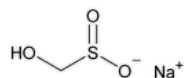


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Sodium Formaldehyde Sulfoxylate



$\text{CH}_3\text{NaO}_3\text{S}$ 118.09

$\text{CH}_3\text{NaO}_3\text{S} \cdot 2\text{H}_2\text{O}$ 154.11

Methanesulfinic acid, hydroxy-, monosodium salt;

Monosodium hydroxymethanesulfinate CAS RN®: 149-44-0.

Dihydrate CAS RN®: 6035-47-8.

DEFINITION

Sodium Formaldehyde Sulfoxylate contains an amount of sodium formaldehyde sulfoxylate ($\text{CH}_3\text{NaO}_3\text{S}$) equivalent to NLT 45.5% and NMT 54.5% of SO_2 , calculated on the dried basis. It may contain a suitable stabilizer, such as sodium carbonate.

IDENTIFICATION

• A.

Sample solution: Dissolve 4 g in 10 mL of water in a test tube.

Analysis: To the *Sample solution* add 1 mL of silver–ammonia–nitrate TS.

Acceptance criteria: Metallic silver is produced, either as a finely divided, gray precipitate or as a bright metallic mirror on the inner surface of the tube.

• B.

Sample solution: Dissolve 40 mg of salicylic acid in 5 mL of sulfuric acid, and add 50 mg of Sodium Formaldehyde Sulfoxylate.

Analysis: Warm very gently.

Acceptance criteria: A permanent, deep red color appears.

ASSAY

• PROCEDURE

Sample: 1 g

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N iodine VS. [NOTE—Prepare an adequate amount for both the Assay and the test for *Sodium Sulfite*.]

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 50-mL volumetric flask, dissolve in 25 mL of water, and dilute with water to volume. Reserve a portion of this solution for the test for *Sodium Sulfite*. Transfer 4.0 mL of the remaining solution to a conical flask containing 100 mL of water. Titrate with *Titrant*, adding 3 mL of starch TS as the endpoint is approached. Each mL of 0.1 N iodine is equivalent to 1.602 mg of SO_2 .

Acceptance criteria: 45.5%–54.5% of SO_2 on the dried basis

IMPURITIES

• SULFIDE

Analysis: Dissolve 6 g in 14 mL of water in a test tube, and wet a strip of lead acetate test paper with the clear solution.

Acceptance criteria: No discoloration is evident within 5 min.

• IRON

Standard solution: Dissolve 43.2 mg of ferric ammonium sulfate in 10 mL of 2 N sulfuric acid, and add water to make 1000 mL, each mL representing 5 µg of Fe.

Sample solution: Transfer 1.0 g of Sodium Formaldehyde Sulfoxylate to a suitable crucible, and carefully ignite, initially at a low temperature until thoroughly charred, and finally, preferably in a muffle furnace, at 500°–600° until the carbon is all burned off. Cool, dissolve the residue in 2 mL of hydrochloric acid, and dilute with water to 50 mL.

Analysis: To 5.0 mL of the *Standard solution* and 50 mL of the *Sample solution* add 50 mg of ammonium persulfate and 5 mL of ammonium thiocyanate TS, and transfer each to a separate color comparison tube.

Acceptance criteria: 0.0025%; the color of the *Sample* is not deeper than that of the *Standard solution*.

• SODIUM SULFITE

Sample solution: 4.0 mL of the solution prepared for the Assay in a conical flask containing 100 mL of water

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N iodine VS, prepared in the Assay

Endpoint detection: Visual

Analysis: Add 2 mL of formaldehyde TS to the *Sample solution*, and titrate with the *Titrant*, adding 3 mL of starch TS as the endpoint is approached.

Calculate the percentage of sodium sulfite (Na_2SO_3) in the Sodium Formaldehyde Sulfoxylate taken:

$$\text{Result} = (V_2 - V_1) \times (N/W) \times (F \times 1.25)$$

V_2 = volume of 0.1 N iodine VS consumed in the titration performed in the Assay (mL)

V_1 = volume of 0.1 N iodine VS consumed in this titration (mL)

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

W = weight of the *Sample* in the Assay (g)

F = equivalency weight of sodium sulfite, 63.02 mg/mEq

Acceptance criteria: NMT 5.0% on the dried basis

SPECIFIC TESTS

• [pH \(791\)](#)

Sample solution: 20 mg/mL

Acceptance criteria: 9.5–10.5

• [Loss on Drying \(731\)](#)

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 27.0%

• ALKALINITY

Sample solution: 1.0 g of Sodium Formaldehyde Sulfoxylate in 50 mL of water

Analysis: To the *Sample solution* add phenolphthalein TS, and titrate with 0.10 N sulfuric acid.

Acceptance criteria: NMT 3.5 mL is required for neutralization.

• CLARITY AND COLOR OF SOLUTION

Sample solution: 1 g of Sodium Formaldehyde Sulfoxylate in 20 mL of water

Analysis: Transfer 10 mL of the *Sample solution* to a 20- × 150-mm test tube. Compare with water in a similar test tube.

Acceptance criteria: The *Sample solution* and the water are equally clear and, when viewed transversely by transmitted light, exhibit no apparent difference in color.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers, and store at controlled room temperature.

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

Topic/Question	Contact	Expert Committee
SODIUM FORMALDEHYDE SULFOXYLATE	Documentary Standards Support	SE2020 Simple Excipients

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

Chromatographic Database Information: [Chromatographic Database](#)

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