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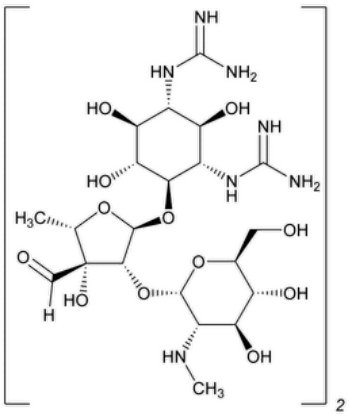
Streptomycin Sulfate



• $3\,H_2SO_4$

$(C_{21}H_{39}N_7O_{12})_2 \cdot 3H_2SO_4$ 1457.38

D-Streptamine, *O*-2-deoxy-2-(methylamino)-α-L-glucopyranosyl-(1→2)-*O*-5-deoxy-3-*C*-formyl-α-L-lyxofuranosyl-(1→4)-*N*,*N*′-bis(aminoiminomethyl)-, sulfate (2:3) (salt).

Streptomycin sulfate (2:3) (salt) CAS RN®: 3810-74-0; UNII: CW25IKJ202.

» Streptomycin Sulfate has a potency equivalent to not less than 650 µg and not more than 850 µg of streptomycin ($C_{21}H_{39}N_7O_{12}$) per mg.

Packaging and storage—Preserve in tight containers.

Labeling—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

USP Reference standards ⟨11⟩—

USP Streptomycin Sulfate RS

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⟩.

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—Where the label states that Streptomycin Sulfate is sterile, it meets the requirements for *Sterility Tests* and *Bacterial endotoxins* under *Streptomycin for Injection*. Where the label states that Streptomycin Sulfate must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Streptomycin for Injection.*

Assay—

Mobile phase—Use 70 mM sodium hydroxide. During use, store in a plastic bottle flushed with a blanket of helium above the liquid surface. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Streptomycin Sulfate RS in water, and quantitatively dilute with water to obtain a solution having a known concentration of about 0.03 mg per mL. Sonicate for 1 minute, and mix.

Assay preparation—Transfer about 30 mg of Streptomycin Sulfate, accurately weighed, to a 100-mL volumetric flask, dilute with water to volume, sonicate for 1 minute, and mix. Transfer 10.0 mL of this solution to a second 100-mL volumetric flask, dilute with water to volume, and mix.

System suitability solution—Heat about 10 mL of the *Standard preparation* at 75° for 1 hour. Allow to cool.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with an electrochemical detector, a gold working electrode, a pH silver–silver chloride reference electrode, a 4-mm × 5-cm guard column that contains packing L46, and a 4-mm × 25-cm analytical column that contains packing L46. The electrochemical detector is used in the integrated amperometric mode with a range of 300

nC, an output of 1 V full scale, and a rise time of 0.5 second, positive polarity. The potential is programmed as follows.

Step	Time (seconds)	Potential (V)	Integration
1	0.00	+0.1	
2	0.20	+0.1	begins
3	0.40	+0.1	ends
4	0.41	−2.0	
5	0.42	−2.0	
6	0.43	+0.6	
7	0.44	−0.1	
8	0.50	−0.1	

The flow rate is about 0.5 mL per minute. Chromatograph the *System suitability solution*, and measure the peak areas as directed for *Procedure:* the relative retention times are about 0.5 for the main degradation product and 1.0 for streptomycin; and the resolution, *R,* between the two peaks is not less than 3. Chromatograph the *Standard preparation,* and measure the peak areas as directed for *Procedure:* the tailing factor is not more than 2; the column efficiency is not less than 1000 theoretical plates; and the relative standard deviation for replicate injections is not more than 5%.

[Note—If variation of retention time or increase of tailing occurs, clean the columns with 0.2 M sodium hydroxide. Carefully maintain the working and reference electrodes.]

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in µg, of streptomycin ($C_{21}H_{39}N_7O_{12}$) in each mg of Streptomycin Sulfate taken by the formula:

$$1000(CP/W_U)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Streptomycin Sulfate RS in the *Standard preparation; P* is the designated streptomycin content, in µg per mg, of streptomycin ($C_{21}H_{39}N_7O_{12}$) in USP Streptomycin Sulfate RS; W_U is the weight, in mg, of Streptomycin Sulfate taken to prepare the *Assay preparation;* and r_U and r_S are the streptomycin peak areas obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
STREPTOMYCIN SULFATE	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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