Mesna Tablets

Mesna Tablets contains not less than 90.0 per cent and not more than 105.0 per cent of the stated amount of mesna, $C_2H_5NaO_3S_2$.

Usual strengths. 400 mg and 600 mg.

Identification

A. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution (a).

B. Determine by infrared absorption spectrophotometry (2.4.6), Compare the spectrum with that obtained with *mesna RS or* with reference spectrum of mesna.

Tests

Dissolution (2.5.2).

Apparatus No. 1,
Medium. 500 ml of *0.06 M hydrochloric acid,*
Speed and time. 50 rpm for 15 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. Use the filtrate, diluted if necessary, with the dissolution medium.

Reference solution (a). A 0.08 per cent w/v solution of *mesna RS* with the dissolution medium.

Reference solution (b). A 0.4 per cent w/v solution of *mesna RS* and 0.002 per cent w/v solution of *mesna related compound A RS* in the mobile phase.

Chromatographic system
- a stainless steel column 20 cm x 2.1 mm, packed with octylsilane bonded to porous silica (5 µm),
- column temperature: 40º,
- mobile phase: a mixture of 70 volumes of a buffer solution prepared by dissolving 2.72 g of *monobasic potassium phosphate* and 6.79 g of *tetrabutylammonium hydrogen sulphate* in 700 ml of *water* and 30 volumes of *methanol*, adjusted to pH 2.8,
- flow rate: 0.325 ml per minute,
- spectrophotometer set at 230 nm,
- injection volume: 5 µl.

Inject reference solution (a) and (b). The test is not valid unless in the chromatogram obtained with reference solution (b) the resolution between the mesna and mesna related compound A is not less than 1.5 in the chromatogram obtained with reference solution (b) and the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject the reference solution (a) and the test solution.

Calculate the content of $C_2H_5NaO_3S_2$ in the dissolution medium.

D. Not less than 75 per cent of the stated amount of $C_2H_5NaO_3S_2$.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Disperse a quantity of powdered tablets containing 0.4 g of Mesna in 70 ml of the mobile phase with the aid of ultrasound for 20 minutes and dilute to 100.0 ml with the mobile phase.

Reference solution (a). A 0.002 per cent w/v solution of *mesna RS* and 0.01 per cent w/v solution of *mesna related compound B RS* in the mobile phase.

Reference solution (b). A 0.4 per cent w/v solution of *mesna RS* and 0.002 per cent w/v solution of *mesna related compound A RS* in the mobile phase.

Use chromatographic system as described in the dissolution with following modification.

Chromatographic system
- spectrophotometer set at 230 nm [For reference solution (b)],
- spectrophotometer set at 202 nm (For reference solution (a) and test solution),

Name	Relative retention time
Thiouronium ethanesulfonic acid[1,2]	0.6

Guanidinethiouronium ethanesulfonic acid[1,3]	0.6
Mesna	1.0
Mesna related compound A[4]	1.3
Mesna related compound B[5]	2.5

[1]Process related impurity not included in total impurities.
[2]2-(Carbamimidoylthio)ethane-1-sulfonic acid
[3]2-[(*N*-Carbamimidoylcarbamimidoyl)thio]ethane-1-sulfonic acid
[4]2-(Acetylthio)ethane-1-sulfonic acid
[5]2,2-Disulfanediylbis(ethane-1-sulfonic acid)

Inject reference solution (b). The test is not valid unless the resolution between the mesna and mesna related compound A is not less than 1.5 in the chromatogram obtained with reference solution (b) and the relative standard deviation for both mesna and mesna related compound B, for replicate injections is not more than 2.0 per cent.

Inject reference solutions (a) and the test solution. In the chromatogram obtained with the test solution, the area of peak due to mesna related compound B is not more than 6 times the area of the corresponding peak in the chromatogram obtained with the reference solution (a) (3.0 per cent), the area of any other secondary peak is not more than 0.2 times the area of principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent) and the sum of areas of any other secondary peaks is not more than the area of principal peak in the chromatogram obtained with the reference solution (b) (0.5 per cent).

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 20 tablets. Disperse a quantity of powdered tablets containing 0.4 g of Mesna in 70 ml of the mobile phase with the aid of ultrasound for 20 minutes and dilute to 100.0 ml with the mobile phase.

Reference solution (a). A 0.4 per cent w/v solution of *mesna RS* with the mobile phase.

Reference solution (b). A 0.4 per cent w/v solution of *mesna RS* and 0.002 per cent w/v solution of *mesna related compound A RS* in the mobile phase.

Use chromatographic system and reference solution (b) as described in the dissolution.

Inject the reference solution (b). The test is not valid unless the resolution between the mesna and mesna related compound A is not less than 1.5 and the relative standard deviation for replicate injections is not more than 2.0 per cent.
Inject the reference solution (a) and the test solution.

Calculate the content of $C_2H_5NaO_3S_2$ in the tablets.

Storage. Store protected from moisture, at a temperature not exceeding 30º.