

Fursultiamine Hydrochloride Tablets

Dissolution <6.10> Perform the test with 1 tablet of Fursultiamine Hydrochloride 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 14 μg of fursultiamine ($\text{C}_{17}\text{H}_{26}\text{N}_4\text{O}_3\text{S}_2$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 16 mg of Fursultiamine Hydrochloride RS (previously determine the water <2.48> with 0.3 g by direct titration in volumetric titration), and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add water to make exactly 50 mL, and use this solution as the standard solution. Perform the test with the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry <2.24>, and determine the absorbances, A_T and A_S , at 242 nm.

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

Dissolution rate (%) with respect to the labeled amount of fursultiamine ($\text{C}_{17}\text{H}_{26}\text{N}_4\text{O}_3\text{S}_2$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 90 \times 0.916$$

M_S : Amount (mg) of Fursultiamine Hydrochloride RS, calculated on the anhydrous basis

C : Labeled amount (mg) of fursultiamine ($\text{C}_{17}\text{H}_{26}\text{N}_4\text{O}_3\text{S}_2$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
25 mg	45 minutes	Not less than 85%
50 mg	60 minutes	Not less than 85%