Prazosin Hydrochloride Tablets

Dissolution *<6.10>* Perform the test with 1 tablet of Prazosin Hydrochloride Tablets at 75 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 0.56 μg of prazosin ($C_{19}H_{21}N_5O_4$) according to the labeled amount. Pipet 5 mL of this solution, add exactly 5 mL of methanol, and use this solution as the sample solution. Separately, weigh accurately about 20 mg of Prazosin Hydrochloride RS, previously dried at 105ºC for 2 hours, and dissolve in methanol to make exactly 100 mL. To exactly 3 mL of this solution add methanol to make exactly 100 mL. Further, to exactly 5 mL of this solution add methanol to make exactly 50 mL. Pipet 5 mL of this solution, add exactly 5 mL of 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0, 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 prazosin in each solution.

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

Dissolution rate (%) with respect to the labeled amount of prazosin ($C_{19}H_{21}N_5O_4$)

$= M_S \times A_T/A_S \times V'/V \times 1/C \times 27/10 \times 0.913$

M_S: Amount (mg) of Prazosin Hydrochloride RS

C: Labeled amount (mg) of prazosin ($C_{19}H_{21}N_5O_4$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 246 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 35ºC.

Mobile phase: Dissolve 3.4 g of potassium dihydrogenphosphate in 500 mL of water, and adjust to pH 3.0 with diluted phosphoric acid (1 in 10). To 450 mL of this solution add 550 mL of methanol.

Flow rate: Adjust the flow rate so that the retention time of prazosin 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 prazosin are not less than 2000 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 prazosin is not more than 2.0%.

Dissolution Requirements

Labeled amount*	Specified minute	Dissolution rate
0.5 mg	60 minutes	Not less than 85%
1 mg	60 minutes	Not less than 80%

*as Prazosin

Prazosin Hydrochloride RS Prazosin Hydrochloride. When dried, it contains not less than 99.0% of prazosin hydrochloride ($C_{19}H_{21}N_5O_4$.HCl).