Ampicillin 125 mg (potency) and Cloxacillin Sodium 125 mg (potency) Capsules

Dissolution <*6.10*> Perform the test with 1 capsule of Ampicillin 125 mg (potency) and Cloxacillin Sodium 125 mg (potency) 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, and use the subsequent filtrate as the sample solution. Separately, weigh accurately an amount of Ampicillin RS and Cloxacillin Sodium RS, equivalent to about 28 mg (potency), and dissolve in water to make them exactly 50 mL. Pipet 5 mL of this solution, add water to make exactly 20 mL, and use this solution as the standard solution. Perform the test with exactly 5 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_{Ta} and A_{Sa}, of ampicillin and, A_{Tb} and A_{Sb}, of cloxacillin of both solutions, respectively.

The requirements are met if Ampicillin 125 mg (potency) and Cloxacillin Sodium 125 mg (potency) Capsules conform to the dissolution requirements.

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

$= M_{Sa} \times A_{Ta}/A_{Sa} \times 1/C_a \times 450$

Dissolution rate (%) with respect to the labeled amount of cloxacillin sodium ($C_{19}H_{17}ClN_3NaO_5S$)

$= M_{Sb} \times A_{Tb}/A_{Sb} \times 1/C_b \times 450$

M_{Sa}: Amount [mg (potency)] of Ampicillin RS

M_{Sb}: Amount [mg (potency)] of Cloxacillin Sodium RS

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

C_b: Labeled amount [mg (potency)] of cloxacillin sodium ($C_{19}H_{17}ClN_3NaO_5S$) in 1 capsule

Operating conditions−

Detector: An ultraviolet absorption photometer (wavelength: 254 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 40ºC.

Mobile phase: A mixture of water, methanol for liquid chromatography, a solution of tetrabutylammonium hydroxide (1 in 10) and diluted phosphoric acid (1 in 10)(250:250:5:1).

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

System suitability−

System performance: When the procedure is run with 5 μL of the standard solution under the above operating conditions, ampicillin and cloxacillin are eluted in this order with the resolution between these peaks being not less than 4.

System repeatability: When the test is repeated 6 times with 5 μL of the standard solution under the above operating conditions, the relative standard deviations of the peak areas of ampicillin and cloxacillin are not more than 2.0%, respectively.

Dissolution Requirements

	Labeled amount	Specified minute	Dissolution rate
Ampicillin	125 mg (potency)	30 minutes	Not less than 80%
Cloxacillin Sodium	125 mg (potency)		Not less than 85%