

Methoxsalen Tablets

Dissolution <6.10> Perform the test with 1 tablet of Methoxsalen 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. 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 a solution of sodium lauryl sulfate (1 in 100) to make exactly V' mL so that each mL contains about 11 μg of methoxsalen ($\text{C}_{12}\text{H}_8\text{O}_4$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Methoxsalen RS (previously determine the water <2.48> with 1g by direct titration in volumetric titration), dissolve in methanol to make exactly 50 mL. Pipet 5 mL of this solution, add a solution of sodium lauryl sulfate (1 in 100) to make exactly 200 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S , of the sample solution and standard solution at 303 nm as directed under Ultraviolet-visible Spectrophotometry <2.24>, using a solution of sodium lauryl sulfate (1 in 100) as the blank.

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

Dissolution rate (%) with respect to the labeled amount of methoxsalen ($\text{C}_{12}\text{H}_8\text{O}_4$)

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

M_S : Amount (mg) of Methoxsalen RS, calculated on the anhydrous basis

C : Labeled amount (mg) of methoxsalen ($\text{C}_{12}\text{H}_8\text{O}_4$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
10 mg	90 minutes	Not less than 80%