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Gentamicin Injection

» Gentamicin Injection contains an amount of Gentamicin Sulfate equivalent to not less than 90.0 percent and not more than 125.0 percent of the labeled amount of gentamicin. It may contain suitable buffers, preservatives, and sequestering agents, unless it is intended for intrathecal use, in which case it contains only suitable tonicity agents.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

USP Reference standards ⟨11⟩—
USP Gentamicin Sulfate RS

Identification—Apply separately a volume of Injection equivalent to 20 µg of gentamicin and the same volume of a similar preparation of USP Gentamicin Sulfate RS to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel having an average pore size of 6 nm. [Note—Dilute the Injection with water, if necessary, to obtain a test solution containing 1000 µg of gentamicin per mL. Where the Injection contains less than 1000 µg per mL, apply a volume of it, equivalent to 20 µg of gentamicin, to the chromatographic plate, in separate portions of not more than 20 µL each, each application being allowed to dry before the next is applied.] Place the plate in a suitable chromatographic chamber, and develop the chromatogram in a solvent system consisting of the lower phase of a mixture of chloroform, methanol, and ammonium hydroxide (20:13:10) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, air-dry, and expose the plate to vapors of iodine in a detection jar containing iodine crystals: the intensities and R_F values of the three principal spots obtained from the test solution correspond to those obtained from the Standard solution.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.71 USP Endotoxin Unit per mg of gentamicin.

pH ⟨791⟩: between 3.0 and 5.5.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—Proceed as directed under *Antibiotics—Microbial Assays ⟨81⟩*, using an accurately measured volume of Injection diluted quantitatively and stepwise with *Buffer B.3* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard (0.1 µg of gentamicin per mL).

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
GENTAMICIN INJECTION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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