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Neomycin Boluses

» Neomycin Boluses contain an amount of Neomycin Sulfate equivalent to not less than 90.0 percent and not more than 125.0 percent of the labeled amount of neomycin.

Packaging and storage—Preserve in tight containers.

Labeling—Label Boluses to indicate that they are for veterinary use only.

USP Reference standards ⟨11⟩—

USP Neomycin Sulfate RS

Identification—Blend a Bolus with 250 mL of water. Filter a portion of the suspension obtained. If necessary, dilute a portion of the filtrate with water to obtain a test solution containing about 2 mg of neomycin per mL. Dissolve a quantity of USP Neomycin Sulfate RS in water to obtain a Standard solution containing about 2 mg of neomycin per mL. Separately apply 1 µL of each solution to a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Develop the chromatogram in a solvent system consisting of a mixture of water, butyl alcohol, glacial acetic acid, and pyridine (35:30:22:6) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and dry at about 110° for about 5 minutes. Spray the plate evenly with a solution of ninhydrin (2 mg per mL), and dry the plate at about 100° for about 5 minutes. Locate the spots on the plate: the R_F value of the principal spot in the chromatogram obtained from the test solution corresponds to that of the principal spot in the chromatogram obtained from the Standard solution.

Uniformity of dosage units ⟨905⟩: meet the requirements for *Weight Variation.*

Disintegration ⟨701⟩: 60 minutes.

Assay—Proceed as directed for the assay of neomycin under *Antibiotics—Microbial Assays* ⟨81⟩, the *Test Dilution* being prepared as follows. Blend an accurately counted number of Boluses (not less than 2) at high speed in a blender jar with a sufficient accurately measured volume of *Buffer B.3* to obtain a stock solution having a convenient concentration. Dilute this stock solution quantitatively and stepwise with *Buffer B.3* to obtain 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 BOLUSES	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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