Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-EEFEB148-EAB0-4429-B5CF-D62EA8AA6812_3_en-US
DOI: https://doi.org/10.31003/USPNF_M9788_03_01
DOI Ref: u7vi1

Bismuth Subsalicylate Tablets

DEFINITION

Bismuth Subsalicylate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of bismuth subsalicylate ($C_7H_5BiO_4$).

IDENTIFICATION

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

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 stock solution: Equivalent to 90 mg of bismuth subsalicylate from finely powdered Tablets in a 200-mL volumetric flask. Add 150 mL of 1 N nitric acid, and sonicate for 2 min. Dilute with 1 N nitric acid to volume.

Sample solution: Transfer 20.0 mL of the *Sample stock solution* to a 100-mL volumetric flask, and dilute with 1 N nitric acid to volume. Centrifuge a portion 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: 10% ascorbic acid solution, 20% potassium iodide solution, and 1 N nitric acid (2:5:1)

Analysis

Samples: *Standard solution* and *Sample solution*

Transfer 10.0 mL of the *Standard solution* and the *Sample solution* to separate 50.0-mL volumetric flasks, and dilute with the *Blank* to volume. Concomitantly determine the absorbance of the solutions at the wavelength of maximum absorbance at 463 nm with a suitable spectrophotometer, using the combined reagent solutions as the blank.

Calculate the percentage of the labeled amount of bismuth subsalicylate ($C_7H_5BiO_4$) in the portion of Tablets 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 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%

PERFORMANCE TESTS

- **Disintegration ⟨701⟩**

This test does not apply to Tablets labeled as chewable.

Time: 10 min

Acceptance criteria: Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Avoid excessive heat (over 40°).
- **Labeling:** Label chewable Tablets to indicate that they are to be chewed before swallowing.

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 32(5)

Current DocID: GUID-EEFEB148-EAB0-4429-B5CF-D62EA8AA6812_3_en-US
Previous DocID: GUID-EEFEB148-EAB0-4429-B5CF-D62EA8AA6812_1_en-US
DOI: https://doi.org/10.31003/USPNF_M9788_03_01
DOI ref: u7vi1