Rokitamycin Dry Syrup

Dissolution *<6.10>* Perform the test with an accurately weighed quantity of Rokitamycin Dry Syrup, equivalent to about 100 mg (potency) of rokitamycin ($C_{42}H_{69}NO_{15}$) according to the labeled amount, at 50 revolutions per minute according to the Paddle method, using 900 mL of 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 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, pipet 2 mL of the subsequent filtrate, add 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 to make exactly 10 mL, and use this solution as the sample solution. Separately, weigh accurately an amount of Rokitamycin RS, equivalent to about 22 mg (potency), and dissolve in 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 to make exactly 100 mL. Pipet 2 mL of this solution, add 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 to make exactly 20 mL, and use this solution as the standard solution. Perform the test with the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*, and determine the absorbances, A_T and A_S, at 232 nm.

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

Dissolution rate (%) with respect to the labeled amount of rokitamycin ($C_{42}H_{69}NO_{15}$)

$= M_S/M_T \times A_T/A_S \times 1/C \times 450$

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

M_T: Amount (g) of sample

C: Labeled amount [mg (potency)] of rokitamycin ($C_{42}H_{69}NO_{15}$) in 1 g

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
200 mg (potency)/g	45 minutes	Not less than 75%

Rokitamycin RS Rokitamycin (JP).