

## Methylmethioninesulfonium Chloride Tablets

**Dissolution** <6.10> Perform the test with 1 tablet of Methylmethioninesulfonium Chloride Tablets at 75 revolutions per minute according to the Paddle method, using 900 mL of water 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 0.45  $\mu\text{m}$ . Discard not less than 10 mL of the first filtrate, pipet  $V$  mL of the subsequent filtrate, add water to make exactly  $V'$  mL so that each mL contains about 28  $\mu\text{g}$  of methylmethioninesulfonium chloride ( $\text{C}_6\text{H}_{14}\text{ClNO}_2\text{S}$ ) according to the labeled amount. Pipet 5 mL of this solution, add 0.2 mol/L hydrochloric acid TS to make exactly 10 mL, and use this solution as the sample solution. Separately, weigh accurately about 25 mg of Methylmethioninesulfonium Chloride RS, previously dried under reduced pressure for 3 hours using silica gel as a desiccant, and add water to make exactly 50 mL. Pipet 5 mL of this solution, and add water to make exactly 100 mL. Pipet 5 mL of this solution, add 0.2 mol/L hydrochloric acid TS to make exactly 10 mL, and use this solution as the standard solution. Perform the test with exactly 20  $\mu\text{L}$  each of the sample solution and standard solution as directed under Liquid Chromatography <2.01> according to the following conditions, and determine the peak areas,  $A_T$  and  $A_S$ , of methylmethioninesulfonium chloride of both solutions.

The requirements are met if Mosapride Citrate Tablets conforms to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of methylmethioninesulfonium chloride ( $\text{C}_6\text{H}_{14}\text{ClNO}_2\text{S}$ )

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 90$$

$M_S$ : Amount (mg) of Methylmethioninesulfonium Chloride RS

$C$ : Labeled amount (mg) of methylmethioninesulfonium chloride ( $\text{C}_6\text{H}_{14}\text{ClNO}_2\text{S}$ ) in 1 tablet of Methylmethioninesulfonium Chloride Tablets

### *Operating conditions—*

Detector: Fluorophotometer (excitation wavelength: 340 nm, fluorescence wavelength: 455 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with sulfonylpropylsilanized silica gel for liquid chromatography (10  $\mu\text{m}$  in average pore size).

Column temperature: A constant temperature of about 40°C.

Reaction coil: A stainless steel tube 0.5 mm in inside diameter and 1.5 m in length.

Reaction temperature: A constant temperature of about 40°C.

Mobile phase: To 51.0 g of potassium dihydrogen phosphate add water to make 2500 mL.

Reaction agent: Dissolve 25.0 g of boric acid in 950 mL of water, and adjust the pH to 10.5 with a solution of potassium hydroxide (1 in 2). Dissolve 2 mL of 2-mercaptoethanol and 1 g of polyoxyethylene (23) lauryl ether in 1000 mL of this solution, dissolve 0.8 g of *o*-phthalaldehyde, and add 10 mL of ethanol (99.5).

Flow rate of the mobile phase: Adjust the flow rate so that the retention time of methylmethioninesulfonium chloride is about 7 minutes.

Flow rate of the reaction reagent: About 1 mL per minute.

*System suitability*—

System performance: When the procedure is run with 20 µL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of methylmethioninesulfonium chloride are not less than 2000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 20 µL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of methylmethioninesulfonium chloride is not more than 3.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
25 mg	60 minutes	Not less than 85%

**Methylmethioninesulfonium Chloride RS** Methylmethioninesulfonium Chloride. When dried, it contains not less than 99.0% of methylmethioninesulfonium chloride (C<sub>6</sub>H<sub>14</sub>CINO<sub>2</sub>S).

**Sulfonylpropylsilanized silica gel for liquid chromatography** Prepared for liquid chromatography.