Ampicillin Dry Syrup

Dissolution <*6.10*> Weigh accurately an amount of Ampicillin Dry Syrup, equivalent to about 250 mg (potency) of ampicillin ($C_{16}H_{19}N_3O_4S$) 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, and use the subsequent filtrate as the sample solution. Separately, weigh accurately an amount of Ampicillin RS, equivalent to about 28 mg (potency), dissolve in water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 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 ampicillin of both solutions.

The requirements are met if Ampicillin Dry Syrup conforms to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of ampicillin ($C_{16}H_{19}N_3O_4S$)

$= M_S/M_T \times A_T/A_S \times 1/C \times 900$

M_S: Amount [mg (potency)] of Ampicillin RS

M_T: Amount (g) of sample

C: Labeled amount [mg (potency)] of ampicillin ($C_{16}H_{19}N_3O_4S$) in 1 g

Operating conditions−

Detector: An ultraviolet absorption photometer (wavelength: 230 nm).

Column: A stainless steel column 4 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 25ºC.

Mobile phase: Dissolve 6.6 g of diammonium hydrogen phosphate in 1000 mL of water, add 130 mL of acetonitrile, and adjust the pH to 6.25 with phosphoric acid.

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

System suitability−

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of ampicillin are not less than 4000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of ampicillin is not more than 2.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
100 mg (potency)/g	15 minutes	Not less than 85%