Archived Content

LABELLING STANDARD

BISMUTH SUBSALICYLATE

I) **Description:**

This Labelling Standard applies to those products containing bismuth subsalicylate as a single ingredient and intended to be taken by mouth in the form of tablets, caplets, and oral suspension for the treatment of upset stomach (including heartburn, nausea and indigestion) and/or diarrhea

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:**

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
Bismuth subsalicylate	mg

b) **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 bioavailability, 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**

Adults Only:

For the treatment of upset stomach: heartburn, indigestion, nausea

Adults and/or Children:

For the relief of diarrhea;

Relief of cramps associated with diarrhea;

ii) **Dosage Directions:**

a) Bismuth Subsalicylate liquid 17.5-17.6mg/ml

b) Bismuth Subsalicylate 262mg/tablet (caplet)

	Tablet / Caplet	Liquid	Maximum 8 doses or
Adult	2 tablets/caplets	30ml (2 tablespoon)	4.2g
10-14	1 tablet/caplet	15ml (1 tablespoon)	2.1g
5-9	1/2 tablet/caplet or use liquid	7.5ml (1/2 tablespoon)	1g
2-4	use liquid	5ml (1 teaspoon)	0.7g
<2 yrs	as directed by physician		

Dosage may be repeated every 1/2 to 1 hour as needed. Up to a maximum of 8 dosages in 24 hours

V) **Warnings:**

All Indications:

i) Keep out of the reach of children (C.01.029(1));

ii) There is enough drug in the package to seriously harm a child (C.01.029(2c)). For those packages containing more than 1.5g salicylic acid;

iii) The above cautionary statements should be preceded by a prominently displayed symbol that is octagonal in shape, conspicuous in colour and on a background of a contrasting colour

(C.01.029(3))

iv) At least one of the package sizes must be provided in a child resistant container and the outer label of all containers that are not child resistant shall bear a statement that the product is also available in a child resistant package (C.01.031)

v) Consult a physician before taking the drug during the last 3 months of pregnancy or when nursing (C.09.012)

vi) Do not take within 2 hours of tetracycline antibiotics as their effectiveness may be reduced

vii) May cause temporary darkening of the stool and tongue

viii) Do not take with other salicylates such as acetylsalicylic acid (ASA) except on the advice of a physician.

ix) If you are taking a medication for "thinning of the blood", diabetes, gout or arthritis, consult a physician before taking this product.

x) If symptoms of upset stomach worsen, recur or persist for more than two weeks, consult a physician.

xi) (**Optional**) Children and teenagers who have or are recovering from chicken pox, flu symptoms, or flu should not use this product. If nausea, vomiting, or fever occur, consult a doctor because these symptoms could be an early sign of Reye syndrome, a rare but serious illness.

For treatment of diarrhea:

i) If diarrhea persists for more than 2 days or in the presence of fever, consult a doctor.

created: May 17, 1996

REFERENCES

1. Canadian Pharmaceutical Association, **Self-Medication: A Reference for Health Professionals**, Chapt. 22, 3rd ed., pp. 337-343, 1988

2. Canadian Pharmaceutical Association, **Self-Medication: A Reference for Health Professionals**, Chapt. 16, 4th ed., pp. 257-264, 1992

3. Canadian Pharmaceutical Association, **Self-Medication: A Reference for Health Professionals**, Chapt. 15, 4th ed., pp. 245-253, 1992

4. 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

5. Gilman, A. and L.S. Goodman, **The Pharmacological Basis of Therapeutics**, 8th Ed., Pergamon Press, Chapt. 42, p. 925, 1990.

6. Department of Health and Human Services, Food and Drug Administration, Federal Register, **Antidiarrheal Drug Products for Over-the Counter Products for Human Use**:**Tentative Final Monograph; Proposed Rulemaking,** Vol 51, No.83, pp.16138-16149, 1986

7. American Pharmaceutical Association, **Handbook of Nonprescription Drugs,** 9th Ed., Chapt.13, p. 321, 1990.

8. United States Pharmacopoeial Convention, **Drug Information for the Health Professional,** United States Pharmacopoeial Convention, Inc., pp. 517-520, 1995.

9. American Pharmaceutical Association, **Handbook of Nonprescription Drugs,** 9th Ed., Chapt.11, pp. 260-261, 1990.

10. The Pink Sheet, F-D-C Reports, vol 53, No. 30, July 29, 1991.