Mefenamic Acid Suspension

Mefenamic Acid Suspension contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amounts of mefenamic acid, $C_{15}H_{15}NO_2$,

Usual strength. 100 mg per 5 ml.

Identification

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.

Tests

pH (2.4.24). 4.0 to 5.5.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Weigh a quantity of the suspension containing 100 mg of Mefenamic Acid and disperse in 70 ml of the mobile phase with the aid of ultrasound for 15 minutes with intermittent shaking and dilute to 100.0 ml with the mobile phase.

Reference solution (a). A 0.001 per cent w/v solution of *mefenamic acid IPRS* in the mobile phase.

Reference solution (b). A solution containing 0.001 per cent w/v, each of, solution of *mefenamic acid IPRS* and *2,3-dimethylaniline IPRS* in the mobile phase.

Chromatographic system
- a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 40 volumes of a buffer solution prepared by dissolving 5.75 g of *ammonium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 5.0 with *dilute ammonia*, 46 volumes of *acetonitrile* and 14 volumes of *tetrahydrofuran,*
- flow rate: 1 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 10 µl.

Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to mefenamic acid and 2,3-dimethylaniline is not less than 2.0 in the chromatogram obtained with reference solution (b), the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 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. Run the chromatogram 3 times the retention time of the principal peak. The area of any secondary peak is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent) and the sum of areas of all the secondary peaks is not more than the area of principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent).

Other tests. Comply with the tests stated under Oral Liquids.

Assay. Determine by liquid chromatography (2.4.14).

Solvent mixture. A 0.04 per cent v/v solution of *sodium hydroxide* in *methanol*.

Test solution. Weigh a quantity of the suspension containing 100 mg of Mefenamic Acid and disperse in 70 ml of the solvent mixture with the aid of ultrasound for 15 minutes with intermittent shaking and dilute to 100.0 ml with the solvent mixture. Dilute 2.0 ml of the solution to 100.0 ml with the mobile phase.

Reference solution. A 0.02 per cent w/v solution of *mefenamic acid IPRS* in the solvent mixture. Dilute 5.0 ml of the solution to 50.0 ml with the mobile phase.

Chromatographic system
- a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm)
- mobile phase: a mixture of 20 volumes of a buffer solution prepared by dissolving 2.72 g of *potassium dihydrogen phosphate* in 1000 ml of *water*, adjusted to pH 3.0 with *dilute orthophosphoric acid* and 80 volumes of *acetonitrile,*
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 285 nm,
- injection volume: 10 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Determine the weight per ml of the oral suspension (2.4.29) and calculate the content of $C_{15}H_{15}NO_2$ in the suspension.

Storage. Store protected from light, at a temperature not exceeding 30°.