

Clocapramine Hydrochloride Granules

Dissolution <6.10> Weigh accurately an amount of Clocapramine Hydrochloride Granules, equivalent to about 50 mg of clocapramine hydrochloride ($C_{28}H_{37}ClN_4O \cdot 2HCl$) according to the labeled amount, and perform the test at 50 revolutions per minute according to the Paddle method, using 900 mL of disodium hydrogenphosphate-citric acid buffer solution, pH 6.0 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, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 28 mg of Clocapramine Hydrochloride RS, previously dried under reduced pressure not exceeding 0.67 kPa at 105°C for 4 hours using phosphorus (V) oxide as a desiccant, and dissolve in water to make exactly 50 mL. Pipet 5 mL of this solution, add disodium hydrogenphosphate-citric acid buffer solution, pH 6.0 to make exactly 50 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S , at 251 nm of the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry <2.24>, using disodium hydrogen phosphate-citric acid buffer solution, pH 6.0 as the blank.

The requirements are met if Clocapramine Hydrochloride Granules conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of clocapramine hydrochloride ($C_{28}H_{37}ClN_4O \cdot 2HCl$)

$$= M_S/M_T \times A_T/A_S \times 1/C \times 180$$

M_S : Amount (mg) of Clocapramine Hydrochloride RS

M_T : Amount (g) of sample

C: Labeled amount (mg) of clocapramine hydrochloride ($C_{28}H_{37}ClN_4O \cdot 2HCl$) in 1 g

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
96.85 mg/g	45 minutes	Not less than 70%

Clocapramine Hydrochloride RS Clocapramine Hydrochloride Hydrate (JP). When dried, it contains not less than 99.0% of clocapramine hydrochloride ($C_{28}H_{37}ClN_4O \cdot 2HCl$).

Disodium hydrogen phosphate-citric acid buffer solution, pH 6.0 To 1000 mL of 0.05 mol/L disodium hydrogen phosphate TS add a solution, prepared by dissolving 5.25 g of citric acid monohydrate in water to make 1000 mL, and adjust the pH to 6.0.