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Bismuth Subsalicylate Oral Suspension

DEFINITION

Bismuth Subsalicylate Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of bismuth subsalicylate ($C_7H_5BiO_4$). It may contain one or more suitable buffers, coloring agents, flavors, preservatives, stabilizers, sweeteners, and suspending agents.

IDENTIFICATION

- **A. Identification Tests—General ⟨191⟩, *Bismuth*:** Meets the requirements
- **B. Identification Tests—General ⟨191⟩, *Salicylate*:** Meets the requirements of test *A* after acidifying with nitric acid

ASSAY

- **Procedure**

Standard stock solution: 2.5 mg/mL of bismuth in nitric acid. Prepare by dissolving in 6% of the flask volume of nitric acid and diluting with 0.01 N nitric acid to volume.

Standard solution: 0.05 mg/mL of bismuth in 1 N nitric acid from the *Standard stock solution*

Sample solution: Transfer 10 g of Oral Suspension, previously well shaken in its original container to ensure homogeneity, to a 200-mL volumetric flask. Add about 100 mL of 1 N nitric acid, and dilute with 1 N nitric acid to volume. Mix well without shaking, transfer 10.0 mL of this mixture to a 100-mL volumetric flask, and dilute with 1 N nitric acid to volume. Centrifuge about 20 mL at 4500 rpm for at least 10 min.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV-Vis

Analytical wavelength: 463 nm

Cell: 1 cm

Blank: 1 N nitric acid

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Transfer a measured volume of the *Sample solution* that contains 0.9 mg of bismuth subsalicylate and 10 mL of the *Standard solution* to separate 50-mL volumetric flasks. Add 10.0 mL of 10% ascorbic acid solution and 25.0 mL of 20% potassium iodide solution to each volumetric flask, and dilute with water to volume. Concomitantly determine the absorbances of both solutions, using the *Blank* to set the spectrophotometer.

Calculate the percentage of the labeled amount of bismuth subsalicylate ($C_7H_5BiO_4$) in the portion of Oral Suspension taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of bismuth in the *Standard solution* (mg/mL)

C_U = nominal concentration of bismuth subsalicylate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of bismuth subsalicylate, 362.09

M_{r2} = molecular weight of bismuth, 208.98

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **Microbial Enumeration Tests ⟨61⟩ and Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 10^2 cfu/g, and the total combined molds and yeasts count is NMT 5×10^1 cfu/g. It meets the requirements of the test for the absence of *Escherichia coli*.
- **pH ⟨791⟩:** 3.0–5.5

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Protect from freezing. Avoid excessive heat (over 40°).

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BISMUTH SUBSALICYLATE ORAL SUSPENSION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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