Standard Manufacturing Practice of Quasi-Drugs

MFDS Notification No. 2015-16 (Enacted on March 27, 2015)
MFDS Notification No. 2015-68 (Revised on September 25, 2015)
MFDS Notification No. 2016-95 (Revised on August 31, 2016)

Article 1 (Purpose) The purpose of this regulation is to improve the efficiency of approval and declaration management in accordance with Articles 31, 42, and 52 Paragraph 2 of Pharmaceutical Affairs Act, Articles 5 and 12 of the Regulations on Safety of Pharmaceuticals etc. by standardizing types, size, contents of ingredients, and prescriptions among each ingredient used in quasi-drugs.

Article 2 (Definition) "Effective ingredients" used in this standard refer to the direct or indirect expectation of efficacy and effect of pharmacological actions of the ingredients themselves.

Article 3 (Standard Manufacturing Practice of Quasi-drugs) ① The standard manufacturing practice of quasi-drugs is described in the Attached Table.

② Despite Paragraph 1, the attached specifications of the effective ingredients of the items which have the effective ingredients in the following shall be recognized as the specification of effective ingredients by the Attached Table according to this notification.

1. Lactobacillus Bifidus
2. Lactobacillus acidophilus
3. Clostridium Butyricum Miyairi II-588
4. Retinol Palmitate
5. Ascorbic Acid

6. Ergocalciferol
7. Cholecalciferol
8. Pancreatin

Article 4 (Re-review Period) The Minister of MFDS shall review the validity of this notification every 3 years (refers to December 31 of every third year) based on January 1, 2017 and take actions of improvement, etc. according to the Regulation on Announcement and Control of Directives, Established Rules, Etc.

Addendum <No. 2015-16, March 27, 2015>

Article 1 (Enforcement Date) This notification shall be enforced since the notification date.

Article 2 (Transitional Measures) ① In accordance with the Standard Manufacturing Practice of Pharmaceuticals, Etc. which has been enforced prior to the enforcement of this notification, the previous notification shall be applied to the declaration of quasi-drugs received to the Commissioner of Regional KFDA. This will also be applied to the application for amendment.

② The quasi-drugs of which item declaration has been made according to the previous Standard Manufacturing Practice of Pharmaceuticals, Etc. shall be regarded to be the ones declared according to this notification.

Article 3 (Revision of Other Notifications) In the Standard Manufacturing Practice of Pharmaceuticals, Etc. (MFDS Notification No. 2014-194, December 5, 2014) which was notified by the Minister of MFDS with this notification, Article 4 and Attached Table 2 related to Article 4 shall be deleted.

Article 4 (Relationship with Other Notifications) If the regulations such as other notifications at the time of this notification cite the Standard Manufacturing Practice of Pharmaceuticals, Etc. or its provisions, and

this notification contains the provisions applicable to the above provisions, it shall be regarded that this notification or the provision of this notification is cited in replacement of the previous provisions.

Addendum <No. 2015-68, September 25, 2015>

Article 1 (Enforcement Date) This notification shall be enforced since the notification date.

Article 2 (Transitional Measures) ① In accordance with the previous Standard Manufacturing Practice of Quasi-drugs which has been enforced prior to the enforcement of this notification, the previous notification shall be applied to the declaration of quasi-drugs received to the Commissioner of Regional KFDA. This will also be applied to the application for amendment.

② The quasi-drugs of which item declaration has been made according to the previous Standard Manufacturing Practice of Quasi-drugs shall be regarded to be the ones declared according to this notification.

③ If the quasi-drugs declared according to the previous Standard Manufacturing Practice of Quasi-drugs are not appropriate for the revised regulation in this notification, the manufacturer (importer) of the quasi-drugs shall correct the applicable quasi-drugs to be appropriate for the revised regulations of this notification within 6 months from the enforcement date of this notification. According to Article 8 Paragraph 8 Subparagraph 7 of the Regulation on Safety of Pharmaceuticals, Etc. (Ordinance of the Prime Minister), the manufacturer/importer shall describe the amendment date on the date column and amendment details, notification name and notification No. in the detail column in ‘Amendment and Disposition Information Etc.’ on the backside of the quasi-drug’s notification certificate. Then, they shall attach the details to the notification certificate.

Article 3 (Transitional Measures on Container or Package) ① The container or package of the quasi-drugs manufactured (imported) after

declaration according to the previous Standard Manufacturing Practice of Quasi-Drugs prior to the implementation of this notification shall be regarded to contain the descriptions according to the revised regulations of this notification.

② Despite Paragraph 1, the containers or packages with descriptions according to the previous Standard Manufacturing Practice of Quasi-drugs prior to the enforcement of this notification may be used in the manufacture (import) of the items until December 31, 2016.

Addendum <No. 2016-95, August 31, 2016>

Article 1 (Enforcement Date) This notification shall be enforced since the notification date.

Article 2 (Application Example) This notification shall be applied from the quasi-drugs manufactured by manufacturers or imported by importers for the first time after the enforcement of this notification.

Article 3 (Transitional Measures on Declared Quasi-drugs) If the quasi-drugs declared according to the previous regulation prior to the enforcement of this notification are not appropriate for the revised regulation in this notification, the manufacturer (importer) of the quasi-drugs shall correct the applicable quasi-drugs to be appropriate for the revised regulations of this notification within 6 months from the enforcement date of this notification. According to Article 8 Paragraph 8 Subparagraph 7 of the Regulation on Safety of Pharmaceuticals, Etc. (Ordinance of the Prime Minister), the manufacturer/importer shall describe the amendment date on the date column and amendment details, notification name and notification No. in the detail column in ‘Amendment and Disposition Information Etc.’ on the backside of the quasi-drug’s notification certificate. Then, they shall attach the details to the notification certificate.

Article 4 (Transitional Measures on Container or Package) The containers or packages with descriptions according to the previous regulations prior

to the enforcement of this notification may be used in the manufacture of the items up to 2 years after the enforcement date of this notification.

[Attached Table]

Chapter 1 Standard Manufacturing Practice of Hair-dying Products

< Omission of translations >

Chapter 2 Standard Manufacturing Practice of Toothpaste

1. Scope

The criteria are applied to toothpaste of which purpose is to maintain tooth white, strengthen teeth, clean the mouth, and prevent teeth, gum, and disease within the mouth.

2. Criteria

The standard manufacturing practice of toothpaste is as follows.

1) Types, Specifications, and Mixing Limit of Effective Ingredients

The types of ingredients available for use are described in <Table 1>, and the specifications should be the ones specified in the Official Compendium and National Drug Formulary Recognized by the Minister of MFDS in accordance with Attached Table 1-2 relevant to the Korean Pharmacopoeia, Standards and Analytical Methods of Quasi-drugs, and Article 2 Subparagraph 7 of the Regulation on Pharmaceutical Approval, Notification and Review (hereinafter referred to as "the official compendium and national drug formulary recognized by the Minister of MFDS"), and the ingredients of which mixing limit is defined should not deviate their standards.

In <Table 1>, from Ⅰ to Ⅳ, one or more types of ingredients shall be contained, and if necessary, effective ingredients in Ⅴ shall be mixed.

2) The available preserving agents are described in <Table 2>, and other additives should be in accordance with Article 9 Paragraph 3 and Article 5 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification), and they should not be included in the raw materials in Attached Table 1 in the Regulations on Safety Criteria, etc. of Cosmetics (MFDS Notification).

3) Formulations include paste, liquid, gel, and powders.

4) Efficacy and Effects

(1) General Efficacy and Effects

Maintain teeth white and strengthen them. Maintain the inner mouth clean. Refresh the inner mouth. Prevent tooth decay (for a toothpaste which contains 1,000 ppm of total fluorine, 'prevent tooth decay' should be 'prevent tooth decay by fluorine'). Remove bad breath. Increase aesthetic effect.

(2) In addition to general efficacy and effects, prevention of gingivitis and paradentitis (peridonticlasia), prevention of peridontal disease, prevention of gum disease, prevention of dental calculus, and prevention of deposition of dental calculus may be added. In this case, 1 and more types of effective ingredients applicable for each prevention should be mixed.

5) Dose and Administration

(Paste, gel, powder) Apply an adequate amount to a toothbrush and brush the teeth by tooth-brushing.

(Liquid) Keep the adequate amount (10 ~ 15 mL) in the mouth, gargle about 30 seconds, spit out, and then brush teeth by tooth-brushing.

6) Precautions in Use <Provisory clause deleted>

(1) The contents of fluorine in this toothpaste is ○○ppm.(Limited in fluorine-containing toothpaste)

(2) Be careful not to swallow it, and after use, wash out the mouth enough

(3) If abnormalities occur such as damages of gum or oral cavity, stop using this toothpaste and consult with a doctor or dentist

(4) If children under 6 years of age use this toothpaste, a small amount of toothpaste about the size of a pea per time should be used, and the toothpaste should be used under guidance of guardians so that children should not take a suck or swallow.

(5) If children under 6 swallowed a large amount of toothpaste, consult with a doctor or dentist immediately

(6) Keep toothpaste out of the reach of children under 6 years of age

7) Storage Method and Validity (Effective) Period

(1) Storage Method: Airtight container

(2) Validity (Effective) Period: The validity (effective) period should be not more than 3 years, but comply with Article 16 Paragraph 2 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

<Table 1>

Types of Effective Ingredients of Toothpaste and Mixing Limit or Mixing Concentration

Item	Ingredient	Mixing Limit or Mixing Concentration (%)	
I	Sodium Monofluorophosphate Sodium Fluoride Stannous Fluoride Amin Fluoride 297(N,N,N'-tris-(2-hydroxyethyl)-N'-octadecyl-1,3-diaminopropane dihydrofluoride)	0.76 0.22 0.4 1.31	Not more than 1,000ppm as a total fluorine
II	Calcium glycerophosphate	0.13	
III	Sodium Chloride Tocopherol Acetate Pyridoxin Hydrochloride Allantoin Aluminium Chlorohydroxy Allantoinate Tranexamic Acid Aminocaproic Acid	0.5 ~ 10.0 0.01 ~ 1.0 0.02 ~ 0.06 0.01 ~ 2.0 0.001 ~ 0.3 0.05 0.001 ~ 0.2	
IV	Sodium Pyrophosphate	0.1 ~ 3.4	
V	Dibasic Calcium Phosphate·$2H_2O$ Dibasic Calcium Phosphate Precipitated Calcium Carbonate Calcium Carbonate Tribasic Calcium Phosphate Colloidal Silicon Dioxide Silicon Dioxide Calcium Phosphate Hydrated silicon dioxide Dental type silica	48.0 15.0 42.0 50.0 32.0 15.0 20.0 31.0 19.0 20.0	

※ When precipitated calcium carbonate and calcium carbonate are mixed at the same time, the total amount of them should not exceed 65.0%.

<Table 2>

Efficacy and Effects in Addition to General Efficacy and Effects of Toothpaste

Prevention of gingivitis and paradentitis(peridonticlasia), prevention of peridontal disease, and prevention of gum disease	Column Ⅲ of effective ingredients
Prevention of deposition of dental calculus	Column Ⅳ of effective ingredients
Removal of dental plaque(anti-plaque)	Column Ⅴ of effective ingredients

Chapter 3 Standard Manufacturing Practice of Hair-dying Products

< Omission of translation >

Chapter 4 Standard Manufacturing Practice of External Spray Patch

1. Scope

This practice is applied to pain relief adjuvant used by spraying to skin as a spray patch only externally used in accordance with Subparagraph 2 Item G of the of Scope of Quasi-drugs (MFDS Notification).

2. Criteria

The standard manufacturing practice for external spray patch is as follows.

1) Types of Mixing Ingredients

(1) As effective ingredients, 2 and more ingredients included in column I or column Ⅰ and Ⅱ should be mixed, and their specifications should be the ones specified in the KP and the Official Compendium and National Drug Formulary notified by the Minister of MFDS.

(2) The additives should be in accordance with Article 9 Paragraph 3 and Article 5 of the Regulation on Quasi-drugs Approval, but when new additives which haven't been used in Korea are mixed, they should be appropriate for Article 21 Paragraph 2 of the same Notification. Also, the additives should not be included in the raw materials in Attached Table 1 in the Regulations on Safety Criteria, etc. of Cosmetics (MFDS Notification).

2) Contents of Mixing Ingredients

The content and concentration of mixing ingredients should be the amount described in <Table 1>.

3) Formulation: Aerosol in accordance with the regulation of general provisions of KP.

4) Dose and Administration

Spray an adequate amount to the affected area once to several times a day.

5) Efficacy and Effects

Assistance for treatment of sprain, bruise, contusion, and muscle pain

6) Storage Method and Validity (Effective) Period

(1) Storage: Store in an airtight container at dry place under the room temperature avoiding direct sunlight.

(2) Validity (Effective) Period: The validity (effective) period should be not more than 3 years, but comply with Article 16 Paragraph 2 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

3. Precautions in Use

1) Do not use in the following patients

(1) Children under 3 years of age

(2) Patients with hypersensitivity to the ingredients conained in this product

2) Do not use in the following areas

(1) Areas around eyes, mucous membrane, etc.

(2) Dermatitis caused by wetting, lacquer, etc. and wounded area

3) Administer carefully in the following

(1) Persons who have had allergic symptoms (rash, flare, itching, dermatitis caused by lacquer) caused by drugs or cosmetics

(2) Person with severe wetting or erosion

(3) Patients receiving treatment of a doctor

4) Side Effects

(1) If symptoms such as rash, flare (swelling), itching, etc. occur because of the use of this product, stop using it and consult with a doctor or a pharmacist.

(2) If the symptoms are not improved despite the administration of several days, consult with a doctor or a pharmacist.

5) General Precautions

(1) Keep the fixed dose and administration.

(2) If you administer in children, administer under guidance and supervision of guardians.

(3) Be careful that the product should not come in the eyes. If it enters the eyes, wash the eyes with water. If the symptom is severe, receive treatment from an ophthalmologist.

(4) Use this product externally only. Do not use it for internal use.

(5) Shake the product well before use

(6) Spray at distance of 10 cm from the affected area

(7) Do not spray it over 3 seconds in the same area continuously

6) Precautions in Storage

(1) Keep the product out of the reach of children

(2) Avoid direct sunlight. Airtight in less humid, cool place as much as possible

(3) No dot store it in place with temperature of 40℃ and over

(4) Do not put it in other containers in order to avoid misuse and maintain the quality

(5) Do not put it around fire

(6) Do not use to toward blaze

(7) Do not use in the indoor where flammables are used

(8) Do not through it in the fire

(9) Do not use it around flammables such as a heater and a stove

(10) After using it in a sealed place, you must ventilate the place

(11) After using it, make sure no gas remains in it when you throw it away

<Table 1>

Item	Ingredient	Content (%w/v) (Included in propellants)
Ⅰ	Benzyl nicotinate ester Menthol (*l,d,dl*) Glycol salicylate Methyl salicylate Camphor (*d,dl*)	0.04 3.2 ~ 6 1.75 1.75 ~ 6 3.0
Ⅱ	Diphenhydramine	0.04

Chapter 5 Standard Manufacturing Practice of Low-content Vitamin and Minerals

1. Scope

This practice is applied to complex among oral supplements such as vitamin and minerals containing 1 type of vitamin, as low-content vitamin and mineral agents in accordance with Subparagraph 2 Item H of the Designation of Scope of Quasi-drugs (MFDS Notification). However, if an ingredient exceeding the maximum content for a day is contained, Chapter 1 Standard Manufacturing Practice of Vitamin, Minerals, etc. in Attached Table 1 of Standard Manufacturing Practice of Pharmaceuticals (MFDS Notification) will be applied.

2. Criteria

The standard manufacturing practice of low-content vitamin and mineral agents is as follows.

1) Type, Specification, and Mixing Limit of Mixing Ingredients

(1) The types of available effective ingredients should be the ones described in <Table 1> and <Table 2>. The specification of them should be the ones specified in the Official Compendium and National Drug Formulary Recognized by the Minister of MFDS. As the additives, the ingredients which have been used as additives in domestic pharmaceuticals should be used. Other details should be in accordance with Article 9 Paragraphs 3 and 5 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

(2) If there is no specification specified in (1), AS which has been approved (notified) may be used. However, if AS is different, it should be reviewed according to Article 10 of Standard and Analytical Method in the Enforcement Regulation on the Safety of Pharmaceuticals, etc.

(3) The total amount of mixing ingredients of each item described in <Table 1> and <Table 2> should not exceed the maximum amount defined in individual ingredient per day.

e.g.) Amount of retinol acetate + amount of retinol palmitate ≦ 2,000IU (Vit A 1 day maximum amount)

2) Formulation

Formulations should include powder (including fine grain), granules, capsules, tablets (including foaming tablets and chewable tablets), pills, troche, syrups, and syrup solutions.

3) Dose and Administration

(1) The dose for children and adults with 14 years of age and older (8 years of age if minerals are not contained) is to take within the range of 3 times a day. The administration dose, administration time (for the products which need to distinguish administration time such as before meal, after meal, with meal, etc., the time must be described), and the number of administration should be described in detail.

(2) For chewable tablets, the phrase “Melt or chew in the mouth to take.” should be additionally described.

(3) For foaming tablets, the phrase “You must take it by melting it in the water.” should be additionally described.

4) Efficacy and Effects

The efficacy and effects of vitamin and mineral-containing agents should be described as follows.

Vitamin or mineral-containing agents	Efficacy and Effects
Vitamin (X: B_1, B_2, C) containing agents	Vitamin X supply in body fatigue, pregnancy, lactating period, and physique decline during and after disease
Vitamin A containing agents	Vitamin A supply in pregnancy, lactating period, and physique decline during and after disease (however, elderly period is added if liver oil is contained)
Vitamin B_6 containing agents	Vitamin B_6 supply in pregnancy, lactating period, and physique decline during and after disease
Vitamin C containing agents	Easing stains and freckles
Vitamin E containing agents	Vitamin E supply in the elderly if vitamin E is contained
Vitamin D containing agents	Vitamin D supply in pregnancy, lactating period, development period and elderly
Minerals (X: Ca, Fe, Zn, P) containing agents	Supply of X

5) Storage Method and Validity (Effective) Period

(1) Storage Method: Avoid direct sunlight and store in an airtight container at dry place under the room temperature.

(2) Validity (Effective) Period: The validity (effective) period should be not more than 3 years, but comply with Article 16 Paragraph 2 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

3. Precautions in Use

The precautions in use of vitamin and minerals are as follows.

1) Warnings

(1) If 5,000 IU per day and more of vitamin A (retinol) is administerd in pregnant women, congenital deformity may be caused. Thus, do not 5,000

IU/day of vitamin A in pregnant women within 3 months pregnancy or women possible for pregnancy. (except patients with vitamin A deficiency) (Vitamin A-containing agents)

(2) If children under 6 years of age take this product, toxicity may occur.(iron-containing agents)

2) Do not administer in the following patients

(1) Patients with hypercalciumia (a condition that calcium is excessive in the blood), patients with sarcoidosis, patients with renal disease (vitamin D-containing agents and calcium agents)

(2) Patients with hypersensitivity to this product and ingredients included in this product

(3) Infants under 3 months of age

(4) Infants under 1 year of age(minerals-containing agents)

(5) Hematochromatosis (a disease in which iron is deposited in the liver and pancreas due to iron metabolic abnormality), hemosiderinuria, and non-iron-deficiency anemia(iron-containing agents)

3) Administer carefully in the followings(consult with a doctor or a pharmacist before administration)

(1) Infants under 1 year of age (Vitamin A and D-containing agents)

(2) Patients receiving treatment of a doctor

(3) Avoid administration of vitamin D or calcium in children who see sunlight a lot and have normal meals.(Vitamin D and calcium-containing agents)

(4) Patients with hyperoxaluria (a condition that excessive amount of oxalate is excreted in the urine)(Vitamin C-containing agents)

(5) Pregnant women and lactating women (Vitamin A, C, D, E, and nicotinic acid-containing agents)

(6) Patients with gastric diseases such as peptic ulcer, chronic ulcerative colitis, regional colitis, etc. (iron-containing agents)

(7) Patients with heart and circulatory dysfunctions (minerals-containing

agents)

(8) Patients with renal diseases (minerals-containing agents)

(9) Patients with hypoproteinemia (minerals-containing agents)

4) Side Effects

(1) If the following symptoms occur because of administration of this product, stop taking the product and consult with doctors or pharmacists.(Describe side effects by mixing ingredients in each of the following items.)

① Vitamin A-containing agents: nausea, vomiting, pruritus, dry and bad skin, and painful arthredema
② Vitamin D-containing agents: nausea, vomiting, and diarrhea
③ Vitamin E-containing agents: abdominal discomfort, diarrhea, constipation, rash, and flare
④ Vitamin C-containing agents: nausea, vomiting, and diarrhea
⑤ Vitamin B_1-containing agents: nausea, vomiting, and loose feces
㉮ Diarrhea (Vitamin B_1-containing agents except thiamine salts, thiamine disulfide, and its salts),
㉯ stomatitis (agents containing fursultiamine)
⑥ Vitamin B_2 (riboflavin butyrate)-containing agents: nausea, anorexia, and abdominal inflation
⑦ Vitamin B_6(pyridoxal phosphate)-containing agents: nausea, anorexia, and abdominal inflation
⑧ Calcium-containing agents: constipation, hypotension, face flushing, irregular heartbeat, nausea, vomiting, and rash
⑨ Iron-containing agents: urticaria, pruritus, photohypersensitivity, abdominal and gastric pain, spasm, nausea, diarrhea, fever, coma
⑩ Zinc-containing agents: gastrointestinal disorders, indigestion, upper abdominal pain, nausea, hypotension, pulmonary edema, vomiting

(2) Because of the administration of this product, menstruation may be faster than expected or amount of menstruation may be gradually increased. Also, bleeding may continue longer. (Vitamin E-containing agents)

(3) Women who take oral contraceptives including estrogen or patients with thrombotic disposition take vitamin E, the risk of thrombosis may increase.(Vitamin E-containing agents)

(4) If you take this product at high dose for a long time, tolerance may be

generated.(Vitamin C-containing agents)

(5) If you take pyridoxine at 500 ㎎ ~ 2g per day for a long time, sensory neuropathy or neuropathy (peripheral sensory dysfunction or abnormal change) may occur. (Vitamin B_6–containing agents)

(6) If 10㎍ and more of vitamin B_{12} is administered in patients lack of folic acid daily, hematologic reactions may occur. (Vitamin B_{12}–containing agents)

(7) The high dose may promote a peptic ulcer and cause glucose tolerance impairment (dysfunction of metabolizing glucose in the body), hyperurisemia (a condition that uric acid is excessive in the blood), and liver damage.(nicotinamide, and nicotinic acid-containing agents)

(8) The administration of large amount may cause gastric symptoms such as nausea and vomiting and other symptoms including hypernatremia, congestive heart failure, edema, etc.(minerals-containing agents)

5) General Precautions

(1) Keep the determined dose and administration.

(2) When administering in children, administer under guidance and supervision of guardians.(agents of which children's dose is set)

(3) If symptoms are not improved in the administration of 1 month or more, consult with a doctor or a pharmacist.

(4) Take the product after consulting with a doctor, a Korean medicine doctor, and a pharmacist(herb medicine-containing agents)

(5) Use this product for only oral agents, and do not use it as injection(ample packaged liquid)

(6) Since vitamin A contained in this product is supplied in normal diet, the dose of adjuvant therapy should not exceed 5,000IU per day.(Vitamin A-containing agents)

6) Interaction

(1) If the products are concomitantly administered with aldosterone antagonists and triamterene, hyperkalaemia may be caused.

(minerals-containing agents)

(2) When this product is administered, do not administer the following drugs

① Phosphate, calcium salts, oral tetracycline agents, and antiacids (minerals-containing agents)

② Levodopa (pyridoxine-containing agents)

(3) Avoid teas containing tannin such as green tea and red tea during, before and after taking the products(minerals-containing agents)

7) Administration in Pregnant Women, Lactating Women, Premature Babies, and Infants

(1) Since there is a result of overseas epidemiologic survey that increase of deformity occurrence is assumed centered on head neural crest, etc. in babies born from women who take vitamin A 10,000 IU/day and more from 3 months before the beginning of the pregnancy to 3 months after the pregnancy, women who are within 3 months of the pregnancy or possible to be pregnant should not take this product except for the use in treatment of vitamin A deficiency. In addition, if this product is used for purpose of distributing vitamin A, be careful with the amount of ingestion from food, and vitamin A administration by this product should be less than 5,000 IU/day. (vitamin A-containing agents)

(2) Vitamin D may cause hypercalcemia in new born baby because it is excreted to breast milk. (vitamin D-containing agents)

(3) Do not administer in infants under 3 months of age

(4) Do not administer in infants under 1 year of age(minerals-containing agent)

8) Effect on Clinical Laboratory Tests

(1) It may bother detection of blood glucose in all kinds of urinalysis. (Vitamin C-containing agents)

(2) It may change the urine to brown to affect the clinical laboratory test results.(Vitamin B_2–containing agents)

9) Precautions in Storage

(1) Keep the product out of the reach of children.

(2) Avoid direct sunlight, and if possible, store airtightly in a less humid, cool place.

(3) Avoid misuse and abuse. To protect and maintain the quality, do not put the product in other containers.

<Table 1>

Item		Ingredient	Minimum Content per Day	Maximum Content per Day
Ⅰ (Vit.A)	1	Retinol Acetate (as Vitamin A) Retinol Palmitate (as Vitamin A) Vitamin A Oil (as Vitamin A)	500(IU)	2,000(IU)
	2	Liver Oil (as Vitamin A)	500(IU)	2,000(IU)
Ⅱ (Vit.D)		Ergocalcifero (as Vitamin D) Cholecalciferol (as Vitamin D)	50(IU)	200(IU)
Ⅲ (Vit.E)		dl-α-Tocopherol Acetate (as Vitamin E) d-α-Tocopherol Acetate (as Vitamin E) Succinic acid dl-α-Tocopherol (as Vitamin E) Succinic acid dl-α-Tocopherol calcium (as Vitamin E) Succinic acid d-α-Tocopherol (as Vitamin E) dl-α-Tocopherol (as Vitamin E) d-α-Tocopherol (as Vitamin E)	10(IU)	100(IU)
Ⅳ (Vit.B_1)		Thiamin hydrochloride Thiamin nitrate Thiamin disulfide (as Thiamin) Octotiamine Bisbentiamine (as Thiamin hydrochloride) Fursultiamine Fursultiamine hydrochloride (as Fursultiamine) Prosultiamine hydrochloride Benfotiamine (as Thiamin hydrochloride)	1	25(10) 25(10) 25(10) 25 25 25 25 25 25
Ⅴ (Vit.B_2)	1	Riboflavin Riboflavin sodium phosphate (as Riboflavin) Flavin adenine dinucleotide sodium (as Flavine adenine dinucleotide)	1	12
	2	Riboflavin butyrate(as Riboflavin tetrabutyrate)	2	12
Ⅵ (Vit.B_6)		Pyridoxine hydrochloride Pyridoxine phosphate	1	50 50
Ⅶ (Vit.B_{12})		Cyanocobalamin Hydroxocobalamin Hydroxocobalamin hydrochloride (as Hydroxocobalamin) Hydroxocobalamin acetate (as Hydroxocobalamin)	1(㎍)	60(㎍)

Ⅷ (Vit.C)		Ascorbic acid Sodium ascorbic acid (as Ascorbic acid) Calcium ascorbic acid (as Ascorbic acid)		50	500
Ⅸ	1	Sodium pantothenate Calcium pantothenate Dexpanthenol Panthenol		5 5 5 10	30 30 30 60
	2	Nicotinic acid Nicotine acid amid		10	100
	3	Biotin		10(㎍)	500(㎍)
Ⅹ	1	Calcium glycerophosphate (as Calcium) Precipitated calcium carbonate (as Calcium) Calcium gluconate (as Calcium) Calcium lactate (as Calcium) Dibasic calcium phosphate hydrate (as Calcium) Anhydrous dibasic potassium phosphate (as Calcium)		30 30 30 30 30 30	300 300 300 300 300 300
	2	Ursodesoxycholic acid		10	30
	3	ɣ-Orizanol		5	10
	4	Orotic acid		60	200
	5	Sulfuric acid		180	600
	6	L-Cysteine L-Cysteine hydrochloride		30	120
Ⅹ	7	Glucuronolactone Glucuronamide		200 200	1,000 1,000
	8	Inositol		20	60
Ⅺ	1	White ginseng	Extract (amount of original herbal medicine)	0.6(g)	3(g)
			Powder	0.3(g)	1.5(g)
	2	Garlic	Extract	20	200
(Note) The values in ( ) among the maximum amount or minimum amount per day refer to one-time maximum or minimum amounts, respectively.					

<Table 2>

Item	Ingredient	Maximum Content per Day
Iron	Ferric Ammonium Citrate (as Iron) Ferrous Fumarate (as Iron) Ferrous Heptogluconate (as Iron) Soluble Ferrous(ferric) pyrophosphate (as Iron) Ferrous succinate (as Iron) Ferrous sulfate dried (as Iron) Beta ferrous phosphate (as Iron) Ferrous gluconate (as Iron) Ferritin extractive (as Iron) Ferric hydroxide polymaltose complex (as Iron) Ferrous aminoacetosulfate (as Iron) Ferrocholinate (as Iron)	12
Phosphorus	Calcium phosphate (as Phosphorus) Calcium hydrogen phosphate (as Phosphorus) Monobasic Calcium Phosphate (as Phosphorus) Potassium phosphate dibasic (as Phosphorus) Potassium dihydrogenphosphate (as Phosphorus)	700
Zinc	Zinc oxide (as Zinc) Zinc sulfate (as Zinc) Zinc lactate (as Zinc)	15

Chapter 6 Standard Manufacturing Practice of Nutrients, Tonic and Alternatives

1. Scope

This practice is applied to the internal liquid medicine as nutrients, tonic and alternatives in accordance with Subparagraph 2 Item H of the Designation of Scope of Quasi-drugs (MFDS Notification). However, if an ingredient exceeding the maximum content for a day is contained, or the composed prescription is the same as Chapter 1 Standard Manufacturing Practice of Vitamin, Minerals, etc. in Attached Table 1 of Standard Manufacturing Practice of Pharmaceuticals (MFDS Notification), the criteria in Attached Table 1 in Chapter 1 will be applied.

2. Practice

1) Types of Mixing Ingredients

(1) The essential mixing ingredients should be one or more ingredients in Item Ⅰ Subparagraph 1 or 3 in <Table 1> and Item Ⅱ ingredients in <Table 1> or herbal ingredients Item I Subparagraph 1 in <Table 2>, and ingredients available for mixing should be Item I Subparagraph 4 in <Table 1> or Item Ⅲ in <Table 1> and Item I Subparagraph 2 or Subparagraph 5 in <Table 2>.

(2) Among the mixing ingredients in <Table 1>, the mixing of the mixing ingredients in each item should be 1 type in the same subparagraph.

(3) When herb medicine will be mixed by <Table 2>, the prescription by Herbal Medicine Book in accordance with the Regulation on Pharmaceuticals Approval, Notification and Review should not be cited.

(4) In addition to the mixture by <Table 1> and <Table 2>, the prescription by item described in <Table 3> may be applied. The specifications should be the ones specified in the Official Compendium and National Drug Formulary Recognized by the Minister of MFDS. However, the specifications of domestic nutrients, tonic and alternatives are also recognized.

2) Content of Mixing Ingredients

(1) The daily minimum and maximum contents of the mixing ingredients in <Table 1> should be the amounts described in <Table 1>.

(2) The daily maximum content of herbal medicine in <Table 2> should be the amount described in <Table 2>. However, this amount should be indicated as the amount of original herbal medicine or fluid extracts (extracts) or powder applicable to the amount of original herbal medicine.

(3) The lower limit of mixing amount of herbal medicine should be 1/10 of daily maximum content.

(4) The item prescription in <Table 3> should be the ones combining all ingredients described in each item in <Table 3> by applicable contents.

3) Dosage Form: Internal liquid medicine

4) Dose and Administration

(1) The dose and administration of the agents mixed by combining the ingredients in <Table 1> and <Table 2> are as follows. Take the product within the range of 1 ~ 3 times a day for adults. The dose and administration for children under 14 years of age is not approved.

(2) The dose and administration of drugs according to prescription by item in <Table 3> are as follows.

Adults at age of 15 and older: Take 1 bottle once a day. Children under 15 years of age should not take it.

5) Efficacy and Effects

The efficacy and effects of the agents mixed by combining the ingredients in <Table 1> and <Table 2> are as follows. However, for the agents in accordance with prescription by item in <Table 3>, describe efficacy and effects by prescription in <Table 3>.

(1) Nutritions and tonic

(2) Weak constitution

(3) Nutritional supply for physical fatigue, during and after disease, and

pyrogenic wasting diseases

6) Storage Method and Validity (Effective) Period

(1) Storage Method: Avoid direct sunlight and store in an airtight container at dry place under the room temperature.

(2) Validity (Effective) Period: The validity (effective) period should be not more than 3 years, but comply with Article 16 Paragraph 2 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

3. Precautions in Use

1) Do Not Administer in the Following Patients

(1) Patients with hypersensitivity to this product and ingredients included in this product

(2) Infants under 3 months of age (however, for the agents from the prescription by item in <Table 3>, 'children under 15 years of age' will be included

(3) Since there is an overseas report that side effects such as asthma and serious allergic symptoms occurred due to the use of agents containing royal jelly, patients with asthma and allergy should not take this product (royal jelly-containing agents)

2) Administer Carefully in the Following Patients (Consult with doctors or pharmacists before taking the product)

(1) Infants under 1 year of age (however, this is only applied to the agents mixed by combining the ingredients in <Table 1> and <Table 2>

(2) Patients receiving treatment of a doctor

3) Side Effects

(1) If the following symptoms occur because of the administration of this product, stop taking it and consult with doctors or pharmacists. When consulting with them, bring this attached document if possible: (Describe

side effects by mixing ingredients in each of the following items)

① Vitamin B_1-containing agents: nausea, vomiting, and loose feces, ㉮ stomatitis(agents containing fursultiamine) ② Vitamin B_2(riboflavin butyrate)-containing agents: nausea, anorexia, and abdominal inflation ③ Vitamin B_6(pyridoxal phosphate)-containing agents: nausea, anorexia, and abdominal inflation ④ Prescription No. 7 Agents in <Table 3>: Rash

(2) If you take pyridoxine at 500 ㎎ ~ 2g per day for a long time, sensory neuropathy or neuropathy (peripheral sensory dysfunction or abnormal change) may occur. (Vitamin B_6–containing agents)

(3) If 10㎍ and more of vitamin B_{12} is administered in patients lack of folic acid daily, hematologic reactions may occur. (Vitamin B_{12}–containing agents)

(4) The high dose may promote a peptic ulcer and cause glucose tolerance impairment (dysfunction of metabolizing glucose in the body), hyperurisemia (a condition that uric acid is excessive in the blood), and liver damage.(nicotinamide, and nicotinic acid-containing agents)

4) General Precautions

(1) Keep the determined dose and administration.

(2) When administering in children, administer under guidance and supervision of guardians.

(3) If symptoms are not improved in the administration of 1 month or more, consult with doctors or pharmacists.

(4) When taking the product, consult with doctors, Korean medicine doctors, and pharmacists (herbal medicine-containing agents)

(5) Use this product for only oral agents, and do not use it as injection.

(6) Because this drug is herbal extract mixture, precipitation may occur sometimes, but efficacy will not be changed. Shake it well and take it (herbal extract mixing agents)

(7) When shaking to mix, sustained matter occurs. Since this is caused by the ingredients contained in ginseng extracts, do not worry about it.

(ginseng extracts-containing agents)

(8) If th is drug is administered excessively, patients with depression would be even more depressed. Do not exceed 500 mg as caffeine for one-time dose. (Caffeine-containing agents)

5) Effects on Clinical Laboratory Tests

It may change urine to brown color to affect the clinical laboratory test results. (Vitamin B_2–containing agents)

6) Precautions in Storage

(1) Keep the product out of the reach of children.

(2) Avoid direct sunlight, and if possible, store airtightly in a less humid, cool place.

(3) Avoid misuse and abuse. To protect and maintain the quality, do not put the product in other containers.

<Table 1>

Item		Ingredient	Daily Dose (mg)		Remarks
			Min	Max	
Ⅰ	1	Thiamin hydrochloride Thiamin nitrate Fursultiamine Prosultiamine	1 1 5 5	30 30 100 100	
	2	Riboflavin Riboflavin sodium phosphate	2 2	30 30	as Riboflavin
	3	Pyridoxine hydrochloride Pyridoxal phosphate	1 1	100 60	
	4	Cynocobalamin Hydroxocobalamin Hydroxocobalamin hydrochoride Hydroxocobalamin acetate Cobamamide	1(㎍)	60(㎍)	as Hydrocobalamin
	5	Sodium pantothenate Calcium pantothenate Dexpanthenol Panthenol	5 5 5 10	30 30 30 60	
	6	Nicotinic acid Nicotinic acid amide	10 10	100 100	
	7	Inositol	20	60	
	8	γ-Orizanol	5	10	
Ⅱ	1	Lysine hydrochloride	50	500	
	2	L-Leucine	10	100	
	3	L-valine	10	100	
	4	Aminoacetic acid	20	200	
	5	L-Isoleucine	10	100	
	6	L-Threonine	10	100	
	7	L-Tryptophan	10	100	
	8	Phenylalanine	10	100	
	9	L-Cysteine L-Cysteine hydrochloride	30 30	120 120	
	10	Hydrochloride-L-Arginine	10	100	
	11	Hydrochloride-L-Histidine	10	100	
	12	DL-Methionine L-Methionine	10 10	100 100	
Ⅲ	1	Aminoethyl sulfonic acid (taurine)	100	1,000	
	2	Glucuronolactone Glucuronic acid amide	20 20	200 200	

<Table 2>

Item		Ingredient	Maximum Dose per Day (g)	
			Extract (Converted Amount of Original Herbal Medicine)	Powder
ㅣ	1	White ginseng Red ginseng Root hair of ginseng	3	1.5
	2	Royal jelly	200(mg)	-
	3	Milk vetch root White atractylis Licorice Polygonatum	0.9 0.6 0.3 0.9	0.3 0.24 0.1 0.28
	4	Cistanche deserticola Epimedium koreanum	0.6 0.6	0.24 0.24
	5	Dried orange peel Chinese magnolia vine Betony Cnidium Poncirus Korean angelica Chinese matrimony vine Wilfordi root Peony Cinnamon Chinese bellflower Garlic Garlic extracts	0.6 0.15 0.8 0.1 0.6 0.9 0.6 0.9 0.9 0.3 0.3 2 -	0.36 0.11 0.3 0.07 0.24 0.28 0.24 0.28 0.28 0.06 0.1 - 0.2

<Table 3>

Prescription No.	Ingredient	Amount in 1 bottle(mg)	Efficacy and Effects
1	Aminoethyl sulfonic acid (taurine) Inositol Nicotinic acid amide Thiamine nitrate Riboflavin sodium phosphate Pyridoxine hydrochloride Anhydrous caffeine	2,000 50 20 5 5 5 30	Physical fatigue, physical decline after disease, anorexia, nutritional disorder, nutritional supply in pyrogenic and wasting diseases, invigorating vital energy, and constitutional weakness
2	Aminoethyl sulfonic acid (taurine) Inositol Nicotinic acid amid Thiamine nitrate Riboflavin sodium phosphate Pyridoxine hydrochloride Anhydrous caffeine DL-Carnitine hydrochloride	1,000 50 20 5 5 5 30 100	Invigorating vital energy, constitutional weakness, physical fatigue, physical decline after disease, anorexia, and nutritional disorder
3	Aminoethyl sulfonic acid (taurine) Nicotinic acid amide Thiamine nitrate Riboflavin sodium phosphate Anhydrous caffeine Raw royal jelly Calcium pantothenate Glucuronolactone	500 20 10 2 30 100 10 200	Invigorating vital energy, constitutional weakness, and fatigue recovery
4	Aminoethyl sulfonic acid (taurine) Inositol Nicotinic acid amide Thiamine nitrate Riboflavin sodium phosphate Pyridoxine hydrochloride Anhydrous caffeine DL-Carnitine hydrochloride	2,000 50 20 5 5 5 30 100	Invigorating vital energy, physical fatigue, constitutional weakness, physique decline after disease, anorexia, nutritional disorder, nutritional supply in pyrogenic and wasting diseases, pregnancy, and lactating period

5	Aminoethyl sulfonic acid (taurine) Nicotinic acid amide Thiamine nitrate Calcium pantothenate Glucuronolactone Caffeine hydrate	1,000 10 10 10 100 30	Invigorating vital energy and fatigue recovery
6	Nicotinic acid amide Thiamine nitrate Riboflavin sodium phosphate Pyridoxine hydrochloride Anhydrous caffeine Raw royal jelly Epimedium koreanum 10% ethanol fluid extracts Ginseng 70% ethanol fluid extract	30 5 5 5 30 100 100 (㎕) 600 (㎕)	Pyrogenic and wasting diseases, physical fatigue, anorexia during and after diseases, nutritional disorder, nutritional supply before or after pregnancy, invigorating vital energy, and constitutional weakness
7	Nicotinic acid amide Riboflavin sodium phosphate Pyridoxine hydrochloride Raw royal jelly Caffeine hydrate Epimedium koreanum extracts Garlic extracts Ginseng extract	25 5 10 50 30 100 200 45	Invigorating vital energy, constitutional weakness, physical fatigue, physical decline after disease, anorexia, nutritional disorder, pyrogenic and wasting diseases, and nutritional supply in pregnancy or lactating period
8	Aminoethyl sulfonic acid (taurine) Nicotinic acid amide Thiamine nitrate Riboflavin sodium phosphate Pyridoxine hydrochloride Anhydrous caffeine	500 10 10 5 5 30	Invigorating vital energy, constitutional weakness, nutritional supply in physical fatigue, nutritional disorder, during and after disease, anorexia, pyrogenic and wasting diseases, pregnancy and lactating period

Chapter 7 Standard Manufacturing Practice of Hair Removal Agents

< Omission of translation >

Chapter 8 Standard Manufacturing Practice of Stomachic Digestive Adjuvant

1. Scope

This practice is applied to quasi-drugs which show efficacy and effects of stomachic digestive adjuvant.

2. Criteria

The criteria of stomachic digestive adjuvant are as follows. However, the ones not adequate to the criteria should be reviewed individually by the data on safety, efficacy and mixing reasons as pharmaceuticals.

1) Type and Content of Active Ingredient

(1) The prescription by item should be limited to <Table 1>, and the specification should be the ones specified in the KP and the National Drug Formulary notified by the Minister of MFDS. However, regarding the specifications of herbal medicine extracts, the specifications of domestic stomachic digestive adjuvants are also recognized.

2) Dosage Form: Internal liquid medicine.

3) Dose and Administration

The dose and administration described in <Table 1>.

4) Efficacy and Effects

The efficacy and effects that may be described by prescription number in <Table 1> are as follows.

Classification	Efficacy and Effects
1, 4	Digestive disorder, excessive drinking, overeating, dyspepsia (indigestion), stomachache, nausea, vomiting, anorexia (loss of appetite), abdominal inflation
2~3, 5~6, 8~10	Anorexia (loss of appetite), abdominal inflation, digestive disorder, overeating, dyspepsia (indigestion), stomachache, nausea, vomiting, anorexia (loss of appetite), nausea, vomiting
7	Anorexia (loss of appetite), abdominal inflation, digestive disorder, overeating, dyspepsia (indigestion), nausea, vomiting, gastric stasis, chest pain, chest stasis

3. Precautions in Use

1) The following persons should consult with doctors, dentists, and pharmacists before taking (using) this product

(1) Infants under 30 months of age (Agents No. 1, 4, and 7 in prescription No. in <Table 1>)

(2) Patients taking other drugs

(3) Do not administer this product in infants under 3 months of age. In addition, if infants are older than 3 months, infants under 1 year of age should receive treatment of a doctor first. Unless it's absolutely necessary, it is desirable not to take this product.

2) Administer carefully in the following patients

(1) Children (Spasm may be caused.)(Agents No. 4 and 7 in prescription No. in <Table 1>)

3) Other Precautions in Administration (Use) of this Product

(1) Keep the determined dose and administration.

(2) When administering in children, administer under guidance and supervision of guardians.

(3) If symptoms are not improved in the administration of several days, stop taking this product and consult with doctors or pharmacists. (Agents containing 40㎎ and more of glycyrrhizinate or 1 g and more of licorice in the maximum mixing amount per day)

(4) If symptoms are not improved in the administration of 2 weeks (the agents composed of only herbal medicine, 2 weeks may be changed to 1 month), stop taking this product and consult with doctors or pharmacists.

4) Precautions in Storage: Describe temperature, humidity, ray, etc. in detail within the range of storage approved and notified for the product, and describe general precautions in each item according to the characteristics of agents.

(1) Keep the product out of the reach of children

(2) If you take out the product from the original container and store in another container, it may be the reason of generation of accident by misuse or quality deterioration. Thus, you must keep the product in the original container and close the cover

<Table 1>

Prescription No.	Ingredient	Dose per one-time dosage (unit)	Dose and Administration
1	Ginger Cinnamon l-menthol Cardamon Catechu Chili pepper	250 mg 400 mg 2.5 mg 50 mg 66.67 mg 25 mg	Adults 1 bottle (75 mL) at a time. Take 3 times a day after meals.
2	Ginseng fluid extract dl-Carnitine hydrochloride Cinnamon fluid extract Ginger fluid extract Clove tincture	0.3 mL 150 mg 0.5 mL 0.15 mL 0.5 mL	Adults: 1 bottle (75mL) at a time. Children: At a time 11 ~ 14 years old 2/3 bottle (50mL), 8 ~ 10 years old 1/2bottle (40mL), 5 ~ 7 years old 1/3 bottle (25mL), 3 ~ 4 years old 1/4 bottle (20mL), 1 ~ 2 years old 1/5 years old (15mL) Take twice a day after meals. The administration interval should be not less than 4 hours.

3	Cinnamon, catechu, cardamon, chili soft extract (5→1) l-menthol	62.4 mg 10 mg	Adults aged 15 and older: 1 bottle (75mL) at a time. 11 ~ 15 years old: 2/3 bottle at a time, 8 ~ 11 years old: 1/2 bottle at a time, 5 ~ 8 years old: 1/3 bottle at a time, 3 ~ 5 years old: 1/4 bottle at a time, 1 ~ 3 years old: 1/5 bottle at a time, 3 months ~ 1 year old: 1/10 bottle at a time. Take 3 times a day after meals.
4	Cinnamon, catechu, cardamon, and chili 50% ethanol soft extract	26 mg	Adult 1 bottle (75mL) at a time. Take 3 times a day after meals.
5	Cinnamon Ginger Catechu Cardamon Chili pepper l-menthol	400 mg 250 mg 50 mg 50 mg 25 mg 2.5 mg	Adult 1 bottle (75mL) at a time. Take 3 times a day after meals.
6	Dried orange peel 30% ethanol soft extract (5:1) dl-Carnitine hydrochloride Cinnamon 70% ethanol tincture Ginger 70% ethanol tincture Ginseng 30% ethanol dried extract	20 mg 150 mg 0.25 mL 0.225 mL 20 mg	Adults: 1 bottle (75mL) at a time. Children: 11~14 years old 50mL, 8~10 years old 40mL, 5~7 years old 25mL, 3~4 years old 20mL, 1~2years old 15mL, 3 months~1 year old 7.5mL at a time. Take twice a day. The administration interval should be not less than 4 hours.
7	Dried orange peel 30% ethanol soft extract(5:1) dl-Carnitine hydrochloride Fennel 70% ethanol tincture (1:5) Cinnamon 70% ethanol tincture (1:5) Ginseng thin ethanol dried extract (7:1)	25 mg 150 mg 0.5 mL 0.5 mL 20 mg	Normal twice a day 1 bottle (75mL) at a time for adults, The administration interval should be not less than 4 hours.

8	dl-Carnitine hydrochloride Ginseng dried extract (20→3) Ginger tincture (1→5) Cinnamon tincture (1→5) Dried orange peel soft extract (5→1)	150 mg 20 mg 0.225 mL 0.250 mL 20 mg	Adults: 1 bottle (75mL) at a time. Children: At a time 11 ~ 14 years old 2/3 bottle (50mL), 8 ~ 10 years old 1/2 bottle (40mL), 5 ~ 7 years old 1/3 bottle (25mL), 3 ~ 4 years old 1/4 bottle (20mL), 1 ~ 2 years old 1/5 bottle (15mL), 3 months ~ 1 year old 1/10 bottle (7.5mL) Take twice a day. The administration interval should be not less than 4 hours.
9	Ginger Cinnamon l-menthol dried orange peel	0.5 g 0.5 g 4 mg 1 g	Adults: 1 bottle (75mL) at a time. Children: At a time 11 ~ 14 years old 2/3 bottle (50mL), 8 ~ 10 years old 1/2 bottle (40mL), 5 ~ 7 years old 1/3 bottle (25mL), 3 ~ 4 years old 1/4 bottle (20mL), 1 ~ 2 years old 1/5 bottle (15mL) Take 3 times a day after meals.
10	Ginger tincture Cinnamon tincture dl-Carnitine hydrochloride Ginseng dried extract Dried orange peel soft extract	225 μℓ 250 μℓ 150 mg 20 mg 20 mg	Adults: 1 bottle (75mL) at a time. Children: At a time 11 ~ 14 years old 50mL, 8 ~ 10 years old 40mL, 5 ~ 7 years old 25mL, 3 ~ 4 years old 20mL, 1 ~ 2 years old 15mL, 3 months old ~ 1 year old 7.5mL Take twice a day. The administration interval should be not less than 4 hours.

Chapter 9 Standard Manufacturing Practice of Intestinal Drugs

1. Scope

This practice is applied to the quasi-drugs that show efficacy and effects of intestinal drugs.

2. Practice

The criteria of intestinal drugs are as follows.

1) Type and Content of Active Ingredients

(1) The prescription by item should be limited to the ones described in <Table 1>, and the specifications should be the ones be the ones specified in the KP and the Official Compendium and National Drug Formulary notified by the Minister of MFDS. However, in terms of vitamin specifications, to increase the stability, separate specifications that are used in the domestic pharmaceuticals and quasi-drugs are also recognized. For the specifications of herbal medicine extracts, the specifications for domestic intestinal drugs are also recognized.

(2) When describing the ingredients of intestinal viable cells in the ingredient content column, describe in mg or g. The product specifications should be described with the intestinal viable cell count.

2) Dosage Form

Dosage form described in <Table 1>.

3) Dose and Administration

The dose and administration described in <Table 1>.

4) Efficacy and Effects

The efficacy and effects that may be described by prescription No. in <Table 1> are as follows.

Prescription No.	Efficacy and Effects
1~8	Digestion, abdominal inflation, constipation, loose feces (including intestinal abnormal fermentative symptoms)
9	Digestive disorder, anorexia (loss of appetite), overeating, indigestion (dyspepsia), digestion stimulation, stomach inflation due to digestive disorder, digestion, loose feces, constipation, abdominal inflation

3. Precautions in Use

1) Administer carefully in the following patients.

(1) Patients receiving treatment of a doctor

(2) Patients taking other drugs

2) General Precautions

(1) Keep the determined dose and administration.

(2) When administering in children, administer under guidance and supervision of guardians.

(3) If symptoms are not improved in the administration of 2 weeks or 1 month, stop taking this product and consult with doctors or pharmacists.

3) Administration in Children

(1) When administering in infants under 3 months of age, consult with pharmacists or doctors.

(2) Do not administer this drug in infants and you children under 7 years of age.(Agent No. 9 in prescription No. in <Table 1>)

4) Precautions in Storage

(1) Keep the product out of the reach of children.

(2) Avoid direct sunlight, and store airtightly in a less humid, cool place.

(3) To prevent misuse and maintain the quality, do not put the product in another container.

<Table 1>

Prescription No.	Dosage Form	Ingredient	Content in 1 tablet or 1 capsule (Unit)	Dose and Administration
1	Tablet/ Capsule	Clostridium butyricum miyairi II-588	30 mg	Take 3 times a day after meals. Adults: 2~4 tabs(caps) at a time. Children: At a time 11~14 years old 1~3 tabs(caps), 8~10 years old 1~2 tabs(caps)
2	Tablet	Clostridium butyricum miyairi II-588 Thiamine nitrate	30 mg 0.5 mg	Take 3 times a day after meals. Adults: 2~4 tabs at a time. Children: At a time 11~14 years old 1~3 tabs, 8~10 years old 1~2 tabs
3	Tablet	Clostridium butyricum miyairi II-588 Ursodeoxycholic acid	50 mg 10 mg	Take 3 times a day after meals Adults: 2 tabs at a time. Children: At a time 11~14 years old 4/3 tabs, 8~10 years old 1 tab
4	Powder	Clostridium butyricum miyairi II-588	60 mg	Take 3 times a day after meals. Adults: 1~2g at a time. Children: At a time 11~14 years old: 0.7~1.3g 8~10 years old: 0.5~1.0g 5~7 years old: 0.300.6g 3~4 years old: 0.3~0.5g 1~2 years old: 0.2~0.4g 3 months~1 year old: 0.1~0.2g
5	Tablet	Lactobacillus bifidus Streptococcus faecalis Lactobacillus acidophilus	2 mg 2 mg 2 mg	Take 3 times a day after meal. Adults: 3 tabs at a time. Children: 8~14 years old 2 tabs at a time, take 3 times a day after meals.
6	Tablet	Lactobacillus acidophilus Streptococcus faecalis Lactobacillus bifidus Shinbiofermin-S powder for tablet	2 mg 2 mg 2 mg 220 mg	Take 3 times a day after meal. Adults: 3 tabs at a time. Children: 8~14 years old 2 tabs at a time.

7	Powder	Lactobacillus bifidus Streptococcus faecalis Lactobacillus acidophilus	6 mg 6 mg 6 mg	Take 3 times a day after meal or combined with water, milk, baby food, etc. Adults: 3 packs at a time. Children: 5~14 years old 2/3g, 3 months~4 years old 1/3g at a time.
8	Tablet	Butyric acid bacteria powder Bacillus natto power (digestive bacteria powder) Streptococcus faecalis (lactic acid bacteria powder)	22.2 mg 5.6 mg 11.0 mg	Adult 3 tabs at a time. Take 3 times a day after meals.
9	Tablet	Clostridium butyricum miyairi II-588 Diasman SS Pancreatin Pholipase 1000(fat digestion enzyme powder) Cellulase AP3I	50.00 mg 6.67 mg 26.67 mg 25.00 mg 2.50 mg	Take 3 times a day after meals. Adults: 2 tabs at a time. Children: 8~14 years old 1 tab at a time.

Note) For prescriptions 4 and 7, the content of 1 pack

Chapter 10 Standard Manufacturing Practice of Cataplasma

1. Scope

This practice is applied to cataplasma agents which are applied to the skin as external use for purpose of anti-inflammation.

2. Criteria

The standard manufacturing practice of cataplasma agents is as follows.

1) Type and Specification of Mixing Ingredients

(1) The type and specifications of available effective ingredients are described in <Table 1>, and the ingredients should be mixed by the prescription in item Ⅰ or Ⅱ. The specifications should be the ones be the ones specified in the KP and the Official Compendium and National Drug Formulary notified by the Minister of MFDS. However, the specifications of domestic cataplasma agents which are already used are also recognized.

(2) Regarding additives, comply with Article 9 Paragraphs 3 and 5 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification), but if new additives of which examples of use in Korea do not exist are used, they must be adequate for Article 21 Paragraph 2 of the same notification.

2) Content of Mixing Ingredients

The content and concentration of mixing ingredients should be the amounts described in <Table 1>.

3) Dosage forms should be cataplasma agents.

4) Dose and Administration

Apply the product to the affected area once or twice a day.

5) Efficacy and Effects

Anti-inflammation of the following symptoms: Sprain, bruise, muscle pain, arthralgia, fracture pain, backache, shoulder discomfort, neuralgia, rheumatalgia

6) Storage Method and Validity (Effective) Period

(1) Storage Method: Light-shielded airtight container

(2) Validity (Effective) Period: The validity (effective) period should be not more than 3 years, but comply with Article 16 Paragraph 2 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification) determined by the Minister of MFDS.

3. Precautions in Use

1) Do not use in the following patients (areas)

(1) Infants under 30 months of age

(2) Dermatitis caused by eczema, lacquer, etc. and wounded areas

2) Administer carefully in the following patients

(1) Patients who have shown allergic symptoms caused by drugs or cosmetics (e.g. rash, flare, pruritus, dermatitis caused by lacquer, etc.)

(2) Patients themselves or family members with allergic constitution

(3) Patients with serious wetting or erosion (maceration)

(4) Patients receiving treatment of a doctor

(5) Children (spasm may be caused)

3) Side Effects

(1) If symptoms such as rash, flare (swelling), pruritus, etc. occur due to use of this product, stop using it and consult with pharmacists or doctors.

(2) If serious pruritus or pain occasionally occurs due to use of this product, stop using it.

4) General Precautions

(1) Keep the determined dose and administration.

(2) When administering in children, administer under guidance and supervision of guardians.

(3) If symptoms are not improved in the administration of 5 − 6 days, stop using this product and consult with pharmacists or doctors.

5) Precautions in Application

(1) Use this drug only for external use.

(2) Do not warm the applied diseased area with circuit or electric blanket, etc.

6) Precautions in Storage

(1) Keep the product out of the reach of children.

(2) Avoid direct sunlight, and store airtightly in a less humid, cool place.

(3) To prevent misuse and maintain the quality, do not put the product in another container.

<Table 1>

Ingredient	Specification	Content (In 1 sheet 10 × 14cm^2, in 17.5g)	
		I	II
l-menthol	KP	49.4 mg	-
Thymol	KP	16.5 mg	-
dl-camphor	KP	82.4 mg	131.8 mg
Nonulic acid vanillylamide	-	-	8.2 mg
Peppermint oil	KP	164.7 mg	98.8 mg
Eucalyptus oil	KP	16.5 mg	32.9 mg

KP: Korean Pharmacopoeia

Chapter 11 Standard Manufacturing Practice of Dermatologic Ointment

1. Scope

This practice is applied to dermatologic ointments defined by the Designation of Scope of Quasi-drugs (MFDS Notification).

2. Criteria

The criteria for dermatologic ointment are as follows.

1) Type, Content, and Specification of Effective Ingredients

The types, contents and specifications of available ingredients are the ones described in <Table 1>.

2) As the available additives, the raw materials specified in the KP and the Official Compendium and National Drug Formulary notified by the Minister of MFDS may be used. In terms of other details, comply with the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

3) Dosage form is ointment.

4) Dose and Administration

The dose and administration by prescription No. in <Table 1> are as follows.

Prescription No.	Dose and Administration
1	Apply in the diseased area once or twice a day.
2	Apply the product in the diseased area once to several times a day.

5) Efficacy and Effects

The efficacy and effects by prescription No. in <Table 1> are as follows.

Prescription No.	Efficacy and Effects
1	Assistant partial treatment of wound and skin ulcer
2	- Anti-inflammation of the following symptoms: sprain, bruise, muscle pain, arthralgia, fracture pain, backache, shoulder discomfort, neuralgia, rheumatalgia - Itching skin and insect bite - Chilblain

6) Precautions in Use

The precautions in use by prescription No. in <Table 1> are as follows.

Prescription No.	Precautions in Use
1	1. Do not use this drug in the following persons (cases). 1) Patients with hypersensitivity to this drug and composing ingredients of this drug 2) The second-infected wound 3) Do not use this drug for ophthalmology 2. General precautions 1) Do not exceed the recommended dose.
2	1. Do not administer in the following patients (areas). 1) Infants under 30 months of age 2) Areas around eyes, mucous membrane, etc. 3) Dermatitis caused by eczema, lacquer, etc. and wounded areas 2. Administer in the following patients carefully. 1) Patients who have shown allergic symptoms caused by drugs or cosmetics (e.g. rash, flare, pruritus, dermatitis caused by lacquer, etc.) 2) Patients themselves or family members with allergic constitution 3) Patients with serious wetting or erosion (maceration) 4) Patients receiving treatment of a doctor 5) Children (spasm may be caused) 3. Side Effects If symptoms such as rash, flare, pruritus, etc. occur due to use of this drug, stop using it and consult with pharmacists or doctors. 4. General Precautions 1) Keep the determined dose and administration. 2) When administering in children, administer under guidance and supervision of guardians.

	3) If symptoms are not improved in the administration of 5 − 6 days, stop using this product and consult with pharmacists or doctors. 5. Precautions in Application 1) Use this drug only for external use. Do not use it for internal use. 2) Be careful that the product should not come in the eyes. If it enters the eyes, wash the eyes with water immediately. If the symptom is severe, receive treatment from an ophthalmologist. 6. Precautions in Storage 1) Keep the product out of the reach of children. 2) Avoid direct sunlight, and store airtightly in a less humid, cool place. 3) To prevent misuse and maintain the quality, do not put the product in another container.

7) Storage and Validity (Effective) Period

(1) Storage Method: Airtight container, room temperature

(2) Validity (effective period): The validity (effective) period should be not more than 3 years, but comply with the provisions in the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification) determined by the Minister of MFDS.

<Table 1>

Prescription No.	Ingredient	Specification	Content (%)
1	Titrated extract of centella	KHP	1.0
2	L-Menthol	KP	0.8
	DL-Camphor	KP	5.9
	Methyl salicylate	KP	4.6

KHP: Korean Herbal Pharmacopoeia(MFDS Notification)

KP: Korean Pharmacopoeia

Chapter 12 Standard Manufacturing Practice of Contact Lens Cleaning Solution

1. Scope

This practice is applied to the contact lens cleaning solution used for cleaning, maintenance, disinfection, rinsing, and other methods similar to them to manage contact lenses.

2. Criteria

The standard manufacturing practice of contact lens cleaning solution is as follows.

1) Types, Specifications, and Mixing Concentrations of Effective Ingredients

The types, specifications, and mixing concentrations of the available effective ingredients are described in <Table 1>. Also, they must be in pH range 5.5 ~ 8.0.

2) Dosage Form

The dosage form is liquid formulation.

3) Efficacy and Effects

Efficacy and effects are described in <Table 2>.

4) Dose and Administration

The dose and administration are described in <Table 3>.

5) Precautions in Use

The precautions in use are described in <Table 4>.

6) Storage Method and Validity (Effective) Period

The product should be stored in an airtight container. The validity (effective)

period should be not more than 3 years, but it should comply with Article 15 Paragraph 2 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

<Table 1>

Type, Specification, and Mixing Concentration of Effective Ingredients

Item	Ingredient	Specification	Mixing Concentration (w/v%)
I	Sodium chloride	KP	0.42 ~ 0.9
II	Poloxamer 338	NF	6
III	Poloxamer 407	NF	10 ~ 15

<Table 2>

Efficacy and Effects

Item	Ingredient	Efficacy and Effects Note)
I	Sodium chloride	Rinsing contact lenses, and rinsing after heat disinfection, and chemical disinfection
II	Poloxamer 338	Cleaning of contact lenses
III	Poloxamer 407	Cleaning of contact lenses

※ Note) Depending on the characteristics of agents, the type of contact lens (soft contact lens or hard contact lens) may be described in detail.

<Table 3>

Dose and Administration

1. < Ⅰ > Contact Lens Cleaning Solution Of Which Effective Ingredient is Sodium Chloride

1) Rinsing: Before wearing and disinfecting lenses, clean the lenses with the lens cleaner, and rinse with this product.
2) Rinsing after heat disinfection and chemical disinfection: After heat disinfection and chemical disinfection, rinse the disinfectant solution with this product completely.

2. <Ⅱ, Ⅲ> Contact Lens Cleaning Solution Of Which Effective Ingredient is Poloxamer 338, 407

Put the lens on the palm, drop 3 ~ 4 drops of the solution on both sides of the lens, and then scrub the lens to wipe it for about 30 seconds using the index finger of the opposite hand, or scrub for about 30 seconds between the thumb and index finger. After wiping it enough, rinse both sides of the lens with saline or purified water.

<Table 4>

Precautions in Use

1. Warning
1) Do not use the product for other purposes than management of contact lenses.
2) If there are problems in contact lenses and lens management products, they may cause serious disorders in the eyes. To use the lenses and lens management products in appropriate ways, it is essential to following the direction of medical specialists and all directions described in the manual. Visual acuity may be caused rapidly because of problems in eyes including keratohelcosis. Thus, if you are uncomfortable with you eyes, or excessive tears, blunt visual acuity, or inflamed eyes occur, remove the lenses immediately and consult with medical specialists.
3) If you administer eye drops while wearing contact lenses, consult with medical specialists in advance.
4) Do not use it for injection solution.(Agents of which effective ingredient is sodium chloride)

2. Do not administer in the following patients.
Persons who show hypersensitivity to this solution

3. Side Effects

Problems including eye irritation, ㅠburning sensation, pruritus, sense of stimulation, more discomfort than wearing contact lenses for the first time, foreign body sensation, excessive tears, abnormal tear fluid excretion, red eyes, blurred images, rainbow, or objects seen as several ones, hypersensitivity to light, or corneal xerosis may occur. If the above symptoms are observed, remove the lenses immediately. If you still have discomfort after that or the above problems do not disappear, look at the lenses carefully. Do not wear them again if lenses are damaged. If there are foreign bodies are in the lenses, or problems continued, remove the lenses immediately and consult with medical specialists. Since the above symptoms may be developed to infection, keratohelcosis, and vascularization, receive treatment from ophthalmologists.

4. General Precautions

1) Before handling contact lenses, always clean and rinse your hands.
2) When removing contact lenses, remove one by one and put them in a container accurately to prevent confusion between left and right.
3) After removing contact lenses, clean and disinfect contact lenses always.
4) To prevent contamination of this solution, do not touch the stopper area of the container. You must close the stopper while not using it.
5) After wearing contact lenses in the eyes, throw away the solution within the container, clean it, and dry it always. (Always maintain contact lens container clean, an exchange containers every 2 to 3 months.)
6) Keep the product out of the reach of children.

5. Precautions in Application

1) Do not apply this solution to eyes directly or do not ingest it.
2) Do not use the solution twice.
3) Avoid direct sunlight. You should never use the product of which validity period is passed.
4) When preserving contact lenses with this solution, you must not heat it.
5) Do not use this solution to soft contact lenses.(Agents applied to hard contact lenses)
6) Do not use this solution to hard contact lenses.(Agents applied to soft contact lenses)

Chapter 13 Standard Manufacturing Practice of Mosquito Repellent

1. Scope

This practice is applied to mosquito repellent for purpose of repelling mosquito among repellents in accordance with Subparagraph 2 Item C of the Designation of Scope of Quasi-drugs (MFDS Notification).

2. Criteria

The standard manufacturing practice of mosquito repellent is as follows.

1) Types, Specifications, and Mixing Concentrations of Mixing Ingredients

The types, specifications, and mixing concentrations of available effective ingredients are described in <Table 1>. Additives should be in accordance with Article 9 Paragraphs 3 and 5 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification), but when mixing new additives without examples of use in Korea, they should be adequate for Article 21 Paragraph 2 of the same notification. Also, the ones not applicable to unavailable raw materials in Attached Table 1 and raw materials exceeding limit of use in Attached Table 2 of the Regulations on Safety Criteria, etc. of Cosmetics (MFDS Notification).

2) Dosage Form

Dosage forms include liquid formulation, lotion formulation, and aerosol formulation.

3) Efficacy and Effects

Repelling mosquito

4) Efficacy and Effects

The dose and administration are described in <Table 2>.

5) Precautions in Use

The precautions in use are described in <Table 3>.

(6) Storage and Validity (Effective) Period

Dosage Form	Storage Method	Validity (Effective) Period
Liquid, Lotion	Avoid direct sunlight and store in an airtight container under room temperature	Not more than 3 years
Aerosol	Avoid direct sunlight and store in a pressure airtight container under room temperature	Not more than 3 years

※ The validity (effective) period should be in accordance with Article 16 Paragraph 2 of the Regulation of Quasi-drugs Approval, Notification and Review (MFDS Notification).

<Table 1>

Types, Specification, and Mixing Concentration of Effective Ingredients

No.	Ingredient	Specification	Mixing Concentration(w/v%)
1	Diethyltoluamide	USP	7 ~ 30

※ However, for aerosol, the concentration based on bulk except spray agents

USP: The United States Pharmacopoeia

<Table 2>

Dose and Administration

Ⅰ. Lotion or liquid formulations with diethyltoluamide 10 % and less

- 12 years old ~ adults: Apply an adequate amount to exposed areas including face (except the areas around eyes and mouth), neck, arms, legs, etc.
- 2 years old ~ less than 12 years old: Apply a small amount to exposed areas except face and hands once to 3 times a day.
- 6 months old ~ less than 2 years old: Apply a small mount to exposed areas except face and hands once a day (However, use only in situation with high possibility of infection by insect).
- Less than 6 months old: Do not use.

※ When using it in children, take the product in hands of adults first and then apply to children. (Do not use it directly to children)

Ⅱ. Aerosol agents with diethyltoluamide 10% and less

- 12 years old ~ adults: Spray the product to exposed areas including arms and legs, and shoes, socks and clothes at distance of 10 ~ 20 cm. When applying it to face (except areas around eyes and mouth) and neck, take an adequate amount on the palm and apply it.
- 2 years old ~ less than 12 years old: Apply a small amount to exposed areas except face and hands once to 3 times a day.
- 6 months old ~ less than 2 years old: Apply a small amount to exposed areas except face and hands once a day (However, use it only situation with high possibility of infection due to insect bite).
- Less than 6 months old: Do not use.

※ When using it in children, take the product in hands of adults first and then apply to children. (Do not use it directly to children)

Ⅲ. Lotion or liquid formulation with diethyltoluamide exceeding 10 % and not more than 30%

- 12 years old ~ adults: Apply an adequate amount to exposed areas including face (except areas around eyes and mouth), neck, arms, legs, etc.

Ⅳ. Aerosol formulation with diethyltoluamide exceeding 10% and not more than 30%

- 12 years old ~ adults: Spray the product to exposed areas including arms and legs, and shoes, socks and clothes at distance of 10 ~ 20 cm. When applying it to face (except areas around eyes and mouth) and neck, take an adequate amount on the palm and apply it.

<Table 3>

Precautions in Use

Ⅰ. Lotion or liquid formulations with diethyltoluamide 10 % and less

1. The following persons should not use this drug
   Infants less than 6 months of age

2. In the following cases, stop using this drug immediately, and consult with doctors and pharmacists. In consultation, bring this attached document if possible
   1) Allergic reactions and hypersensitivity including symptoms of skin congestion which becomes red may occur. In this case, stop using the drug, clean the area with water sufficiently, and if necessary, receive treatment of doctors
   2) When this drug comes in the eyes, it may cause wound. If this drug comes in the eyes, wash the eyes with water sufficiently for 15 to 20 minutes, and if

stimulant continues, receive treatment of doctors (if you wear contact lenses, remove them).
3) If you ingest it, receive treatment of doctors immediately.

3. Other Precautions in Use
1) Use this product for external use only.
2) Do not use it to skin areas which can absorb it promptly (wound, inflammatory areas, joint areas, mucous membrane, areas around eyes, areas around mouth, etc.) and sunburnt skin.
3) Avoid applying it to the entire body except exposed areas (arms, legs, neck, etc.), and do not apply it excessively, not exceeding 20% of the body surface (surface of both arms).
4) Do not use excessive amount more than necessity or for a long time.
5) Wash your hands before you have food, drink beverages, chew gums, smoke cigarettes, and go to washroom.
6) If you come back from outside, wash the skin with this product with soap and water.
7) Do not use it to your underwear.
8) Do not use it in a sealed room.
9) It may give damages to plastic glasses frame, acetate, rayon, spandex, or other synthetic fiber (other than nylons), plastic, glass in wrist watch, rubber, automobiles, paint, or surface of varnish.
10) Do not use it in food, kitchen utensils, toys of children, animal's food, etc.

4. Precautions in Storage
1) Store this product in cool and dry place
2) Keep this product out of the reach of children.
3) If you take out the product from the original container and store in another container, it may be the reason of generation of accident by misuse or quality deterioration. Thus, you must keep the product in the original container and close the cover.

Ⅱ. Aerosol agents with diethyltoluamide 10% and less

1. The following persons should not use this drug
Infants less than 6 months of age

2. In the following cases, stop using this drug immediately, and consult with doctors and pharmacists. In consultation, bring this attached document if possible
1) Allergic reactions and hypersensitivity including symptoms of skin congestion which becomes red may occur. In this case, stop using the drug, clean the area with water sufficiently, and if necessary, receive treatment of doctors
2) When this drug comes in the eyes, it may cause wound. If this drug comes in the eyes, wash the eyes with water sufficiently for 15 to 20 minutes, and if stimulant continues, receive treatment of doctors (if you wear contact lenses,

remove them).
3) If you ingest it, receive treatment of doctors immediately.

3. Other Precautions in Use
1) Use this product for external use only.
2) Do not use it to skin areas which can absorb it promptly (wound, inflammatory areas, joint areas, mucous membrane, areas around eyes, areas around mouth, etc.) and sunburnt skin.
3) Avoid applying it to the entire body except exposed areas (arms, legs, neck, etc.), and do not apply it excessively, not exceeding 20% of the body surface (surface of both arms).
4) Do not use excessive amount more than necessity or for a long time.
5) Wash your hands before you have food, drink beverages, chew gums, smoke cigarettes, and go to washroom.
6) If you come back from outside, wash the skin with this product with soap and water.
7) Do not use it to your underwear.
8) Do not use it in a sealed room.
9) It may give damages to plastic glasses frame, acetate, rayon, spandex, or other synthetic fiber (other than nylons), plastic, glass in wrist watch, rubber, automobiles, paint, or surface of varnish.
10) Do not use it in food, kitchen utensils, toys of children, animal's food, etc.
11) You must wash clothes or socks before wearing them again if the product is applied to them.
12) Do not use toward flames.
13) Do not use it around flammables such as a heater and a stove.
14) Do not go toward flame or blaze until the processed surface is dried.
15) Do not throw it into the fire.
16) After use, throw it away without remaining gas.
17) Do not use the product indoor where flammables are used
18) Do not store the product in a place with temperature of 40℃
19) You must ventilate after using the product in a sealed space
20) Do not keep it in a sealed place

4. Precautions in Storage
1) Store this product in cool and dry place
2) Keep this product out of the reach of children.
3) If you take out the product from the original container and store in another container, it may be the reason of generation of accident by misuse or quality deterioration. Thus, you must keep the product in the original container and close the cover.

Ⅲ. Lotion or liquid formulation with diethyltoluamide exceeding 10 % and not more than 30%

1. The following persons should not use this drug
Infants less than 6 months of age

2. In the following cases, stop using this drug immediately, and consult with doctors and pharmacists. In consultation, bring this attached document if possible
1) Allergic reactions and hypersensitivity including symptoms of skin congestion which becomes red may occur. In this case, stop using the drug, clean the area with water sufficiently, and if necessary, receive treatment of doctors
2) When this drug comes in the eyes, it may cause wound. If this drug comes in the eyes, wash the eyes with water sufficiently for 15 to 20 minutes, and if stimulant continues, receive treatment of doctors (if you wear contact lenses, remove them).
3) If you ingest it, receive treatment of doctors immediately.

3. Other Precautions in Use
1) Use this product for external use only.
2) Do not use it to skin areas which can absorb it promptly (wound, inflammatory areas, joint areas, mucous membrane, areas around eyes, areas around mouth, etc.) and sunburnt skin.
3) Avoid applying it to the entire body except exposed areas (arms, legs, neck, etc.), and do not apply it excessively, not exceeding 20% of the body surface (surface of both arms).
4) Do not use excessive amount more than necessity or for a long time.
5) Wash your hands before you have food, drink beverages, chew gums, smoke cigarettes, and go to washroom.
6) If you come back from outside, wash the skin with this product with soap and water.
7) Do not use it to your underwear.
8) Do not use it in a sealed room.
9) It may give damages to plastic glasses frame, acetate, rayon, spandex, or other synthetic fiber (other than nylons), plastic, glass in wrist watch, rubber, automobiles, paint, or surface of varnish.
10) Do not use it in food, kitchen utensils, toys of children, animal's food, etc.

4. Precautions in Storage
1) Store this product in cool and dry place
2) Keep this product out of the reach of children.
3) If you take out the product from the original container and store in another container, it may be the reason of generation of accident by misuse or quality deterioration. Thus, you must keep the product in the original container and close the cover.

Ⅳ. Aerosol formulation with diethyltoluamide exceeding 10% and not more than 30%

1. The following persons should not use this drug
Infants less than 6 months of age

2. In the following cases, stop using this drug immediately, and consult with doctors and pharmacists. In consultation, bring this attached document if possible
1) Allergic reactions and hypersensitivity including symptoms of skin congestion which becomes red may occur. In this case, stop using the drug, clean the area with water sufficiently, and if necessary, receive treatment of doctors
2) When this drug comes in the eyes, it may cause wound. If this drug comes in the eyes, wash the eyes with water sufficiently for 15 to 20 minutes, and if stimulant continues, receive treatment of doctors (if you wear contact lenses, remove them).
3) If you ingest it, receive treatment of doctors immediately.

3. Other Precautions in Use
1) Use this product for external use only.
2) Do not use it to skin areas which can absorb it promptly (wound, inflammatory areas, joint areas, mucous membrane, areas around eyes, areas around mouth, etc.) and sunburnt skin.
3) Avoid applying it to the entire body except exposed areas (arms, legs, neck, etc.), and do not apply it excessively, not exceeding 20% of the body surface (surface of both arms).
4) Do not use excessive amount more than necessity or for a long time.
5) Wash your hands before you have food, drink beverages, chew gums, smoke cigarettes, and go to washroom.
6) If you come back from outside, wash the skin with this product with soap and water.
7) Do not use it to your underwear.
8) Do not use it in a sealed room.
9) It may give damages to plastic glasses frame, acetate, rayon, spandex, or other synthetic fiber (other than nylons), plastic, glass in wrist watch, rubber, automobiles, paint, or surface of varnish.
10) Do not use it in food, kitchen utensils, toys of children, animal's food, etc.
11) You must wash clothes or socks before wearing them again if the product is applied to them.
12) Do not use toward flames.
13) Do not use it around flammables such as a heater and a stove.
14) Do not go toward flame or blaze until the processed surface is dried.
15) Do not throw it into the fire.
16) After use, throw it away without remaining gas.
17) Do not use the product indoor where flammables are used
18) Do not store the product in a place with temperature of 40℃
19) You must ventilate after using the product in a sealed space
20) Do not keep it in a sealed place

4. Precautions in Storage

1) Store this product in cool and dry place
2) Keep this product out of the reach of children.
3) If you take out the product from the original container and store in another container, it may be the reason of generation of accident by misuse or quality deterioration. Thus, you must keep the product in the original container and close the cover.

Chapter 14 Standard Manufacturing Practice of External Disinfectants

1. Scope

This practice is applied to a single external disinfectant agent of which active ingredients is isopropanol, benzalkonium chloride, or ethanol which are directly used in human body.

2. Criteria

The standard manufacturing practice of external disinfectant is as follows.

1) Types, Contents and Specifications of Effective Ingredients

The types, contents and specifications of available ingredients are described in <Table 1>, and the specifications are the ones specified in the KP and the Official Compendium and National Drug Formulary notified by the Minister of MFDS.

2) As **the additives**, the ingredients which have been used as additives in domestic pharmaceuticals and quasi-drugs should be used. Other details should be in accordance with Article 9 Paragraphs 3 and 5 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification), but the additives should not be included in the raw materials in Attached Table 1 and the ones exceed the limit of use in Attached Table 2 in the Regulations on Safety Criteria, etc. of Cosmetics (MFDS Notification).

3) Dosage form should be liquid or gel formulation according to <Table 1>.

4) Efficacy and Effects

Sterile disinfection of hands and skin

5) Dose and Administration

Spray or take an adequate amount in hands and scrub well to dry.

6) Precautions in Use

The precautions in use of external disinfectants are as follows.

1. Do not use the product in the following body parts.
   Areas around the eyes and ears, in the mouth, wide body parts and damaged skin (irritation may occur)

2. If the following symptoms occur, stop using the product immediately, and consult with doctors and pharmacists.
   1) Hypersensitive symptoms such as rash, erythema, edema, etc. occur
   2) Skin-irritating symptoms occur

3. Other Precautions in Use
   1) Use the product only for external use (do not ingest it).
   2) Be careful to keep the eyes out of the product. If it enters the eyes, wash the eyes with water and then consult with doctors or pharmacists.
   3) Do not use the product in mucous membrane, wound surface, and inflammation areas for a long time or extensively (Systemic absorption may cause myasthenia).(Only for products containing benzalkonium chloride)
   4) When using the product extensively or for a long time, be careful not to inhale vapor (If you inhale a large amount of the vapor of ethanol or inhale it repeatedly, irritation in mucous membrane, headache, etc. may occur).(Only for products containing ethanol)
   5) When using the product extensively or for a long time, be careful with inhale of vapor.(Only for products containing isopropanol)
   6) When using in the same area repeatedly, be careful since skin may become coarse due to removal of fat.
   7) Do not use the product to occlusive dressing, plaster bandage, pack, etc. since it may cause irritating symptoms.
   8) Do not use the product to anal passage or vaginal fomentation because it may cause irritation or chemical burn.
   9) Do not use the product with soap or anion detergent.(Only for products containing benzalkonium chloride)
   10) Do not use the product for purposes other than the original usage.

4. Precautions in Storage
   1) Light-shielded storage avoiding flammables.
   2) Keep the product out of the reach of children. If children swallow the product, see a doctor immediately.
   3) Close the container with a lid to prevent the product to be dried or to keep the product free from foreign matters after use.
   4) If you take out the product from the original container and store it in another container, it may be the reason of generation of accident by misuse or quality deterioration. Thus, you must keep the product in the original container.

7) Storage and Validity (Effective) Period

(1) Storage Method: Store in airtight container under room temperature (1 ~ 30℃)

(2) Validity (Effective) Period: The validity (effective) period should be not more than 3 years from the manufactured date, but should be in accordance with Article 16 Paragraph 2 of the Regulation of Quasi-drugs Approval, Notification and Review (MFDS Notification).

<Table 1> Types, Contents, and Dosage Forms of External Disinfectants

Category	Ingredient	Content	Dosage Form
1	Isopropanol	70.0%(w/w)	Gel
2	Benzalkonium chloride	0.066%(w/w, w/v)	Liquid
3	Ethanol※	54.7 ~ 70.0%(w/w, v/v)	Gel and liquid

※ Ethanol should not contain a denaturant.

Chapter 15 Standard Manufacturing Practice of Deodorant

1. Scope

This practice is applied to external application used for purpose of preventing underarm order through inhibition of sweat occurrence.

2. Criteria

The standard manufacturing practice of deodorant is as follows.

1) Types, Contents and Specifications of Effective Ingredients

The types and contents of available ingredients are described in <Table 1>. The specifications are the ones specified in the KP and Standard and Analytical Methods of Quasi-drugs notified by the Minister of MFDS and the Official Compendium and National Drug Formulary recognized by the Minister of MFDS.

2) As the additives, the ingredients which have been used as additives in domestic pharmaceuticals and quasi-drugs should be used. Other details should be in accordance with Article 9 Paragraphs 3 and 5 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

3) Dosage forms include aerosol, liquid, and external solid preparations (stick) according to <Table 1>.

4) Efficacy and Effects

Prevention of underarm odor through inhibition of sweat occurrence

5) Dose and administration are described in <Table 2>.

6) Precautions in use are described in <Table 3>.

7) Storage Method and Validity (Effective) Period

Dosage Form	Storage Method	Validity (Effective) Period
Aerosol	(Pressure) airtight container, light-shielded under room temperature (1 ~ 30℃)	Not more than 2 years from the manufactured date
Liquid	Airtight container, room temperature (15 ~ 25℃)	Not more than 2 years from the manufactured date
External solid (stick)	Airtight container, room temperature (1 ~ 30℃)	Not more than 2 years from the manufactured date

※ The validity (effective) period should be in accordance with Article 16 Paragraph 2 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

<Table 1> Types, Contents and Dosage Forms of Effective Ingredients of Deodorant

Category	Ingredient	Content	Dosage Form
1	Aluminum chlorohydrate	20.0 ~ 35.0%(w/w)[1)]	Aerosol
2	Aluminum chlorohydrate solution(50%)	20.0 ~ 30.0%(w/w)	Liquid
3	Aluminum zirconium tetrachlorohydrex glycine	16.0 ~ 24.0%(w/w)	External solid (stick)

1) The contents of effective ingredients of aerosol refer to contents (%) in the bulk except spray formulation.

<Table 2> Dose and Administration by Dosage Form

Category	Dosage Form	Dose and Administration
1	Aerosol	Shake the content enough before use, and spray about 2 seconds at distance of about 15 cm from armpit.
2	Liquid	Apply an adequate amount under the arm and scrub softly.
3	External solid (stick)	Apply an adequate amount under the arm.

<Table 3> Precautions in Use

Ⅰ. Aerosol

1. Precautions in Use
   1) If you have experience hypersensitivity after using other deodorants (quasi-drugs) or deodorant (cosmetics) or skin troubles such as eczema, dermatitis or allergy, do not use this product because they may be aggravated
   2) If you feel dermatitis or irritation, stop using this product
   3) Do not spray more than 3 seconds in the same area, and use it at distance of 15 cm and more
   4) Shake the spray sufficiently before use, and do not spray on clothes
   5) Be careful not to inhale the sprayed gas
   6) Do not spray in the areas around the eyes and mucous membrane, and do not use the product in the area with wound or shortly after waxing
   7) If abnormal phenomena such as red spot, pruritus, irritation, etc. are discovered in the skin during or after use of the product, stop using it and consult with doctors or pharmacists

2. Precautions in Storage
   1) Do not keep the product in a sealed place or with high temperature of 40℃ and more
   2) Do not use the product indoor area in which flammables such as a heater and a stove are used, and keep the product out of direct sunlight and flammables
   3) Keep the product out of the reach of infants and children
   4) Do not use it toward flames
   5) You must ventilate after the use of the product in a sealed place
   6) Make sure no gas is remained in the product after use, and do not throw the product into the fire

Ⅱ. Liquid

1. Precautions in Use
   1) If you have experience hypersensitivity after using other deodorants (quasi-drugs) or deodorant (cosmetics) or skin troubles such as eczema, dermatitis or allergy, do not use this product because they may be aggravated
   2) If you feel dermatitis or irritation, stop using this product and consult with doctors or pharmacists
   3) Do not use the product in the area with wound or shortly after waxing
   4) If abnormal phenomena such as red spot, swelling, pruritus, irritation, etc. occur during or after the use, stop using the product immediately and consult with doctors and pharmacists
   5) Apply the product under the arm, and wear the clothes after they are completely dried

2. Precautions in Storage
1) You must cover the stopper after use
2) Keep the product out of the reach of infants and children
3) Keep the product under 25℃. Do not store the product in place with high or low temperature as well as direct sunlight

Ⅲ. External Solid (Stick)

1. Precautions in Use
1) If you have experience hypersensitivity after using other deodorants (quasi-drugs) or deodorant (cosmetics) or skin troubles such as eczema, dermatitis or allergy, do not use this product because they may be aggravated
2) If you feel dermatitis or irritation in the applied area by direct sunlight, stop using the product and consult with doctors or pharmacists
3) Do not use the product in the area with wound or shortly after waxing
4) If abnormal phenomena such as red spot, swelling, pruritus, irritation, etc. occur during or after the use, stop using the product immediately and consult with doctors or pharmacists
5) Apply the product under the arm, and wear the clothes after they are completely dried
6) The persons with renal disease should consult with doctors or pharmacists before using this drug

2. Precautions in Storage
1) Keep the product out of the reach of infants and children
2) If you take out the product from the original container and store in another container, it may be the reason of generation of accident by misuse or quality deterioration. Thus, you must keep the product in the original container and close the cover.
3) Do not store the product in place with high or low temperature as well as direct sunlight

Chapter 16 Standard Manufacturing Practice of Tooth Whitener

1. Scope

This practice is applied to the preparations used by applying to teeth for tooth whitening.

2. Criteria

The standard manufacturing practice of tooth whitener is as follows.

1) Types, Contents and Specifications of Effective Ingredients

The types and contents of available ingredients are described in <Table>. The specifications are the ones specified in the KP and Standard and Analytical Methods of Quasi-drugs notified by the Minister of MFDS and the Official Compendium and National Drug Formulary recognized by the Minister of MFDS.

2) Additives

The ingredients which have been used as additives in domestic pharmaceuticals and quasi-drugs should be used. Other details should be in accordance with Article 9 Paragraphs 3 and 5 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification), but they should not be included in the raw materials in [Attached Table 1] and raw materials exceed the limit of use in [Attached Table 2] in the Regulations on Safety Criteria, etc. of Cosmetics (MFDS Notification).

3) Dosage Form

Gel

4) Efficacy and Effects

Tooth whitening

5) Dose and Administration

The dose and administration described in <Table>.

6) Precautions in Use

The precautions in use of tooth whitener is as follows.

1. Do not use the product in the following patients
   1) Patients with hypersensitivity to hydrogen peroxide
   2) Patients with oral infection or wound
   3) Pregnant and lactating women
   4) Persons with orthodontics

2. General Precautions
   1) Do not swallow this product. If you ingest it, follow the directions of doctors, dentists, or pharmacists
   2) Keep the areas around the eyes, gums, salivary gland and wounded areas free from the product. If the product touches them, wash the areas with water immediately, and consult with doctors, dentists, or pharmacists
   3) A temporary gum stimulation or hypersensitive symptoms of hemodia (e.g. cold teeth). If the symptoms continue, stop using the product and consult with dentists
   4) Do not use the product in meal, drinking beverage, smoking, and washing face
   5) After the use, wrap the product with tissue, etc. so that the product should not touch fiber, leather products, and other substances
   6) Do not use it for purposes other than the original usage
   7) When children under 12 years old use this product, they should use it after consulting with dentists
   8) If you need or receive dental treatment, use the product after consulting with dentists

3. Precautions in Storage
   1) Keep the product out of the reach of children

7) Storage Method and Validity (Effective) Period

(1) Storage Method: Store in airtight under room temperature(1～30℃)

(2) Validity (Effective) Period: The validity (effective) period should be not more than 3 years from the manufactured date, but in accordance with Article 16 Paragraph 2 of the Regulation on Quasi-drugs Approval, Notification and Review (MFDS Notification).

<Table>

Types, Contents, Dose & Administration of Effective Ingredients of Tooth Whitener

Ingredient & Content	Dose and Administration
Hydrogen Peroxide 35% 8.57g/100g	After removing water in the teeth, apply an adequate amount of gel in the teeth you desire, and make sure gel should not be leaked outside the teeth. Then, do not close the mouth for about 30 seconds to 1 minute until the product is dried. Rinse your month with water after 30 minutes. Use the product twice a day, for 2 weeks