Epalrestat Tablets

Epalrestat Tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of epalrestat, $C_{15}H_{13}NO_3S_2$.

Usual strength. 50mg.

Identification

Extract a quantity of the powdered tablets containing 50 mg of Epalrestat, with 100.0 ml of *methanol*, filter. Dilute 1.0 ml of the filtrate to 100.0 ml with *methanol.* When examined in the range 200 nm to 400 nm (2.4.7), the solution exhibits maxima between 235 nm and 239 nm, between 290 nm and 294 nm and between 387 nm and 391nm.

Tests

Note – Carryout the tests protected from light.

Dissolution (2.5.2).

Apparatus No.2 (Paddle),
Medium. 900 ml of equal volumes of *phosphate buffer pH 6.8* and *water,*
Speed and time. 50 rpm and 45 minutes.
Withdraw a suitable volume of the medium and filter. Dilute a suitable volume of the filtrate with dissolution medium, measure the absorbance of the resulting solution at the maximum at about 398 nm (2.4.7). Calculate the content of epalrestat, $C_{15}H_{13}NO_3S_2$ in the medium from the absorbance obtained from a solution of known concentration of *epalrestat IPRS* in the dissolution medium.
Q. Not less than 70 per cent of the stated amount of $C_{15}H_{13}NO_3S_2$.
Other tests. Comply with the tests stated under Tablets.
Assay. Determine by liquid chromatography (2.4.14).

Internal standard solution. A 1.0 per cent v/v solution of *propyl parahydroxy benzoate* in *N,N-dimethylformamide.*

Test solution. Weigh and powder 20 tablets. Disperse a quantity of powder containing 200 mg of Epalrestat in 20.0 ml of internal standard and dilute to 100.0 ml with *N,N-dimethylformamide.* Dilute 1.0 ml of the solution to 10.0 ml with *N,N-dimethylformamide.*

Reference solution. Dissolve 20 mg of *epalrestat IPRS* in 2.0 ml of internal standard and dilute to 10.0 ml with *N,N-dimethylformamide.* Dilute 1.0 ml of the solution to 10.0 ml with *N,N-dimethylformamide.*

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 70 volumes of the buffer solution prepared by dissolving 6.8 g of *potassium dihydrogen phosphate* and 7.09 g of *disodium hydrogen phosphate* in 1000 ml of *water,* adjusted to pH 6.5, and 35 volumes of *acetonitrile,*
- flow rate: adjust, so that the retention time of epalrestat is about 12 minutes,
- spectrophotometer set at 280 nm,
- injection volume: 3 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation of the ratio of peak area of epalrestat and internal standard for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.
Calculate the content of $C_{15}H_{13}NO_3S_2$ in the tablets, using the ratio of peak area of epalrestat and internal standard.
Storage. Store protected from light and moisture, at a temperature not exceeding 30°.