Pravastatin Sodium Tablets

Dissolution <*6.10*> Perform the test with 1 tablet of Pravastatin Sodium Tablets at 50 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium. Start the test, 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 5.6 μg of pravastatin sodium ($C_{23}H_{35}NaO_7$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 23 mg of Pravastatin 1,1,3,3-Tetramethylbutylamine RS (separately, determine the water <*2.48*> with 0.5 g by direct titration in volumetric titration), and dissolve in water to make exactly 100 mL. Pipet 3 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotomatry <*2.24*>, and determine the absorbances, A_{T1} and A_{S1}, at 238 nm, and absorbances, A_{T2} and A_{S2}, at 265 nm, respectively

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

Dissolution rate (%) with respect to the labeled amount of pravastatin sodium ($C_{23}H_{35}NaO_7$)

$= M_S \times (A_{T1} - A_{T2})/(A_{S1} - A_{S2}) \times V'/V \times 1/C \times 27 \times 0.806$

M_S: Amount (mg) of Pravastatin 1,1,3,3-tetramethylbutylamine RS, calculated on the anhydrous basis

C: Labeled amount (mg) of pravastatin sodium ($C_{23}H_{35}NaO_7$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
5 mg	15 minutes	Not less than 85%
10 mg	30 minutes	Not less than 85%