

Epirizole Tablets

Dissolution <6.10> Perform the test with 1 tablet of Epirizole 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 epirizole ($\text{C}_{11}\text{H}_{14}\text{N}_4\text{O}_2$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 28 mg of Epirizole RS, previously dried for 4 hours using silica gel as a desiccant, and dissolve in water to make exactly 100 mL. Pipet 2 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S , at 250 nm of the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry <2.24>.

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

Dissolution rate (%) with respect to the labeled amount of epirizole ($\text{C}_{11}\text{H}_{14}\text{N}_4\text{O}_2$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 18$$

M_S : Amount (mg) of Epirizole RS

C : Labeled amount (mg) of epirizole ($\text{C}_{11}\text{H}_{14}\text{N}_4\text{O}_2$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
50 mg	90 minutes	Not less than 85%
100 mg	120 minutes	Not less than 80%

Epirizole RS Epirizole (JP).