Amoxicillin 100 mg/g (potency) and Potassium Clavulanate 50 mg/g (potency) Granules

Dissolution <*6.10*> Perform the test with an accurately weighed quantity of Amoxicillin 100 mg/g (potency) and Potassium Clavulanate 50 mg/g (potency) Granules, equivalent to about 100 mg (potency) of amoxicillin ($C_{16}H_{19}N_3O_5S$) and about 50 mg (potency) of potassium clavulanate ($C_8H_8KNO_5$) according to the labeled amount, at 50 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium. 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 Amoxicillin RS, equivalent to about 22.2 mg (potency), and an amount of Lithium Clavulanate RS, equivalent to about 11.1 mg (potency), dissolve in water to make exactly 200 mL, and use this solution as the standard solution. Perform the test with exactly 20 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 amoxicillin, and the peak areas, A_{Tb} and A_{Sb}, of clavulanic acid in each solution.

The requirements are met if Amoxicillin 100 mg/g (potency) and Potassium Clavulanate 50 mg/g (potency) Granules conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$)

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

Dissolution rate (%) with respect to the labeled amount of potassium clavulanate ($C_8H_8KNO_5$)

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

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

M_{Sb}: Amount [mg (potency)] of Potassium Clavulanate RS

M_T: Amount (g) of sample

C_a: Labeled amount [mg (potency)] of amoxicillin ($C_{16}H_{19}N_3O_5S$) in 1 g

C_b: Labeled amount [mg (potency)] of potassium clavulanate ($C_8H_8KNO_5$) 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 25ºC.

Mobile phase: Dissolve 1.36 g of sodium acetate trihydrate in 900 mL of water, adjust to pH 4.5 with dilute acetic acid (100) (3 in 25), add 30 mL of methanol, and add water to make 1000 mL.

Flow rate: Adjust the flow rate so that the retention time of amoxicillin is about 11 minutes.

System suitability —

System performance: When the procedure is run with 20 μL of the standard solution under the above operating conditions, clavulanic acid and amoxicillin are eluted in this order with the resolution between these peaks being not less than 8.

System repeatability: When the test is repeated with 20 μL of the standard solution under the above operating conditions, the relative standard deviations of the peak areas of amoxicillin and clavulanic acid are not more than 2.0%, respectively.

Dissolution Requirements

	Labeled amount	Specified minute	Dissolution rate
Amoxicillin	100 mg/g (potency)	15 minutes	Not less than 85%
Potassium Clavulanate	50 mg/g (potency)		Not less than 80%