LABELLING STANDARD

ANTIFLATULENTS

I) Description:

This Labelling Standard applies to products, intended to be taken by mouth in the form of capsules, tablets, or oral suspension, for the symptomatic relief of flatulence.

II) Pharmaceutical Quality:

a) All ingredient (medicinal and nonmedicinal) and finished product specifications should, as a minimum, meet the standards described in the publications referred to in Schedule B to the *Food and Drugs Act*, or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

b) **Special Notes:**

i) Pharmacopoeial standards (Schedule B) for formulated single and multiple ingredient antiflatulent preparations are shown in Appendix I. Note that this list is intended only as a guide and is not necessarily current or all inclusive.

ii) Finished product specifications should include tests for identification and an assay with suitable limits for the medicinal ingredient(s) including its components. The specifications for all dosage forms should include a description of the dosage form including organoleptic properties as well as physico-chemical testing e.g., pH, specific gravity, viscosity, appropriate to the dosage form. Where antimicrobial preservatives are added, an assay with suitable limits should be included. Antimicrobial preservative effectiveness should be determined in order to establish that the product is capable of resisting microbial contamination.

III) Ingredients:

a) **Single Medicinal ingredients:**

Ingredient	Unit
Simethicone	mg
Activated Charcoal	mg

b) **Combinations of Medicinal Ingredients:**

Simethicone may be combined with those antacid ingredient(s) which are listed in the Antacid Labelling Standard, provided the requirements of both labelling standards are met.

c) **Nonmedicinal Ingredients:**

Nonmedicinal ingredients should be restricted to those substances, necessary for the formulation of the dosage form. Their concentration must not exceed the minimum required to provide their intended effect. They must be harmless in the amounts used, their presence must not affect the therapeutic efficacy or safety of the medicinal ingredients and they must not interfere with assays and tests for the medicinal ingredients and, if present, antimicrobial preservatives.

IV) **Labelling:**

a) 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* must also be met.

b) **Directions for Use:**

i) **Indications**

One or more of the following statements are acceptable:

Simethicone:

1) To relieve the symptoms of flatulence / excess gas;

2) To relieve the bloating / pressure / pain / fullness / stuffed feeling due to gas / excess gas;

Infant Formulation Only:

3) To relieve your infant's symptoms of excess gas associated with colic.

Activated Charcoal:

Indications 1 and 2

Simethicone + Antacid:

Indications 1 and 2 or any mention of alleviation of gas associated with heartburn, sour stomach, or acid indigestion.

ii) **Unacceptable Claims:**

Any reference to spastic colon, irritable colon or diverticulitis

iii) **Dosage Directions:**

Simethicone:

Adults and Children 12 years and older:

1) 40 - 180 mg as needed after meals and at bedtime (three to four times a day) up to a maximum daily dose of 640 mg

For Chewable tablets:

2) Chew the tablets thoroughly before swallowing.

Children (2- 12 years):

3) Use only on the advice of a doctor

Infants (up to 2 years):

4) Use only on the advice of a doctor.

10 to 20 mg of an oral suspension as needed with or after meals. Up to a maximum daily dose of 60 mg

Activated Charcoal:

Adults and Children 12 years and older:

1) 0.5 - 1 g as needed after meals. May be repeated in 2 hours. Up to a maximum of 4 g daily.

Simethicone In Combination with Antacid:

Adults and Children 12 years and older:

Up to 180 mg per dose to a maximum of 640 mg per day

V) **Warnings**

All Ingredients

i) Do not take for more than two weeks, or if symptoms recur, unless directed by a doctor.

Activated Charcoal

ii) Do not take within 2 hours of another medication because the effect of the other medication may be reduced/altered.

iii) Do not use in children under 12 years of age except on the advice and under the supervision of a doctor.

Simethicone

iv) Do not use in children under 2 years of age except on the advice and under the supervision of a doctor.

VI) **REFERENCES:**

1. **United States Federal Register** Vol. 39. No. 108, 1974, pp. 19870-19877, Over-the-Counter Drugs: Antacid and Antiflatulent Products.

2. **United States Federal Register** Vol. 49, No. 73, 1984, pp. 14907-14910, Antacid Drug Products and Antiflatulent Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Monographs; Proposed Rulemaking.

3. **United States Federal Register** Vol. 51, No. 148, 1986, pp. 27751-27763, Antacid and Antiflatulent Drug Products for Over-the-Counter Human Use; Amendment of the Monographs.

4. **United States Federal Register** Vol. 51, No. 175, 1986, p. 32212, Antacid and Antiflatulent Drug Products for Over-the-Counter Human Use; Amendment of Monographs; Correction.

5. **United States Federal Register** Vol. 53, No. 19, 1988, pp. 2715-2717, Antiflatulent Drug Products for Over-the-Counter Human Use; Proposed Amendment of Monograph; Notice of Proposed Rulemaking.

6. **Self Medication**, Fourth Edition, 1992, Canadian Pharmaceutical Association.

7. **American Handbook of Nonprescription Drugs**, 9th Edition, 1990, American Pharmaceutical Association.

8. **United States Pharmacopoeia USP XXIII, National Formulary XVIII**, Twenty-second Revision, United States Pharmacopoeial Convention, Inc., 1995.

9. **British Pharmacopoeia**, Volume II, London, 1993.

10. **The Pharmaceutical Codex**, 12th Edition, The Pharmaceutical Press, London, 1994.

11. **USP DI**, Drug Information For The Health Care Professional, Volume I, 16th Edition, 1996.

12. **American Hospital Formulary Service Drug Information** '92, American Society of Hospital Pharmacists, 1992.

13. **Remington's Pharmaceutical Sciences**, 18th Edition, Mack Publishing Co., 1990.

14. **Drug Evaluations Annual 1992**, 7th Edition, American Medical Association, 1992.

15. **Drug Facts and Comparisons**, 1989 Edition, Facts and Comparisons, St. Louis, 1989.

16. **Martindale, The Extra Pharmacopoeia,** 30th Edition, The Pharmaceutical Press, 1993.

Appendix I

Single Ingredient Simethicone Preparations

FORMULATED PROPER NAME	U.S.P.23 (1995)	B.P. (1993)	Pharmaceutical Codex (1994)
Simethicone Emulsion	X		
Simethicone Oral Suspension	X		
Simethicone Tablets	X		
Simethicone Capsules	X		

Multi-ingredient Formulated Simethicone Preparations

FORMULATED PREPARATIONS	U.S.P.23 (1995)	B.P. (1993)	Pharmaceutical Codex (1994)
Alumina, Magnesia, Calcium carbonate, and Simethicone Tablets	X		
Alumina, Magnesia, and Simethicone Oral Suspension	X		
Alumina, Magnesia, and Simethicone Tablets	X		
Calcium Carbonate, Magnesia, and Simethicone Tablets	X		
Magaltrate and Simethicone Oral Suspension	X		
Magaltrate and Simethicone Tablets	X		