

Bisbentiamine Tablets

Dissolution <6.10> Perform the test with 1 tablet of Bisbentiamine Tablets at 75 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. 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 0.5 μm . Discard the first 10 mL of the filtrate, pipet V mL of the subsequent filtrate, add 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 to make exactly V' mL so that each mL contains about 13 μg of bisbentiamine ($\text{C}_{38}\text{H}_{42}\text{N}_8\text{O}_6\text{S}_2$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 25 mg of Bisbentiamine RS, previously dried under reduced pressure for 24 hours using phosphorus (V) oxide as a desiccant, and dissolve in 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 to make exactly 100 mL. Pipet 5 mL of this solution, add 0.05 mol/L acetic acid-sodium acetate buffer solution, pH 4.0 to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S , at 232 nm of the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry <2.24>.

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

$$\begin{aligned} &\text{Dissolution rate (\%)} \text{ with respect to the labeled amount of bisbentiamine } (\text{C}_{38}\text{H}_{42}\text{N}_8\text{O}_6\text{S}_2) \\ &= M_S \times A_T/A_S \times V'/V \times 1/C \times 45 \end{aligned}$$

M_S : Amount (mg) of Bisbentiamine RS

C : Labeled amount (mg) of bisbentiamine ($\text{C}_{38}\text{H}_{42}\text{N}_8\text{O}_6\text{S}_2$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
28.58 mg	45minutes	Not less than 85%

Bisbentiamine RS Bisbentiamine. When dried, it contains not less than 99.0% of bisbentiamine ($\text{C}_{38}\text{H}_{42}\text{N}_8\text{O}_6\text{S}_2$).