

Faropenem Sodium Tablets

Dissolution <6.10> Perform the test with 1 tablet of Faropenem Sodium 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 55 μg (potency) of faropenem ($\text{C}_{12}\text{H}_{15}\text{NO}_5\text{S}$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately an amount of Faropenem Sodium RS, equivalent to about 18 mg (potency), and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add water to make exactly 20 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 306 nm.

The requirements are met if Faropenem Sodium Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of faropenem ($\text{C}_{12}\text{H}_{15}\text{NO}_5\text{S}$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 225$$

M_S : Amount [mg (potency)] of Faropenem Sodium RS

C : Labeled amount [mg (potency)] of faropenem ($\text{C}_{12}\text{H}_{15}\text{NO}_5\text{S}$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
150 mg (potency)	30 minutes	Not less than 85%
200 mg (potency)	30 minutes	Not less than 85%