

Kanamycin for injection (Kanamycini ad injectionem)

2015-01

Description. A white or almost white powder.

Category. Antibacterial.

Storage. Kanamycin for injection should be kept in a hermetically closed container.

Labelling. The designation on the container of kanamycin for injection should state that the active ingredient is in a sulfate form and the quantity should be indicated in International Units.

Additional information

The injection is reconstituted by dilution of Kanamycin for injection in Water for injections.

The reconstituted injection should be used immediately after preparation.

Requirements

The powder for injection and the reconstituted injection comply with the monograph for [Parenteral preparations](#).

Definition. Kanamycin for injection is a sterile powder containing Kanamycin monosulfate or Kanamycin acid sulfate.

The powder is sterilized by a suitable method (see [5.8 Methods of sterilization](#)).

Identity tests

-Either tests A and D or tests B, C and D may be applied.

A. Carry out the test as described under [1.14.1 Chromatography, Thin-layer chromatography](#) using silica gel R5 as the coating substance and a 0.75 M phosphate buffer pH 7.0 as the mobile phase. Prepare the 0.75 M phosphate buffer pH 7.0 by mixing 0.75 M potassium dihydrogen phosphate R with 0.75 M dipotassium dihydrogen phosphate R until pH 7.0 is reached.

Apply separately to the plate 2 µL of each of the following solutions in water R. For solution (A) dissolve a quantity of the powder to obtain a solution of kanamycin with a concentration of 5 mg per mL. For solution (B) use a solution of kanamycin monosulfate RS containing 5 mg per mL. For solution (C) use a mixture containing 5 mg per mL each of kanamycin monosulfate RS and neomycin sulfate RS. After removing the plate from the chromatographic chamber heat it at 110 °C for 5 minutes, spray it with triketohydrindene/methanol reagent TS and heat further at 110 °C for 15 minutes.

The principal spot obtained with solution A corresponds in position, appearance and intensity with that obtained with solution B. The test is not valid unless the chromatogram obtained with solution C shows two clearly separated spots.

B. Dissolve a quantity of the powder to obtain a solution of kanamycin with a concentration of 20 mg per mL. Use 1 mL of this solution, add 1 mL of sodium hydroxide (~80 g/L) TS and mix, then add 2 mL of cobalt(II) nitrate (10 g/L) TS; a greyish colour with precipitate is produced.

C. Dissolve a quantity of the powder to obtain a solution of kanamycin with a concentration of 20 mg per mL. Use 3 mL of this solution and add 4 mL of anthrone TS; a bluish violet colour is produced.

D. A solution prepared in dissolving the powder to obtain a concentration of kanamycin of 20 mg per mL yields reaction A described under [2.1 General identification tests](#) as characteristic of sulfates.

pH value (1.13). pH of the reconstituted injection, 4.0–6.0.

Assay

Carry out the assay as described under [3.1 Microbiological assay of antibiotics](#) using either (a) *Bacillus subtilis* (ATCC 6633) as the test organism, culture medium Cm1 with a final pH of 7.9, sterile phosphate buffer pH 8.0 TS1, an appropriate concentration of kanamycin (usually 5–20 IU per mL) and an incubation temperature of 30–37 °C, or (b) *Staphylococcus aureus* (ATCC 6538 P) as the test organism, the same culture medium and phosphate buffer, an appropriate concentration of kanamycin (usually 10 IU per mL) and an incubation temperature of 35–39 °C. The precision of the assay is such that the fiducial limits of error of the estimated potency ($P = 0.95$) are not less than 95% and not more than 105% of the estimated potency. The upper fiducial limit of error of the estimated potency ($P = 0.95$) is not less than 90.0% and the lower fiducial limit of error is not more than 120.0% of the stated number of International Units.

Bacterial endotoxins. Carry out the test as described under [3.4 Test for bacterial endotoxins](#); contains not more than 0.67 IU x 10–3 IU of endotoxin per IU of kanamycin activity.