Benzylhydrochlorothiazide Tablets

Dissolution <*6.10*> Perform the test with 1 tablet of Benzylhydrochlorothiazide Tablets at 100 revolutions per minute according to the Paddle method, using 900 mL of a solution, prepared by adding water to 1 g of polysorbate 80 to make 20 mL, 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 *V* mL of the subsequent filtrate, add a solution, prepared by adding water to 1 g of polysorbate 80 to make 20 mL, to make exactly *V′* mL so that each mL contains about 4.4 μg of benzylhydrochlorothiazide ($C_{14}H_{14}ClN_3O_4S_2$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Benzylhydrochlorothiazide RS, previously dried at 105ºC for 4 hours, and dissolve in acetonitrile to make exactly 100 mL. Pipet 2 mL of this solution, add a solution, prepared by adding water to 1 g of polysorbate 80 to make 20 mL, to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 30 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 benzylhydrochlorothiazide of both solutions.

The requirements are met if Benzilhydrochlorothiazide Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of benzylhydrochlorothiazide ($C_{14}H_{14}ClN_3O_4S_2$)

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

M_S: Amount (mg) of Benzylhydrochlorothiazide RS

C: Labeled amount (mg) of benzylhydrochlorothiazide ($C_{14}H_{14}ClN_3O_4S_2$) in 1 tablet

Operating conditions−

Detector: An ultraviolet absorption photometer (wavelength: 272 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 35ºC.

Mobile phase: A mixture of diluted phosphoric acid (1 in 1000) and acetonitrile (1:1)

Flow rate: Adjust the flow rate so that the retention time of benzylhydrochlorothiazide is about 4 minutes.

System suitability−

System performance: When the procedure is run with 30 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of benzylhydrochlorothiazide are not less than 3000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 30 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of benzylhydrochlorothiazide is not more than 1.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
4 mg	60 minutes	Not less than 70%

Benzylhydrochlorothiazide RS Benzylhydrochlorothiazide. When dried, it contains not less than 99.0% of benzylhydrochlorothiazide ($C_{14}H_{14}ClN_3O_4S_2$).