Clemastine Fumarate Tablets

Dissolution *<6.10>* Perform the test with 1 tablet of Clemastine Fumarate Tablets at 50 revolutions per minute according to the Paddle method, using 900 mL of water 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 0.5 μm. Discard the first 10 mL of the filtrate, pipet V mL of the subsequent filtrate, add the mobile phase to make exactly V' mL so that each mL contains about 0.56 μg of clemastine ($C_{21}H_{26}ClNO$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 30 mg of Clemastine Fumarate RS, previously dried at 105ºC for 4 hours, and dissolve in water to make exactly 100 mL. To exactly 5 mL of this solution add water to make exactly 100 mL. Further, to exactly 10 mL of this solution add water to make exactly 100 mL. Pipet 5 mL of this solution, add the mobile phase to make exactly 10 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 clemastine in each solution.

The requirements are met if Clemastine Fumarate Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of clemastine ($C_{21}H_{26}ClNO$)

$= M_S \times A_T/A_S \times V'/V \times 1/C \times 9/4 \times 0.748$

M_S: Amount (mg) of Clemastine Fumarate RS

C: Labeled amount (mg) of clemastine ($C_{21}H_{26}ClNO$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 220 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 9.0 g of potassium dihydrogen phosphate and 2.0 g of sodium 1-octanesulfonate in 1100 mL of water, add 900 mL of acetonitrile, and adjust to pH 4.0 with phosphoric acid.

Flow rate: Adjust the flow rate so that the retention time of clemastine 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 clemastine are not less than 3000 and not more than 2.0, 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 clemastine is not more than 2.0%.

Dissolution Requirements

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

* as Clemastine

Clemastine Fumarate RS Clemastine Fumarate (JP). When dried, it contains not less than 99.0% of clemastine fumarate ($C_{21}H_{26}ClNO.C_4H_4O_4$).