



ANTACID LABELLING STANDARD

CATEGORY: Antacid

DESCRIPTION: Single and multiple ingredient drugs, containing medicinal ingredients suitable for self-medication, which are intended to relieve symptoms such as heartburn and dyspepsia, traditionally associated with gastric hyperacidity.

MEDICINAL INGREDIENTS AND DOSAGE FORMS:

Dosage forms covered by this standard:

gel, powder, suspension, liquid, tablets, effervescent tablets

The finished product and all ingredients used in the manufacture of the product should comply with the specifications of Schedule B pharmacopoeial or equivalent standard (Appendix I).

The medicinal ingredients of a product complying with this monograph consist of the following when used singly, within the established limits or in an acceptable combination.

INGREDIENTS (Single or Combination):

- a) aluminum containing: aluminum hydroxide **
dihydroxyaluminum aminoacetate
(aluminum glycinate)
dihydroxyaluminum sodium carbonate
- b) magnesium-containing: magnesium carbonate
magnesium hydroxide
magnesium oxide
magaldrate*
- c) calcium carbonate
- d) sodium bicarbonate

NOTE: * contains magnesium and aluminum

** The declaration of aluminum hydroxide should be made using the proper name of the ingredient used (eg. Dried Aluminum Hydroxide Gel) but giving the equivalent weight of aluminum hydroxide (mol.wt. 78).

For example:

*Dried Aluminum Hydroxide gel equivalent to x mg aluminum hydroxide
(where 1 mg dried gel provides 0.765 mg aluminum hydroxide)*

or

*Aluminum Hydroxide Gel equivalent to x mg aluminum hydroxide
(where 100g aluminum hydroxide gel USP provides 5.5 - 6.7 g aluminum hydroxide)*

PERMITTED COMBINATIONS:

1. Antacid Ingredient Combinations:

Any of the antacid ingredients listed above (a-d) may be combined with each other or with those ingredients listed below (e and f), provided each contributes at least 25% of the acid neutralising capacity (ANC) as calculated by the following formula:

$$\% \text{ contribution} = \frac{\text{Total mEq antacid active ingredient} \times 100}{\text{Total mEq antacid product}}$$

e) magnesium trisilicate

f) glycine

2. Antacid and Non-antacid Combinations:

The following non-antacid ingredients (g and h) will be permitted in combination with any acceptable single or combination ingredient listed above provided the indication statement refers to their action (see indications permitted):

g) alginic acid / alginates

h) simethicone

NOTE:

combination of antacid with an analgesic ingredient is not included in this labelling standard

DIRECTIONS FOR USE:

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INDICATIONS:

1. For antacid ingredients, to the effect:

For the relief of heartburn, (indigestion), (upset stomach), (sour stomach) associated with excess stomach acid (hyperacidity), (acid indigestion)

Alternative acceptable claims are as follows:

- . antacid
- . neutralizes excess stomach acid

NOTE: Any reference to the following claims is **unacceptable** in antacid products:

- . reflux esophagitis
- . hiatus hernia
- . gastric or intestinal ulcers
- . consumes "x" times its weight in stomach acid

2. For combination ingredients:

i) Alginic acid/Alginates, to the effect:

- . for the relief of heartburn due to backward flow of stomach acid
- . stomach acid reflux

ii) Simethicone, to the effect:

- . antifatulent
- . relieves gas due to heartburn, indigestion, sour or upset stomach

3. For calcium carbonate: *

- . calcium/mineral supplement

4. For magnesium (carbonate, hydroxide or oxide): *

- . magnesium/mineral supplement

* a mineral supplement claim may be made in addition to an antacid claim provided that:

- i) the product contains one or more of these 4 salts as the only medicinal ingredient(s)
- ii) the amount of the elemental mineral (calcium or magnesium) per dosage unit is declared
- iii) separate dosage directions that conform with the Minerals Labelling Standard are also given

DOSAGE:

1. Antacid ingredients:

. The minimum recommended dosage must provide a minimum acid neutralising capacity (ANC) of 5 mEq and result in a pH of 3.5 or greater at the end of the initial ten minute period as measured by the procedure outlined in the United States Pharmacopeia XXII/National Formulary XVII. Evidence that a product meets this standard must be available on request.

. The maximum daily dose of acceptable ingredients should not exceed the following levels:

Aluminum hydroxide	10000 mg
Dihydroxyaluminum aminoacetate	4000 mg
Dihydroxyaluminum sodium carbonate	8016 mg
Magnesium carbonate	3288 mg
Magnesium hydroxide	7200 mg
Magnesium oxide	1920 mg
Magaldrate	10800 mg
Calcium carbonate	8000 mg
Sodium bicarbonate	6000 mg
Magnesium trisilicate	4680 mg
Glycine	8000 mg

2. Combination non-antacid ingredients:

The maximum daily dose should not provide more than the following levels:

Alginic acid	4000 mg
Simethicone	640 mg

3. Dosage as an antacid should be specified as being for adults

4. Dosages for mineral supplementation (where applicable) should not exceed those given in the Mineral Supplement Labelling Standard:

for calcium, up to a maximum of 1500 mg per day

for magnesium, up to a maximum of 500 mg per day

WARNINGS:

For all ingredients:

1. Do not take for more than two weeks, or if symptoms recur, unless directed by a doctor
2. Do not take within two hours of another medicine because the effectiveness of the other medicine may be altered.

For products containing magnesium or aluminum:

3. Individuals with kidney disease should not take this product except on the advice of a doctor

For products with more than 115 mg sodium in daily dose:

4. Do not use if you are pregnant or on a low salt diet

NOTE: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

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- 19) Department of Health and Human Services, Food and Drug Administration, Federal Register, **Establishment of a Monograph for Orally Administered Products for Relief of Symptoms Associated with Overindulgence in Alcohol and Food**.vol.47, No.191, pp. 43558-43559,October 1,1982

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APPENDIX I FORMULATED PREPARATIONS

	U.S.P. XXII (1990)	B.P. 1993	B.P.C. 1976
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Alumina and Magnesia Oral Suspension	X		
Alumina and Magnesia Tablets	X		
Alumina, Magnesia and Calcium Carbonate Oral Suspension	X		
Alumina, Magnesia and Calcium Carbonate Tablets	X		
Alumina, Magnesia and Simethicone Oral Suspension	X		
Alumina, Magnesia and Simethicone Tablets	X		
Alumina and Magnesium Carbonate Oral Suspension	X		
Alumina and Magnesium Carbonate Tablets	X		
Alumina, Magnesium Carbonate, and Magnesium Oxide Tablets	X		
Alumina and Magnesium Trisilicate Oral Suspension	X		
Alumina and Magnesium Trisilicate Tablets	X		
Basic Aluminum Carbonate Gel	X		
Dried Basic Aluminum Carbonate Gel Capsules	X		
Dried Basic Aluminum Carbonate Gel Tablets	X		
Aluminum Hydroxide Gel	X		
Dried Aluminum Hydroxide Gel	X		
Dried Aluminum Hydroxide Gel Capsules	X		
Dried Aluminum Hydroxide Gel Tablets	X		
Aluminum Hydroxide Tablets	X	X	
Calcium Carbonate Oral Suspension	X		
Calcium Carbonate Powder, Compound	X		X
Calcium Carbonate Tablets	X		
Calcium Carbonate and Magnesia Tablets	X		
Calcium and Magnesium Carbonates Tablets	X		
Dihydroxyaluminum Aminoacetate Capsules	X		
Aluminum Glycinate	X	X	
Dihydroxyaluminum Aminoacetate Magma	X		
Dihydroxyaluminum Aminoacetate Tablets	X		

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Dihydroxyaluminum Sodium Carbonate Tablets	X		
Magaldrate Oral Suspension	X		
Magaldrate Tablets	X		
Magaldrate and Simethicone Oral Suspension	X		
Magaldrate and Simethicone Tablets	X		
Milk of Magnesia	X		
Magnesia Tablets	X		
Magnesia and Alumina Oral Suspension	X		
Magnesia and Alumina Tablets	X		
Magnesium Carbonate Mixture			X
Aromatic Magnesium Carbonate Mixture		X☺	X
Magnesium Carbonate Powder, Compound	X		X
Magnesium Carbonate Tablets, Compound			X
Magnesium Carbonate and Sodium Bicarbonate for Oral Suspension			
Magnesium Hydroxide Mixture		X♥	
Magnesium Hydroxide Paste	X		
Magnesium Oxide Capsules			
Magnesium Oxide Tablets			
Magnesium Trisilicate Mixture	X	X♦	X
Magnesium Trisilicate Tablets	X		
Compound Magnesium Trisilicate (Oral) Powder		X	X
Compound Magnesium Trisilicate Tablets		X♣	X♣
Sodium Bicarbonate Oral Powder	X		
Sodium Bicarbonate Tablets	X		
Compound Sodium Bicarbonate Tablets		X♠	

Alternates:

- ☺ - Oral Suspension; Mixture
- ☹ - Oral Suspension
- ♥ - Oral Suspension; Cream of Magnesia
- ♦ - Oral Suspension; Compound Magnesium Trisilicate Mixture
- ♣ - Aluminum Hydroxide and Magnesium Trisilicate Tablets
- ♠ - Soda Mint Tablets

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