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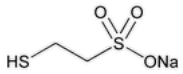
Mesna



$C_2H_5NaO_3S_2$ 164.18

Ethanesulfonic acid, 2-mercapto-, monosodium salt;

Sodium 2-mercaptoethanesulfonate CAS RN®: 19767-45-4; UNII: NR7O1405Q9.

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*

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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:

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

r_U = peak response of mesna related compound A from the *Sample solution*

r_S = peak response of mesna related compound A from *Standard solution 1*

C_S = concentration of USP Mesna Related Compound A RS in *Standard solution 1* (mg/mL)

C_U = concentration of Mesna in the *Sample solution* (mg/mL)

Calculate the percentage of mesna related compound B 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 related compound B from the *Sample solution*

r_S = peak response of mesna related compound B from *Standard solution 1*

C_S = concentration of USP Mesna Related Compound B RS in *Standard solution 1* (mg/mL)

C_U = concentration of Mesna in the *Sample solution* (mg/mL)

Calculate the percentage of any specified impurities (thiouronium ethanesulfonic acid, guanidinethiouronium ethanesulfonic acid, and mesna triazine analog) and any unspecified impurities in the portion of Mesna taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of any specified or unspecified, individual impurity from the *Sample solution*

r_S = peak response of mesna from *Standard solution 2*

C_S = concentration of USP Mesna RS in *Standard solution 2* (mg/mL)

C_U = concentration of Mesna in the *Sample solution* (mg/mL)

F = relative response factors (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Thiouronium ethanesulfonic acid[a]	0.6	100	0.3
Guanidinethiouronium ethanesulfonic acid[b]	0.6	100	0.3
Mesna triazine analog[c]	0.8	100	0.3
Mesna	1.0	—	—
Mesna related compound A	1.4	—	0.2
Mesna related compound B	2.3	—	3.0
Individual, unspecified impurities	—	1.0	0.1
Total unspecified impurities	—	—	0.3

[a] 2-(Carbamimidoylthio)ethane-1-sulfonic acid.

[b] 2-[(*N*-Carbamimidoylcarbamimidoyl)thio]ethane-1-sulfonic acid.

[c] 2-((4,6-Diamino-1,3,5-triazin-2-yl)thio)ethane-1-sulfonic acid.

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SPECIFIC TESTS

Change to read:

• ▲**Loss on Drying** ⟨731⟩▲2S *(USP41)*

Sample: 1 g

Analysis: Dry the *Sample* under vacuum at a pressure not exceeding 1 mm of mercury at 60° over phosphorus pentoxide for 2 h.

Acceptance criteria: NMT 1.0%

• **pH** ⟨791⟩

Sample solution: 100 mg/mL of Mesna in carbon dioxide-free water

Acceptance criteria: 4.5–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in a tight container, and store at room temperature.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Mesna RS

USP Mesna Related Compound A RS

2-(Acetylthio)ethane-1-sulfonic acid, ▲potassium salt, crystal adduct with potassium chloride.
$C_4H_7KO_4S_2 \cdot KCl$ 296.86▲ (ERR 1-Mar-2019)

USP Mesna Related Compound B RS

2,2'-Disulfanediylbis(ethane-1-sulfonic acid), ▲dipotassium salt, crystal adduct with sodium chloride.
$C_4H_8K_2O_6S_4 \cdot NaCl$ 416.98▲ (ERR 1-Mar-2019)

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

Topic/Question	Contact	Expert Committee
MESNA	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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