

late according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(3) Arsenic—Dissolve 2.0 g of Gabexate Mesilate in 20 mL of 1 mol/L hydrochloric acid TS by heating in a water bath, and continue the heating for 20 minutes. After cooling, centrifuge, and use 10 mL of the supernatant liquid as the test solution. Perform the test using Apparatus B (not more than 2 ppm).

(4) Ethyl parahydroxybenzoate—Weigh 0.050 g of Gabexate Mesilate, previously dried, and dissolve in dilute ethanol to make exactly 100 mL. Pipet 5 mL of this solution, add exactly 5 mL of the internal standard solution, and use this solution as the sample solution. Separately, dissolve 5.0 mg of ethyl parahydroxybenzoate in dilute ethanol to make exactly 100 mL. Pipet 1 mL of this solution, and add dilute ethanol to make exactly 20 mL. To exactly 5 mL of this solution add exactly 5 mL of the internal standard solution, and use this solution as the standard solution. Perform the test with 3  $\mu$ L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios,  $Q_T$  and  $Q_S$ , of the peak area of ethyl parahydroxybenzoate to that of the internal standard:  $Q_T$  is not larger than  $Q_S$ .

**Internal standard solution**—A solution of butyl parahydroxybenzoate in dilute ethanol (1 in 5000).

**Operating conditions**—

Proceed as directed in the operating conditions in the Assay.

**System suitability**—

Proceed as directed in the system suitability in the Assay.

(5) Related substances—Dissolve 0.20 g of Gabexate Mesilate in 5 mL of ethanol (95), and use this solution as the sample solution. Pipet 1 mL of the sample solution, add ethanol (95) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5  $\mu$ L each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water and acetic acid (100) (3:1:1) to a distance of about 10 cm, and air-dry the plate until it has no acetic odor. Spray evenly a solution of 8-quinolinol in acetone (1 in 1000) on the plate, and after air-drying, spray evenly bromine-sodium hydroxide TS: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

**Loss on drying** Not more than 0.30% (1 g, in vacuum, silica gel, 4 hours).

**Residue on ignition** Not more than 0.10% (1 g).

**Assay** Weigh accurately about 0.05 g each of Gabexate Mesilate and Gabexate Mesilate Reference Standard, previously dried, and dissolve each in dilute ethanol to make exactly 100 mL. Pipet 5 mL each of these solutions, add exactly 5 mL each of the internal standard solution, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with 3  $\mu$ L each of the sample solution and the standard solution as directed under the Thin-layer Chromatography according to the following conditions, and calculate the ratios,  $Q_T$  and  $Q_S$ , of the peak area of gabexate to that of the internal standard.

Amount (mg) of  $C_{16}H_{23}N_3O_4 \cdot CH_4O_3S$   
= amount (mg) of Gabexate Mesilate  
Reference Standard

$$\times \frac{Q_T}{Q_S}$$

**Internal standard solution**—A solution of butyl parahydroxybenzoate in dilute ethanol (1 in 5000).

**Operating conditions**—

**Detector:** An ultraviolet absorption photometer (wavelength: 245 nm).

**Column:** A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5  $\mu$ m in particle diameter).

**Column temperature:** A constant temperature of about 25°C.

**Mobile phase:** A mixture of methanol, a solution of sodium lauryl sulfate (1 in 1000), a solution of sodium 1-heptane sulfonate (1 in 200) and acetic acid (100) (540:200:20:1).

**Flow rate:** Adjust the flow rate so that the retention time of gabexate is about 13 minutes.

**System suitability**—

**System performance:** When the procedure is run with 3  $\mu$ L of the standard solution under the above operating conditions, the internal standard and gabexate are eluted in this order with the resolution between these peaks being not less than 5.

**System repeatability:** When the test is repeated 6 times with 3  $\mu$ L of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of gabexate to that of the internal standard is not more than 1.0%.

**Containers and storage** Containers—Tight containers.

## Gallium (<sup>67</sup>Ga) Citrate Injection

クエン酸ガリウム (<sup>67</sup>Ga) 注射液

Gallium (<sup>67</sup>Ga) Citrate Injection is an aqueous solution for injection containing gallium-67 (<sup>67</sup>Ga) in the form of gallium citrate.

It conforms to the requirements of Gallium (<sup>67</sup>Ga) Citrate Injection in the Minimum Requirements for Radiopharmaceuticals.

The Insoluble Particulate Matter Test for Injections is not applied to this injection.

**Description** Gallium (<sup>67</sup>Ga) Citrate Injection is a clear, colorless or light red liquid.