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Streptomycin for Injection

» Streptomycin for Injection contains an amount of Streptomycin Sulfate equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of streptomycin ($C_{21}H_{39}N_7O_{12}$).

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

USP Reference standards ⟨11⟩—
USP Streptomycin Sulfate RS

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

Identification—

A: Dissolve 5 g of ferric chloride in 50 mL of 0.1 N hydrochloric acid. Transfer 2.5 mL of this stock solution to a 100-mL volumetric flask, dilute with 0.01 N hydrochloric acid to volume, and mix. Prepare *Iron reagent* at the time of use. Dissolve the specimen in water, and dilute with water to obtain a solution containing about 1 mg of streptomycin per mL. To 5 mL of this solution add 2.0 mL of 1 N sodium hydroxide, and heat in a water bath for 10 minutes. Cool in ice water for 3 minutes, then add 2.0 mL of 1.2 N hydrochloric acid, and mix. Add 5 mL of *Iron reagent*, and mix: a violet color is produced.

B: It responds to the tests for *Sulfate ⟨191⟩*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.25 USP Endotoxin Unit per mg of streptomycin.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH ⟨791⟩: between 4.5 and 7.0, in a solution containing 200 mg of streptomycin per mL.

Loss on drying ⟨731⟩—Dry about 100 mg, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 5.0% of its weight.

Other requirements—It meets the requirements for *Uniformity of Dosage Units ⟨905⟩* and *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

Assay—

Mobile phase, *Standard preparation*, *System suitability solution*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Streptomycin Sulfate.*

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Streptomycin for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively, and stepwise if necessary, with water to obtain a solution containing about 0.025 mg of streptomycin per mL.

Assay preparation 2 (where the label states the quantity of streptomycin in a given volume of constituted solution)—Constitute Streptomycin for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively, and stepwise if necessary, with water to obtain a solution containing about 0.025 mg of streptomycin per mL.

Procedure—Proceed as directed in the *Assay* under *Streptomycin Sulfate.* Calculate the quantity, in mg, of streptomycin ($C_{21}H_{39}N_7O_{12}$) withdrawn from the container, or in the portion of constituted solution taken by the formula:

$$(CP/1000)(L/D)(r_U/r_S)$$

in which L is the labeled quantity, in mg, of streptomycin ($C_{21}H_{39}N_7O_{12}$) in the container, or in the volume of constituted solution taken; D is the concentration, in mg of streptomycin per mL, of *Assay preparation 1* or *Assay preparation 2*, based on the labeled quantity in the container, or in the volume of constituted solution taken, respectively; and the other terms are as defined therein.

Topic/Question	Contact	Expert Committee
STREPTOMYCIN FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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