

## Promethazine Methylenedisalicylate Fine Granules

**Dissolution** <6.10> Perform the test with an accurately weighed quantity of Promethazine Methylenedisalicylate Fine Granules, equivalent to about 13.5 mg of promethazine methylenedisalicylate ( $C_{34}H_{40}N_4S_2 \cdot C_{15}H_{12}O_6$ ) according to the labeled amount, at 50 revolutions per minute according to the Paddle method, using 900 mL of 1st fluid for dissolution test 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  $\mu\text{m}$ . Discard the first 10 mL of the filtrate, pipet 5 mL of the subsequent filtrate, add 1st fluid for dissolution test to make exactly 10mL, and use this solution as the sample solution. Separately, weigh accurately about 15 mg of Promethazine Methylenedisalicylate RS, previously dried at 105°C for 3 hours, and dissolve in methanol to make exactly 100 mL. Pipet 5 mL of this solution, add 1st fluid for dissolution test 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 249 nm as directed under Ultraviolet-visible Spectrophotometry <2.24>, using 1st fluid for dissolution test as the blank.

The requirements are met if Promethazine Methylenedisalicylate Fine Granules conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of promethazine methylenedisalicylate ( $C_{34}H_{40}N_4S_2 \cdot C_{15}H_{12}O_6$ )

$$= M_S/M_T \times A_T/A_S \times 1/C \times 90$$

$M_S$ : Amount (mg) of Promethazine Methylenedisalicylate RS

$M_T$ : Amount (g) of sample

$C$ : Labeled amount (mg) of promethazine methylenedisalicylate ( $C_{34}H_{40}N_4S_2 \cdot C_{15}H_{12}O_6$ ) in 1 g

### Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
135 mg/g	90 minutes	Not less than 70%

**Promethazine Methylenedisalicylate RS** Promethazine Methylenedisalicylate. When dried, it contains not less than 99.0% of promethazine methylenedisalicylate ( $C_{34}H_{40}N_4S_2 \cdot C_{15}H_{12}O_6$ ).