

Pentoxifyverine Citrate Tablets

Dissolution <6.10> Perform the test with 1 tablet of Pentoxifyverine Citrate 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 0.45 μm . Discard the first 10 mL of the filtrate, pipet V mL of the subsequent filtrate, add water to make V' mL so that each mL contains about 11 μg of pentoxifyverine citrate ($\text{C}_{20}\text{H}_{31}\text{NO}_3 \cdot \text{C}_6\text{H}_8\text{O}_7$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Pentoxifyverine Citrate RS, previously dried in vacuum with phosphorus (V) oxide at 60°C for 4 hours, and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test exactly with 100 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 pentoxifyverine in each solution.

The requirements are met if Pentoxifyverine Citrate Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of pentoxifyverine citrate

($\text{C}_{20}\text{H}_{31}\text{NO}_3 \cdot \text{C}_6\text{H}_8\text{O}_7$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 45$$

M_S : Amount (mg) of Pentoxifyverine Citrate RS

C : Labeled amount (mg) of pentoxifyverine citrate ($\text{C}_{20}\text{H}_{31}\text{NO}_3 \cdot \text{C}_6\text{H}_8\text{O}_7$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 230 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 40°C.

Mobile phase: Adjust the pH of a mixture of water, acetonitrile and triethylamine (600:400:1) to 3.0 with phosphoric acid.

Flow rate: Adjust the flow rate so that the retention time of pentoxifyverine is about 7 minutes.

System suitability —

System performance: When the procedure is run with 100 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of pentoxifyverine are not less than 2000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 100 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of pentoxifyverine is not more than 2.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
10 mg	120 minutes	Not less than 80%
15 mg	45 minutes	Not less than 80%
30 mg	90 minutes	Not less than 85%

Pentoxiverine Citrate RS Pentoxiverine Citrate (JP). When dried, it contains not less than 99.0% of pentoxiverine citrate ($C_{20}H_{31}NO_3 \cdot C_6H_8O_7$).