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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- μ m 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 $\times$ 20-cm; 5- μ m packing [L7](#)

Column temperature: 40°

Flow rate: 0.325 mL/min

Injection volume: 5 μ L

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*