

Diphenhydramine Hydrochloride Tablets

Dissolution <6.10> Perform the test with 1 tablet of Diphenhydramine 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 11 μg of diphenhydramine hydrochloride ($\text{C}_{17}\text{H}_{21}\text{NO}\cdot\text{HCl}$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Diphenhydramine Hydrochloride RS, previously dried at 105°C for 3 hours, and dissolve in water to make exactly 100 mL. Pipet 5 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 Spectrophotometry <2.24>, and determine the absorbances, A_T and A_S , at 220 nm.

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

Dissolution rate (%) with respect to the labeled amount of diphenhydramine hydrochloride ($\text{C}_{17}\text{H}_{21}\text{NO}\cdot\text{HCl}$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 45$$

M_S : Amount (mg) of Diphenhydramine Hydrochloride RS

C : Labeled amount (mg) of diphenhydramine hydrochloride ($\text{C}_{17}\text{H}_{21}\text{NO}\cdot\text{HCl}$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
10 mg	30 minutes	Not less than 75%

Diphenhydramine Hydrochloride RS Diphenhydramine Hydrochloride (JP). When dried, it contains not less than 99.0% of diphenhydramine hydrochloride ($\text{C}_{17}\text{H}_{21}\text{NO}\cdot\text{HCl}$).