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Sodium Metabisulfite

$Na_2S_2O_5$ 190.11
Disulfurous acid, disodium salt;
Disodium pyrosulfite CAS RN®: 7681-57-4.

DEFINITION

Sodium Metabisulfite contains an amount of sodium metabisulfite ($Na_2S_2O_5$) equivalent to NLT 65.0% and NMT 67.4% of SO_2.

IDENTIFICATION

• **A. Identification Tests—General, *Sodium* ⟨191⟩ and *Sulfite* ⟨191⟩:** A solution (1 in 20) meets the requirements.

ASSAY

• **Procedure**

Sample: 200 mg of Sodium Metabisulfite

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

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Residual titration

Titrant: 0.1 N iodine VS

Back-titrant: 0.1 N sodium thiosulfate VS

Endpoint detection: Visual

Analysis: Add the *Sample* to 50.0 mL of 0.1 N iodine VS in a glass-stoppered conical flask, and swirl to dissolve. Allow to stand for 5 min, protected from light. Add 1 mL of hydrochloric acid, and titrate the excess iodine with *Back-titrant*, adding 3 mL of starch TS as the endpoint is approached. Perform a blank determination.

Calculate the percentage of sulfur dioxide (SO_2) in the portion of Sodium Metabisulfite taken:

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

V_B = *Back-titrant* volume consumed by the *Blank* (mL)

V_S = *Back-titrant* volume consumed by the *Sample* (mL)

N = *Back-titrant* normality (mEq/mL)

F = equivalency factor, 32.03 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 65.0%–67.4% of SO_2

IMPURITIES

• **Limit of Chloride**

Standard solution: 0.71 mL of 0.020 N hydrochloric acid in 100 mL of water

Sample solution: 1.0 g in 10 mL of water. [Note—Pass through a small chloride-free filter, if necessary.] Add 6 mL of 30% hydrogen peroxide. Add 1 N sodium hydroxide until the solution is slightly alkaline to phenolphthalein, and dilute with water to 100 mL.

Analysis

Samples: *Standard solution* and *Sample solution*

Dilute 2.0 mL of the *Samples* with water to 20 mL. Add 1 mL of nitric acid and 1 mL of silver nitrate TS. Allow to stand for 5 min protected from direct sunlight, and compare the turbidity from the *Samples* (see *Visual Comparison ⟨630⟩*).

Acceptance criteria: Any turbidity produced by the *Sample solution* does not exceed that of the *Standard solution* (0.05%).

• **Limit of Thiosulfate**

Standard solution: Mix 0.10 mL of 0.10 N sodium thiosulfate with 10 mL of 1 N hydrochloric acid.

Sample solution: Mix 2.2 g with 10 mL of 1 N hydrochloric acid.

Analysis

Samples: *Standard solution* and *Sample solution*

Gently boil the *Samples* for 5 min. Cool, then transfer each solution to a small test tube.

Acceptance criteria: Any turbidity produced by the *Sample solution* does not exceed that of the *Standard solution* (0.05%).

Change to read:

• ▲**Iron ⟨241⟩, *Procedures, Procedure 1***▲ (CN 1-Jun-2023)

Test preparation: Dissolve 500 mg of Sodium Metabisulfite in 14 mL of dilute hydrochloric acid (2 in 7), and evaporate on a steam bath to dryness. Dissolve the residue in 7 mL of dilute hydrochloric acid (2 in 7), and again evaporate to dryness. Dissolve the resulting residue in a mixture of 2 mL of hydrochloric acid and 20 mL of water. Add 3 drops of bromine TS, and boil to expel the bromine. Cool, then dilute with water to 47 mL.

Analysis: Proceed as directed in the chapter.

Acceptance criteria: NMT 20 ppm

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-filled, tight containers, and avoid exposure to excessive heat.

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

Topic/Question	Contact	Expert Committee
SODIUM METABISULFITE	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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