

Rifampicin Capsules

Dissolution <6.10> Perform the test with 1 capsule of Rifampicin Capsules at 75 revolutions per minute according to the Paddle method, using the sinker, 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 17 μg (potency) of rifampicin ($\text{C}_{43}\text{H}_{58}\text{N}_4\text{O}_{12}$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately an amount of Rifampicin RS, equivalent to about 17 mg (potency), dissolve in 5 mL of methanol, and add water to make exactly 100 mL. Pipet 2 mL of this solution, add water to make exactly 20 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S , of the sample solution and standard solution at 334 nm as directed under Ultraviolet-visible Spectrophotometry <2.24>, using water as the blank.

The requirements are met if Rifampicin Capsules conform to the dissolution requirements.

$$\begin{aligned} &\text{Dissolution rate (\%)} \text{ with respect to the labeled amount of rifampicin } (\text{C}_{43}\text{H}_{58}\text{N}_4\text{O}_{12}) \\ &= M_S \times A_T/A_S \times V'/V \times 1/C \times 90 \end{aligned}$$

M_S : Amount [mg (potency)] of Rifampicin RS

C : Labeled amount [mg (potency)] of rifampicin ($\text{C}_{43}\text{H}_{58}\text{N}_4\text{O}_{12}$) in 1 capsule

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
150 mg (potency)	45 minutes	Not less than 80%

Rifampicin RS Rifampicin (JP).