Griseofulvin Tablets

Dissolution *<6.10>* Perform the test with 1 tablet of Griseofulvin Tablets at 100 revolutions per minute according to the Paddle method, using 900 mL of a solution of sodium lauryl sulfate (1 in 100) 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 6.9 μg (potency) of griseofulvin ($C_{17}H_{17}ClO_6$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately an amount of Griseofulvin RS, equivalent to about 28 mg (potency), and dissolve in ethanol (95) to make exactly 200 mL. Pipet 5 mL of this solution, add 5 mL of a solution of sodium lauryl sulfate (1 in 100), add water to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, at 295 nm of the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*, using water as the blank.

The requirements are met if Griseofulvin Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of griseofulvin ($C_{17}H_{17}ClO_6$)

$= M_S \times A_T/A_S \times V'/V \times 1/C \times 45/2$

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

C: Labeled amount [mg (potency)] of griseofulvin ($C_{17}H_{17}ClO_6$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
125 mg (potency)	120 minutes	Not less than 70%