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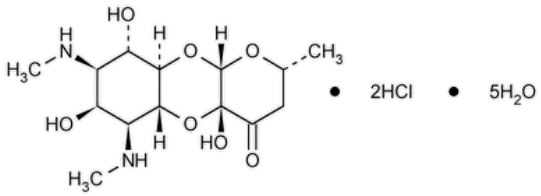
Spectinomycin Hydrochloride



$C_{14}H_{24}N_2O_7 \cdot 2HCl \cdot 5H_2O$ 495.35

4*H*-Pyrano[2,3-*b*][1,4]benzodioxin-4-one, decahydro-4a,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-, dihydrochloride, pentahydrate, [2*R*-(2α,4aβ,5aβ,6β,7β,8β,9α,9aα,10aβ)]-.

(2*R*,4a*R*,5a*R*,6*S*,7*S*,8*R*,9*S*,9a*R*,10a*S*)-Decahydro-4a,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-4*H*-pyrano[2,3-*b*]1,4]benzodioxin-4-one dihydrochloride pentahydrate CAS RN®: 22189-32-8; UNII: HWT06H303Z.

Anhydrous 405.28 CAS RN®: 21736-83-4; UNII: 296JEI210Z.

» Spectinomycin Hydrochloride has a potency equivalent to not less than 603 µg of spectinomycin ($C_{14}H_{24}N_2O_7$) 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 Spectinomycin Hydrochloride RS

Change to read:

Identification, ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197M**▲ (CN 1-May-2020) —Do not dry specimen.

Crystallinity ⟨695⟩: meets the requirements.

Bacterial Endotoxins Test ⟨85⟩ —Where the label states that Spectinomycin Hydrochloride is sterile or that it must be subjected to further processing during the preparation of injectable dosage forms, it contains not more than 0.09 USP Endotoxin Unit per mg of spectinomycin.

Sterility Tests ⟨71⟩ —Where the label states that Spectinomycin Hydrochloride is sterile, it meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH ⟨791⟩: between 3.8 and 5.6, in a solution containing 10 mg per mL.

Water Determination, *Method I* ⟨921⟩: between 16.0% and 20.0%.

Residue on Ignition ⟨281⟩: not more than 1.0%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid.

Assay—

Internal standard solution—Dissolve triphenylantimony in dimethylformamide to obtain a solution containing about 2 mg per mL.

Standard preparation—Transfer about 30 mg of USP Spectinomycin Hydrochloride RS, accurately weighed, to a glass-stoppered, 25-mL conical flask. Add 10.0 mL of *Internal standard solution* and 1.0 mL of hexamethyldisilazane, and shake intermittently for 1 hour.

Assay preparation—Proceed as directed under *Standard preparation* using Spectinomycin Hydrochloride.

Chromatographic system (see *Chromatography* ⟨621⟩)—The gas chromatograph is equipped with a flame-ionization detector and contains a 3-mm × 60-cm glass column packed with 5 percent phase G27 on 80- to 100-mesh support S1AB. The column and detector are maintained at about 190° and 220°, respectively, and the injection port at about 215°, and dry helium is used as the carrier gas at a flow rate of about 45 mL per minute. Chromatograph the *Standard preparation*, and record the chromatogram as directed for *Procedure:* the resolution, *R,* between the major peaks is not less than 2.0; and the relative standard deviation of the peak response ratios, R_S, from replicate injections of the *Standard preparation* is not more than 3.5%.

Procedure—Separately inject equal volumes (about 1 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the ratio, R_U, of the response of the spectinomycin peak to the

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response of the internal standard peak in the chromatogram from the *Assay preparation*, and similarly calculate the ratio, R_S, in the chromatogram from the *Standard preparation.* Calculate the quantity, in µg, of $C_{14}H_{24}N_2O_7$ in the portion of Spectinomycin Hydrochloride taken to prepare the *Assay preparation* by the formula:

$$P(W_S)(R_U/R_S)$$

in which P is the potency of USP Spectinomycin Hydrochloride RS, in µg of spectinomycin per mg; and W_S is the weight, in mg, of USP Spectinomycin Hydrochloride RS taken from the *Standard preparation;* and the other terms are as defined above.

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

Topic/Question	Contact	Expert Committee
SPECTINOMYCIN HYDROCHLORIDE	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

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

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