

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-14BE1D88-7818-4CEA-B902-7E210198B05F_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M77812_04_01
 DOI Ref: plv16

© 2025 USPC
 Do not distribute

Spectinomycin for Injectable Suspension

» Spectinomycin for Injectable Suspension contains an amount of Spectinomycin Hydrochloride equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of spectinomycin ($C_{14}H_{24}N_2O_7$).

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

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.

pH (791): between 4.0 and 7.0, in the suspension constituted as directed in the labeling.

Other requirements—It conforms to the Definition, and meets the requirements for *Crystallinity*, *Bacterial endotoxins*, *Sterility*, *Water*, and *Residue on ignition* under *Spectinomycin Hydrochloride*. It meets also the requirements for [Uniformity of Dosage Units \(905\)](#), and [Labeling \(7\)](#), [Labels and Labeling for Injectable Products](#).

Assay—

Internal standard solution, *Standard preparation*, and *Chromatographic system*—Prepare as directed in the [Assay](#) under [Spectinomycin Hydrochloride](#).

Assay preparation 1—Suspend the contents of 1 container of Spectinomycin for Injectable Suspension in water, and dilute quantitatively with water to obtain a stock solution containing about 20 mg of spectinomycin per mL. Transfer 1.0 mL of this solution to a glass-stoppered, 25-mL conical flask, and freeze-dry. Add 10.0 mL of *Internal standard solution* and 1.0 mL of hexamethyldisilazane, and shake intermittently for 1 hour.

Assay preparation 2 (where the label states the quantity of spectinomycin in a given volume of constituted suspension)—Constitute 1 container of Spectinomycin for Injectable Suspension in a volume of water, accurately measured, corresponding to the volume of diluent specified in the labeling. Dilute an accurately measured portion of the constituted suspension quantitatively with water to obtain a stock solution containing about 20 mg of spectinomycin per mL. Transfer 1.0 mL of this solution to a glass-stoppered, 25-mL conical flask, and freeze-dry. Add 10.0 mL of *Internal standard solution* and 1.0 mL of hexamethyldisilazane, and shake intermittently for 1 hour.

Procedure—Proceed as directed in the [Assay](#) under [Spectinomycin Hydrochloride](#). Calculate the quantity, in g, of $C_{14}H_{24}N_2O_7$ in the container of Spectinomycin for Injectable Suspension taken to prepare *Assay preparation 1* taken by the formula:

$$(L_1/D_1)(P/1000)(W_S)(R_U/R_S)$$

in which L_1 is the labeled quantity, in g, of $C_{14}H_{24}N_2O_7$ in the container, and D_1 is the concentration, in mg per mL, of spectinomycin in the stock solution used to prepare *Assay preparation 1*, on the basis of the labeled quantity in the container and the extent of dilution, and the other terms are as defined therein. Calculate the quantity, in mg, of $C_{14}H_{24}N_2O_7$ in each mL of constituted Injectable Suspension taken to prepare

Assay preparation 2 taken by the formula:

$$(L_2/D_2)(P/1000)(W_S)(R_U/R_S)$$

in which L_2 is the labeled quantity, in mg, of $C_{14}H_{24}N_2O_7$ in each mL of constituted suspension of Spectinomycin for Injectable Suspension, and D_2 is the concentration, in mg per mL, of spectinomycin in the stock solution used to prepare *Assay preparation 2*, on the basis of the labeled quantity in each mL of constituted suspension and the extent of dilution.

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

Topic/Question	Contact	Expert Committee
SPECTINOMYCIN FOR INJECTABLE SUSPENSION	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. PF 34(5)

Current DocID: GUID-14BE1D88-7818-4CEA-B902-7E210198B05F_4_en-US

DOI: https://doi.org/10.31003/USPNF_M77812_04_01

DOI ref: [plv16](#)

OFFICIAL