Tamsulosin Hydrochloride Capsules

Dissolution <6.10> Perform the test with 1 capsule of Tamsulosin Hydrochloride Capsules at 50 revolutions per minute according to the Paddle method, using the sinker, using 900 mL of 2nd fluid for dissolution test as the dissolution medium. Start the test, withdraw 20 mL of the medium at the specified minute after starting the test, and immediately fill up the dissolution medium with exactly 20 mL of the 2nd fluid for dissolution test, previously warmed to 37 ± 0.5ºC, carefully. Filter these media through a membrane filter with a pore size not exceeding 0.45 μm. Discard the first 10mL 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 0.11 μg of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S$·HCl) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 15 mg of Tamsulosin Hydrochloride RS, previously dried at 105ºC for 2 hours, and dissolve in 2nd fluid for dissolution test to make exactly 20 mL. Pipet 2 mL of this solution, add 2nd fluid for dissolution test to make exactly 200 mL. Then, pipet 3 mL of this solution, add 2nd fluid for dissolution test to make exactly 200 mL, and use this solution as the standard solution. Perform the test with exactly 200 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, $A_{T(n)}$ and A_S, of tamsulosin of both solutions.

The requirements are met if Tamsulosin Hydrochloride Capsules conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S$·HCl) on the *n*th dissolution medium withdrawing (*n*=1,2,3)

$$= M_S \times \left[\frac{A_{T(n)}}{A_S} + \sum_{i=1}^{n-1} \left(\frac{A_{T(i)}}{A_S} \times \frac{1}{45} \right) \right] \times \frac{V'}{V} \times \frac{1}{C} \times \frac{27}{40}$$

M_S: Amount (mg) of Tamsulosin Hydrochloride RS

C: Labeled amount (mg) of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S$·HCl) in 1 capsule

Operating conditions−

Detector: An ultraviolet absorption photometer (wavelength: 225 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: Dissolve 4.4 mL of perchloric acid and 1.5 g of sodium hydroxide in 950 mL of water, adjust the pH to 2.0 with sodium hydroxide TS, and add water to make 1000 mL. To 700 mL of this solution add 300 mL of acetonitrile.

Flow rate: Adjust the flow rate so that the retention time of tamsulosin is about 6 minutes.

System suitability−

System performance: When the procedure is run with 200 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of tamsulosin are not less than 3000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 200 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of tamsulosin is not more than 2.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
0.1 mg	120 minutes	20−50%
	3 hours	30−60%
	10 hours	Not less than 75%
0.2 mg	120 minutes	15−45%
	4 hours	35−65%
	10 hours	Not less than 75%

Tamsulosin Hydrochloride RS Tamsulosin Hydrochloride (JP). When dried, it contains not less than 99.0% of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$).