

Provisional Translation
from Japanese Original

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The Standards for Marketing Approval of Enemas

1. Scope of Enemas

The scope of preparations subject to these standards covers medicines for rectal application formulated with the intent of treating constipation.

2. Approval Standards

The approval standards for enemas 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 those listed in Table 1 for liquid preparations and those listed in Table 2 for suppositories.
- (b) The active ingredients that must be included are those from Column I of Table 1 and Column I or II of Table 2.
- (c) The active ingredients from Column II of Table 1 can be combined with the active ingredients from Column I.
- (d) The active ingredients from Columns I and II of Table 2 may not be used in the same preparation.

(2) Quantities of Active Ingredients

- (a) The maximum and minimum single doses of the active ingredients in Tables 1 and 2 are those specified in the respective tables.
- (b) The concentration of glycerin in Column I of Table 1 for liquid preparations is 42% to 50%.

(3) Dosage Form

The dosage forms are liquids and suppositories.

(4) Dosage and Administration

(a) Liquid preparations

- [1] When dilution is required, water should be added so that the concentration of glycerin reaches 42% to 50%.
- [2] When no effect is obtained by intra-rectal administration of a single dose of the preparation, administer the same amount again.

(b) Suppositories

If no effect is obtained by the insertion of a single suppository, insert 1 more. In the case of suppositories containing ingredients from Column II of Table 2, the daily dose is limited to 0.02 g.

- (c) Dosages for children under 3 years of age is not approved.

- (d) For children under 12 years of age, the single dose of the active ingredients in Table 1 is that obtained by multiplying the single doses listed in the table by the coefficient for the corresponding age range in Table 3. The single dose of the active ingredients from Column I of Table 2 is that obtained by multiplying the single doses listed in the table by the coefficient in Table 4. The single dose of the active ingredients from Column II of Table 2 is that obtained by multiplying the single doses listed in the table by the coefficient in Table 5.
- (5) Indications
The indication is limited to constipation.

Table 1
Liquids

Column	Active ingredient	Single dose (g)	
		Minimum	Maximum
I	Glycerin	12	18
II	D-Sorbitol	–	10

Table 2 Suppositories

Column	Active ingredient	Single dose (g)	
		Minimum	Maximum
I	Glycerin	1.5	2.5
II	Bisacodyl	0.005	0.01

Table 3

Age	Coefficient
12 years of age or over	1
6 to under 12 years of age	2/3
1 to under 6 years of age	1/3
Under 1 year of age	1/6

Table 4

Age	Coefficient
12 years of age or over	1
3 to under 12 years of age	2/3

Table 5

Age	Coefficient
12 years of age or over	1
6 to under 12 years of age	1/2
3 to under 6 years of age	1/5

