

Provisional Translation  
from Japanese Original

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## The Standards for Marketing Approval of Anthelmintics

### 1. Scope of Anthelmintics

The scope of preparations subject to these standards covers all oral preparations intended to eradicate parasites (Kampo medicine\* formulas are not covered).

\* Kampo medicine is traditional Japanese medicine.

### 2. Approval Standards

The approval standards for anthelmintics 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) One or more of the active ingredients from Column A of Table 1 must be included.
- (c) Preparations mainly containing active ingredients from Group 1 of Column A in Table 1 may include active ingredients from Column B or C.
- (d) Preparations mainly containing active ingredients from Group 2a of Column A in Table 1 may include active ingredients from Column B.
- (e) Preparations mainly containing active ingredients from Group 2b of Column A in Table 1 may include active ingredients from Group 2 of Column B, or Column D. However, the active ingredient from Group 2 of Column D may be included only when an active ingredient from Group 2 of Column B is also included.
- (f) Preparations mainly containing active ingredients from Group 3 of Column A or Group 4 of Column A in Table 1 may not include any other active ingredient.
- (g) Preparations mainly containing active ingredients from Groups 1 and 2 of Column A, those mainly containing active ingredients from Groups 1 and 3 of Column A, and those mainly containing active ingredients from Groups 1, 2, and 3 of Column A in Table 1 may also include active ingredients from Column B or C.
- (h) In the case of Columns B and C in Table 1, only 1 active ingredient from each column may be used in the preparation.
- (i) Only 1 active ingredient from Group 2 of Column A in Table 1 may be included from this group.

#### (2) Quantities of Active Ingredients

- (a) The maximum daily dose of each of the active ingredients in Table 1 is the amount shown in this table.
- (b) When an active ingredient from Group 1 of Column A in Table 1 is combined

with another active ingredient from Column A, or when active ingredients from Group 1 of Column B in Table 1 are combined, the lower limit of the daily dose is half of the maximum daily dose.

- (c) When an active ingredient from Group 2 of Column A in Table 1 is combined with another active ingredient from Column A, the lower limit of the daily dose is 1/4th of the maximum daily dose.
- (d) When an active ingredient from Group 3 of Column A in Table 1 is combined with another active ingredient from Column A, the lower limit of the daily dose is 3/4 of the maximum daily dose.
- (e) The lower limit of the daily dose of the active ingredients from Group 4 of Column A in Table 1 is 2/5th of the maximum daily dose.
- (f) The lower limit of the daily dose of the active ingredients from Group 2 of Column B, and Column D of Table 1 is 1/10th of the maximum daily dose.
- (g) The lower limit of the daily dose of the active ingredients from Column C of Table 1 is 1/5th of the maximum daily dose.
- (h) When 2 or more of the active ingredients from Column A of Table 1 are combined, the lower limit of the daily dose of each active ingredient is 1/5th of the maximum daily dose, and the sum of the values obtained by dividing the amount of each active ingredient combined by its maximum daily dose must be at least half, and should not exceed 2/3. However, when 2 or more of the active ingredients only from Group 3 of Column A are combined, the sum of the values obtained by dividing the amount of each active ingredient combined by its maximum daily dose should be at least 3/4 and not exceed 1.
- (i) When 2 or more of the active ingredients from Group 1 of Column D in Table 1 are combined, the sum of the values obtained by dividing the amount of each active ingredient combined by its maximum daily dose should not exceed 1.

### (3) Dosage Form

The dosage forms are capsules, granules, pills, powders, tablets, decoctions (only preparations mainly containing the active ingredients from Group 2b of Column A in Table 1), chocolate tablets, and oral liquids.

### (4) Dosage and Administration

#### (a) Dose regimen

- (i) Preparations mainly containing the active ingredients from Group 1 of Column A in Table 1  
Take twice a day on an empty stomach, or take once before bed after a light evening meal and once on the following morning.  
Do not take more than twice in succession.
- (ii) Preparations mainly containing the active ingredients from Group 2a of Column A in Table 1  
Take once or twice a day on an empty stomach. Do not take more than twice in succession.
- (iii) Preparations mainly containing the active ingredients from Group 2b of Column A in Table 1  
Take once or twice a day on an empty stomach.
- (iv) Preparations mainly containing the active ingredients from Group 3 of Column A in Table 1
  - [1] For eradication of ascarids  
Take once or twice a day on an empty stomach for 1 to 2 days. Do not take for more than 2 successive days.
  - [2] For eradication of oxyurids

Take once or twice a day on an empty stomach for 1 week. Do not take for more than 7 successive days.

- (v) Preparations mainly containing the active ingredients from Group 4 of Column A in Table 1

Take once a day.

Do not take more than twice in succession.

- (vi) Preparations mainly containing the active ingredients from Groups 1 and 2 of Column A, those mainly containing the active ingredients from Groups 1 and 3 of Column A, and those mainly containing the active ingredients from Groups 1, 2, and 3 of Column A in Table 1

Take once or twice a day on an empty stomach, or take once before bed after a light evening meal and once on the following morning.

Do not take more than twice in succession.

- (b) For decoctions, the method of preparation at the time of use should be clearly described.
- (c) Dosage for infants younger than 3 months of age is not approved.
- (d) For capsules, and pills and tablets larger than 6 mm in diameter, dosage for children under 5 years of age is not approved.
- (e) For pills and tablets, dosage for infants younger than 3 years of age is not approved, even if the diameter is less than 6 mm.
- (f) The maximum daily doses for children under 15 years of age are the amounts obtained by multiplying the maximum daily dose in Table 1 by the coefficients for the respective age groups shown in Table 2.

(5) Indications

- (i) Preparations mainly containing the active ingredients from Group 3 of Column A in Table 1

Eradication of ascarids and oxyurids

- (ii) Preparations mainly containing the active ingredients from Group 4 of Column A in Table 1

Eradication of oxyurids

- (iii) Other preparations

Eradication of ascarids

Table 1

Classification		Active ingredient	Maximum daily dose		Remarks	
Column A	Group 1	Santonin	200 mg			
	Group 2	a	Kainic acid	20 mg		
		b	Digenea	Powder	Extract (converted to the crude drug amount)	
				–	10 g	
	Group 3		For ascarids	For oxyurids		
		Piperazine adipate	4000 mg	2000 mg	As piperazine hexahydrate	
		Piperazine citrate	4000 mg	2000 mg	As piperazine hexahydrate	
		Piperazine hexahydrate	4000 mg	2000 mg		
		Piperazine malate	4000 mg	2000 mg	As piperazine hexahydrate	
		Piperazine phosphate	4000 mg	2000 mg	As piperazine hexahydrate	
	Group 4	Pyrvinium pamoate	250 mg		As pyrvinium base	
Column B	Group 1	Sulfur	1000 mg			
		Magnesium oxide	2000 mg			
		Dioctyl sodium sulfosuccinate	200 mg			
		Bisacodyl	20 mg			
	Group 2		Powder	Extract (converted to the crude drug amount)		
		Aloes	0.75 g	0.75 g		
		Senna Leaf	1.5 g	6 g		
		Rhubarb	3 g	4 g		
Column C		Aminoethylsulfonic acid	2000 mg			
		Bile extract (powder)	500 mg			
		Bile powder	1500 mg			
		Dehydrocholic acid	500 mg			
Column D	Group 1		Powder	Extract (converted to the crude drug amount)		
		Melia Bark	–	10 g		
		Japanese Zanthoxylum Peel	–	3 g		
		Rangoon Creeper Fruit	–	3 g		
	Group 2	Glycyrrhiza	–	3.3 g		

Table 2

Age group	Coefficient
15 years of age and over	1
11 to under 15 years of age	2/3
8 to under 11 years of age	1/2
5 to under 8 years of age	1/3
3 to under 5 years of age	1/4
1 to under 3 years of age	1/5
3 months to under 1 year of age	1/7