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# 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.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| SPECTINOMYCIN FOR INJECTABLE SUSPENSION | Documentary Standards Support | SM12020 Small Molecules 1 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM12020 Small Molecules 1 |

**Chromatographic Database Information:** Chromatographic Database

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