

Hydroxyzine Hydrochloride Tablets

Dissolution <6.10> Perform the test with 1 tablet of Hydroxyzine Hydrochloride Tablets at 100 revolutions per minute according to the Paddle method, using 900 mL of 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 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 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 to make exactly V' mL so that each mL contains about 11 μg of hydroxyzine hydrochloride ($\text{C}_{21}\text{H}_{27}\text{ClN}_2\text{O}_2 \cdot 2\text{HCl}$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 28 mg of Hydroxyzine Hydrochloride RS, previously dried at 105°C for 2 hours, and dissolve in 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 to make exactly 100 mL. Pipet 2 mL of this solution, add 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 to make exactly 50 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 232 nm.

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

Dissolution rate (%) with respect to the labeled amount of hydroxyzine hydrochloride ($\text{C}_{21}\text{H}_{27}\text{ClN}_2\text{O}_2 \cdot 2\text{HCl}$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 36$$

M_S : Amount (mg) of Hydroxyzine Hydrochloride RS

C : Labeled amount (mg) of hydroxyzine hydrochloride ($\text{C}_{21}\text{H}_{27}\text{ClN}_2\text{O}_2 \cdot 2\text{HCl}$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
10 mg	90 minutes	Not less than 75%
25 mg	180 minutes	Not less than 75%

Hydroxyzine Hydrochloride RS Hydroxyzine Hydrochloride (JP). When dried, it contains not less than 99.0% of hydroxyzine hydrochloride ($\text{C}_{21}\text{H}_{27}\text{ClN}_2\text{O}_2 \cdot 2\text{HCl}$).