

## Cyclofenil Tablets

**Dissolution** <6.10> Perform the test with 1 tablet of Cyclofenil Tablets at 100 revolutions per minute according to the Paddle method, using 900 mL of a solution of sodium lauryl sulfate (1 in 40) 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  $\mu\text{m}$ . Discard the first 10 mL of the filtrate, pipet  $V$  mL of the subsequent filtrate, add methanol to make exactly  $V'$  mL so that each mL contains about 11  $\mu\text{g}$  of cyclofenil ( $\text{C}_{23}\text{H}_{24}\text{O}_4$ ) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 20 mg of Cyclofenil RS, previously dried at 105°C for 3 hours, and dissolve in methanol to make exactly 200 mL. Pipet 2 mL of this solution, add exactly 2 mL of a solution of sodium lauryl sulfate (1 in 40), then add methanol to make exactly 20 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 methanol as the blank.

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

Dissolution rate (%) with respect to the labeled amount of cyclofenil ( $\text{C}_{23}\text{H}_{24}\text{O}_4$ )

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

$M_S$ : Amount (mg) of Cyclofenil RS

$C$ : Labeled amount (mg) of cyclofenil ( $\text{C}_{23}\text{H}_{24}\text{O}_4$ ) in 1 tablet

### Dissolution Requirements

Labeled amount	Specified time	Dissolution rate
100 mg	6 hours	Not less than 75%

**Cyclofenil RS** Cyclofenil. When dried, it contains not less than 99.0% of cyclofenil ( $\text{C}_{23}\text{H}_{24}\text{O}_4$ ).