

## Clomipramine Hydrochloride Tablets

**Dissolution** <6.10> Perform the test with 1 tablet of Clomipramine 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 0.5  $\mu\text{m}$ . 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 11  $\mu\text{g}$  of clomipramine hydrochloride ( $\text{C}_{19}\text{H}_{23}\text{ClN}_2\cdot\text{HCl}$ ) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 28 mg of Clomipramine Hydrochloride RS, previously dried at 105°C for 3 hours, and dissolve in water to make exactly 100 mL. Pipet 4 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry <2.24>, and determine the absorbances,  $A_T$  and  $A_S$ , at 252 nm.

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

Dissolution rate (%) with respect to the labeled amount of clomipramine hydrochloride ( $\text{C}_{19}\text{H}_{23}\text{ClN}_2\cdot\text{HCl}$ )

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 36$$

$M_S$ : Amount (mg) of Clomipramine Hydrochloride RS

$C$ : Labeled amount (mg) of clomipramine hydrochloride ( $\text{C}_{19}\text{H}_{23}\text{ClN}_2\cdot\text{HCl}$ ) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
10 mg	45 minutes	Not less than 80%
25 mg	90 minutes	Not less than 80%

**Clomipramine Hydrochloride RS** Clomipramine Hydrochloride (JP). When dried, it contains not less than 99.0% of clomipramine hydrochloride ( $\text{C}_{19}\text{H}_{23}\text{ClN}_2\cdot\text{HCl}$ ).