

Pentoxiverine Citrate Powder

Dissolution <6.10> Weigh accurately an amount of Pentoxiverine Citrate Powder, equivalent to about 30 mg of pentoxiverine citrate ($C_{20}H_{31}NO_3 \cdot C_6H_8O_7$) according to the labeled amount, and perform the test 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 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 2 mL of the subsequent filtrate, add exactly 4 mL of 1st fluid for dissolution test, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Pentoxiverine Citrate RS, previously dried under reduced pressure at 60°C or 4 hours using phosphorus (V) oxide as a desiccant, and dissolve in water to make exactly 100 mL. Pipet 3 mL of this solution, and add water to make exactly 20 mL. Pipet 2 mL of this solution, add exactly 4 mL of 1st fluid for dissolution test, and use this solution as the standard solution. Perform the test with exactly 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 pentoxiverine of both solutions.

The requirements are met if Pentoxiverine Citrate Powder conforms to the dissolution requirements.

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

($C_{20}H_{31}NO_3 \cdot C_6H_8O_7$)

$$= M_S/M_T \times A_T/A_S \times 1/C \times 135$$

M_S : Amount (mg) of Pentoxiverine Citrate RS

M_T : Amount (g) of sample

C: Labeled amount (mg) of pentoxiverine citrate ($C_{20}H_{31}NO_3 \cdot C_6H_8O_7$) in 1 g

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 pentoxiverine is about 7 minutes.

System suitability—

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

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

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
100 mg/g	15 minutes	Not less than 75%