Cyproheptadine Hydrochloride Tablets

Dissolution <*6.10*> Perform the test with 1 tablet of Cyproheptadine Hydrochloride Tablets at 50 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium. Start the test, withdraw not less than 30 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 20 mL of the filtrate, pipet *V* mL of the subsequent filtrate, add water to make exactly *V′* mL so that each mL contains about 4.4 μg of cyproheptadine hydrochloride ($C_{21}H_{21}N$·HCl) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Cyproheptadine Hydrochloride RS, previously dried at 100ºC for 5 hours under reduced pressure (not more than 0.67 kPa), and dissolve in the mobile phase to make exactly 100 mL. Pipet 2 mL of this solution, add the mobile phase to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 50 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 cyproheptadine of both solutions.

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

Dissolution rate (%) with respect to the labeled amount of cyproheptadine hydrochloride ($C_{21}H_{21}N$·HCl)

$= M_S \times A_T/A_S \times V'/V \times 1/C \times 18$

M_S: Amount (mg) of Cyproheptadine Hydrochloride RS

C: Labeled amount (mg) of cyproheptadine hydrochloride ($C_{21}H_{21}N$·HCl) in 1 tablet

Operating conditions−

Detector: An ultraviolet absorption photometer (wavelength: 285 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 30ºC.

Mobile phase: A mixture of water, acetonitrile, methanol and methanesulfonic acid (520:240:240:1).

Flow rate: Adjust the flow rate so that the retention time of cyproheptadine is about 5 minutes.

System suitability−

System performance: When the procedure is run with 50 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of

cyproheptadine are not less than 3000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 50 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of cyproheptadine is not more than 1.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
4 mg	30 minutes	Not less than 80%

Cyproheptadine Hydrochloride RS Cyproheptadine Hydrochloride Hydrate (JP). When dried, it contains not less than 99.0% of cyproheptadine hydrochloride ($C_{21}H_{21}N \cdot HCl$: 323.86).