Gentamicin Sulfate Ointment

ゲンタマイシン硫酸塩軟膏

Gentamicin Sulfate Ointment 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 Ointments, with Gentamicin Sulfate.

Identification Dissolve an amount of Gentamicin Sulfate Ointment, equivalent to 5 mg (potency) of Gentamicin Sulfate, in 10 mL of diethyl ether. Add 5 mL of water, shake for 10 minutes, centrifuge, and use the water layer as the sample solution. Separately, dissolve an amount of Gentamicin Sulfate RS, equivalent to 10 mg (potency), in 10 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 10 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.

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－Weigh accurately an amount of Gentamicin Sulfate Ointment, equivalent to about 1 mg (potency) of Gentamicin Sulfate, transfer to a separator, add 50 mL of diethyl ether, and shake until the solution becomes uniform. Add 25 mL of 0.1 mol/L phosphate buffer solution (pH 8.0), shake, and collect the water layer. Repeat the same procedure with 25 mL of 0.1 mol/L phosphate buffer solution (pH 8.0), and combine the water layers. To this solution add 0.1 mol/L phosphate buffer solution (pH 8.0) to make exactly 100 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－Tight containers.