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Add the following:

▲Mesna Tablets

DEFINITION

Mesna Tablets contain NLT 90.0% and NMT 105.0% of the labeled amount of mesna ($C_2H_5NaO_3S_2$).

IDENTIFICATION

• **A.** The retention time of the mesna peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

Change to read:

• **B.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Standard: Mix 1.2 mg of USP Mesna RS with potassium bromide.

Sample: Grind 1 Tablet in a mortar heated to 30°–50°. Mix a nominal amount of 1.2 mg of mesna of this powder with potassium bromide.

Acceptance criteria: The IR spectra of the *Sample* exhibit the absorption bands at about 1180, 1120, and 1060 cm^{-1}, similar to the *Standard*.

ASSAY

• **Procedure**

Solution A: Dissolve 2.72 g of monobasic potassium phosphate and 6.79 g of tetrabutylammonium hydrogen sulfate in 700 mL of water.

Mobile phase: Methanol and *Solution A* (30:70). [Note—The pH of the *Mobile phase* is about 2.8.]

System suitability solution: 4 mg/mL of USP Mesna RS and 0.02 mg/mL of USP Mesna Related Compound A RS in *Mobile phase*

Standard solution: 4 mg/mL of USP Mesna RS in *Mobile phase*

Sample solution: Nominally 4 mg/mL of mesna in *Mobile phase* prepared as follows. Transfer an adequate amount of mesna from NLT 10 finely powdered Tablets to a suitable volumetric flask. Add about 70% of the total volume of *Mobile phase* and sonicate for about 20 min. Dilute with *Mobile phase* to volume. Pass through a suitable filter of 0.45-µm pore size and discard the first 5 mL of the filtrate.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 2.1-mm × 20-cm; 5-µm packing L7

Column temperature: 40°

Flow rate: 0.325 mL/min

Injection volume: 5 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between mesna and mesna related compound A, *System suitability solution*

Relative standard deviation: NMT 2%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mesna ($C_2H_5NaO_3S_2$) in the portion of Tablets 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 = nominal concentration of mesna in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–105.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.06 N hydrochloric acid; 500 mL

Apparatus 2: 50 rpm

Time: 15 min

Mobile phase, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.8 mg/mL of USP Mesna RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size and discard the first 5 mL of the filtrate.

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between mesna and mesna related compound A, *System suitability solution*

Relative standard deviation: NMT 2%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mesna ($C_2H_5NaO_3S_2$) dissolved:

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

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)

V = volume of the *Medium*, 500 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of mesna ($C_2H_5NaO_3S_2$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Solution A, Mobile phase, System suitability solution, and **Sample solution:** Prepare as directed in the *Assay*.

Standard solution: 0.02 mg/mL of USP Mesna RS and 0.1 mg/mL of USP Mesna Related Compound B RS in *Mobile phase*

Chromatographic system: Proceed as directed in the *Assay*, except for the *Detector*.

(See *Chromatography ⟨621⟩, System Suitability*.)

Detector

For *System suitability solution*: UV 230 nm

For *Standard solution* and ***Sample solution*:** UV 202 nm

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between mesna and mesna related compound A, *System suitability solution*

Relative standard deviation: NMT 2% for both mesna and mesna related compound B, *Standard solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of mesna related compound B in the portion of Tablets 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 the *Standard solution*

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

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

Calculate the percentage of any individual unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of any individual unspecified degradation product 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 = nominal concentration of mesna in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Thiouronium ethanesulfonic acid[a,b]	0.6	—
Guanidinethiouronium ethanesulfonic acid[a,c]	0.6	—
Mesna	1.0	—
Mesna related compound A[a]	1.3	—
Mesna related compound B[a]	2.5	3
Individual unspecified degradation product	—	0.1
Total degradation products (except mesna related compound B)	—	0.5

[a] Not included in the total degradation products.

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

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers and store at controlled 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)

▲2S *(USP41)*

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

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

Chromatographic Database Information: Chromatographic Database

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