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Neomycin for Injection

» Neomycin for Injection contains an amount of Neomycin Sulfate equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of neomycin.

Packaging and storage—Preserve as described in [Packaging and Storage Requirements \(659\), Injection Packaging, Packaging for constitution](#).

USP REFERENCE STANDARDS (11)—

[USP Neomycin Sulfate RS](#)

THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST (201BNP): meets the requirements.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 1.30 USP Endotoxin Units per mg of neomycin.

STERILITY TESTS (71)—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

Other requirements—It meets the requirements for *pH* and *Loss on drying* under [Neomycin Sulfate](#) and for [Uniformity of Dosage Units \(905\)](#) and [Labeling \(7\), Labels and Labeling for Injectable Products](#).

Assay—

Assay preparation 1 (where it is packaged for dispensing)—Constitute Neomycin for Injection as directed in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively with *Buffer B.3* to obtain a solution having a convenient concentration.

Assay preparation 2 (where it is packaged for dispensing and where the labeling states the quantity of neomycin in a given volume of constituted solution)—Constitute Neomycin for Injection as directed in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively with *Buffer B.3* to obtain a solution having a convenient concentration.

Procedure—Proceed as directed for neomycin under [Antibiotics—Microbial Assays \(81\)](#), using an accurately measured volume of *Assay preparation* 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.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
NEOMYCIN FOR INJECTION	Kishan Chandra Senior Scientist I, Documentary Standards	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

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