Appendix 12

Provisional Translation
from Japanese Original

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The Standards for Marketing Approval of Nasal Drops for Rhinitis

1. Scope of Nasal Drops for Rhinitis

The scope of preparations subject to these standards covers intranasal medicines intended for the relief of symptoms of rhinitis.

2. Approval Standards

The approval standards for nasal drops for rhinitis are as follows.

For preparations not conforming 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 types of active ingredients that may be used are shown in Table 1.
b. The active ingredients that must be included are those from Column I of Table1.
c. Active ingredients from different columns of Table 1 may be combined with each other.
d. When the active ingredients from Column I, II, III, or IV of Table 1 are combined, only 1 ingredient per column is permitted.

(2) Quantities of Active Ingredients

a. The maximum concentration of each of the active ingredients is shown in Table1.
b. The minimum concentration of each of the active ingredients from Column I of Table 1 is half of the respective maximum concentrations, and that of the active ingredients from the other columns is 1/5th of the respective maximum concentrations.

(3) Dosage Form

The dosage forms are intranasally-applied liquid preparations.

(4) Dosage and Administration

a. Preparations are to be applied intranasally not more than 6 times a day. The application method and intervals must be clearly indicated. The application interval is to be at least 3 hours.
b. Dosages for infants under 2 years of age are not approved.
c. The maximum concentrations for children under 7 years of age are half of the maximum concentration shown in Table 1.

(5) Indications

The indications are to be within the following scope: relief of the following

symptoms due to acute rhinitis, allergic rhinitis or sinusitis; stuffy nose, runny nose (excessive nasal discharge), sneezing, dull headache (heaviness in head).

(6) Packaging Units

The maximum volume of containers for liquids is limited to 30 mL.

Table 1

Classification	Active ingredient	Maximum concentration (%)
Column I	Epinephrine	0.01
	Ephedrine hydrochloride	0.5
	Tetrahydrozoline hydrochloride	0.1
	Naphazoline hydrochloride	0.05
	Phenylephrine hydrochloride	0.5
	dl-Methylephedrine hydrochloride	0.5
	Tetrahydrozoline nitrate	0.1
	Naphazoline nitrate	0.05
Column II	Iproheptine hydrochloride	0.5
	Diphenhydramine hydrochloride	0.2
	Diphenhydramine	0.2
	Chlorpheniramine maleate	0.5
Column III	Acrinol	0.05
	Cetylpyridinium chloride	0.05
	Benzalkonium chloride	0.02
	Benzethonium chloride	0.02
Column IV	Lidocaine hydrochloride	0.5
	Lidocaine	0.5
Column V	Dipotassium glycyrrhizinate	0.3
	Methyl salicylate	0.05