

Carpipramine Hydrochloride Tablets

Dissolution <6.10> Perform the test with 1 tablet of Carpipramine Hydrochloride Tablets at 75 revolutions per minute according to the Paddle method, using 900 mL of 2nd fluid for dissolution test 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 2nd fluid for dissolution test to make exactly V' mL so that each mL contains about 27 μg of carpipramine hydrochloride ($\text{C}_{28}\text{H}_{38}\text{N}_4\text{O}\cdot 2\text{HCl}$) according to the labeled amount. Separately, weigh accurately about 28 mg of Carpipramine Hydrochloride RS, previously dried in vacuum with phosphorus (V) oxide at 105°C to constant mass, and dissolve in water to make exactly 50 mL. Pipet 5 mL of this solution, add 2nd fluid for dissolution test to make exactly 100 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 250 nm as directed under Ultraviolet-visible Spectrophotometry <2.24>, using 2nd fluid for dissolution test as the blank.

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

Dissolution rate (%) with respect to the labeled amount of carpipramine hydrochloride ($\text{C}_{28}\text{H}_{38}\text{N}_4\text{O}\cdot 2\text{HCl}$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 90$$

M_S : Amount (mg) of Carpipramine Hydrochloride RS

C : Labeled amount (mg) of carpipramine hydrochloride ($\text{C}_{28}\text{H}_{38}\text{N}_4\text{O}\cdot 2\text{HCl}$) in 1 tablet

Dissolution Requirements

| Labeled amount | Specified minute | Dissolution rate |
|----------------|------------------|-------------------|
| 24.16 mg | 45 minutes | Not less than 70% |
| 48.32 mg | 60 minutes | Not less than 80% |

Carpipramine Hydrochloride RS Carpipramine Hydrochloride. When dried, it contains not less than 99.0% of carpipramine hydrochloride ($\text{C}_{28}\text{H}_{38}\text{N}_4\text{O}\cdot 2\text{HCl}$).