

Ethambutol Hydrochloride Tablets

Dissolution a <6.10> Perform the test with 1 tablet of Ethambutol Hydrochloride Tablets 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, pipet V mL of the subsequent filtrate, add water to make exactly V' mL so that each mL contains about 56 μg of ethambutol hydrochloride ($\text{C}_{10}\text{H}_{24}\text{N}_2\text{O}_2 \cdot 2\text{HCl}$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 28 mg of Ethambutol Hydrochloride RS, previously dried at 105°C for 3 hours, and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add water to make exactly 25 mL, and use this solution as the standard solution. To 1 mL each of the sample solution, standard solution and water add 7 mL of bromocresol green-sodium hydroxide-acetic acid-sodium acetate TS, and shake. Then, add exactly 10 mL of dichloromethane, shake well, centrifuge, and take the dichloromethane layer. Determine the absorbances, A_T , A_S and A_B , of these dichloromethane layers at 415 nm as directed under Ultraviolet-visible Spectrophotometry <2.24>, using dichloromethane as the blank.

The requirements are met if Ethambutol Hydrochloride Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of ethambutol hydrochloride ($\text{C}_{10}\text{H}_{24}\text{N}_2\text{O}_2 \cdot 2\text{HCl}$)

$$= M_S \times (A_T - A_B) / (A_S - A_B) \times V' / V \times 1 / C \times 180$$

M_S : Amount (mg) of Ethambutol Hydrochloride RS

C : Labeled amount (mg) of ethambutol hydrochloride ($\text{C}_{10}\text{H}_{24}\text{N}_2\text{O}_2 \cdot 2\text{HCl}$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
125 mg	45 minutes	Not less than 85%
250 mg	60 minutes	Not less than 85%

Dissolution b <6.10> Perform the test with 1 tablet of Ethambutol Hydrochloride Tablets 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, pipet V mL of the subsequent filtrate, add water to make exactly V' mL so that each mL contains about 56 μg of ethambutol hydrochloride ($\text{C}_{10}\text{H}_{24}\text{N}_2\text{O}_2 \cdot 2\text{HCl}$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 28 mg of Ethambutol Hydrochloride RS, previously dried at 105°C for 3 hours, and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add water to make exactly 25 mL, and use this solution as the standard solution. To 1 mL each of the sample solution, standard solution and water add 7 mL of bromocresol green-sodium hydroxide-acetic acid-sodium acetate TS, and shake. Then, add exactly 10 mL of dichloromethane, shake well, centrifuge, and take the dichloromethane layer. Determine the absorbances, A_T , A_S and A_B , of these dichloromethane layers at 415 nm as directed under Ultraviolet-visible Spectrophotometry <2.24>, using dichloromethane as the blank.

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Dissolution rate (%) with respect to the labeled amount of ethambutol hydrochloride ($\text{C}_{10}\text{H}_{24}\text{N}_2\text{O}_2 \cdot 2\text{HCl}$)

$$= M_S \times (A_T - A_B) / (A_S - A_B) \times V' / V \times 1 / C \times 180$$

M_S : Amount (mg) of Ethambutol Hydrochloride RS

C : Labeled amount (mg) of ethambutol hydrochloride ($\text{C}_{10}\text{H}_{24}\text{N}_2\text{O}_2 \cdot 2\text{HCl}$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
125 mg	60 minutes	Not less than 70%
250 mg	120 minutes	Not less than 75%

Ethambutol Hydrochloride RS Ethambutol Hydrochloride (JP). When dried, it contains not less than 99.0% of ethambutol hydrochloride ($\text{C}_{10}\text{H}_{24}\text{N}_2\text{O}_2 \cdot 2\text{HCl}$).