

Dasatinib Tablets

Dasatinib Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of dasatinib, $C_{22}H_{26}ClN_7O_2S$

Usual strengths. 20 mg; 50mg; 70mg; 100mg.

CAUTION- Dasatinib is cytotoxic, extra care required to prevent inhaling particles and exposing the skin to it.

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

Dissolution (2.5.2).

Apparatus No. 2 (Paddle),

Medium. 1000 ml of a buffer prepared by dissolving 2.99 g of *sodium acetate trihydrate* in 1000 ml of *water*, adjusted to pH 4.0 with *glacial acetic acid*. Add 10 g of *triton-X 100*,

Speed and time. 60 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Solvent mixture. 60 volumes of a buffer solution prepared by dissolving 2.72 g of *potassium dihydrogen orthophosphate monohydrate* in 1000 ml of *water*, adjusted to pH 2.5 with *orthophosphoric acid* and 40 volumes of *methanol*.

Buffer solution. Dissolve 2.72 g of *potassium dihydrogen orthophosphate monohydrate* in 1000 ml of *water*, adjusted to pH 3.0 with *orthophosphoric acid*.

Test solution. Use the filtrate. Dilute the filtrate if necessary, with the solvent mixture.

Reference solution. A 0.001 per cent w/v solution of *dasatinib IPRS* in the solvent mixture.

Chromatographic systems

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 μ m) (Such as Kromasil),
- mobile phase: A mixture of 52 volumes of the buffer solution and 48 volumes of *methanol*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 320 nm,
- injection volume: 50 μ l.

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 for replicate injection is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{22}H_{26}ClN_7O_2S$ in the medium.

Q. Not less than 75 per cent of the stated amount of $C_{22}H_{26}ClN_7O_2S$.

Related substances. Determine by liquid chromatography (2.4.14), as described under Dissolution with the following modifications.

Test solution. Disperse a quantity of powdered tablets containing 100 mg of Dasatinib in the solvent mixture with the aid of ultrasound for 15 minutes and dilute to 100.0 ml with the solvent mixture, filter.

Reference solution. A 0.0002 per cent w/v solution of *dasatinib IPRS* in the solvent mixture.

- mobile phase: A. the buffer solution,
B. *methanol*,
- a gradient programme using the conditions given below,
- injection volume: 10 μ l.

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	60	40
42	60	40
52	25	75
74	25	75
75	60	40
85	60	40

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 for replicate injection is not more than 5.0 per cent.

Inject the reference solution and test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.2 per cent) and sum of the areas of all the secondary peaks is not more than 10 times the area of the principal peak in the chromatogram obtained with the reference solution (2.0 per cent).

Other tests. Comply with the tests stated in the tablets.

Assay. Determine by liquid chromatography (2.4.14), as described under Dissolution with the following modifications.

Test solution. Weigh and powder 20 tablets. Disperse a quantity of powdered tablets containing 100 mg of Dasatinib in the solvent mixture with the aid of ultrasound for 15 minutes and dilute to 100.0 ml with the solvent mixture. Dilute 1.0 ml of this solution to 10.0 ml with the solvent mixture.

Reference solution. A 0.01 per cent w/v solution of *dasatinib IPRS* in the solvent mixture.

Chromatographic systems

– injection volume: 10 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 for replicate injection is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{22}H_{26}ClN_7O_2S$, in the tablets.

Storage. Store at a temperature not exceeding 30°.