Hydroxyzine Pamoate Tablets

Dissolution <*6.10*> Perform the test with 1 tablet of Hydroxyzine Pamoate Tablets at 50 revolutions per minute according to the Paddle method, using 900 mL of 1st 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 1st fluid for dissolution test to make exactly V' mL so that each mL contains about 28 μg of hydroxyzine hydrochloride ($C_{21}H_{27}ClN_2O_2.2HCl$) 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 105ºC for 2 hours, and dissolve in 1st fluid for dissolution test to make exactly 100mL. Pipet 5 mL of this solution, add 1st fluid for dissolution test to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 20 μL each of the sample solution and standard solution as directed under Liquid Chromatography <*2.01*> according to the following conditions, and determine the peak areas, A_T and A_S, of hydroxyzine in each solution.

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

Dissolution rate (%) with respect to the labeled amount of hydroxyzine hydrochloride ($C_{21}H_{27}ClN_2O_2.2HCl$)

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

M_S: Amount (mg) of Hydroxyzine Hydrochloride RS

C: Labeled amount (mg) of hydroxyzine hydrochloride ($C_{21}H_{27}ClN_2O_2.2HCl$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 232 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40ºC.

Mobile phase: To 3 mL of phosphoric acid and 33 mL of sodium hydroxide TS add 900 mL of water, adjust to pH 2.4 with diluted phosphoric acid (1 in 10), and add water to make 1000 mL. To 350 mL of this solution add 650 mL of methanol.

Flow rate: Adjust the flow rate so that the retention time of hydroxyzine is about 4 minutes.

System suitability —

System performance: When the procedure is run with 20 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of hydroxyzine are not less than 3000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of hydroxyzine is not more than 1.5%.

Dissolution Requirements

Labeled amount*	Specified minute	Dissolution rate
25 mg	120 minutes	Not less than 80%

* as Hydroxyzine Hydrochloride

Hydroxyzine Hydrochloride RS Hydroxyzine Hydrochloride (JP). When dried, it contains not less than 99.0% of hydroxyzine hydrochloride ($C_{21}H_{27}ClN_2O_2.2HCl$).