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Sodium Sulfite

Na_2SO_3 126.04 CAS RN®: 7757-83-7.

DEFINITION

Sodium Sulfite contains NLT 95.0% and NMT 100.5% of sodium sulfite (Na_2SO_3).

IDENTIFICATION

- **A.**

  Sample solution: 50 mg/mL of Sodium Sulfite. [NOTE—Reserve portions of the solution so obtained for use in *Identification* test *B* and in the test for *Color and Clarity of Solution*.]

  Analysis: Add a drop of phenolphthalein TS.

  Acceptance criteria: A pink color is produced.

- **B.** **IDENTIFICATION TESTS—GENERAL** ⟨191⟩, *Sulfate*

  Analysis: To 5 mL of the solution from *Identification* test *A* add 0.5 mL of iodine TS.

  Acceptance criteria: The solution is colorless and meets the requirements of test *A*

- **C.** **IDENTIFICATION TESTS—GENERAL** ⟨191⟩, *Sodium*: Meets the requirements of test *A*

ASSAY

- **PROCEDURE**

  Sample: 250 mg

  Titrimetric system

  (See *Titrimetry* ⟨541⟩.)

  Mode: Residual titration

  Titrant: 0.1 N iodine VS

  Back titrant: 0.1 N sodium thiosulfate VS

  Blank: 50.0 mL of 0.1 N iodine VS, accurately measured

  Endpoint detection: Colorimetric

  Analysis: Add the *Sample* to a 500-mL beaker, add 50.0 mL of 0.1 N iodine VS, accurately measured, and shake to dissolve. Add 1 mL of starch TS, and titrate with 0.1 N sodium thiosulfate VS to a clear endpoint. Perform a blank determination, and make any necessary correction. Calculate the percentage of sodium sulfite (Na_2SO_3) in the *Sample* taken:

$$\text{Result} = [(B - V) \times N \times F \times 100]/W$$

  B = 0.1 N sodium thiosulfate VS volume consumed by the *Blank*

  V = 0.1 N sodium thiosulfate VS volume consumed by the *Sample*

  N = actual normality of the *Back titrant* (mEq/mL)

  F = equivalency factor, 63.0 mg/mEq

  W = weight of *Sample* (mg)

  Acceptance criteria: 95.0%–100.5%

IMPURITIES

- **LIMIT OF IRON**

Standard solution: Immediately before use, dilute 1 volume of *Standard Iron Solution*, prepared as directed under *Iron ⟨241⟩, Procedures, Procedure 1*, to 10 mL with water. [NOTE—This solution contains the equivalent of 1 µg/mL of iron.]

Sample solution: 10.0 g of Sodium Sulfite in 25 mL of water. Shake until mostly dissolved, and add 15 mL of hydrochloric acid. Heat to boiling. Cool, and dilute with water to 100.0 mL. Use a 10-mL portion.

Analysis: To the *Standard solution* and the *Sample solution*, separately add 2 mL of a citric acid solution (200 g/L), and then add 0.1 mL of thioglycolic acid. Make alkaline with stronger ammonia water, and dilute with water to 20 mL. Allow to stand for 5 min.

Acceptance criteria: Any pink color in the *Sample solution* is not more intense than that in the *Standard solution* (NMT 10 ppm).

• **LIMIT OF SELENIUM**

[**CAUTION—**Selenium is toxic; handle with care.]

Selenium standard solution: 100 µg/mL of selenium is prepared as follows. Dissolve 0.1 g of metallic selenium in 2 mL of nitric acid. Evaporate to dryness, add 2 mL of water, and evaporate to dryness. Repeat the addition of water and the evaporation to dryness three more times. Dissolve the residue so obtained in 50 mL of diluted hydrochloric acid. Transfer to a 1000-mL volumetric flask, and dilute with diluted hydrochloric acid to volume.

Standard solution: To 1.0 g of Sodium Sulfite add 0.2 mL of *Selenium standard solution* and 10 mL of formaldehyde TS, and slowly add 2 mL of hydrochloric acid. Heat in a water bath for 20 min.

Sample solution: To 3.0 g of Sodium Sulfite add 10 mL of formaldehyde TS, and slowly add 2 mL of hydrochloric acid.

Analysis: Heat the *Standard solution* and the *Sample solution* in a water bath for 20 min.

Acceptance criteria: Any pink color in the *Sample solution* is not more intense than that in the *Standard solution* (NMT 10 ppm).

Change to read:

• **LIMIT OF THIOSULFATES**

Sample solution: 20 mg/mL of Sodium Sulfite

Analysis: To 100 mL of the *Sample solution*, add 10 mL of formaldehyde TS and 10 mL of acetic acid. Allow to stand for 5 min. Add 0.5 mL of starch TS, and titrate with 0.1 N iodine VS. Perform a blank determination (see ▲*Titrimetry ⟨541⟩*▲ (CN 1-Aug-2024)), and note the difference in volumes required.

Acceptance criteria: The difference in volumes is NMT 0.15 mL (NMT 0.1%).

• **LIMIT OF ZINC**

Zinc standard stock solution: A solution of 1 mL of acetic acid and the amount of zinc sulfate equivalent to 0.440 g of $ZnSO_4 \cdot 7H_2O$ in 100.0 mL of water. [NOTE—This solution contains the equivalent of 1000 µg/mL of Zn.]

Zinc standard solution: 25 µg/mL of zinc from *Zinc standard stock solution*

Standard solutions: Transfer 1.0-, 2.0-, and 4.0-mL portions of *Zinc standard solution* to separate 100-mL volumetric flasks. Dilute the contents of each flask with water to volume, and mix to obtain solutions having known concentrations of 0.25, 0.5, and 1.0 µg/mL of zinc.

Sample stock solution: 100 mg/mL of Sodium Sulfite is prepared as follows. To 10.0 g of Sodium Sulfite add 25 mL of water. Shake until mostly dissolved, and slowly add 15 mL of hydrochloric acid. Heat to boiling. Cool, and dilute with water to 100.0 mL.

Sample solution: 20.0 mg/mL of Sodium Sulfite from the *Sample stock solution*

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Zinc emission line at 213.9 nm

Lamp: Zinc hollow-cathode

Flame: Air–acetylene

Analysis

Samples: *Standard solutions* and the *Sample solution*

Plot the absorbances of the *Standard solutions* versus concentration of zinc, in µg/mL, and draw the straight line best fitting the plotted points. From the graph so obtained, determine the concentration of zinc, in µg/mL, in the *Sample solution*.

Acceptance criteria: NMT 25 ppm

SPECIFIC TESTS

• **COLOR AND CLARITY OF SOLUTION**

Analysis: Examine the solution prepared for *Identification* test *A*.

Acceptance criteria: The solution is clear and colorless.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers. Store at room temperature.

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

Topic/Question	Contact	Expert Committee
SODIUM SULFITE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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