Gentamicin Sulfate Injection

ゲンタマイシン硫酸塩注射液

Gentamicin Sulfate Injection is an aqueous injection.

It contains not less than 90.0% and not more than 110.0% of the labeled potency of gentamicin C_1 ($C_{21}H_{43}N_5O_7$: 477.60).

Method of preparation Prepare as directed under Injections, with Gentamicin Sulfate.

Description Gentamicin Sulfate Injection is a clear and colorless liquid.

Identification To a volume of Gentamicin Sulfate Injection, equivalent to 40 mg (potency) of Gentamicin Sulfate, add water to make 10 mL, and use this solution as the sample solution. Separately, dissolve an amount of Gentamicin Sulfate RS, equivalent to 20 mg (potency), in 5 mL of water, and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography *<2.03>*. Spot 5 μL each of the sample solution and standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with the lower layer of a mixture of chloroform, ammonia solution (28) and methanol (2:1:1) to a distance of about 15 cm, and air-dry the plate. Spray evenly 0.2% ninhydrin-water saturated 1-butanol TS on the plate, and heat the plate at 100℃ for 10 minutes: three principal spots obtained from the sample solution are the same with the corresponding spots from the standard solution in color tone and the *R*f value, respectively.

Osmotic pressure ratio Being specified separately when the drug is granted approval based on the Law.

pH *<2.54>* 4.0 – 6.0

Bacterial endotoxins *<4.01>* Less than 0.50 EU/mg (potency).

Extractable volume *<6.05>* It meets the requirement.

Foreign insoluble matter *<6.06>* Perform the test according to Method 1: it meets the requirement.

Insoluble particulate matter *<6.07>* It meets the requirement.

Sterility *<4.06>* Perform the test according to the Membrane filtration method: it meets the requirement.

Assay Perform the test according to the Cylinder-plate method as directed under Microbial Assay for Antibiotics *<4.02>* according to the following conditions.

(i) Test organism, agar media for base and seed layer, agar medium for transferring test organisms, and standard solutions－Proceed as directed in the Assay under Gentamicin Sulfate.

(ii) Sample solutions－Pipet a volume of Gentamicin Sulfate Injection, equivalent to about 40 mg (potency) of Gentamicin Sulfate, add 0.1 mol/L phosphate buffer solution (pH 8.0) to make exactly 200 mL. Pipet a suitable volume of this solution, add 0.1 mol/L phosphate buffer solution (pH 8.0) to make solutions so that each mL contains 4 μg (potency) and 1 μg (potency), and use these solutions as the high concentration sample solution and the low concentration sample solution, respectively.

Containers and storage Containers－Hermetic containers.