

Norethisterone Tablets

Dissolution <6.10> Perform the test with 1 tablet of Norethisterone Tablets at 100 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 time 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 5.6 μg of norethisterone ($\text{C}_{20}\text{H}_{26}\text{O}_2$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 28 mg of Norethisterone RS, previously dried in vacuum with silica gel for 4 hours, dissolve in ethanol (99.5) to make exactly 100 mL. Pipet 2 mL of this solution, add water to make exactly 100 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 248 nm as directed under Ultraviolet-visible Spectrophotometry <2.24>, using water as the blank.

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

Dissolution rate (%) with respect to the labeled amount of norethisterone ($\text{C}_{20}\text{H}_{26}\text{O}_2$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 18$$

M_S : Amount (mg) of Norethisterone RS

C : Labeled amount (mg) of norethisterone ($\text{C}_{20}\text{H}_{26}\text{O}_2$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified time	Dissolution rate
5 mg	3 hours	Not less than 70%

Norethisterone RS Norethisterone (JP). When dried, it contains not less than 99.0% of norethisterone ($\text{C}_{20}\text{H}_{26}\text{O}_2$).