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## Bismuth Subcarbonate

### DEFINITION

Bismuth Subcarbonate contains NLT 97.6% and NMT 100.7% of bismuth subcarbonate  $[(\text{BiO})_2\text{CO}_3]$ , calculated on the dried basis.

### IDENTIFICATION

- **A.** ~~IDENTIFICATION TESTS—GENERAL~~, [Bismuth and Carbonate\(191\)](#).

### ASSAY

#### • PROCEDURE

**Sample solution:** 500 mg of Bismuth Subcarbonate in 3 mL of nitric acid. Dilute with water to 250 mL, and add 0.3 mL of xylenol orange TS.

#### Titrimetric system

**Mode:** Direct titration

**Titrant:** 0.05 M edetate disodium VS

**Endpoint detection:** Visual

**Analysis:** Titrate with *Titrant* to a yellow endpoint. Each mL of 0.05 M edetate disodium is equivalent to 12.75 mg of bismuth subcarbonate  $[(\text{BiO})_2\text{CO}_3]$ .

**Acceptance criteria:** 97.6%–100.7% on the dried basis

### IMPURITIES

- ~~CHLORIDE AND SULFATE~~, [Chloride\(221\)](#).

**Sample stock solution:** 5.0 g in 10 mL of water. Add 20 mL of nitric acid, warm to achieve dissolution, and allow to cool. Dilute with water to obtain 100 mL of solution.

**Sample solution:** To 6.6 mL of the *Sample stock solution* add 4 mL of nitric acid, and dilute with water to 50 mL.

**Acceptance criteria:** A 15.0-mL portion of the *Sample solution* shows no more chloride than corresponds to 70  $\mu\text{L}$  of 0.020 N hydrochloric acid (0.05%).

- LIMIT OF ALKALIES AND ALKALINE EARTHS

**Sample solution:** Boil 1.0 g with 20 mL of a mixture of acetic acid and water (1:1). After 2 min, cool, and filter.

**Analysis:** Collect the filtrate, wash the residue with 20 mL of water, and add the washing to the filtrate. To this solution add 2 mL of 2 N hydrochloric acid and 20 mL of water. Heat to boiling, and precipitate the bismuth by adding hydrogen sulfide. Cool the mixture, and filter. Collect the filtrate, wash the residue with water, and add the washing to the filtrate. Evaporate this solution to dryness on a water bath. To the residue add 0.5 mL of sulfuric acid, dry slowly, and cool.

**Acceptance criteria:** The weight of the residue does not exceed 10 mg (1.0%).

- LIMIT OF NITRATE

**Indigo carmine titrant:** To 4 g of indigo carmine in 900 mL of water add 2 mL of sulfuric acid, and dilute with water to 1000 mL.

**Standard solution:** 0.0815 mg/mL of potassium nitrate (equivalent to 0.05 mg/mL of nitrate) in water. Place 20.0 mL in a 125-mL conical flask.

**Sample solution:** To 250 mg of Bismuth Subcarbonate in a 125-mL conical flask add 20 mL of water, and swirl to suspend.

**Analysis:** To the *Standard solution* and the *Sample solution* add 0.05 mL of *Indigo carmine titrant*. Carefully add 30 mL of sulfuric acid, and immediately titrate with *Indigo carmine titrant* to a stable blue endpoint.

**Acceptance criteria:** The volume of *Indigo carmine titrant* consumed by the *Sample solution* does not exceed that consumed by the *Standard solution* (0.4%).

- LIMIT OF SILVER

**Standard solution:** 7.87  $\mu\text{g}$ /mL of silver nitrate

**Sample solution:** To 2.0 g of Bismuth Subcarbonate add 1 mL of water and 4 mL of nitric acid.

**Analysis:** Heat the *Sample solution* gently to achieve dissolution, add water to obtain 11 mL of solution, and cool. Add 2 mL of 1 N hydrochloric acid, and allow to stand in a dark place for 5 min. Treat the *Standard solution* concomitantly with 1 mL of nitric acid and 2 mL of 1 N hydrochloric acid.

**Acceptance criteria:** The turbidity produced from the *Sample solution* is NMT that produced from the *Standard solution* (0.0025%).

**Change to read:**

- **▲** [ARSENIC \(211\)](#), [Procedures, Procedure 1](#) ▲ (CN 1-JUN-2023)

**Test preparation:** 600 mg in 35 mL of 3 N hydrochloric acid

**Acceptance criteria:** NMT 5 ppm

• **LIMIT OF COPPER**

**Standard stock solution 1:** 5 mg/mL of copper prepared as follows. To a 100-mL volumetric flask add 1.34 g of cupric chloride, 10 g of ammonium chloride, and 3 mL of sodium metabisulfite solution (275 mg/mL), and dilute with water to volume.

**Standard stock solution 2:** 10 µg/mL of copper in 2 N nitric acid from *Standard stock solution 1*

**Standard solution:** Mix 0.25 mL of *Standard stock solution 2* and 9.75 mL of water.

**Sample solution:** To 5 mL of the *Sample stock solution* retained from the test for *Chloride and Sulfate*, *Chloride* add 2 mL of 6 N ammonium hydroxide, dilute with water to 50 mL, mix, and filter.

**Analysis:** To 10 mL each of the *Standard solution* and the *Sample solution* add 1 mL of a solution of sodium diethyldithiocarbamate (1 in 1000).

**Acceptance criteria:** No more color is obtained from the *Sample solution* than is obtained from the *Standard solution* (0.005%).

• **LIMIT OF LEAD**

**Diluent:** 6 N nitric acid, lead-free

**Standard stock solution:** 0.1598 mg/mL of lead nitrate in *Diluent*. This solution contains 100 µg/mL of lead.

**Standard solutions:** 1.0, 2.0, and 3.0 µg/mL of lead from the *Standard stock solution* in *Diluent*

**Sample solution:** 12.5 g of Bismuth Subcarbonate in 75 mL of *Diluent*. Heat to boiling for 1 min, cool, and dilute with water to 100 mL.

**Analysis:** Concomitantly determine the absorbances of the *Standard solutions* and the *Sample solution* at the lead emission line of 283.3 nm with an atomic absorption spectrophotometer (see [Atomic Absorption Spectroscopy \(852\)](#)) equipped with a lead hollow-cathode lamp and an air–acetylene flame, using a 1:5 dilution of the *Diluent* as the blank. Plot the absorbances of the *Standard solutions* versus concentration, in µg/mL, of lead, and draw the straight line best fitting the three plotted points. From the graph, determine the concentration, C, in µg/mL, of lead in the *Sample solution*.

Calculate the percentage of lead (Pb) in the portion of Bismuth Subcarbonate taken:

$$\text{Result} = C/1250$$

C = concentration of lead in the *Sample solution* (µg/mL)

**Acceptance criteria:** NMT 0.002%

**SPECIFIC TESTS**

• **Loss on Drying (731)**

**Analysis:** Dry at 105° to constant weight.

**Acceptance criteria:** NMT 1.0% of its weight

**ADDITIONAL REQUIREMENTS**

• **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
BISMUTH SUBCARBONATE	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

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