the Minister of MFDS.
4. For herbal medicines, indications shall be described in contemporary terms on the basis of medical/herbal medicine dictionaries, a guide for herbal drug codex, and other specifications prescribed by the Minister of MFDS, etc. In general, intended use shall be stated as "treatment, improvement, relief or supplement for specific symptoms under certain condition or case". But, if justified, this may not apply. However, if there is no objective justification for interpretation of terms, such interpretation may be acceptable if it complies with subparagraphs 1 to 6 based on the review of attached documents.
5. If the indications are limited to specific populations (based on gender, age, or others), such information shall be clearly described.
6. For combination products, all indications of individual drug substances shall not be described, in principle. Unless otherwise justified, only the indications of the active ingredient are acceptable. For addition or potentiation effects, objective supporting data shall be provided.

Article 13 (Dosage and Administration)

Information on dosage and administration shall be provided as follows:

1. Dosage shall be reasonable and justifiable on the basis of pharmacological and pharmaceutical data, and clinical data, etc., and consistent with composition and indications, etc. In addition, dose, administration time (if necessary, indicate specifically as "before meal", "after meal", "between meals") and frequency, etc. shall be specified in detail.
2. Notwithstanding subparagraph 1, for quasi-drugs in accordance with subparagraph 7 (a) of Article 2 of the Pharmaceutical Affairs Act, it may be stated as "appropriate amount shall be applied to the affected area." However, for products with specific instructions for use, such instructions may be stated additionally according to subparagraph 1.
3. If it is intended to be administered to specific populations (based on gender, age, or others), inappropriate dosage information considering the indications shall not be indicated. In particular, for quasi-drugs for infants or children, the dosage for different age groups shall be clearly described. Except for certain special cases, proportional reduction of adult dose shall not be used.
4. For products for multiple administrations, such as pediatric products, they shall be pharmaceutically appropriate products or preparations.

5. For quasi-drugs subject to notification pursuant to Article 3 (1), the indications shall comply with those already approved or notified. For products subject to the Manufacturing Standards for Drugs, etc. shall comply with such manufacturing standards, and in other cases, they shall comply with regulations prescribed by the Minister of MFDS.
6. Clear expressions shall be used to prevent misuse. Any term and expression that may cause abuse or highlight certain characteristics shall not be used.

Article 14 (Precautions in Use)

(1) All information on safety (including the additives) required to assure safe and reasonable use of the quasi-drugs shall be provided. Such information shall be prepared in contemporary terms on the basis of medical/herbal medicine dictionaries, a guide for herbal drug codex, and other specifications prescribed by the Minister of MFDS, etc. for easy understanding.

(2) For quasi-drugs subject to notification pursuant to Article 3 (1), information on precautions for use shall comply with those already approved or notified, and products subject to the Manufacturing Standards for Drugs, etc., it shall comply with the relevant manufacturing standards. In other cases, it shall comply with specifications prescribed by the Minister of MFDS.The precautions shall be described as follows:

1. Do not administer this product to the following patients: List the patients to whom administration of the product is prohibited when considering the type or symptoms of the disease, complications, personal and family medical history, predisposition, possibility of pregnancy, breastfeeding, gender or other factors, even though whose disease or symptoms correspond to the indications (the scope of efficacy and effects) of the quasi-drug; and patients whose disease or symptoms do not correspond, but very similar to the indications of the quasi-drug, thus, who are highly likely to misuse the quasi-drug. Other expressions, such as “Do not administer this product to the following parts (indicate the body part)” may be stated.
2. Do not administer (or use) this product in parallel with the following products: Statement that the product shall not be used with other quasi-drugs of the same kind or effects or that may cause drug interactions.
3. Avoid the following actions while this quasi-drug is administered (or used): actions that shall not be performed while the quasi-drug is administered (or used) shall be stated as follows:

(a) Warning that this product shall not be administered (or used) to breastfeeding women shall be stated if the product (or substances) may be transferred and carry a risk to the baby through breast-milk.

(b) If a serious accident may occur due to adverse reactions caused by administration (or use) of the quasi-drug while engaging in a particular occupation or activity, list the relevant adverse reactions and include warning that such occupations or activities shall be avoided while the product is administered (or used)..

(c) If the quasi-drug may interact with a particular food or drink such as alcohol, warning that such food or drink shall not be taken while the quasi-drug is administered (or used) shall be stated.

(d) Other warnings needed to prevent clinically significant adverse reactions or accidents shall be stated.

4. The following person shall consult a physician, dentist, or a pharmacist before taking (or using) this quasi-drug: The cases where this quasi-drug shall not be administered (or used) to a healthy person shall be stated, if there is a high risk of adverse reactions considering the type or symptoms of disease, complications, personal and family medical history, predispositions, possibility of pregnancy, breast-feeding, gender or other factors of the person.

5. In the following cases, administration (or use) of this quasi-drug shall be stopped immediately and consult a physician, dentist, or a pharmacist. And, bring the attached instructions for consultation, if possible: adverse reactions that may worsen or continue if the administration (or use) of the quasi-drug is continued shall be stated for each affected area, and the initial adverse reactions that may be recognized by an ordinary person shall be stated, in principle. In addition, follow-up measures if there is no improvement in the symptoms after the quasi-drug was used for a certain period of time or multiple administrations shall be stated, in this case, the period or number of administrations shall be indicated in detail.
6. Other precautions in administration (or use) of this quasi-drug: minor or durable adverse reactions expected to occur considering the pharmacological efficacy of the quasi-drug, and other precautions shall be stated.
7. Precautions in storage: Information on temperature, humidity, sunlight, etc. shall be stated in detail within the scope of the storage method for products that have been approved or notified. And, depending on the nature of the preparations, general precautions shall be stated as follows:

(a) Store beyond the children's reach.

(b) Change of the product container may lead to accidents or quality deterioration. Therefore, store the product in the original container and seal it tightly.

Article 15 (Packing Unit)

(1) The package unit of quasi-drugs shall be as small as possible for an easy and convenient handling, and it shall be consistent with its dosage and administration method.

(2) For liquid products, the packing unit shall be indicated as "200 mL or less for disposable packaging" and "400-500 ml" for economic packaging; however, exceptions may be allowed if special characteristics are recognized when considering the dosage form or dosage, or if it is justifiable when considering the intended purpose.

(3) For other package units that do not correspond to paragraph (2), the packing unit shall be indicated as "in-house packing unit" for manufacturing, or " packing unit of the manufacturer" for importing.

Article 16 (Storage Condition and Period of Use (Shelf-life))

(1) In order to assure the stability of the product considering the physicochemical characteristics, the types of containers shall be categorized as sealed, tight, and hermetic container, etc, and specific storage conditions (e.g.: store at 2-8℃, refrigerated, etc.) and precautions (e.g.: keep away from light, etc.), etc. shall be described.

(2) Period of use shall be indicated as "Period of use: O months from the date of manufacture," and comply with the following. This also shall apply to revisions:

1. Period that is approved based on the safety and efficacy data pursuant to 'Chapter 3 Evaluation of Safety and Efficacy.'
2. If one intends to manufacture an item same as the one already approved or notified, its period of use may be applied, and such period shall not exceed 36 months; however, if the pharmaceutical safety needs to be identified, safety test data or other supporting data shall be provided.
3. In order to extend the period of use for a product that has been approved or notified, long-term stability data shall be provided..

Article 17 (Specifications and Test Methods)

(1) Specifications and test methods shall be prepared in accordance with Chapter 4 'Review of Specifications and Test Methods' in a manner that assures appropriate quality control. 'Specifications and Test Methods' shall be indicated as "Appendix," If 'Standards and Test Methods of the Quasi-Drugs (MFDS Notice)' is applied, it shall be indicated as "In accordance with the Section "OOO" in the Standards and Test Methods Concerning Quasi-Drugs." However, for products that correspond to the proviso to Article 5 (2), it shall be indicated as "in-house standards."

Article 18 (Manufacturer, etc.)

(1) If the whole or part of the manufacturing process or testing is commissioned to other manufacturers of drugs, etc., the name and address of the contracted manufacturer shall be provided.

(2) For imported product, the address of the manufacturer and manufacturing sites, etc. indicated on the certificate of manufacture shall be provided.

Article 19 (Approval Condition, etc.)

(1) For quasi-drugs for export, Article 4 (1) 6 of the Rules on the Safety of Drugs, etc. and Articles 7 to 18 of this Notice may not apply. For military or government supply (for stockpile use), the above provisions also may not apply if there is a purchase notice or other regulations such as specifications. However, if one intends to sell a product domestically that has been approved, for import, or military or government supply, conditions for such purposes may be waived based on the review of safety, efficacy, and specifications and test methods pursuant to Chapters 3 and 4 and GMP for drugs pursuant to Article 4 (1) 6 of the Rules on the Safety of Drugs, etc., provided that the product is not restricted by Article 11 of the Rules on the Safety of Drugs, etc. In such case, such products shall comply with Articles 7 through 18.

(2) If one intends to apply for approval or notification of manufactured or imported products in connection with transfer and/or assumption under Article 8 of the Rules on the Safety of Drugs, etc., approval may be granted or notification may be accepted, provided that all conditions previously imposed on the transferor are transferred.

Article 20 (Approval of Cigarette-Type Anti-Smoking Aids)

(1) Harmful substances of a cigarette-type anti-smoking aid shall not exceed the following criteria per cigarette, and nicotine shall not be detected:

1. Tar 10 mg;
2. Carbon monoxide 10 mg.

(2) For cigarette-type anti-smoking aids, the following shall be described on the front or rear side of the external packaging for each recognition:

1. Warning
   1) This product is not intended to be a long term alternative to cigarettes. Excessive use may cause lung cancer or other diseases, and in particular, harmful to pregnant women and adolescence.
   2) The level of tar and carbon monoxide contained in this product is almost equivalent to cigarettes.
2. Amounts of tar and carbon monoxide in one piece of cigarette (e.g.: Tar OO mg, carbon monoxide OO mg)

(3) When measuring harmful ingredients indicated in the external packaging, the acceptable margin of error shall be

as follows:

1. Tar: if 5 mg or more, within ±20%; if less than 5 mg, within ±1 mg
2. Carbon monoxide: if 5mg or more, within ±20%; if less than 5mg, within ±1mg

(4) Amounts of harmful ingredients in cigarette-type anti-smoking aids shall be identified according to the following standards:

1. Tar: Measurement standards of International Organization for Standardization (ISO) 4387;
2. Carbon monoxide: Measurement standards of International Organization for Standardization (ISO) 8454
3. Nicotine: Measurement standards of International Organization for Standardization (ISO) 10315

Chapter 3 Safety and Efficacy Evaluation

Article 21 (Products subject to safety and efficacy evaluation): Safety and efficacy evaluation in accordance with Article 4 (1) 1 and 9 of the Rules on the Safety of Drugs, etc. shall be conducted for quasi-drugs filing for approval or notification of products or changes to such products; however, this is not applied to any of the following:

1. Products with the same type, specifications and quantities of active ingredient, (for liquid products, concentration), dosage form, indications, and dosage and administration as those that have been approved or notified.
2. Products that are listed in the Korean Pharmacopoeia or compendia or products for which specifications and test methods are notified by the Minister of MFDS; however, for products listed in a compendium, supporting documents such as drug formularies demonstrating their current use in the country shall be provided.
3. As cotton products (including papers) used for sanitary purpose and quasi-drugs subject to the Manufacturing Standards for Drugs, etc., products using as active ingredients substances listed in the Korean Pharmacopoeia or compendia, or other substances notified by the Minister of MFDS, or approved; products listed in foreign drug formularies (Physicians' Desk Reference, PDR in U.S., drug formulary in Japan, ABPI Data Sheet Compendium in U.K., Rote Liste in Germany, Vidal in France, L'iniformatore Farmaceutico in Italy, Arzneimittel Kompendium der Schweiz in Switzerland, and Compendium of Pharmaceuticals and Specialties in Canada); or products with a certificate of manufacture issued by the relevant country, demonstrating that they are sold in the country as general drugs.

(2) Notwithstanding paragraph (1), drugs falling under any of the following are subject to safety and efficacy evaluation and in this case, data specified in Articles 23 and 24 shall be provided:

1. If new excipients that have not been used in drugs or quasi-drugs are added. However, safety and efficacy evaluation may be waived for substances that fall under any of the following:

(a) Substances listed in the Korean Pharmacopoeia, Korean Pharmaceutical Codex, Specifications and Test Methods for Quasi-Drugs, Korean Herbal Codex, or compendia

(b) Substances that have been used domestically and a mixture made of these substances (including flavoring agents)

(c) Raw materials registered in the Standards and Specifications of Food Additives.

(d) Raw materials listed in the Japanese Quasi-Drugs, Raw materials Codex and Japanese Drug Additive Codex

(e) Deleted.

(f) Substances with drug formularies as specified in paragraph (1) 3 or other reliable data on their use in foreign

countries

2. If one intends to file for approval of changes regarding safety and efficacy (indications, dosage and administration and types or quantities of boosters, etc) of the product that have been approved; however, simple changes in precautions for use, etc. based on case information, etc. for quasi-drugs that have been already approved, Regulations on the Management of Safety Information for Drugs, etc. (MFDS Notice) shall apply. However, it is applied where changes are intended for indications, dosage and administration etc, within a scope that is consistent with the Manufacturing Standards for Drugs, etc..
3. If one intends to amend approval conditions from export sale to domestic sale.
4. If a substance that has not been used as an additive of inhalable products (drugs or quasi-drugs) domestically is used in an inhalable product.

Article 22 (Data Requirements for Safety and Efficacy evaluation)

(1) Data required for safety and efficacy evaluation of quasi-drugs shall be prepared using Annex Form 1, and data specified in Articles 23 through 25 shall be provided.

(2) Data submission shall comply with the requirements of Article 25, and for individual product, the list index numbers and page numbers of data shall be indicated in the order specified in Article 23; however, if data submission is waived or exempted, the reasons shall be provided in detail.

(3) In general, for data provided from overseas, a summary written in Korean (excerpt of main contents) and the original document shall be submitted. And if necessary, the complete translation of the entire document (signed by a responsible person with expertise in medicine and pharmacy) may be requested.

Article 23 (Types of Data for Safety and Efficacy Evaluation)

Data required for safety and efficacy evaluation pursuant to Articles 4 (1) and 9 (1) of the Rules on the Safety of Drugs, etc. shall be as follows:

1. Origin or discovery, and history of development;
2. Specifications and test methods;
3. Safety data (long-term stability data or accelerated test data);
4. Toxicity data
   (a) Single dose toxicity data
   (b) Multiple dose toxicity data
   (c) Reproductive and developmental toxicity data
   (d) Genotoxicity study data
   (e) Immunological toxicity data (including skin sensitization data)
   (f) Carcinogenicity data
   (g) Local toxicity data
5. Supporting data for indications (efficacy and effects)
6. Data on use in foreign countries
7. Data on other characteristics such as a comparative study etc. with similar domestic products.

Article 24 (Scope of Data Submission for Safety and Efficacy evaluation)

(1) The scope of data submission for safety and efficacy evaluation depending on the types and nature of quasi-drugs is described in Appendix 3.

(2) For quasi-drugs falling under Article 2, subparagraph 7 (a) of the Pharmaceutical Affairs Act, toxicity data may be waived if they are sold in two or more countries; however, for products containing new materials, toxicity data shall be provided pursuant to paragraph (1).

(3) For new additives specified in Article 21 (2) 1, the following data shall be provided:

1. Origin and discovery (including data on the purpose of mixing and intended use)
2. Physicochemical characteristics and specifications
3. Safety data (data on finished products are also acceptable)
4. Toxicity data (for preservatives and tar colorants, data shall be provided in accordance with requirements on attachments for new drugs specified in the Regulations on Approval, Notification, and Evaluation of Drugs. In other cases, single dose toxicity, multiple dose toxicity, and other necessary toxicity data (local toxicity data, skin sensitization data, etc.) shall be submitted.); however, it is not applied for flavoring agents.

(4) For excipients to inhalable products pursuant to Article 21 (2) 4, the following data shall be provided:

1. Origin and discovery (including data on the purpose of mixing and intended use)
2. Physicochemical characteristics and specifications
3. Safety data (data on finished products are also acceptable)
4. Toxicity data (single dose inhalation toxicity, multiple dose inhalation toxicity, and other necessary toxicity data (local toxicity data, skin sensitization data, etc.) shall be provided.). However, for raw materials that do not fall under Article 21 (2) 1, toxicity data other than inhalation toxicity data may be waived..

Article 25 (Data Requirements for Safety and Efficacy evaluation)

(1) Data requirements for safety and efficacy evaluation of quasi-drugs shall be as follows:

1. Origin or discovery and history of development:

Data clearly described according to the five Ws and one H (5W1H) principles to help judgment of the product (e.g.: when, where, who extracted, separated from what or synthesized; the origin of discovery; when and where preliminary testing or clinical trial, etc. began, etc.)

2. Specifications and test methods

Specifications and test methods used to identify the level of quality and specifications of the product subject to evaluation, or the results of review of specifications and test methods

3. Stability data

(a) General requirements

1) In general, data obtained from tests that are domestically conducted in accordance with the Standards for Drug Stability Test (MFDS Notice), shall be provided with raw data (including a chromatogram data. Validation data may be provided, instead). However, if data ontained from further studies performed in compliance with the Standards for Stability Studies of Medicines and Other Products are additionally submitted, they may be regarded as those submitted at the time of application.

2) Notwithstanding the provisions of the above 1), stability data generated in foreign countries may be acceptable,

provided that review of such data indicates that stability of the product is secured.

(b) Subjects for test

1) Quasi-drugs containing new substances: Period of use shall be established based on long-term stability data, but if there is no significant change such as contents etc., period of use may be established within 36 months on the basis of accelerated test data conducted for 6 months.

2) Quasi-drugs besides 1): Period of use for items that been approved or notified may apply without additional safety data, and in this case, such period shall not exceed 36 months. It is also applied to revisions.

4. Toxicity data

(a) General requirements: Data obtained from tests performed in accordance with the Good Laboratory Practices (GLP) (MFDS Notice)

(b) Test methods: Data in compliance with the Standards for Drug Toxicity Test (MFDS Notice), or data showing that the specifications and test methods are justifiable scientifically and reasonable.

(c) Evaluation

1) Immunotoxicity data: This data may be waived if there is no abnormal reaction found as a result of repeated dose toxicity test.

2) Carcinogenicity data

a) Carcinogenicity test data shall be submitted in the any of the following cases:

(1) Quasi-drugs with carcinogenic potential: If the chemical structure or a biological activity of the quasi-drug or its metabolite is similar to a substance known to be carcinogenic, or a quasi-drug suspected to be carcinogenic considering the results of multiple dose toxicity test or a genotoxicity study.

(2) Quasi-drugs that are used clinically for a long period of time: In most cases, over 6 months.

3) Local toxicity data: For quasi-drugs directly applied on skin or mucous membrane or easily applied to skin or mucous membrane, even not directly. However, local toxicity data may be conducted as part of other toxicity tests.

5. Supporting data for indications (efficacy and effects)

5-1. Data on the pharmacological action

(a) General requirements

One of the following shall be provided:

1) Data obtained from tests performed at testing laboratories such as a university or research institution in Korea or foreign countries. Such data shall be issued by the head of the organization and accepted as valid (in this case, summary of facilities in the research organization, research staff and relevant experiences of testers, etc. shall be described.)

2) All pharmacological data that are submitted and evaluated at the time of application. Such data shall be notarized or recognized as submitted or approved by the authority that granted approval, received notification of the product, or registration authority.

3) Data published in an academic journal registered in the Science Citation Index.

(b) Test method

In non-clinical data, the route of administration shall be identical to that of clinical data. However, depending on the type, bioaccessibility, etc. of the test, different routes of administration may be employed, as appropriate. If it

is impossible or not meaningful to carry out a non-clinical trial, clinical trial data may be provided, instead:

1) Efficacy data: data on the pharmacological actions related to the effectiveness including the efficacy subject to evaluation shall be provided. Such data also contains the mechanism of action for the appearance of effectiveness.

2) Pharmacological data

a) General pharmacological data (safety pharmacological data may be provided, instead): data that comply with the Guidelines for General Pharmacological Test of Drugs, etc. (MFDS Notice) including testing results on the effects on each body part (system) and functions except for toxicity test, efficacy test, and testing on absorption, distribution, metabolism, and excretion. Or data for which the testing methods and evaluation criteria, etc., are justifiable scientifically and rationally.

b) Safety pharmacology data: Data for evaluating the potential undesirable pharmacodynamic effects of a quasi-drug on physiological functions in relationship to exposure in the therapeutic range or above.

c) Absorption, distribution, metabolism, and excretion data: Information including analysis and validation methods.

5-2 Clinical data

(a) General requirements

1) Domestic clinical data:

a) For products for internal use or inhalable preparations, clinical data shall be obtained from tests performed by a clinical research institution designated by the Minister of MFDS and shall comply with the provisions of the Korea Good Clinical Practices (KGCP) (MFDS Notice). Revisions to the protocol and final protocol, etc. also shall be provided.

b) For other clinical data, clinical tests shall be conducted and evaluated at an academic institution or other testing laboratories in Korea or foreign countries under instruction and supervision by a medical specialist or a person who has at least 5 years of relevant testing experience at a research institution, hospital, or other related organizations. And such tests shall be managed by an institutional review board (IRB) defined by Articles 7 and 8 of the KGCP and the data shall be issued by the head of the relevant organization (summary of testing facilities, key equipment, research staff, relevant experiences of the testers shall described)

2) Foreign clinical data:

a) Clinical test results that are submitted and evaluated at the time of application. Such data shall be recognized or notarized as submitted to or approved by the government (authority that granted approval or accepted notification, or registration authority) of the relevant country.

b) Data published in an academic journal registered in the Science Citation Index;

c) Data obtained from testing regarded as implemented in accordance with the KGCP by a reliable testing organization.

(b) Test method, etc.

1) For new quasi-drugs under development in Korean or foreign countries, testing shall be conducted pursuant to research methodology with scientific and medical validity. For clinical data, testing shall be conducted pursuant to the KGCP.

(c) Number of test cases

The number of test subjects shall be determined reasonably depending on the characteristics of quasi-drugs, clinical trial methods, etc., and statistically valid so that the safety and efficacy can be verified according to the available evaluation method.

(d) Evaluation

1) There shall be clinical significance with regards to the relevant indications, etc.

2) For sterilizers and disinfectants, the efficacy test data may be provided instead of the clinical test results.

6. Data on use in foreign countries

Data on use of the quasi-drug in other counties to aid in making judgment about the utility of the product. Such data shall contain updated information on the drug substances and their quantities (including supporting data for the enclosed specifications), indications, dosage and administration, precautions, etc.; current use and listing in the drug formularies of other countries; and the actions taken in relation to the safety and efficacy of the product.

7. Other data on characteristics of the product (comparison with similar domestic products, etc.)

A comparative table shall contain information on drug substances and their quantities, indications, dosage and administration, and precautions, etc of the product in comparison with other existing drugs and quasi-drugs (including imported products) of similar efficacies. Such data shall contain comparison data on characteristics and defects with regards to the pharmaceutical efficacy, adverse effects or safety.

Chapter 4 Review of Specifications and Test Methods

Article 26

Deleted.

Article 27 (Description of Specifications and Test Methods)

(1) Specifications and test methods shall be described in accordance with the following principles:

1. The format, terms, unit and marks, etc. for specifications and test methods shall be consistent with the Korean Pharmacopoeia.
2. Information to be described in the specifications and test methods shall comply with Appendix 4 on specifications and test Methods in; however, omission may be allowed depending on dosage forms, as appropriate.
3. Specifications and test methods shall be consistent with the general principles, general provisions for preparations, sections on general testing methods, reference standards, reagents and test solutions, etc. of the Korean Pharmacopoeia. Except where omission is allowed for the whole or part of testing methods pursuant to subparagraph 4, the testing methods shall be stated in detail.
4. For products for which the test methods listed in the Korean Pharmacopoeia, Korean Pharmaceutical Codex, Specifications and Test Methods for Quasi-Drugs, Korean Herbal Codex, compendia and other specifications and testing methods notified or recognized by the Minister of MFDS (hereinafter referred to as “MFDS Specifications”), their description may be omitted as a whole or in part. In this case, test methods shall be described as follows:

E.g.: 1) Sterility test: This product shall be tested according to the sterility test described in the general test methods in the Korean Pharmacopoeia.

E.g.: 2) Content testing: This product shall be tested according to the clause 1) quantification methods for

sodium monofluorophosphate, sodium fluoride, and silica dioxide paste described in the Specifications and Test Methods for Quasi-Drugs.

5. Test methods stated in the specifications and test methods shall be verified by methods listed in the Implementation Guidelines for Validation of Analysis Methods for Drugs, etc. in the Korean Pharmacopoeia or in compendia, etc.; however, test methods listed in the MFDS Specifications shall be excluded.
6. If the reagents, test solutions, equipment, instruments, reference standards or substances for assay are used, the description of the reagents, test solutions shall contain the purity, concentration and manufacturing methods, the description of equipment shall contain the types and other information, instructions for use, and the descriptions of reference standards or substances for assay (hereinafter referred to as "reference standard") shall contain their specifications etc. And reagents harmful to humans and the environment (e.g. mercury compound, benzene, carbon tetrachloride, and 1, 4-dioxane) shall not be used where possible.
7. The specifications and test methods shall be established on the basis of the efficacy, stability and process validation, etc. of the product.

(2) The drug substances and their quantities, manufacturing method, storage and period of use, etc. in the specifications and test methods shall be described in accordance with the provisions in Articles 9 to 18.

(3) For fabric, rubber, or papers used for sanitary purposes, the structural diagrams including the shape and size shall be provided if necessary.

(4) If a container is used for solid insecticides to reduce the risks of accidental intake, the manufacturing methods shall include the material of the container, and a structural diagram shall be prepared separately.

(5) If necessary, relevant literatures, working standards, drug substances used, and special reagents, equipment, strains and culture medium, etc. may be provided separately.

(6) In general, regarding data from overseas, a summary written in Korean (an excerpt of the main terms) and the original document shall be submitted. And only when necessary, complete translation of the entire document (signed by a confirmer who has an expert knowledge in medicine and pharmacy) may be requested to be submitted.

For information in foreign languages, in principal, original documents and their summary in Korean (excerpts) shall be provided. However, if necessary, their full translation (signed by a person having medical and pharmaceutical expertise) may be provided.

Article 28 (Establishment of Criteria)

(1) The contents or potency of raw materials and finished product shall be indicated according to the any of the following criteria. However, if there are different criteria approved by the manufacturing country or country of origin, or if it is justifiable, separate criteria may be established. If the supporting data are obtained from testing results, the criteria may be established considering the actual statistical value from tests conducted at least three times on one lot for three or more lots of samples.

1. General criteria

(a) Raw material: ≥99.0%

(b) Finished product: ≥90.0%

2. Other criteria

(a) Fluorine compound in toothpastes: 90.0%-110.0%

(b) Hydrogen peroxide solution in toothpastes, mouth freshener, teeth whitener and hair dye: 90.0 - 110.0%

(c) Hormones in hair loss-preventive products and hair tonic: 90.0% - 110%

(d) Thioglycolic acid in external applications used for depilatory purpose: 90.0 - 110%.

(e) Sterilizers and disinfectants: 90.0% - 110.0%

(f) Vitamins

1) Vitamin composites, vitamins and metal elements added in very small amounts to vitamin composites: 90.0% - 150.0%

2) Vitamin derivatives: 90.0% - 130.0%

(g) Disinfecting and insecticidal ingredient (including boosters) in disinfectants and insecticides for preventing infectious diseases: Their contents shall be consistent with the following criteria depending on the amounts of active ingredients.

Amounts of active ingredient	Criteria
Solid form, ≤2.5%	75.0% - 125.0%
Liquid form, ≤2.5%	85.0% - 115.0%
>2.5%	90.0% - 110.0%

3. If the criteria for contents are not established because content testing for the active ingredient is not possible or necessary, efficacy test, performance test, or a formulation test. (e.g.: hair-dye testing of hair coloring products)

(2) Other criteria necessary for quality control are as follows. However, other criteria may be established if justifiable. If the validity of supporting data cannot be acknowledged according to the following clauses 1 to 4, the range of criteria may be adjusted. If the supporting data are obtained from test results, the criteria may be established considering the actual statistical value obtained from tests conducted at least three times on one lot for three or more lots of samples.

1. pH: Criteria shall be established within ± 1.0 of the actual statistical value.
2. Specific gravity: Criteria shall be established within ± 0.05 of the actual statistical value.
3. Evaporation residue: The upper limit of the actual statistical value shall be established.
4. Alcohol content: Criteria shall be established for products for internal use containing 4% or more ethanol, and shall be 90% or more of the indicated value in the labelling.
5. Homogeneity test: Criteria shall be consistent with the provisions of the Korean Pharmacopoeia and the General Test Methods besides the Korean Pharmacopoeia.
6. Microbial limit test: Criteria shall be established in compliance with the General Test Methods besides the Korean Pharmacopoeia.
7. Refraction index: Criteria shall be within ± 0.05 of the actual statistical value.
8. Adhesion test: Criteria shall be established for adhesive bandages. When testing is performed according to the section for an adhesive bandage in the Korean Pharmacopoeia, the adhesive strength shall be 150g or more per

width of 12mm for synthetic resin film and felt bandage.

9. Elasticity test: Criteria shall be established for adhesive bandages. When testing is performed according to the section for an adhesive bandage in the Korean Pharmacopoeia, the adhesive strength shall be 1kg or more per width of 12mm for synthetic resin film and felt bandage.
10. Shape test: Criteria shall be established for adhesive bandages in compliance with the shape tests in the section for adhesive bandages in the Korean Pharmacopoeia. However, for disposable bandages, the length of the pad (gauze or felt, etc.) shall be no less than 98.0% of the indicated value, and the width shall be no less than 94.0% of the indicated value in the labelling.
11. Preservative content test: Criteria shall be established for products for internal use among quasi-drugs containing preservatives. In such cases, preservatives contained in the product shall be identified, and the amount shall be 80.0% - 120.0% of the indicated value in the labeling. If necessary, the separate criteria may be defined.
12. Dust collection efficiency test: Criteria shall be established for sanitary masks. When testing is performed pursuant to Article 30 (4) 14, dust collection efficiency shall be no less than 80.0% for KF80 (sodium chloride test), no less than 94.0% for KF94 (sodium chloride and paraffin oil tests), and no less than 99.0% for KF99 (sodium chloride and paraffin oil tests).
13. Facial inhalation resistance test: Criteria shall be established for sanitary masks. testing is performed pursuant to Article 30 (4) 15, facial inhalation resistance shall be 6.2 mmH_2O or less for KF80, 7.2 mmH_2O or less for KF94, and 10.3 mmH_2O or less for KF99.

Article 29 (Description Guidelines for Specifications and Test Methods of Raw Materials)

(1) Enclosed specifications of raw materials shall be described according to Appendix 5 on Example of Enclosed Specifications for Raw Materials.

(2) In the enclosed specifications in the above paragraph (1), necessary information specified in the following paragraph (3) shall be described to ensure proper quality control of drug substances on the basis of data submitted for evaluation of specifications and test methods. Other information may be provided, if necessary.

(3) The enclosed specifications of raw materials shall be described in the following order:

1. Name

(a) The Korean names of raw materials shall be indicated pursuant to Article 9 (3) and the relevant guidelines on drugs names defined by the Minister of MFDS.

(b) The English names of raw materials shall be indicated in accordance with the International Nonproprietary Names for Pharmaceutical Substances (INNPS) and pursuant to the relevant guidelines on drug names defined by the Minister of MFDS.

2. Structural (or rational) formula

Structural (or rational) formula shall be stated following the examples of description of the structural (or rational) formulas in the Pharmacopoeia.

3. Molecular formula and molecular weight

Molecular formula and molecular weight shall be described in line with the relevant provisions in the Pharmacopoeia.

4. Origin and manufacturing method

The origin and manufacturing method may be omitted for synthetic products of which the chemical structures are determined. But, this information shall be stated for protein or organ extracts (hydrolysis), enzymes, etc. However, for materials containing at least two compounds of similar structures such as the optical, geometric stereoisomer, high polymer, etc., it may be difficult to separate or refine such compounds or such operation is unnecessary. In this case, their ratio shall be stated.

5. Composition

The contents of ingredients shall be described according to the following provisions. But, this may be omitted if there is a clear reason why such criteria cannot be established.

(a) The contents shall be indicated in percentage (%), and the molecular formula shall be stated in the parenthesis; however, if it is not appropriate to indicate the contents in percentage (%), it may be indicated as potency, unit, etc. If not possible to describe the contents of the ingredients, the contents of pure chemical substances may be indicated (e.g.: magnesium silicate).

(b) The upper and lower limits shall be established, in principle, and for unstable drug substances, the range of such limits shall be established on the basis of the information on the safety of their decomposed materials.

6. Appearance

Appearance shall be stated according to the requirements in the following subparagraphs. Color and shape are key criteria to determine the suitability of quality of products. Other necessary criteria shall be established and stated in the sections of the physicochemical properties and purity test:

(a) Color, shape, smell, taste, etc. shall be stated; however, if the smell and taste may affect the health of testers, such information shall not be stated.

(b) For solubility, information on water, ethanol, and ether shall be stated. Also, how pH affects the solubility shall be stated, and the solvent used in testing also shall be established.

(c) Liquidity, stability (hygroscopic property, light stability, etc.), etc. shall be stated.

7. Identification test

(a) For identification test, color reaction, precipitation reaction, decomposition reaction, derivative formation reaction, infrared/visible/ultraviolet spectrum, special reaction, qualitative reaction, etc. of positive and negative ions, etc. shall be stated with a specific focus on o chemical tests on the basis of the chemical properties of drug substances. And unnecessary information may be omitted.

(b) Specific testing methods to distinguish structurally similar materials shall be established. If the testing method is only to identify the retention time in chromatography, it shall not be considered as being specific; however, it may be recognized as specific, if a detector that may identify the specificity is used.

(c) For sodium drug substances, a testing method that can detect sodium shall be included.

(d) For drug substances that may be identified in other tests besides identification test, such information may be quoted in the section of identification test.

8. Physicochemical properties

In order to indicate the nature and purity of drug substances, necessary information shall be established and stated following the definition in subparagraph (a):

(a) Whole numbers that are measured by physical or chemical methods such as the refraction index, saponification value, unsaponifiable matters, specific optical rotation, boiling point, specific gravity, acid value, hydroxyl value,

ester value, iodine value, melting point, freezing point, viscosity, freezing point of fatty acids, pH, optical density, etc.

(b) Measurement of physicochemical properties of a compound shall follow the general test method of the Korean Pharmacopoeia and shall state the standard values (e.g.: pH 3.0 - 5.0); however, for the tests for which details are to be stated in each article, relevant details shall be stated. If there are at least two test methods or devices, the names of the test methods or devices shall be stated together with the names of test methods in the Pharmacopoeia.

(c) If a testing method specified in a compendium is used, the names of the compendium and the test method shall be stated in the test method. If the details are to be stated in each article, or if there are two or more test methods or devices, names of the test methods or devices shall be stated along with the standard values.

(d) If not listed in the Korean Pharmacopoeia or compendia test method shall be stated with standard values.

(e) Physicochemical properties that need not be the standards of determining suitability of quality of products shall be stated under the section of Appearance.

9. Purity test

(a) Purity test shall be stated in the order of color; smell; taste; dissolution status; liquidity; acid or alkali; mineral salt (sulphate, chlorides, nitrates); ammonium; heavy metal; metal (zinc, iron, etc.); arsenic; organic matter; general foreign substances (referring to impurities that can get mixed, remained, created or added); evaporation residue; starting material, intermediate material, and by product that exist due to impurities; decomposition product (hereinafter referred to as “flexible material”); other adulterated substances (isomer, residual solvent, etc.); and color reaction material for sulfuric acid. And unnecessary items shall be excluded.

(b) Dissolution status shall be established and stated if it is possible to determine the purity of drug substances.

(c) For mineral salt, heavy metal, and arsenic, necessary items shall be established and stated by taking into consideration the manufacturing procedure, usage directions and dose, etc.

(d) For flexible materials, the limit shall be established and indicated as a percentage (%) of the drug substances or as a mass based on the data submitted pursuant to Articles 30 through 32. If a test is conducted by using a liquid chromatography or a gas chromatography instead of using a reference standard of flexible materials, measurement range for areas, quantitative limit, and a method for verifying flexible materials (e.g. relative peak duration) shall be stated.

(e) For drug substances from which isomers are separated, unintended isomers shall be established and stated.

(f) Residual solvent shall be established and stated regarding the solvents that have been used during the manufacturing process according to the data submitted pursuant to Articles 46 through 48 and a method that is approved pursuant to the Guidelines of Residual Solvent for Drugs in the Korean Pharmacopoeia or in the official compendium, etc.

10. Loss on drying, loss on ignition, and moisture

These items shall be established and stated according to the relevant test methods in the general test methods of the Korean Pharmacopoeia.

11. Ignition residue, ash or acid-insoluble ash

These items shall be established and stated according to the relevant test method in the general test method of the Korean Pharmacopoeia.

12. Special tests

If it is necessary for enzymes and protein or organ extracts (hydrolysis), safety test, antigenicity test, and histamine test shall be established and stated.

13. Other tests

Other test shall be established when there is a test item other than the items in subparagraphs 1 to 12 that is directly related to the evaluation of quality and securing safety and efficacy. (e.g.: isomer ratio, polymorphism, microbial limit test, particle size test)

14. Quantification method

As a method that measures the material's content, unit of content, etc. through a physical, chemical or biological method, a test method that has a high accuracy, precision, and specificity shall be established; however, in purity tests, if a test method that has a high specificity of being able to simultaneously analyze the flexible materials is being established, it shall be approved even if the specificity is low (e.g.: if a test method that can separate the main ingredient and the flexible ingredient simultaneously and quantify them during a purity test is set as a HPLC, etc., a titration method is possible for quantification methods.)

15. Reference standard, reagent and test solution

When reference standards, reagents, or test solution snot listed in the Korean Pharmacopoeia and compenda are used, the relevant following subparagraphs shall be stated:

(a) Reference standard shall establish specifications that are proper for its purpose, and a purification method (including a manufacturing method when it is difficult to obtain materials other than the pertinent drug substances) shall be stated as necessary. Raw materials for quantification shall state a method that measures the content through a test method that is able to measure the absolute amount.

(b) In general, content of reference standard shall be no less than 99.0%.

(c) Reagent and test solution shall state preparation methods.

16. Storage method

Storage method shall be stated pursuant to Article 16.

(4) Stating manufacturing methods of drug substances shall comply with Article 11.

Article 30 (Description Guidelines for Standards and Test Methods of Finished Products)

(1) Standards and test methods of finished products shall be written separately for standards and test methods following the Example of Completed Standards and Test Methods in Appendix 6, but the items to be listed for standards and test methods and their order shall each be the same.

(2) Items to be listed for the standards and test methods shall include items from the items listed in paragraphs (3) and (4) that are needed for providing reasonableness in quality control of quasi-drugs based on the data submitted for the evaluation of standards and test methods. Other items may be added if necessary.

(3) Standards shall be written in the following order:

1. Appearance

Appearance shall be written pursuant to Article 10.

2. Identification test

For all active ingredients (including the booster), it shall be stated that "it shall be appropriate to a test conducted according to the confirmation test method for OOO (name of the ingredient)." However, if there is a clear reason

for not being able to set up a confirmation test, this may be omitted.

3. Physicochemical properties

Regarding the items for the physicochemical property of drug substances, items that are directly related with the quality control, safety, and efficacy of finished products shall be established (e.g., pH, specific gravity, etc. of liquid products, etc.) and their values shall be listed.

4. Purity test

Limits for the active ingredient or the unit dosage form of a finished product shall be established and stated in percentage (%), mass, etc. by considering the data to be submitted pursuant to Articles 31 and 32 and the following subparagraphs (a) and (b) and shall each be categorized into individual flexible materials of which the structure is established, other flexible materials, and the entire flexible materials.

(a) Among finished products, necessary items such as the flexible material, reagent, catalyst, heavy metal, mineral salt, solvent, etc. that have a possibility of getting mixed shall be established.

(b) Limits shall be established when a change is expected during the process of formulating products or during the storage.

5. Loss on drying or moisture

Values shall be stated in percentage (%), etc. of the mass of the finished product.

6. Formulation test

Formulation test items that are necessary for defining characteristics or functions of products shall be established.

7. Other tests

Other tests shall be described according to the other tests item pursuant to Article 29 (3) 13.

8. Content test

Amount or potency indicated of all active ingredients shall be written in percentage (%). In addition to the name of main ingredients, molecular formula and molecular weight shall be written in the parentheses. (E.g., When testing is carried out according to the following test method, at least 90.0% of the amount indicated for OOO (molecular formula: molecular weight) shall be contained.)

(a) For toothpastes, the content criteria for active ingredients including abrasives and anti-plaques shall be established.

(b) For insecticides, the content criteria for active ingredients including boosters shall be established..

(c) For hair coloring products, hair-dying test may be conducted instead of the content test.

9. The criteria for preservatives shall be established only for the products for internal use falling under subparagraph 2 (h) of the Designation of the Scope of Quasi-Drugs (MFDS Notice), and they shall be indicated in percentage (%) of the preservatives that have been used. In addition to the names of preservatives, molecular formula and molecular weight shall be indicated in the parentheses. (E.g., When testing is carried out according to the following test method, OOO (molecular formula: molecular weight) shall be identified and shall be 80.0% - 120.0% of the amount indicated.)

10. Hair-dying test

This item shall be established only for hair dye products, and it shall state that “it shall be appropriate to a test conducted according to the following test method.”

11. Adhesive strength test for band-aids

In the adhesive strength test for band-aids, it shall be stated that "when testing is carried out according to the following test method, it shall be at least OOO (g or N, etc.)/OOO mm."

12. Elasticity test for band-aids

In the elasticity test for band-aids, it shall be stated that "when testing is carried out according to the following test method, it shall be at least OOO (kg or N, etc.)/OOO mm."

13. Shape test for band-aids

In the shape test for band-aids, it shall be stated that "when testing is carried out according to the following test method, the length shall be at least 98.0% of the indicated length, and the width shall be at least 94.0% of the indicated width."

14. Dust collection efficiency test

Dust collection efficiency test shall be established only for sanitary masks, and it shall be stated that "when testing is carried out according to the following test method, each individual measurement value shall be no less than OOO%."

(4) Test methods shall be described in the following order:

1. Appearance

Test methods that utilize senses shall be mentioned. (e.g.: visually observe)

2. Identification test

In general, identification tests shall be written for all active ingredients, mostly focusing on chemical tests, following the preparation guidelines for drug substances. But such testing method can separate and identify each active ingredient.

3. Physicochemical properties

(a) If general test methods in the Korean Pharmacopoeia and compendia are used, the Korean Pharmacopoeia and the names of the compendia and test method shall be mentioned altogether. If details are supposed to be stated in each Article, or there are two or test methods or devices, the name of the test method or the device shall be stated. If a prior operation is necessary, it shall be stated.

(b) For test methods not listed in the Korean Pharmacopoeia or compendia, test methods shall be described in detail.

4. Purity test

(a) If it is necessary to quantify the material, test method considering the precision, accuracy, specificity, limit of quantification, linearity, and range shall be stated, and if quantification is not necessary, test method considering specificity and limit of detection shall be stated.

(b) If a reference standard of flexible material is not used and a test is conducted using liquid chromatography or gas chromatography, a method that can identify the measurement range for areas, limit of quantification, and flexible materials shall be stated (e.g., relative peak holding time).

5. Loss on drying or moisture

Test method in the Korean Pharmacopoeia shall be followed, and the details shall be stated.

6. Formulation test

(a) For test methods specified in the Korean Pharmacopoeia and compendia, the Korean Pharmacopoeia, name of the compendium, and the test method shall be stated. If necessary, the details shall be stated.

(b) For test methods not listed in the Korean Pharmacopoeia or compendia, details shall be stated.

7. Other tests

Other tests shall be described according to the other tests pursuant to Article 29 (3) 13.

8. Content test

(a) Test method that considers precision, accuracy, specificity, linearity, and range shall be prepared and stated.

(b) If there are two or more active ingredients, test method for each ingredient shall be stated; however, if the tests can be carried out simultaneously, they may be stated together.

9. Preservative

The General Test Methods Not Listed in the Korean Pharmacopoeia shall be followed; however, for preservatives not included in this Notice or if the supporting data shall be submitted regarding the test method, test method shall be written separately.

10. Hair-dying test

Following details shall be stated:

Deposit a white cloth or wool in a hair dye solution that has been mixed in a ratio stated in the Usage Directions and Dose. After leaving it unattended for 20 - 30 min at 25℃, wash with water and let it dry; however, if the processing temperature and time are different from the conditions above, dosage and administration shall be followed.

11. Adhesive strength test for band-aids

Following details shall be stated:

Testing shall be conducted according to the adhesive strength test for band-aids in the Korean Pharmacopoeia; however, for disposable band-aids, test shall be conducted according to the adhesive strength test for band-aids (disposable) in the Standards and Test Methods for Quasi-Drugs.

12. Elasticity test for band-aids

Following details shall be stated:

Testing shall be conducted according to the elasticity test for band-aids in the Korean Pharmacopoeia; however, for disposable band-aids, test shall be conducted according to the elasticity test for band-aids (disposable) in the Standards and Test Methods for Quasi-Drugs.

13. Shape test for band-aids

Following details shall be stated:

Testing shall be conducted according to the shape test for band-aids in the Korean Pharmacopoeia; however, for disposable band-aids, gauze shall be tested according to the gauze category in the Pharmacopoeia.

14. Dust collection efficiency test

Following details shall be stated:

(a) Test shall be carried out using a sodium chloride (NaCl) aerosol according to the following test method:

With six specimens, three shall be as they are submitted, and the other three shall be left unattended at temperature 38±2.5℃ and humidity 85±5% RH for 24±1 hours before being used as test specimens. After making a sodium chloride solution, sodium chloride aerosol shall be created using an automatic filter testing device. Facial area shall be placed in the automatic filter testing device, and the sodium chloride aerosol shall be sprayed through the facial area at a flow of 95L per minute. Concentration shall be measured before and after the

aerosol is sprayed on the facial area, and other details of the test method shall be written in detail.

(b) Test shall be carried out using a paraffin oil mist according to the following test method.

With six specimens, three shall be as they are submitted, and the other three shall be left unattended at temperature 38±2.5℃ and humidity 85±5% RH for 24±1 hours before being used as test specimens. Paraffin oil mist shall be created using an automatic filter testing device. Facial area shall be placed in the automatic filter testing device, and the paraffin oil mist shall be sprayed through the facial area at a flow of 95L per minute. Concentration shall be measured before and after the mist is sprayed on the facial area, and other details of the test method shall be prepared and written in detail.

15. Facial inhalation resistance test for sanitary masks

Following details shall be stated:

Test shall be carried out after placing the standard head model on the facial area. With six sanitary masks, three shall be as they are submitted, and the other three shall be left unattended at temperature 38±2.5℃ and humidity 85±5% RH for 24±1 hours before being used as test specimens. Water column shall be measured (mmH_2O) as air is sprayed through the facial area at a continuous flow of 30L per minute, and other details of the test method shall be written in detail.

(5) Reference standard, reagent, and test solution

Relevant items shall be described pursuant to the reference standard, reagent, and test solution sections in Article 29 (3) 15.

Article 31 (Types and Scope of Submission of Data for Evaluation of Standards and Test Methods)

(1) The types of data to be submitted for the evaluation of standards and test methods shall be as follows, and the scope of submission of data for the evaluation of standards and test methods based on the characteristics of each quasi-drug shall be as shown in Appendix 7:

1. Origin or discovery and history of development
2. Structural determination, physicochemical characteristics, and biological characteristics (product quality data)

(a) Raw materials

1) Structural determination
2) Physicochemical characteristics and biological characteristics
3) Manufacturing methods
4) Standards and test methods
5) Supporting data for standards and test methods
6) Test results
7) Reference standards, reagents, and test solutions
8) Containers and packaging

(b) Finished product

1) Drug substances and their quantities
2) Manufacturing methods
3) Standards and test methods
4) Supporting data for standards and test methods

5) Data about test reports

6) Data about reference standard, reagent, and test solution

7) Data about containers and packaging

3. Overseas usage status data

4. Comparative review with similar domestic products and characteristics of a pertinent quasi-drug, etc.

(2) For raw materials that have been manufactured through an extraction and for finished products, reasons for selecting a solvent, etc., data about the basis for selecting drug substances and the amount, etc. shall be submitted as data about manufacturing methods. And the flow of all manufacturing processes and the usage amount, yield, etc. of drug substances shall be stated in detail.

(3) Notwithstanding paragraph (1), if data have been submitted for the safety and efficacy evaluation or if the data have been submitted simultaneously, such fact shall be stated in the submitted data, and data shall not be submitted.

Article 32 (Requirements of Data for Evaluation of Standards and Test methods)

(1) Requirements of data for evaluation of standards and test methods for quasi-drugs shall be as follows:

1. Origin or discovery and the development

Data that are clearly written according to the five Ws and one H (5W1H) principle for aiding in making a judgment about the pertinent quasi-drugs (e.g.: who, when where, what with regards to the extraction, separation or synthesis; what was the origin of discovery; when and where did the primary testing, clinical trials, etc. begin, etc.)

2. Data about structural determination, physicochemical, and biological characteristics (product quality data)

(a) General information

1)Data about structural determination and physicochemical characteristics in which the origin, intrinsic characteristics, composition, manufacturing method, content standards of active ingredients, purity test (content standards, etc. for heavy metals such as arsenic, etc.), etc. of the final raw material specifications – a matter that is related to the review of safety, efficacy, and standards and test methods, which aid in making a judgment about the basic requirements as quasi-drugs – are stated; data about biological characteristics in which biological vitality, content, purity, etc. are stated; and data about standards and test methods that can verify the quality level, specifications, etc. of the items subject to review.

2) Basis for establishing standards shall include specific data about actual measurements, actual measurement statistics, safety test result, and considerations, etc. concerning the safety and efficacy.

3) Actual measurements shall submit data for no less than three times per lot for specimens which represent at least three lots and which reflect the actual manufacturing process. Test results to be expressed in values shall be submitted with specific values, and statistical methods and actual measurement statistics used for collection of specimen and processing of actual measurements shall be submitted.

(b) Raw material data

1) Structural determination data

a) Data that verify the chemical structure of main ingredients

(1) Dataabout raw materials, solvent, purification method, etc. that are related to the establishment of items for the synthesis path diagram with synthesis method and the purity test

(2) Data related to and the consideration of the characteristics of chemical structures such as the analysis of

element, ultraviolet-visible absorption spectrum, infrared spectrum, nuclear magnetic resonance spectrum, mass spectrum, etc.

(3) Chemical data about structural determination (derivatization, etc.) and its consideration

(4) In case of optical isomers, etc., data about their three-dimensional structure

b) Drug substances of which the composition of main ingredients are not clear, such as polymers, etc., shall preferably submit data about physicochemical characteristics and data that can verify that quasi-drugs with a homogeneous composition or potency are produced through a manufacturing process.

2) Data about physical and chemical characteristics: physicochemical characteristics of main ingredients shall submit data that can become a basis for establishing test items of standards and test methods and shall include data about actual measurements.

a) Appearance: data for color, shape, taste, etc.

b) Solubility: solubility data that are determined based on the concentration of a saturated solution

c) Hygroscopic property

d) pH of the solution

e) Melting point (including the decomposition status) and thermal analysis value

f) Dissociation constant

g) Partition coefficient and distribution ratio: octanol-water, etc. partition coefficient, partition coefficient shall be data that contain the influence of pH.

h) Polymorphism: as data about the polymorphism status, mutual relationship between crystal forms, physical characteristics about each crystal forms, etc., data such as the infrared spectrometer measurements, thermal analysis, particle x-ray diffraction, etc.

i) Angle of rotation: status or rotary polarization, if the rotary polarization is verified, data about the influence of the measurement solvent

j) Isomer (Optical isomer, etc.): if the raw material is a mixture of isomer such as the optical isomer, etc., data about the separation and analytical method of isomers and the isomer ratio.

k) Others: if there are other results from a review of material property, etc., relevant data

3) Data about manufacturing methods

It shall comply with the requirements of manufacturing methods of raw materials pursuant to Article 11.

4) Data in which standards and test methods are stated

5) Evidentiary data about standards and test methods

a) As an evidentiary data for establishing specifications, for each test item, data about the test method, reasons for selecting the test method, reasons for establishing test conditions, validation of test methods, actual measurements, evidence of establishing standard values, calculations, examples, etc. shall be included.

b) Purity test data

(1) General information

a. Measurement statistics

Limits that have been established shall provide reasonable basis by considering the actual measurement statistics, results of severe tests and long-term storage test among the safety test, and the safety.

b. For all lots used in the safety test and clinical trials and the lots that reflect the actual production process,

amount of flexible materials including the materials of unknown chemical structures and the analytical method shall be stated and submitted.

c. Limit test among test methods shall submit a verification data about the specificity (including the abundance and recovery rate near the limit values) and the limit of detection. Quantitative test method shall submit data about the specificity for which the amount can be measured accurately. In comparison, test methods that measure flexible materials shall submit data that compare sensitivities of materials used as a reference standard and sensitivities of flexible materials.

(2) In the following cases, data about flexible materials shall be submitted:

a. If in raw materials whose daily maximum administered dose is no greater than 2 g according to the calculation carried out with usage directions and dose of a preparation containing pertinent raw materials, flexible materials are contained in excess of 0.05%.

b. If in raw materials whose daily maximum administered dose is no greater than 2 g according to the calculation carried out with usage directions and dose of a preparation containing pertinent raw materials, flexible materials are contained in excess of 0.03%.

(3) In the following cases, data about the chemical structure of flexible materials shall be submitted:

a. If in raw materials whose daily maximum administered dose is no greater than 2 g according to the calculation carried out with usage directions and dose of a preparation containing pertinent raw materials, flexible materials are contained in excess of 0.10% or a total daily consumption 1.0 mg, whichever is smaller.

b. If in raw materials whose daily maximum administered dose is no greater than 2 g according to the calculation carried out with usage directions and dose of a preparation containing pertinent raw materials, impurities are contained in excess of 0.05%.

(4) In the following cases, as data that verify the safety, repeated dose toxicity test data (Category 1, 14-90 days), genotoxicity study data (reverse mutation test, in vitro chromosome abnormality test), and other necessary toxicity test data in compliance with Article 23 (1) 4 shall be submitted:

a. If in drug substances whose daily maximum administered dose is no greater than 2 g according to the calculation carried out with usage directions and dose of a preparation containing pertinent drug substances, flexible materials are contained in excess of 0.15% or a total daily consumption 1.0 mg, whichever is smaller.

b. If in drug substances whose daily maximum administered dose is no greater than 2 g according to the calculation carried out with usage directions and dose of a preparation containing pertinent drug substances, flexible materials are contained in excess of 0.05%.

c) Loss on drying, loss on ignition, moisture, and ignition residue: when defining the loss on drying, quasi-drugs shall not be decomposed under a drying condition. Even if the tests are not established because the amount is very small amount, etc., it shall be preferred that actual measurements data be submitted.

d) Content test: Data shall be submitted regarding precision, accuracy, linearity, and scope, etc. according to a method that is publicly approved and included in the Guidelines for Validation of Analytical Methods of Drugs, etc. in the Korean Pharmacopoeia or in the official compendium, etc. And an evidentiary data about the validity of test methods shall be submitted; however, when it is not possible to establish a quantification method,

specific reasons and an evidentiary data which shows that it will not affect securing the quality of product shall be submitted.

e) Items that have not been established in the standards and test methods but need a review shall submit the result.

6) Data about test reports

Test report in which test data, test results, etc. are stated shall be submitted.

7) Data about reference standard, reagent, and test solution

a) Reference standard outside the Pharmacopoeia and the official compendium shall submit the pertinent reference standard and data concerning the establishment of specifications, etc. Reagents and test solutions outside the Pharmacopoeia and the official compendium shall submit data concerning their preparation method.

b) Reference standard shall submit data concerning the purification method as necessary (including a manufacturing method when it is not a drug substance and difficult to purchase the material).

(c) Finished product data

1) Drug substances and the amount

Valid purpose of mixing, usage, etc. shall be submitted with regards to the main ingredient and excipients. And the evidentiary data regarding the specification of excipients shall be submitted.

2) Data about manufacturing methods

Data about manufacturing methods shall comply with the requirements of manufacturing methods for quasi-drugs in Article 11.

3) Data in which standards and test methods are stated

4) Evidentiary data about standards and test methods

a) Standards and test methods

As data that are intended to show the grounds for establishing the standards and test methods, for each test item, data about the test method, reasons for selecting the test method, reasons for establishing test conditions, validation of test methods, actual measurements, basis for establishing the standard values, calculations, examples, etc. shall be included.

b) Purity test data

General information shall comply with the purity test data of drug substances.

c) In general, solid products that are administered orally shall establish standards and test methods for dissolution tests according to the methods that are publicly approved and included in the Guidelines for Establishment of Dissolution Specifications of Oral Drugs in the Korean Pharmacopoeia or in the official compendium, etc. and the dissolution condition over time and the evidentiary data shall be submitted. If a disintegration test is established in lieu of a dissolution test, valid reasons shall be submitted.

d) If a sterility test is established, performance test data of a culture medium and bacterial growth inhibition test data defined in the Pharmacopoeia shall be submitted.

e) Content test shall comply with the content test in subparagraph 2 (b) 5) d).

f) Liquid electric mosquito repellent incense shall submit data about fumigation conditions during the usage time prescribed in the usage directions and dose.

g) Items that have not been established in the standards and test methods but need a review shall submit the

result.

5) Data about test reports

Test report in which test data, test result, etc. are stated shall be submitted.

6) Data about reference standard, reagent, and test solution

a) Reference standard outside the Pharmacopoeia and the official compendium shall submit the pertinent reference standard and data concerning the establishment of specifications, etc. Reagents and test solutions outside the Pharmacopoeia and the official compendium shall submit data concerning their preparation method.

b) Reference standard shall submit data about purification methods as necessary (including a manufacturing method when it is difficult to make a purchase with materials other than the pertinent drug substances).

7) Data about containers and packaging

Selection of materials, protection from humidity and light, compatibility between the constituents of a direct container and the quasi-drugs (including container adhesion, glass), and the safety and performance of constituent materials of a direct container shall be stated.

3. Overseas usage status data

As data concerning the usage status in each country for aiding in making a judgment about the utility of a pertinent quasi-drug, data that can verify the date of approval of release, drug substances and the amount (including an evidentiary data for specifications in case of the enclosed specifications), efficacy and effect, usage directions and dose, precautions for use, storage method and period of use (valid period), etc.; data from investigation of usage status and list in drug formulary in each country; and data which include the latest information on the measures taken by each country in relation to the safety and efficacy.

4. Comparative review with similar domestic products and characteristics of a pertinent quasi-drug

Data including a comparative table to compare with existing quasi-drugs (including imported quasi-drugs) of a similar efficacy regarding drug substances and their amount, efficacy and effect, usage directions and dose, precautions for use, etc. And data that compare and review characteristics, defect, etc. in the pharmaceutical efficacy, side effects, safety, etc. shall be submitted; however, for herbal substances and herb medications, list of herb drugs codex shall be submitted.

(2) Notwithstanding paragraph (1), insecticides shall submit a preliminary test data and purity test data that have been prepared according to the standards and test methods for main ingredients, and liquid electric mosquito repellent incense shall submit data about fumigation conditions during the usage time prescribed in the usage directions and dose.

Chapter 5 Permission and Evaluation of Infectious Disease-Preventive Disinfectants, Insecticides, etc.

Article 33 (Scope of Application)

This Chapter shall apply to products that fall under subparagraph 7 of Article 2 of the Pharmaceutical Affairs Act.

Article 34 (Processing, etc. of Permission)

(1) The provisions of Articles 3 through 6 shall apply mutatis mutandis to the processing of permission of products, processing of revisions, preparation of applications, subjects of permissions, etc. for infectious disease-preventive disinfectants and insecticides, etc. In such cases, "Article 7 through Article 18" in Article 4 (1) shall be considered as "Article 36 through Article 42."

(2) If the Director of the Centers for Disease Control and Prevention requests revision to matters permitted for the pertinent product based on the result of implementing an efficacy test such as resistance monitoring, etc. to prevent infectious diseases, the Minister of MFDS may order permission of revisions to efficacy and effect, usage directions and dose, precautions for use, etc. pursuant to the provisions of Article 76 of the Pharmaceutical Affairs Act.

Article 35 (Restriction, etc. on Permission, etc.)

(1) If it is deemed that there is likely to be a risk on human and environment based on the request by relevant authorities such as the Minister of the Ministry of Environment, etc., the Minister of MFDS may take necessary measures such as a restriction, etc. on permission.

(2) With regards to the products that are subject to the safety and efficacy evaluation, the Minister of MFDS shall impose a restriction on permission for pertinent products if they correspond to the following:

1. If the test report of a single dose administration test for infectious disease-preventive disinfectants and insecticides is classified to Level I (Deadly Toxic) or Level II (Highly Toxic) according to the following table; however, if it is determined that safety would be secured for users as a result of an evaluation that took into consideration the standard use concentration or usage of the product, form of the preparations, method of use, etc., permission may be granted.

Type	Median Lethal Dose (LD_{50}, mg/kg Body Weight)			
	Oral		Transdermal	
	Solid	Liquid	Solid	Liquid
Level Ⅰ (Deadly toxic)	< 5	< 20	< 10	< 40
Level Ⅱ (Highly Toxic)	5 – 50	20 – 200	10 - 100	40 - 400
Level Ⅲ (Toxic)	50 – 500	200 - 2,000	100 - 1,000	400 - 4,000
Level Ⅳ (Slightly Toxic)	≥ 500	≥ 2,000	≥ 1,000	≥ 4,000

2. If the primary skin irritation index of the infectious disease-preventive disinfectants and insecticides is at least 5.1; however, if it is determined that safety would be secured for users as a result of an evaluation that took into consideration the standard use concentration or usage of the product, form of the preparations, method of use, etc., permission may be granted.

3. If the acute ocular irritation index of the infectious disease-preventive disinfectants and insecticides is at least 60; however, if it is determined that safety would be secured for users as a result of an evaluation that took into consideration the standard use concentration or usage of the product, form of the preparations, method of use, etc., permission may be granted.
4. If the result of the fish toxicity test is 1/2 $LC_{50} \leq$ PEC; however, if $LC_{50} \leq$ PEC < 1/2 LC_{50}, limited use may be permitted. (PEC, Predicted Environmental Concentration: estimated concentration in the environment)

Article 36 (Product Name, etc.)

(1) The provisions of Articles 7 through 11 shall apply mutatis mutandis to the guidelines for writing sections such as the product name, classification number, drug substance and its amount, appearance, and the method of manufacturing; however, in general, amounts of all excipients shall be indicated; however, excipients added in very small amounts, such as the coloring agent, fragrance ingredients, pH adjuster, viscosity modifier and solvent, may state "optimum dose."

(2) Effect enhancer shall be added based on the safety and efficacy data, and the organic solvent which is used during the manufacturing process shall not be acknowledged for a direct insecticidal, sterilization, and disinfection effect and shall be safe in terms of its usage.

Article 37 (Efficacy and Effect)

Efficacy and effect that have no basis shall not be admitted, and they shall be described in accordance with the following:

1. Actions (extirpation, repellent, disinfection, etc.) on subjects to which the pertinent product shows its effect (flies, mosquitoes, cockroaches, ants, and their larva or imago, etc.) shall be stated.
2. Expressions that are interpreted with vague and indefinite meanings and terms that are exaggerated, excessive, etc. and that may cause misunderstanding for people shall not be used.
3. Efficacy and effect of products that fall under the Scope of Submission of Data 3) in Attachment 8 of Article 46 (1) shall comply with the matters that are already permitted.

Article 38 (Usage Directions and Dose)

Usage directions and dose shall be indicated as follows:

1. The phrase "Do not use directly to human body." shall be written first before any other phrase.
2. If it is possible to categorize the dilution method, application ratio, spraying method, etc., they shall be categorized and stated clearly.

Example)

(a) Application ratio

Targeted harmful insect	Dilution Method	Application ratio (weight(g) or volume(mL)/area(m^2))
Mosquito	150x dilution (Add 1 L of the	g/OO m^2

	product to 149 L of water, and mix well.)	

(b) Spraying method

(c) Location and Method of Use

Article 39 (Precautions for Use)

Precautions for use shall state all of the most recent matters related to safety and efficacy (including the matters concerning excipients) that are necessary for safe and reasonable use of infectious disease-preventive disinfectants and insecticides, and they shall be written according to the following order and guidelines. In such cases, items to be stated may be adjusted depending on the characteristics of each preparation.

1. Chemical substances listed in Appendix 1 of Article 3 of the Designation of Toxic Materials and Materials under Observation (National Institute of Environmental Research Notice) shall state matters to be indicated for toxic materials.

Case of Application)

1. Precautions for toxic materials contained in this quasi-drug are as follows:

(a) Glutaraldehyde

1) Harmful risks

a) Harmful if swallowed

b) Irritating to eyes and skin

c) May cause hypersensitivity if in contact with skin

d) Very toxic to aquatic organisms

2) Precautions for use

a) Avoid contact with skin and eyes.

b) In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

c) Avoid discharging to the environment.

3) Hazard symbols

2. Emergency measures

First aid treatment in case of contacting the drug through skin, eyes, inhalation, etc. shall be stated.

E.g.) (1) In case of contact with skin: Take of all contaminated clothes and shoes. Immediately wash with soap and

water the skin that came into contact. If hives, rash, etc. occurs, seek medical advice.

3. General precautions

(a) When spraying the product, everyone except the person who conducts spraying shall evacuate the area. In particular, children, seniors, patients, etc. can be critically affected.

(b) When using the product, food or drink may not be consumed, and smoking is prohibited.

(c)Wear suitable protective clothing (working clothes of which the top and bottom are connected), gloves, eye/face protection, etc. In such cases, protective clothing shall be regularly washed separately from ordinary laundry.

(d) After carrying out the task, skin that has been exposed must be washed, and if possible, taking a bath is preferred.

(e) Take precautions so that the drug would not come in contact with skin, eyes, etc.

(f) Take precautions so that smokes from spray are not inhaled.

(g) Before using, take measures necessary such as putting a cover, etc. over to prevent the drug from coming in contact with the tableware, food, etc.

(h) Place a lid over the water tank before or during the use to keep the chemical solution from entering.

4. Product may not be used in a situation where it may come in contact with the following animals or plants (state all relevant items):

(a) Animals

(b) Fish

(c) Avian (birds)

(d) Agricultural products

(e) Other items

5. Storage and collection of containers, etc.

(a) It shall not be moved to and stored in other containers that can be misunderstood as food, etc. It shall be stored in a safe place in its original container in conformity with the stated method of storage.

(b) Tightly close the container with a lid and keep out of the reach of children.

(c) Used containers shall be preferably collected by the supplier. Cautions shall be also taken when reusing or discarding the container through a proper method, because the chemical may come in contact.

Article 40 (Packaging Unit)

Matters concerning the container and unit of packaging shall be written according to the following:

1. Packaging containers shall have descriptions so that materials and the level of confidentiality can be known.
2. Weight or dosage unit of a pertinent product shall be indicated properly for its purpose.

Article 41 (Storage Method and Period of Use (Valid Period))

The provisions of Article 16 shall apply mutatis mutandis to the storage method and period of use (valid period).

Article 42 (Standards and Test Methods, etc.)

The provisions of Articles 17 and 18 shall apply mutatis mutandis to the method for writing items such as the

standards, test methods, manufacturer, etc.

Article 43 (Conditions, etc. of Permission)

(1) Notwithstanding the provisions of Article 34 (1), if an emergency such as the outbreak of unexpected infectious disease occurs, but supplying infectious disease-preventive disinfectants and insecticides, etc. is difficult, the Minister of MFDS may grant permission without a separate safety and effective evaluation or a review of standards and test methods, if there is a request made by the Minister of Ministry of National Defense, Director of the Centers for Disease Control and Prevention, etc. for a stable implementation of national disease control. In such cases, following conditions of permission shall apply:

1. Safety and efficacy data and the standards and test methods pursuant to the provisions of Articles 44 through 47 shall be submitted within one year from the permission date.
2. Track record of producing, importing, and selling pertinent products and abnormal responses that are considered to have occurred as a result of using pertinent products shall be reported semi-annually by the 20th of the month following the end of each half-year.
3. Product packaging and container shall indicate that "This is a product for urgent disease control and has not gone through the evaluation of safety, efficacy, and standards and test methods by the Minister of MFDS."

(2) Provisions in Articles 36 through 42 may not apply to the products to be exported and the products that are intended to be supplied to or reserved for military or government, if there is a clear regulation such as the purchase notice or specification, etc.; however, if one intends to domestically sell the products that have been permitted as products for import, for military or for government, conditions for import, for military, or for government may be released for products that are not restricted by Article 11 of the Rules on the Safety of Drugs, etc. based on a reevaluation of safety, efficacy, and standards and test methods. In such cases, it shall comply with the provisions of Articles 36 through 42.

(3) If an application is submitted for permission for a product of manufacture (or import) based on a transfer pursuant to Article 8 of the Rules on the Safety of Drugs, etc., permission may be granted under the condition that all matters permitted to the transferor shall be succeeded.

Article 44 (Subjects of Safety and Efficacy evaluation and Preparation of Evaluation Data)

(1) Infectious disease-preventive disinfectants and insecticides that are subject to the safety and efficacy evaluation shall be the infectious disease-preventive disinfectants and insecticides for which permission or permission for revisions is required; however, changes in the product name, changes in the packaging unit, and transfer (including change of manufacturer due to transfer) shall be excluded.

(2) Data needed for the evaluation of safety and efficacy of infectious disease-preventive disinfectants and insecticides shall be prepared following Annex Form No.2, and the data defined by the provisions of Articles 44 through 47 shall be submitted.

(3) Submitted data shall comply with the requirements pursuant to Article 47, and for each item, list of data, index number and page for each data shall be indicated in the order shown in Article 45; however, if the required data are remitted or omitted according to the provisions of each Article, the reasons shall be stated in detail.

(4) In general, regarding data from overseas, a summary written in Korean (an excerpt of the main terms) and the

original document shall be submitted. And only when necessary, complete translation of the entire document (signed by a confirmer who has an expert knowledge in medicine and pharmacy) may be requested to be submitted.

Article 45 (Types of Data for Safety and Efficacy evaluation)

Data to be submitted for the safety and efficacy evaluation of infectious disease-preventive disinfectants and insecticides shall be as follows:

1. Origin or discovery and the development
2. Data about structural determination and physicochemical characteristics
   (a) Structural determination
   (b) Physicochemical characteristics, etc.
   (c) Data about standards and test methods
3. Safety data
   Long-term storage test data, or accelerated test data
4. Toxicity test data
   (a) Single dose toxicity test data
   1) In general, for single dose toxicity test data, test data shall be submitted for all exposed routes of administration (oral, transdermal, inhalation, etc.).
   2) If single dose oral and transdermal toxicity tests are not possible, and the major route of exposure is inhalation, only the single-dose inhalation toxicity test data shall be submitted.
   3) For products whose main ingredient's steam pressure is no greater than 10^{-3}mmHg (20℃) or for which there is no concern for exposure through a respiratory system, inhalation toxicity test data may be omitted.
   (b) Repeated dose toxicity test data
   1) In general, for repeated administration toxicity test data, test data shall be submitted for all exposed routes of administration (oral, transdermal, inhalation, etc.).
   2) If repeated oral and transdermal toxicity tests are not possible, and the major route of exposure is inhalation, only the repeated inhalation toxicity test data shall be submitted.
   3) For products whose main ingredient's steam pressure is no greater than 10^{-3}mmHg (20℃) or for which there is no concern for exposure through a respiratory system, inhalation toxicity test data may be omitted.
   (c) Reproductive and developmental toxicity test data
   (d) Genotoxicity study data
   (e) Carcinogenicity test data
   (f) Other toxicity test data (local toxicity, nervous toxicity, antigenicity)
   1) Local toxicity test data shall be submitted if infectious disease-preventive disinfectants and insecticides can easily come in contact, even if they are not directly applied to or do not directly apply to the skin or the mucous membrane.
   2) Nervous toxicity test data shall be submitted for infectious disease-preventive disinfectants and insecticides which inhibit or are likely to inhibit vitalization of acetylcholinesterase
   3) Antigenicity test data shall be submitted for insecticides that prevent infectious diseases to which the entire body is exposed, and skin sensitization test data shall be submitted when the skin is likely to be exposed.

(g) Environmental hazard test data

1) Ecology toxicity test data such as the fish toxicity test, etc.

2) Residue test data

If the residue is not likely to pose risk depending on the method of use, formulation (e.g., repellent, etc.) or the result of a toxicity test, these data shall be remitted.

3) Bioconcentration test data

This test shall be remitted when octanol-water partition coefficient is low (log Pow≤3).

5. Efficacy data

6. Absorption, distribution, metabolism, and excretion data

7. Overseas usage status data

8. Comparative review with similar domestic products and characteristics of a pertinent quasi-drug

Article 46 (Scope of Submission, etc. of Data for Safety and Efficacy evaluation)

(1) Scope of submission of data for the safety and efficacy evaluation of infectious disease-preventive disinfectants and insecticides shall be as shown in Appendix 8.

(2) For matters that are not defined by Appendix 8, II. Extirpator, Inhibitor, Repellent and Insect-Attracting Pesticides for Flies, Mosquitoes, etc. used for People and Animals' Health in Appendix 3. Types of Quasi-Drugs and Required Data shall apply.

Article 47 (Requirements of Data for Safety and Efficacy evaluation)

Requirements of data to be submitted for the safety and efficacy evaluation of infectious disease-preventive disinfectants and insecticides shall be as follows:

1. Origin or discovery and the development

Data that are clearly written according to the five Ws and one H (5W1H) principle aiding in making a judgment concerning the safety and efficacy of pertinent infectious disease-preventive disinfectants and insecticides (e.g.: who, when, where, what with regards to the extraction, separation or synthesis; what was the origin of discovery; when and where did the primary testing, etc. begin, etc.)

2. Data about structural determination and physicochemical characteristics

(a) Structural determination

Origin, intrinsic characteristics, composition, etc. of the final raw materials specifications that can aid in making a judgment concerning the basic requirements as infectious disease-preventive disinfectants and insecticides.

(b) Physicochemical characteristics, etc.

1) Manufacturing method of infectious disease-preventive disinfectants and insecticides

2) Physicochemical or biological characteristics such as the melting point, boiling point, steam pressure, solubility and octanol-water partition coefficient

3) As for octanol-water partition coefficient, actual measurement or data based on a calculation shall be submitted; however, this may be omitted for chemical substances with water solubility no less than 100mg/L and high polymers.

(c) Data about standards and test methods

Standards and test methods which are prepared pursuant to the regulations of Article 42, or notification of the result of evaluation of standards and test methods (including the test data prepared by the pertinent business)

3. Safety data

Data shall correspond to one of the following:

(a) General Information

1) As data that are in compliance with the Standards for Drug Stability Test (MFDS Notice) announced by the Minister of MFDS, primary test data of which the test is carried out domestically shall be attached.

2) Notwithstanding the provisions of 1), regarding data for which test is carried out abroad, it may be approved if it is considered, based on a review of details, that the safety can be secured.

(b) Test methods, etc.

1) Long-term storage data or accelerated test data which correspond to one of the following shall be submitted; however, when submitting the accelerated test data, measurement interval shall be no greater than one week:

a) If period of use (valid period) is one year, data that are tested for at least two weeks at 54±2℃

b) If period of use (valid period) is two years, data that are tested for at least four weeks at 54±2℃

c) If period of use (valid period) is three years, data that are tested for at least six weeks at 54±2℃

d) If it is not possible to carry out a test at a previously mentioned temperature due to the characteristics of a main ingredient, data that are tested at other temperatures and periods (data of which the test is carried out at 45±2℃for six weeks, at 40±2℃for eight weeks, at 35±2℃ for 12 weeks, at 30±2℃ for 18 weeks shall each be considered to have a period of use (valid period) of one year) shall be admitted.

4. Toxicity test data

(a) General information

Data shall correspond to one of the following:

1) Data of which the test is carried out according to the Good Laboratory Practices (GLP)

2) As toxicity test data that are submitted and evaluated at the time of applying for permission in the country where the pertinent quasi-drug is developed which, data are verified to be submitted to or approved by the government (permission or registration organization) of the country where development took place; or data that notarize this.

(b) Test Method, etc.

1) For Article 45 (4) (a) through (f), data of which the tests are conducted properly pursuant to the Standards for Drug Toxicity Test, Regulations on the Designation, etc. of Research Institutes for Chemical Hazard Test (National Institute of Environmental Research Notice), and Registration Standards of Agricultural Pesticides (Rural Development Administration Notice) and of which the test methods, etc. are considered to be valid scientifically and rationally.

2) For Article 45 (4) (g), data of which the tests are conducted properly in accordance with the methods for chemical hazard tests pursuant to the Regulations on the Designation, etc. of Research Institutes for Chemical Hazard Test(Ministry of Environment Notice), or data of which the test methods, etc. are considered to be valid scientifically and rationally.

5. Efficacy data

(a) General information

1) Data of which the test is conducted at a professional organization at home or abroad such as a university or a research institute and which are issued by the head of the organization and can be considered as valid based on the review of its content (in this case, summary of the test facilities in the research organization, composition of the human resource for research, research experiences of the testing personnel, etc. shall be described.).

2) As data that are submitted and evaluated at the time of applying for permission in the country where the pertinent quasi-drug is developed, data are verified to be submitted to or approved by the government (permission or registration organization) of the country where development took place; or data that notarize this.

3) Data published in an academic journal registered in the Science Citation Index.

(b) Test method

As data of which the efficacy test is conducted outside or in a laboratory regarding the species, etc. of harmful insects living the nation, summary of the test result shall be prepared according to the example of preparation in Annex Form No.3; however, for insecticides, test data (including sensitivity test data) of which the test is conducted domestically within five years from the date of application for permission shall be attached:

1) For infectious-disease preventive disinfectants and insecticides containing new materials, data shall come from tests that are conducted using each harmful insect under consideration.

2) For products of which the effective insecticidal ingredient shows the effect through transpiration, data that show the relationship between the time and the amount of transpiration shall be additionally submitted.

6. Absorption, distribution, metabolism, and excretion data

(a) General information is the same as the subparagraph 5 (a).

7. Overseas usage status data

8. Comparative review with similar domestic products and characteristics of a pertinent quasi-drug

Comparison with a similar domestic product shall be presented in a comparative table, and data about the packaging and labeling of a pertinent product shall be attached.

Article 48 (Remission of Data Required for Safety and Efficacy evaluation)

If one of the following is applicable, toxicity test data defined in Article 45, subparagraph 4 and data concerning the absorption, distribution, metabolism, and excretion defined in Article 45, subparagraph 6 shall be remitted; however, in the case of subparagraph 3, part of the data may be remitted:

1. If the product (product for which ingredient, content, and formulation are indicated) is acknowledged by the WHO Pesticide Evaluation Scheme (WHOPES); however, data which prove that each subparagraph of Article 35 (2) is not applicable shall be submitted.
2. If data that can objectively prove that the product is used by at least two countries in the OECD countries is attached (excluding the test data on the environmental hazard); however, data which prove that each subparagraph of Article 35 (2) is not applicable shall be submitted.
3. If data are submitted concerning the usage status through which the product can be officially approved as a product that would be considered, based on a comprehensive judgment made at a modern scientific level, as having an equivalent or higher qualification than the product that has already received permission.

Article 49 (Preparation, etc. of Request for Evaluation of Standards and Test Methods)

The provisions of Articles 26 through 32 shall apply mutatis mutandis to the preparation of a request for evaluation of standards and test methods for infectious disease-preventive disinfectants and insecticides, establishment of standards, scope of required data, etc.

Chapter 6 Supplementary Rules

Article 50 (Revision of Items of Permission and Notification)

(1) Notwithstanding the provisions of Articles 8 through 20 and 36 through 43, the Minister of MFDS may re-establish (unify and adjust) the categories for permission or notification by product through the Manufacturing Standards for Drugs, etc., evaluation of safety and efficacy, other evaluations of safety information, evaluation of standards and test methods, list and deletion of the Specification Standards of MFDS, etc.

(2) If the Minister of MFDS re-establishes (unified and adjusted) matters related to the permission for or notification of products in paragraph (1) pursuant to the proviso to Article 8 (1) of the Rules on the Safety of Drugs, etc. and orders changing categories for permission for or notification of the pertinent product by a certain deadline pursuant to Article 76 (1) of the Pharmaceutical Affairs Act, separate procedures for permission for or notification of changes shall be omitted, and it shall be considered as if the permission for or notification of changes has been processed by the Minister of MFDS and the Commissioner of the Regional Office of MFDS for each product. In such cases, the manufacturer or importer of the pertinent product shall write "[deadline for instructing changes] [categories permitted for changes] change (document number and date)" on the reverse side of the certificate of permission for product (or notification certificate) and attach the details of the changes.

Article 51 (Products Containing Problematic Ingredients for Safety and Efficacy)

Products that contain ingredients that are problematic for safety and efficacy pursuant to Article 11 (1) 8 of the Rules on the Safety of Drugs, etc. shall be as follows:

1. Products that contain ingredients that are problematic for safety and efficacy pursuant to Article 54 of the Regulations on the Permission, Notification, and Evaluation of Quasi-Drugs; however, external applications containing acetanilide, insecticides containing boric acid and its salt (but, in case of the boric acid, it may be mixed only for baths products), and hair dye products containing phenacetin shall be excluded;
2. Emulsion that contains chlorpyrifos;
3. Aerosol products that contain more than 0.25% allethrin;
4. Aerosol repellents that contain more than 0.5% permethrin.

Article 52 (Supplementation of Data)

(1) If one of the following reasons is applicable to the permission for or notification of product or the request for evaluations, the Minister of MFDS shall specify the necessary matters in detail and request supplementation from a person who submitted the data.

1. Type, scope or requirement, etc. of the data that have been attached to the application are not in compliance with the provisions of each Article;

2. During the review of a submitted data, it has been considered that additional data, etc. are particularly necessary for resolving a significant issue that may happen to the safety, efficacy and quality of a product.

(2) With regards to the period for supplementing data pursuant to paragraph (1), sufficient time shall be granted for the civil petitioner to prepare the supplementation data, considering the period for processing civil affairs. And the time at which submission is made by the civil petitioner shall be considered as the end point of the supplementation request period, and the review shall resume. If whole or part of the data that have been requested to be supplemented is not submitted within this period, supplementation may be requested again within 10 days as a supplementation request period. However, if the civil petitioner requests extension of period by specifying a necessary period for the reason that he/she is not able to prepare supplementation within the requested supplementation period, supplementation period shall be determined considering this request. In such cases, the number of requests that can be made by a civil petitioner regarding the extension of period shall be limited to two.

(3) If it is determined that one of the following is applicable during a review of, or based on the result of a review of, the application for permission for or notification on product or the request for evaluations, the Minister of MFDS may specify the reasons in detail and return the application to the person who submitted the data:

1. If the data are not submitted within a period during which supplementation has been requested to be submitted pursuant to paragraph (2);
2. If the safety and efficacy as a quasi-drug or its standards and test methods are not adequate due to the noncompliance with the evaluation standards pursuant to Articles 7, 9, 11, 12, 13, 16, 17, 22, 36, 37, 38, 41, 42, 44 and Chapter 4.

Article 53 (Processing of Reapplication Documents)

Regarding a product for which application for permission of the product (including permission for changes; the same shall apply in this Article.), notification of the product (including notification of changes; the same shall apply in this Article.), or a request for evaluation has been returned pursuant to Article 52 (3), reapplications that have been submitted for permission for or notification on the product or for a request for evaluation within a period that has not passed two years from the return date by supplementing the matters specified in each subparagraph of Article 52 (3) may be processed by reviewing only the supplemented data. However, if an additional review of data is necessary, such as the case of additionally discovering a matter that significantly affects the safety and efficacy of a relevant quasi-drug, etc., corresponding reviews shall be executed.

Article 54 (Consultation, etc.)

If it is deemed necessary for permission for or notification of quasi-drugs and the evaluation of safety, efficacy, and standards and test methods of quasi-drugs pursuant to this notice, the Minster of MFDS may listen to the opinion of the Director General of the National Institute of Food and Drug Safety Evaluation or consult the National Pharmacists Committee.

Article 55 (Provisions Applied Mutatis Mutandis)

For matters that are not defined by this Notice concerning the permission or notification of manufacture (import) for quasi-drugs, Regulations on the Permission, Notification, and Evaluation of Drugs; Standards for Drug Stability Test;

or Standards for Drug Toxicity Test shall apply.

Article 56 (Reexamination Deadline)

This Notice shall be examined for its appropriateness every three years as of January 1, 2014 (by December 31 every third year) pursuant to Article 8 of the Framework Act on Administrative Regulations and the Regulations on the Issuance and Management of Instructions, Established Rules, etc. (Presidential Instructions No. 248), and proper measures for improvement, etc. shall be taken.

Supplementary Provision <09/15/2010>

Article 1 (Enforcement Date)

This Notice shall be effective from the date of its announcement.

Article 2 (Revocation of Other Decrees)

Regulations on the Permission for (or Notification of)Disinfectants, Insecticides, etc. for Prevention of Infectious Diseases announced by the Minister of MFDS along with the enforcement of this Notice shall be abolished.

Article 3 (Interim Measures)

(1) Applications that have been submitted already to the Minister of MFDS or the Commissioner of Regional Office of MFDS at the time of this Notice for the permission for (or notification of) quasi-drugs, evaluation of safety and efficacy, and evaluation of standards and test methods shall comply with previous regulations. The same applies to the application for registering changes.

(2) Quasi-drugs that have received the evaluation of safety and efficacy or evaluation of standards and test methods pursuant to the previous Regulations on the Permission, Notification, and Evaluation of Drugs, etc. or the Regulations on the Permission for (or Notification of) Disinfectants, Insecticides, etc. for Prevention of Infectious Diseases shall be considered as having received evaluations pursuant to this Notice.

Article 4 (Amendment of Other Notices)

Part of the Regulations on the Permission, Notification, and Evaluation of Quasi-Drugs, etc. that is announced by the Minister of the Food and Drug Administration along with the enforcement of this Notice shall be amended as follows:

The title “Regulations on the Permission, Notification, and Evaluation of Drugs, etc.” shall be revised as “Regulations on the Permission, Notification, and Evaluation of Drugs.” In Article 1, “permission for, or notification on drugs and quasi-drugs by a manufacturer or an importer of quasi-drugs, and safety and efficacy of drugs and quasi-drugs” shall be revised as “permission for, or notification on drug imports, and safety and efficacy of drugs.” In Articles 5 (1), 6 (1), 7, 10 (8), 14 (2), 21 (2), 25 (2), 31 (1), 57 (1), and 60, “drugs, etc.” shall be revised as “drugs,” and in Article 60, “Standards for Biological Equivalence Test, and the Regulations on the Permission for (or Notification of) Disinfectants, Insecticides, etc. for Prevention of Infectious Diseases” shall be revised as “Standards for Biological Equivalence Test.” In Chapter 3 (Articles 41 through 51), Appendices 16 and 17 shall each be deleted, and in Appendix 18, subparagraphs 1, 30, 145 shall be revised as follows. In the title of Annex

Form 1, “Article 26 and Article 44” shall be revised as “Article 26,” and quasi-drugs section I and sections III through VI shall each be deleted.

1. Products that contain acetanilide

30. Products that contain boric acid and its salt (excluding ophthalmic products and epidermal formulations with a mixing limit no greater than 1.8%)

145. Products that contain phenacetin

Article 5 (Relationship with Other Notices)

When the previous Regulations on the Permission, Notification, and Evaluation of Quasi-Drugs, etc.; the Regulations on the Permission for (or Notification of) Disinfectants, Insecticides, etc. for Prevention of Infectious Diseases; or their provisions are quoted in other regulations at the time of this Notice, corresponding regulations in this Notice, if there are corresponding regulations in this Notice, shall be considered as having been quoted in lieu of the previous regulations.

Supplementary Provision <02/01/2011>

Article 1 (Enforcement Date)

This Notice shall be effective from the date of its announcement.

Article 2 (Interim Measures Concerning the Application for Permission, etc.)

Applications for permission for (or notification of) of quasi-drugs that have been registered already according to the previous regulations at the time of the enforcement of this Notice shall comply with previous regulations.

Supplementary Provision <No.2012-129, 12/27/2012> (Korean Pharmacopoeia)

Article 1 (Enforcement Date)

(1) This Notice shall be effective one month after the date of its announcement.

(2) Omitted.

Article 2 through Article 3

Omitted.

Article 4 (Amendment of Other Notices)

(1) - (3) Omitted.

(4) In the Regulations on the Permission, Notification, and Evaluation of Quasi-Drugs (MFDS Notice No.2011-5), “Kor. Pharmacopoeia” shall be revised as “Korean Pharmacopoeia.”

(5) - (12) Omitted

Article 5 (Relationship with Other Regulations)

Omitted.

Supplementary Provision <No.2013-2, 1/16/2013>

(Regulations on the Safety Standards, etc. of Cosmetics)

Article 1 (Enforcement Date)

This Notice shall be effective one month after the date of its announcement.

Article 2 through Article 4

Omitted.

Article 5 (Amendment of Other Decrees)

(1) Omitted.

(2) Regulations on the Permission, Notification, and Evaluation of Quasi-Drugs (MFDS Notice No.2011-5, 2/1/2011) shall be amended as follows:

In Article 9 (3) 2 (i), "standards for raw materials of cosmetics specified by Appendix 1 in the Regulations on the Designation of Raw Materials for Cosmetics" shall be revised as "Part 4 Additives in each Article of quasi-drugs in the Standards and Test Methods for Quasi-Drugs (Ministry of Food and Drug and Safety Notice)."

(3) - (4) Omitted.

Supplementary Provision <No.2013-9, 3/8/2013>

Article 1 (Enforcement Date)

This Notice shall be effective from the date of its announcement; however, amended regulations in Appendix 1 (applicable only to the part concerning wet tissue for oral hygiene) shall be effective one month after the date of its announcement.

Article 2 (Application)

This Notice shall be applicable beginning with the first application for permission for or notification of quasi-drugs that is submitted to the Minister of MFDS or the Commissioner of Regional Office of MFDS after the enforcement of this Notice.

Article 3 (Interim Measures)

(1) Items that are permitted and notified as quasi-drugs according to the previous laws and regulations at the time of the enforcement of this Notice shall be considered as permitted or notified pursuant to this Notice.

(2) Applications that have been submitted already to the Minister of MFDS and the Commissioner of Regional Office of MFDS for permission for or notification of products as quasi-drugs (including application for changes) at the time of this Notice shall comply with the previous regulations.

Supplementary Provision <No.2013-33, 4/5/2013>

Article 1 (Enforcement Date)

This Notice shall be effective from the date of its announcement.

Supplementary Provision <No.2014-76, 2/12/2014>

This Notice shall be effective from the date of its announcement.

Supplementary Provision <No.2014-153, 9/4/2014>

Article 1 (Enforcement Date)

This Notice shall be effective from the date of its announcement.

Article 2 (Interim Measures about Masks)

Products that are permitted as yellow dust preventive masks or disease prevention masks according to the previous regulations at the time of the enforcement of this Notice shall be considered as public health masks that are permitted pursuant to the regulations of this Notice.

Supplementary Provision <No.2014-169, 10/15/2014>

This Notice shall be effective from the date of its announcement.

Supplementary Provision <No.2014-177, 10/29/2014>

This Notice shall be effective from the date of its announcement.

Supplementary Provision <No.2015-69, 9/25/2015>

Article 1 (Enforcement Date)

This Notice shall be effective from the date of its announcement.

Article 2 (Interim Measures)

Previous manufacturer and importer of a product that falls under the V-2 in Appendix 3 of Article 24 (1) shall report the quasi-drugs manufacture business pursuant to the Pharmaceutical Affairs Act and the Rules on the Safety of Drugs, etc. (Ordinance of the Prime Minister) before October 1, 2016 and receive permission for the pertinent product as a quasi-drug that can be manufactured or imported. In such cases, he/she may submit the report of a manufacturer and apply for permission for the product before October 1, 2016. If registration as a manufacturer and approval of permission for the product have been completed before October 1, 2016, October 1, 2016 shall be considered as the date of registration as a manufacturer and the date of permission for the product.

[Appendix 1]

Preservatives for Quasi-Drugs and the Range of Usage

(In Regards to Article 9, (5) 3)

Name of Ingredient	Solid and Liquid Preparation for Internal Use and Wet Tissue for Oral Hygiene		Preparations for External Use	Toothpastes	Note
	Permissible Range (%)	Daily Permissible Dose	Permissible Range (%)	Permissible Range (%)	
Benzoic acid Sodium benzoate	≤0.06 ≤0.06	≤5mg/kg ≤5mg/kg	0.5 (as an acid); however, for products that are washed after being used, 2.5 (as an acid)	≤0.3	
Methyl peroxybenzoate Ethyl peroxybenzoate Propyl peroxybenzoate Butyl peroxybenzoate	≤0.01 ≤0.01 ≤0.01 ≤0.01	≤10mg/kg ≤10mg/kg ≤10mg/kg ≤10mg/kg	As a single ingredient, no greater than 0.4 (as an acid) If used by mixing, No greater than 0.8 (as an acid)	≤0.2 ≤0.2	
Sorbic acid Potassium sorbate Sodium sorbate	≤0.2 ≤0.2 ≤0.2	≤25 mg/kg ≤25 mg/kg ≤25 mg/kg	≤0.6 (as an acid)		
Chlorobutanol			≤0.5		Not to be used on aerosol products
Benzalconium chloride			≤0.05 (For products that are washed after being used, ≤ 0.1)		
Benzethonium chloride			≤0.1		
Phenol			≤0.1		
Chlorocresol			≤0.2		
Benzyl alcohol			≤1.0 (For hair dye products, ≤10 as a solvent)		
Phenoxyethanol			≤1.0		
Methylchloroisothiazolinone and methylisothiazolinone mixed solution (including magnesium chloride and magnesium nitrate)			≤0.0015 (methylchloroisothiazolinone: methylisothiazolinone = (3:1) as a		

			mixture)		
Imidazolidinyl Urea			≤0.6		

※NOTE

1. Unit of concentration is W/V% for liquid preparations, and W/W% for other preparations.

2. When mixing more than two types of preservatives of the same kind (group), the total amount shall not exceed the maximum for each ingredient.

3. When mixing preservatives of different kinds (groups), there shall be a basis and the total amount shall not exceed the maximum for each ingredient.

4. Among liquid preparations for internal use, for "items that are used repetitively after opening by dividing for administration," permissible ranges for benzoid acids and peroxybenzoic acids shall be no greater than 0.1%.

5. In case of the wet tissues for oral hygiene, if one intends to exceed the valid concentration for manufacturing pharmaceutical reasons, it may be allowed within the range of the daily permissible dose (but, among liquids for internal use, alterative for energy enhancement, stomach-strengthening digestive medicines, and other medications for the circulatory system shall be excluded). However, in such cases, clear reasons, physicochemical explanations, and the preservation power test (B.P.) data shall be submitted.

6. When mixing a preservative to solid preparations for internal use such as pills, tablets, capsules, etc., its permissible range shall comply with the standards for a permissible range of a liquid preparation and a daily permissible dose.

7. Preparations for external use mean preparations for external use among quasi-drugs that fall under subparagraph 2 of the Designation of the Scope of Quasi-Drugs (MFDS Notice), and products that are not directly applied to the skin such as insecticides, etc. shall be excluded.

8. If an ingredient, despite being known already, that is not designated is intended to be used as a preservative, or if a preservative among preparations for external use is used in excess of its usage range, a clear basis for use, physical and chemical evidence (including a preservation power test data), and if necessary, comparative test data shall be attached. And the reasons for mixing and the amount used shall be judged to be valid.

9. For toothpastes, 0.2% of sodium methoxide ρ-oxybenzoate, which is a salt of methyl ρ-oxybenzoate, and 0.1% of sodium propylester ρ-oxybenzoate, which is a salt of propyl ρ-oxybenzoate, may be used. And they shall be considered as preservatives of the same type (group).

[Appendix 2]

Guidelines for Description of Manufacturing Methods

(In Regards to Article 11 (2))

Following form may be used, or a manufacturing diagram or other description methods containing the following form may be used.

Process No.	Process Name	Raw material, reagent, solvent, etc.[Note 1]	Note
1[Note 2]	Weighing of raw materials		Manufacturer of the Main Ingredient[Note 3]
		: : :	
	Packaging[Note 4]		Material of direct containerand packaging

Note 1: Names of raw materials, reagents, solvents, etc. that are added and used shall be stated by process.

Note 2: For Process No.1, 「Process Name」column shall be filled in with "Weighing of raw materials"; 「Raw material, reagent, solvent, etc. 」 shall be filled in with the names of raw materials, reagents, solvents, etc. that are added and used during the entire process; and the 「Note」 column shall be filled in with the manufacturer of the main ingredient.

Note 3: 「Manufacturer of the Main Ingredient」shall be filled in with the name and location of the manufacturer of the main ingredient. If it is manufactured by consigning the whole or part of the process, name and location of the consigned manufacturing business shall be stated by unit process. If the admitter of the item (contract manufacturer) and the actual manufacturer (consigned manufacturer) are different, this shall be distinguished and stated. And if the preparation's main ingredient is in the form of a half-finished product, names and locations of not only the manufacturer of a pertinent main ingredient, but also the manufacturer of the substances that are expected to manifest the efficacy and effect directly or indirectly (e.g.: effect enhancer, etc.) shall be stated together.

Note 4: For the last process, 「Process Name」column shall be filled in with "Packaging," and the 「Note」 column shall be filled in with the materials of a direct container and packaging. If an erroneous consumption preventive container is used for solid formulation insecticides, material and a structural diagram of the erroneous consumption-preventive container shall be stated.

[Appendix 3]

Scope of Submission of Data for Safety and Efficacy evaluation

(In Regards to Article 24 (1))

Ⅰ. As a fiber, rubber or papers provided for sanitary purposes, sanitary pads, cover, wrap, gauze, absorbent cotton, band-aids, and other similar products

Category \ Data to be submitted	Data No.[Note 1]												
	1	2	3	4							5	6	7
				A	B	C	D	E	F	G			
Preparation containing new materials[Note 2]	○	○	○	○	○	△	○	○	×	○	△	○	○
New Materials[Note 3]	○	○	○	○	△	△	△	△	×	○	△	○	○
New Usage Directions	○	○	×	×	×	×	×	×	×	△	△	○	○
New Efficacy	○	○	×	×	×	×	×	×	×	×	△	○	○

○: Data that must be submitted

△: Data that may be remitted based on the judgment for individual items, because the submission is not meaningful or possible

×: Data of which the submission is remitted

Note 1: Data No. 1 through 7 refer to the data in subparagraph 1 through 7 of Article 23, and among the toxicity data (4), those marked with ※ shall be the single dose toxicity test data or the cytotoxicity test data.

Note 2: "Preparation containing new materials" section shall apply to products that contain new materials through spreading, processing, etc. on fiber, rubber, or paper products.

Note 3: “New Materials” section shall apply if the fiber, rubber, or papers that compose the product is a new material.

Ⅱ. Odor inhibitors such as bad breath (halitosis) or body odor eliminators; hair tonic, hair dye, depilatory, etc.; products used for oral hygiene, etc.; and products that are applied directly to human bodies

Category \ Data to be submitted	Data No.[Note 1]													
	1	2	3	4[Note 3]							5	6	7	Note
				A	B	C	D	E	F	G				
Preparation containing new materials	○	○	○	○	○	△	○	○	△	○	○	○	○	
Mixed product of new composition	○	○	○	△	△	×	×	△	×	△	○	○	○	
Content-varying mixed product	○	○	○	△	×	×	×	△	×	○	△	○	○	Note 2
Single product	○	○	○	△	×	×	×	△	×	△	○	○	○	
New efficacy and effect	○	○	×	×	×	×	×	△	×	△	○	○	○	
New usage directions and dose	○	○	×	×	×	×	×	×	×	×	○	○	○	
New formulation	○	○	○	×	×	×	×	×	×	×	○	○	○	

○: Data that must be submitted

△: Data that may be remitted based on the judgment for individual items, because the submission is not meaningful or possible

×: Data of which the submission is remitted

Note 1: Data No. 1 through 7 refer to the data in subparagraph 1 through 7 of Article 23.

Note 2: 1. In case of the preparations that contain new materials and the hair dye, toxicity test data for pertinent new materials and each ingredient shall be submitted.

2.In case of the mixed product for external use that contain new materials (excluding hair dye products), single dose toxicity test data, 1-month repeated dose toxicity test data, and mucous membrane stimulation test data shall be additionally submitted pursuant to Article 4 of the Standards for Quasi-Drug Toxicity Test. And for composite medications, other than the mixed products for external use, that contain new materials, single dose toxicity test data, 1-month repeated dose toxicity test data, and mucous membrane stimulation test data under the toxicity test method by medication for mixed products in the Standards for Quasi-Drug data shall be submitted additionally.

3. If a dermatologic preparation is made as an aerosol product, efficacy test data for the aerosol shall be attached.

Note 3: Remission of toxicity test data

1. If each active ingredient contains a crude drug or a crude drug extract that have precedents of being used as drugs or if each ingredient is listed in the Standards and Specifications of Food Additives (applicable only to the food additives), toxicity test data may be remitted in part or whole for products that are listed in the Korean Pharmacopoeia or in the official compendium as a single product.
2. If each active ingredient is listed in the Korean Pharmacopoeia, Standards and Test Methods for Quasi-Drugs, etc., or if it is used for the same purpose as an ingredient that is permitted already, toxicity test data for mixed products may be remitted.

Ⅲ. Extirpators, inhibitors, repellents and insect-attracting pesticides for flies, mosquitoes, etc. that are used to protect the health of people and animals

Category \ Data to be submitted	Data No.[Note 1]														
	1	2	3	4							5			6	7
				A	B	C	D	E	F	G	A[Note 2]	B	C		
Preparation containing new materials	○	○	○	○	○	○	○	△	○	○	○	○	○	○	○
Mixed product of new composition [Note 3]	○	○	○	△	△	×	×	△	△	△	○	×	×	○	○
Content-varying mixed product[Note 3]	○	○	○	△	△	×	×	×	△	△	△	×	×	○	○
Single product	○	○	○	△	△	×	×	×	△	△	△	×	×	○	○
New efficacy and effect	○	○	×	×	×	×	×	×	×	×	○	×	×	○	○
New usage directions and dose	○	○	×	×	×	×	×	×	×	×	○	×	×	○	○
New formulation[Note 3]	○	○	○	△	△	×	×	×	△	△	○	×	×	○	○

○: Data that must be submitted

△: Data that may be remitted based on the judgment for individual items, because the submission is not meaningful or possible

×: Data of which the submission is remitted

Note 1: Data No. 1 through 7 refer to the data in subparagraph 1 through 7 of Article 23, while clause (f) among the toxicity data (4) shall inhalation toxicity test data. And the data that can verify the efficacy and effect shall be as follows:

5. Data that can verify the efficacy and effect

A. Insecticidal power test data

B. General pharmacological test data (may be substituted by the safety pharmacological test)

C. Absorption, distribution, metabolism, and excretion test data

Note 2: For repellents, insecticidal power test data shall be submitted through repellant power test data.

Note 3: If the active ingredient has a high concentration, a different composition, or a new formulation, toxicity test data shall mean the toxicity test data of a finished product.

※If it falls within the range of the main ingredient content of the item that is permitted (notified) already, separate evaluation data may not need to be submitted.

※Comprehensively judging at the level of modern medicine and pharmacy, if it is considered to be similar or equivalent to a product that is permitted already, data to be submitted may be replaced with e usage status data which can be approved publicly.

Ⅳ. Contact lens care products (cleaning, preserving, sterilizing, rinsing solutions, etc. for lens)

Category \ Data to be submitted	Data No.[Note 1]											
	1	2	3	4					5		6	7
				A	B	C	D	E	A[Note 2]	B		
1. Product of which the residue solution does not directly contact the eyes												
Preparation containing new materials	○	○	○	○	○	○	○	○	○	△	○	○
Other preparations	○	○	○	×	○	×	×	×	○	△	○	○
2. Product of which the residue solution does not directly contact the eyes												
Preparation containing new materials	○	○	○	○	○	×	×	×	○	△	○	○
Other preparations	○	○	○	×	○	×	×	×	○	△	○	○

○: Data that must be submitted

△: Data that may be remitted based on the judgment for individual items, because the submission is not meaningful or possible

×: Data of which the submission is remitted

Note 1: Data No. 1 through 7 refer to the data in subparagraph 1 through 7 of Article 23, and the toxicity data (4) and the data concerning the pharmacological action shall be as follows:

4. Data concerning the toxicity

A. Single dose toxicity test data

B. Ocular irritation test data

C. Cytotoxicity test data

D. Skin sensitization test data

E Ocular membrane's biological synthesis test data

5. Data about pharmacological actions

A. Efficacy test data

B. General pharmacological test data

Note 2: As efficacy test data for sterilizing and disinfection power, cleaning power, protein

removing power, etc. shall be submitted; however, the efficacy test data shall be remitted for a simple rinsing solution or a preserving solution. If one intends to claim a particular material (e.g.:fluorosilicone acrylate) or a type (e.g.: soft, air-permeable hard contact lens (RGP)) of the contact lens in relation to the effect and efficacy of contact lens care products, an efficacy test shall be conducted for the material or type of the pertinent contact lens.

Ⅴ-1. Products that are used for decreasing the desire to smoke

Data to be submitted / Category	Data No.[Note 1]														
	1	2	3	4								5	6	7	Note
				A	B	C	D	E	F	G	H				
Preparation containing new materials	○	○	○	○	○	Δ	○	Δ	Δ	Δ	Δ	○	○	○	
Mixed product of new composition	○	○	○	Δ	Δ	×	×	×	×	Δ	×	○	○	○	
Content-varying mixed product	○	○	○	Δ	×	×	×	×	×	Δ	×	Δ	○	○	
Single product	○	○	○	Δ	×	×	×	×	×	Δ	×	○	○	○	
New formulation	○	○	○	×	×	×	×	×	×	×	×	Δ	○	○	
New usage directions and dose	○	○	×	×	×	×	×	×	×	×	×	○	○	○	

○: Data that must be submitted

Δ: Data that may be remitted based on the judgment for individual items, because the submission is not meaningful or possible

×: Data of which the submission is remitted

Note 1: Data No. 1 through 7 refer to the data in subparagraph 1 through 7 of Article 23, and the toxicity data (4) shall be as follows:

4. Data concerning the toxicity (for products that are used by inhaling, data for a test that is carried out regarding the product)

A. Single dose toxicity test data (for products that are used by inhaling, inhalation toxicity test data)

B. Repeated dose toxicity test data (for products that are used by inhaling, inhalation toxicity test data)

C. Reproductive and developmental toxicity test data

D. Genotoxicity study data

E. Immunotoxicity test data

F. Carcinogenicity test data

G. Local toxicity test data

H. Dependence study data

Ⅴ-2. Products that are inhaled in a similar way as cigarettes and are used for aiding in improvement of smoking habits

Data to be submitted / Category	Data No.[Note 1]														
	1	2	3	4								5	6	7	Note
				A	B	C	D	E	F	G	H				
New preparations (including changes in the kinds of ingredients)	○	○	○	Δ	○	Δ	○	Δ	Δ	Δ	Δ	Δ	○	○	
Preparation of which the ingredients content has changed	○	○	Δ	Δ	Δ	×	×	×	×	×	×	Δ	○	○	

○: Data that must be submitted

Δ: Data that may be remitted based on the judgment for individual items, because the submission is not meaningful or possible

×: Data of which the submission is remitted

Note 1: Data No. 1 through 7 refer to the data in subparagraph 1 through 7 of Article 23, and the toxicity data (4) shall be as follows:

4. Data concerning the toxicity

A. Single dose toxicity test data (inhalation toxicity test data)

B. Repeated dose toxicity test data (inhalation toxicity test data)

C. Reproductive and developmental toxicity test data

D. Genotoxicity study data (applicable only to the micronucleus test)

E. Immunotoxicity test data

F. Carcinogenicity test data

G. Local toxicity test data

H. Dependence study data

Ⅵ. Disinfectants for external use

Data to be submitted / Category	Data No.[Note 1]													
	1	2	3	4							5[Note 2]	6	7	Note
				A	B	C	D	E	F	G				
Disinfectants for External Use	○	○	○	×	×	×	×	×	×	×	○	○	○	

○: Data that must be submitted

△: Data that may be remitted based on the judgment for individual products, because the submission is not meaningful or possible

×: Data of which the submission is remitted

Note 1: Data No. 1 through 7 refer to the data in subparagraph 1 through 7 of Article 23

Note 2: Refers to the efficacy test data, and if there is a valid reason, other data that can verify the efficacy and effect may be submitted.

Ⅶ. Products added to water inside a humidifier to prevent microbial growth or water residues

Category \ Data to be submitted	Data No.[Note 1]													
	1	2[Note 2]	3	4[Note 3]								5[Note 5]	6	7	Note
				A	B	C	D	E	F	G	H[Note 4]				
Preparation containing new materials	○	○	○	○	○	Δ	○	Δ	Δ	○	Δ	○	○	○	
Mixed product of new composition	○	○	○	Δ	Δ	×	×	×	×	Δ	×	○	○	○	
Content-varying mixed product	○	○	○	Δ	Δ	×	×	×	×	Δ	×	○	○	○	
Single product	○	○	○	Δ	Δ	×	×	×	×	Δ	×	○	○	○	
New formulation	○	○	○	Δ	Δ	×	×	×	×	×	×	Δ	○	○	
New usage directions and dose	○	○	×	Δ	Δ	×	×	×	×	×	×	○	○	○	

○: Data that must be submitted

Δ: Data that may be remitted based on the judgment for individual items, because the submission is not meaningful or possible

×: Data of which the submission is remitted

Note 1: Data No. 1 through 7 refer to the data in subparagraph 1 through 7 of Article 23, and the toxicity data (4) shall be as follows:

4. Toxicity data

A. Single dose toxicity test data (including inhalation toxicity test data)

B. Repeated dose toxicity test data (including inhalation toxicity test data)

C. Reproductive and developmental toxicity test data

D. Genotoxicity study data

E. Immunotoxicity test data (including skin sensitization test data)

F. Carcinogenicity test data

G. Local toxicity test data

H. Cytotoxicity test data

Note 2: As physical and chemical data, a profile in a physical form regarding the finished product, such as the changes, etc. of the particle size as the particles are emitted from the humidifier, shall be submitted. If, as a consequence, it changes to a form that can be exposed to human bodies, inhalation toxicity test data about the finished product shall be submitted.

Note 3: In the case of single dose toxicity test data or repeated dose toxicity test data, inhalation toxicity test data shall be included. And for the repeated dose toxicity test, period of administration shall be 90 days.

Note 4: If it is an ingredient that has not been used as an active ingredient for the sterilizer of a humidifier, it shall be considered as a new material, and among the data concerning the toxicity, cytotoxicity test data shall be submitted. Cytotoxicity test shall expose the lung cell for 24 hours and calculate the concentration (LC_{50}) of a test material manifesting the toxicity. If it shows no toxicity according to the inhalation toxicity test result, it may be remitted.

Note 5: Refers to the efficacy test data regarding the sterilizing power of a product when it is added to a humidifier. It shall verify the effect under the concentration with which the product is used. If there is a valid reason, other data that can verify the efficacy and effect may be submitted.

[Appendix 4]

Items to Be Stated for Standards and Test Methods

(In Regards to Article 27 (1))

No.	Items to Be Stated	Raw Material	Finished Product
1	Name	○	×
2	Structural formula or Rational formula	Δ	×
3	Molecular formula and molecular weight	○	×
4	Origin and manufacturing method	Δ	×
5	Content standards	○	○
6	Appearance	○	○
7	Confirmation test	○	○
8	Material property (Physical and chemical characteristics, etc.)	Δ	Δ
9	Purity test	○	Δ
10	Loss on drying, loss on ignition, or moisture	○	Δ
11	Ignition residue, ash or acid-insoluble ash	Δ	×
12	Formulation test	×	○
13	Other tests[Note 1]	Δ	Δ
14	Quantification (content test for finished products)	○	○
15	Reference standard , reagent and test solution	Δ	Δ

○: In principle, to be stated

Δ: To be stated if necessary

×: In principle, not needed to be stated

Note 1: Other tests include microbial limit test, sterility test for sterilized products, and particle size test for raw materials.

※Regarding polymorphism, optical activity, etc., proper specifications shall be established in the items such as the confirmation test, material property (optical density), purity test, other tests

(isomer ratio, abundance ratio of the crystal form), quantification method, etc. depending on the details.

[Appendix 5]

Example of Completed Enclosed Specifications of Raw Materials (In Regards to Article 29 (1))

『Korean Name』

『English Name』

『Structural Formula』

↑

Shingmyungjo, 15 point, Bold, Center Aligned

『Nickname』 ← 12 point, Divided Alignment → 『Molecular formula : Molecular weight』

『Origin and Regulations on the Content』

This medication contains no less than 99.0% of "Korean name" (molecular formula : molecular weight) for a dried material that is converted for quantifying.

Manufacturing Method (Item names shall beJunggodic, 13-point font, bold)

Appearance

Confirmation test

Material Property

Purity Test 1) Dissolution status

2) After weighing approximately 2.0g of a heavy metal, carry out an operation and a test according to the Heavy Metal Test Method No.2 under the General Test Methods in the Korean Pharmacopoeia. In the control solution, add 2.0mL of a standard lead solution. (≤10 ppm)

Loss on drying (Loss on ignition or moisture)

Ignition Residue (Ash or Acid-Insoluble Ash)

Special Test

Quantification

Storage Method

Reagent, Test solution

※Detailed Preparation Guidelines (matters to be noted)

1. Set-up of paper: Paper size A4, Margin (top, bottom, header, footer 12.5mm; right and left 20mm)

2. Paragraph format: Line spacing 180%, Alignment Fully justified

3. Text: It shall be Font Shingmyungjo, Inter-letter spacing 0%, Size 12 point.

[Appendix 6]

Example of Completed Standards and Test Methods for Finished Products (In Regards to Article 30 (1))

Standards

1. Appearance (Item names shall be written in Junggodic, 13-point font, bold): OO (name of the color) circular film-coated pills
2. Confirmation test: It shall comply with this to carry out a test according to the following test methods.

3. Purity test:
4. Homogeneity test for preparations:
5. Content test:

Test method

1. Appearance: Visually observe.
2. Confirmation test:
3. Purity test:
4. Homogeneity test for preparations:
5. Content test:

※Detailed Preparation Guidelines(matters to be noted)

1. Set-up of paper: Paper size A4, Margin (top, bottom, header, footer 12.5mm; right and left 20mm)
2. Paragraph format: Line spacing 180%, Alignment Fully justified
3. Text: It shall be Font Shingmyungjo, Inter-letter spacing 0%, Size 12 point.

[Appendix 7]

Scope of Submission of Data for Evaluation of Standards and Test Methods (In Regards to Article 31 (1))

Data to be submitted / Category	Data No.[Note 1]											
	1	2	3						4			
			A	B	C	D	E	F	A[Note 2]	B	C	D	E
1.Preparation containing new materials	○	○	○	○	○	○	○	○	△	○	○	○	○
2.Quasi-drug of which the specifications, amount, and formulation of the main ingredient are the same as those of a product which is permitted already	×	○	×	×	×	△	○	△	△	△	△	○	△
3.Quasi-drugs that are manufactured according to the manufacturing standards[Note 3]	△	△	×	×	×	△	○	△	×	×	△	○	△
4.Other preparations[Note 4]	○	○	△[Note 5]	△[Note 5]	×	○	○	△[Note 5]	△	△	○	○	△[Note 5]

○: Data that must be submitted

△: Data that may be remitted based on the judgment for individual items, because the submission is not meaningful or possible

×: Data that are remitted

Note 1: Data No. 1 through 4 refer to the following data.

1. Origin or discovery and the development

2. Overseas usage status data

3. Data about raw materials

A. Data about the structural determination

B. Data about physicochemical characteristics

C. Data about manufacturing methods

D. Evidentiary data about standards and test methods

E. Data about test reports

F. Data about reference standards, reagents and test solutions

4. Data about finished products

A. Data about drug substances and the amount

B. Data about manufacturing methods

C. Evidentiary data about standards and test methods

D. Data about test reports

E. Data about reference standards, reagents and test solutions

Note 2: If the specifications of additives are enclosed specifications, evidentiary data about specifications of excipients shall be submitted.

Note 3: Items that fall under the proviso to Article 5 (2) shall be excluded.

Note 4: "Other preparations" means quasi-drugs that do not fall under Articles 1 through 3 and correspond to a new formulation, new composition of main ingredients, adjusted content, isomer, mineral changes, etc. when compared with quasi-drugs that are permitted already.

Note 5: To be submitted when there are changes in isomer and salt of the raw ingredient.

[Appendix 8]

Scope of Submission of Data for Safety and Efficacy evaluation of Infectious Disease-Preventive Disinfectants and Insecticides

(In Regards to Article 46 (1))

Category \ Data to be submitted	Data No.[Note 1]							
	1	2	3	4[Note 2]		5	6	7,8
		ABC[Note 3]		ABCDEF	G			
					1 2 3			
1) Infectious disease-preventive disinfectants and insecticides containing new materials	○	○ ○ ○	○	○ ○ ○ ○ △△	○○○	○	○	○
2)Item that differs from the item which is already permitted as an infectious disease-preventive disinfectant and insecticide in at least one of the following aspects - ingredient composition (active ingredient and its concentration), efficacy and effect, usage directions and dose, and formulation	○	× × ○	○	○ △ × × × △	△△△	○	×	○
3) Item of which the specifications, amount, and formulation of the ingredient that affects the effect, such as the active ingredient, effect enhancer, etc., are the same as those of an item which is permitted already [Note 4]	×	× × ○	×	× × × × × ×	× × ×	×	×	○

○: Data that must be submitted.

△: Data that may be remitted based on the judgment for individual products, because the submission is not meaningful

or possible.

×: Data of which the submission is remitted.

Note 1: Data No. 1 through 8 refer to the data in subparagraphs 1 through 8 of Article 45.

Note 2: In general, toxicity data (4) shall be the data tested for the main ingredient, and the single dose toxicity test data and fish toxicity test data shall be additionally submitted for the preparations. A local toxicity test data among the data in clause (f) and residue test data among the data in clause (g) may be submitted not only through data for main ingredients, but also through data for preparations.

Note 3: In the case of the insecticides, primary test data that have been prepared according to the standards and test methods for main ingredients shall be additionally submitted.

Note 4: A product of which the specifications of the ingredient that affects the effect, such as the active ingredient, effect enhancer, etc., are the same as those of the product which has been permitted already means that among the pertinent ingredient's specifications, content and flexible materials standards are the same or higher than those of an already permitted product.

[Annex Form No.1]

Data to be Submitted for the Safety and Efficacy Evaluation (Excluding Infectious Disease-Preventive Disinfectants and Insecticides) (In Regards to Article 22)

* Data No. is a number in Article 23 and each subparagraph of Appendix 3.

New Additive	Data No.	1	2	3	4	Data No. is a number in each subparagraph of Article 24 (3).
	Submission status					

Quasi-Drugs Ⅰ, Ⅱ, Ⅵ	Data No.	1	2	3	4							5	6	7	Data No. is a number in Article 22 and Appendix 3 I, II, VI.
					A	B	C	D	E	F	G				
	Submission status														

Quasi-Drugs Ⅲ	Data No.	1	2	3	4							5			6	7	Data No. is a number in Article 22 and Appendix 3 III.
					A	B	C	D	E	F	G	A	B	C			
	Submission status																

Quasi-Drugs Ⅳ	Data No.	1	2	3	4					5		6	7	Data No. is a number in Article 22 and
					A	B	C	D	E	A	B			

	Submission status													Appendix 3 IV.

Quasi-Drugs Ⅴ	Data No.	1	2	3	4								5	6	7	Data No. is a number in Article 22 and Appendix 3 V.
					A	B	C	D	E	F	G	H				
	Submission status															

[Annex Form No.2]

Data to be Submitted for the Safety and Efficacy Evaluation of Infectious Disease-Preventive Disinfectants and Insecticides) (In Regards to Article 44)

* Data No. is the number corresponding to each subparagraph of Article 45 and Appendix 8.

Infectious disease-preventive disinfectants and insecticides	Data No.	1	2			3	4									5	6	7.8
			A	B	C		A	B	C	D	E	F	G					
													1	2	3			
	Submission status																	

[Annex Form No.3]

Example of Completed Summary of Insecticidal and Disinfection Power Test

(In Regards to Article 47)

<table>
<tr><td>1. Name of the Insecticide</td><td colspan="5">(for spraying)</td></tr>
<tr><td>2. Main Ingredient</td><td colspan="5">Per 1kg or 1L
Name of the Ingredient (Amount)g</td></tr>
<tr><td>3. Date of Experiment</td><td colspan="5"></td></tr>
<tr><td>4. Harmful Insect under Consideration</td><td colspan="5">Scientific name of the hygienic harmful insect</td></tr>
<tr><td>5. Method of Experiment</td><td colspan="5">1. Location of collection
2. Method of collection
3. Method of rearing
4. Test method
A. Summarize and state the number of harmful insects subjected to the test, area, concentration of the insecticides used, method of application, time, fatality rate, etc.
B. Control group</td></tr>
<tr><td>6. Result of Experiment</td><td>Insecticide Concentration (%)</td><td>Dilution Ratio (X)</td><td>Total Abundance (number of insects)</td><td>Fatalities (number of insects)</td><td>Fatality Rate (%)</td></tr>
<tr><td rowspan="3">Test Group</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table>

Control Group					
7. Recommended Usage Directions					
8. Matters concerning the Testing Organization					