Ampicillin Capsules

Dissolution a <*6.10*> Perform the test with 1 capsule of Ampicillin Capsules at 50 revolutions per minute according to the Paddle method, using the sinker, 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 *V* mL of the subsequent filtrate, add water to make exactly *V'* mL so that each mL contains about 0.28 mg (potency) of ampicillin ($C_{16}H_{19}N_3O_4S$) according to the labeled amount, and use this solution 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 Capsules conform to the dissolution requirements.

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

$= M_S \times A_T/A_S \times V'/V \times 1/C \times 900$

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

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

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 5.94 g of diammonium hydrogen phosphate in 850 mL of water, and add 100 mL of acetonitrile. Adjust the pH of this solution to 5.0 with phosphoric acid, and add water to make exactly 1000 mL.

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
250 mg (potency)	90 minutes	Not less than 70%

Dissolution b *<6.10>* Perform the test with 1 capsule of Ampicillin Capsules at 50 revolutions per minute according to the Paddle method, using the sinker, 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 *V* mL of the subsequent filtrate, add water to make exactly *V'* mL so that each mL contains about 0.56 mg (potency) of ampicillin ($C_{16}H_{19}N_3O_4S$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately an amount of Ampicillin RS, equivalent to about 50 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 Capsules conform to the dissolution requirements.

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

$= M_S \times A_T/A_S \times V'/V \times 1/C \times 900$

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

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

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 5.94 g of diammonium hydrogen phosphate in 850 mL of water, and add 100 mL of acetonitrile. Adjust the pH of this solution to 5.0 with phosphoric acid, and add water to make exactly 1000 mL.

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
500 mg (potency)	60 minutes	Not less than 75%