Mesna Tablets

MesnaTablets contain 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. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *mesna IPRS* or with reference spectrum of mesna.

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

Tests

Dissolution (2.5.2).

Apparatus No. 2 (Paddle),
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, dilute if necessary, with the dissolution medium.

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

Reference solution (b). A solution containing 0.4 per cent w/v of *mesna IPRS* and 0.002 per cent w/v of *mesna related compound A IPRS* 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 *tetrabutyl ammonium 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 the resolution between 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 reference solution (a) and the test solution.

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

Q. 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 the 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 solution containing 0.002 per cent w/v of *mesna IPRS* and 0.01 per cent w/v of *mesna related compound B IPRS* in the mobile phase.

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

Use chromatographic system as described under Dissolution with the following modification.
- 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 ethanesulphonic acid[1,2]	0.6
Guanidinethiouronium ethanesulphonic 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-sulphonic acid
[3]2-[(*N*-Carbamimidoylcarbamimidoyl)thio]ethane-1-sulphonic acid
[4]2-(Acetylthio)ethane-1-sulphonic acid
[5]2,2-Disulfanediylbis(ethane-1-sulphonic acid)

Inject reference solution (a) and (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 replicate injections for mesna and mesna related compound B is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to mesna related compound B is not more than 1.2 times the area of the corresponding peak in the chromatogram obtained with reference solution (a) (3.0 per cent), the area of any other secondary peak is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent) and the sum of the areas of all the secondary peaks other than mesna related compound B is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (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 powder 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 IPRS* in the mobile phase.

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

Use chromatographic system as described under Dissolution.

Inject reference solution (a) and (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 replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject 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.