Appendix 15

Provisional Translation
from Japanese Original

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The Standards for Marketing Approval of Antipruritic and Anti-inflammatory Drugs

1. Scope of Antipruritic and Anti-inflammatory Drugs

The scope of preparations subject to these standards covers medicines mainly containing adrenocortical hormones or antihistamines for dermal application formulated with the intent of using as antipruritic and anti-inflammatory drugs.

2. Approval Standards

The approval standards for antipruritic and anti-inflammatory drugs are as follows: For antipruritic and anti-inflammatory drugs mainly containing adrenocortical hormones or antihistamines that do not conform to these standards, efficacy and safety data and reasons justifying the combination should be submitted; the preparation in question will be reviewed based on these data.

(1) Types of Active Ingredients

a) The active ingredients that may be combined in the preparations are shown in the Table.
b) At least 1 ingredient from either Column I or Column II of the Table must be combined.
c) Preparations mainly containing the active ingredients from Column I of the Table may include the active ingredients from Column II, III, IV, V, VI, VII, VIII, IX, X, or XII.
d) Preparations mainly containing the active ingredients from Column II of the Table may include the active ingredients from Column III, IV, V, VI, VII, VIII, IX, X, XI, or XII.
e) In the case of Column I, II, IV, V, VII, VIII, or IX in the Table, only 1 active ingredient from each column may be used in a preparation. When the active ingredient from Group 1 or 2 of Column X, or Group 1 or 3 of Column XII is combined, only 1 active ingredient from each group may be used in a preparation.

(2) Quantities of Active Ingredients

a) The maximum concentration of each of the active ingredients in the Table is that shown in the table.
b) The minimum concentration of each of the active ingredients listed in Columns II, III, V, VI, VIII, Groups 2 and 3 of Column X, Column XI, and Group 2 of Column XII is 1/5th of the maximum concentration (for ingredients with a concentration in parentheses, the minimum concentration must be the amount shown in the parentheses). However, in the case of preparations mainly containing the active ingredients from Group 1 of Column I or Group 2 of Column II, the minimum concentration of each active ingredient must be at

least half of the maximum concentration, and in the case of preparations mainly containing the active ingredients from Group 2 of Column I or Group 1 of Column II, the concentration is fixed to the maximum concentration.

c) The minimum concentration of each of the active ingredients listed in Column IV, VII, or IX, Group 1 of Column X, or Groups 1 and 3 of Column XII of the Table is 1/10th of the maximum concentration (for ingredients with a concentration in parentheses, the minimum concentration must be the amount shown in the parentheses).

(3) Dosage Form

The dosage forms are liquids for external use, sprays, ointments, creams, and gels. However, for sprays, preparations mainly containing the active ingredients listed in Column I of the Table are excluded.

(4) Dosage and Administration

The preparation should be applied to the skin surface several times a day. The method of application must be clearly indicated.

(5) Indications

The indications are shown by main ingredient in the following table.

Main ingredients	Indications
Group 1 of Column I	Eczema, dermatitis, miliaria, irritated skin, itching, chilblain, insect bites, urticaria
Group 2 of Column I	Eczema, dermatitis, miliaria, irritated skin, itching, insect bites, urticaria
Column II	Eczema, dermatitis, skin sore, miliaria, irritated skin, itching, chilblain, insect bites, urticaria

Table

Classification		Active ingredient	Maximum concentration (%)
Column I	Group 1	Cortisone acetate	0.5
		Dexamethasone acetate	0.025
		Dexamethasone	0.025
		Hydrocortisone acetate	0.5
		Hydrocortisone	0.5
		Prednisolone acetate	0.25
		Prednisolone	0.25
	Group 2	Hydrocortisone butyrate	0.05
		Prednisolone valerate acetate	0.15
Column II	Group 1	Isothipendyl hydrochloride	0.75
		Chlorpheniramine	0.5
		Chlorpheniramine maleate	1
		Diphenhydramine	1
	Group 2	Diphenhydramine hydrochloride	2
Column III		Crotamiton	10
Column IV		Glycyrrhizic acid and its salts	1
		Glycyrrhetic acid	1
Column V		Glycol salicylate	2
		Methyl salicylate	5
Column VI		Allantoin	1
Column VII		Isopropyl methylphenol	0.5
		Benzalkonium chloride	0.3
		Benzethonium chloride	0.1
Column VIII		Calamine	8
		Zinc oxide	37 (1.5)
Column IX		Ethyl aminobenzoate	5
		Oxy polyethoxy dodecane	3
		Dibucaine	0.5
		Dibucaine hydrochloride	0.5
		Lidocaine	2
		Lidocaine hydrochloride	2
Column X	Group1	*d*-Camphor	7 (0.1)
		dl-Camphor	7 (0.1)
	Group 2	Mentha oil	2
		dl-Menthol	5 (0.1)
		l-Menthol	5 (0.1)
	Group 3	*d*-Borneol	0.3
Column XI		Ammonia water	15
Column XII	Group 1	Tocopherol	2 (0.1)
		Tocopherol acetate	2 (0.1)
	Group 2	Panthenol	5
	Group 3	Vitamin A oil	500,000 I.U./100 g as vitamin A
		Retinol palmitate	500,000 I.U./100 g as vitamin A