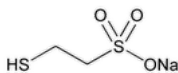


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Mesna



$C_2H_5NaO_3S_2$ 164.18

Ethanesulfonic acid, 2-mercapto-, monosodium salt;

Sodium 2-mercaptoethanesulfonate CAS RN[®]: 19767-45-4; UNII: NR701405Q9.

DEFINITION

Mesna contains NLT 96.0% and NMT 102.0% of mesna ($C_2H_5NaO_3S_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)

Add the following:

- ▲ • **B.** The retention time of the mesna peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲_{2S}
 (USP41)

Change to read:

- **▲C.**▲_{2S} (USP41) [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Sodium](#): Meets the requirements

ASSAY

Change to read:

• PROCEDURE

▲ **Mobile phase:** In a 1000-mL volumetric flask, dissolve 2.94 g of [potassium dihydrogen phosphate](#), 2.94 g of [dipotassium hydrogen phosphate](#), and 2.6 g of [tetrabutylammonium hydrogen sulfate](#) in about 600 mL of [water](#). Adjust with [phosphoric acid](#) to a pH of 2.3, add 335 mL of [methanol](#), and dilute with [water](#) to volume.

Standard solution: 4 mg/mL of [USP Mesna RS](#) in *Mobile phase*

Sample solution: 4 mg/mL of Mesna in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 15-cm; 4-μm packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Run time: NLT 4 times the retention time of mesna

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—If peak splitting is observed for the mesna peak, the peak response of mesna is the sum of split peaks.]

Calculate the percentage of mesna ($C_2H_5NaO_3S_2$) in the portion of Mesna taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of mesna from the *Sample solution*

r_s = peak response of mesna from the *Standard solution*

C_s = concentration of [USP Mesna RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Mesna in the *Sample solution* (mg/mL) ▲_{2S} (USP41)

Acceptance criteria: 96.0%–102.0% on the dried basis

IMPURITIES

Change to read:

• LIMIT OF CHLORIDE

Chloride standard solution: 8.24 µg/mL of [sodium chloride](#) in [water](#)

Sample solution: 200 mg/mL of Mesna in [carbon dioxide-free water](#)

Analysis: To 1 mL of the *Sample solution* and 15 mL of [water](#) add 1 mL of 2 M [nitric acid](#). Add the resulting solution to 1 mL of [silver nitrate](#) solution (17 g in 1000 mL), and allow to stand for 5 min, protected from light. To 10 mL of the *Chloride standard solution* add 5 mL of [water](#) and 1 mL of 2 M [nitric acid](#). To this solution add 1 mL of [silver nitrate](#) solution (17 g in 1000 mL), and allow to stand for 5 min, protected from light. ▲_{2S} (USP41)

Acceptance criteria: ▲When viewed against a dark background, the *Sample solution* is not more turbid than the *Chloride standard solution* (NMT 250 ppm). ▲_{2S} (USP41)

Change to read:

• LIMIT OF SULFATE

Diluent: 30% (v/v) [ethanol](#) in [water](#)

Sulfate standard stock solution: 1.81 mg/mL of [potassium sulfate](#) in *Diluent*

Sulfate standard solution: 0.0181 mg/mL of potassium sulfate in *Diluent*, prepared immediately before use from the *Sulfate standard stock solution*

Sample solution: Add 5.0 mL of the *Sample solution*, prepared as directed in the test for *Limit of Chloride* to a 30-mL volumetric flask, and dilute with [water](#) to volume.

Analysis: Add 3 mL of a 250-g/L solution of [barium chloride](#) to 4.5 mL of the *Sulfate standard solution*. Shake and allow to stand for 1 min. To 2.5 mL of this solution, add 15 mL of the *Sample solution* and 0.5 mL of [acetic acid](#). Use 15 mL of this mixture for comparison with 15 mL of the *Sulfate standard solution*, prepared in the same manner, but using the *Sulfate standard solution* instead of the *Sample solution*. After 5 min, ▲measure the opalescences in the *Sample solution* and in the *Sulfate standard solution*. ▲_{2S} (USP41)

Acceptance criteria: ▲Any opalescence in the *Sample solution* is not more intense than that in the *Sulfate standard solution* (NMT 300 ppm). ▲_{2S} (USP41)

Change to read:

• ORGANIC IMPURITIES

Mobile phase: In a 1000-mL volumetric flask, dissolve 2.94 g of [potassium dihydrogen phosphate](#), 2.94 g of [dipotassium hydrogen phosphate](#), and 2.6 g of [tetrabutylammonium hydrogen sulfate](#) in about 600 mL of [water](#). Adjust with [phosphoric acid](#) to a pH of 2.3, add 335 mL of [methanol](#), and dilute with [water](#) to volume.

System suitability solution: 0.18 mg/mL of [USP Mesna RS](#) and 0.004 mg/mL of [USP Mesna Related Compound A RS](#) in *Mobile phase*

Standard solution 1: 8 µg/mL of [USP Mesna Related Compound A RS](#) and 120 µg/mL of [USP Mesna Related Compound B RS](#) in *Mobile phase*

Standard solution 2: 12 µg/mL of [USP Mesna RS](#) in *Mobile phase*

Sample solution: 4 mg/mL of Mesna in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 25-cm; 10-µm packing [L1](#)

Flow rate: 1 mL/min

Run time: ▲NLT ▲_{2S} (USP41) 4 times the retention time of mesna

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for mesna and mesna related compound A are about 1.0 and 1.4, respectively.]

Suitability requirements

Resolution: NLT 3.0 between mesna and mesna related compound A

Analysis

Samples: *Standard solution 1*, *Standard solution 2*, and *Sample solution*

[NOTE—Identify the peaks using the relative retention times provided in [Table 1](#).]

Calculate the percentage of mesna related compound A in the portion of Mesna taken: