Fursultiamine Tablets

Dissolution <*6.10*> Perform the test with 1 tablet of Fursultiamine Tablets at 50 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium. Withdraw not less than 20 mL of the medium at the specified minute after starting the test, and filter through a membrane filter with a pore size not exceeding 0.45 μm. Discard the first 10 mL of the filtrate, pipet V mL of the subsequent filtrate, add water to make exactly V' mL so that each mL contains about 5.5 μg of fursultiamine ($C_{17}H_{26}N_4O_3S_2$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Fursultiamine RS, previously dried in a desiccator (in vacuum, phosphorus (V) oxide) for 5 hours, and dissolve in water to make exactly 200 mL. Pipet 5 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 50 μL each of the sample solution and standard solution as directed under Liquid Chromatography <*2.01*> according to the following conditions, and determine the peak areas, A_T and A_S, of fursultiamine.

The requirements are met if Fursultiamine Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of fursultiamine ($C_{17}H_{26}N_4O_3S_2$)

$= M_S \times A_T/A_S \times V'/V \times 1/C \times 45/2$

M_S: Amount (mg) of Fursultiamine RS

C: Labeled amount (mg) of fursultiamine ($C_{17}H_{26}N_4O_3S_2$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 242 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 50ºC.

Mobile phase: Dissolve 1.01 g of sodium 1-heptane sulfonate in 1000 mL of dilute acetic acid (100) (1 in 100). To 675 mL of this solution add 325 mL of a mixture of methanol and acetonitrile (3:2).

Flow rate: Adjust the flow rate so that the retention time of fursultiamine is about 9 minutes.

System suitability —

System performance: When the procedure is run with 50 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of fursultiamine are not less than 2000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 50 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of fursultiamine is not more than 2.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
5 mg	15 minutes	Not less than 85%

Fursultiamine RS Fursultiamine. When dried, it contains not less than 99.0% of fursultiamine ($C_{17}H_{26}N_4O_3S_2$).