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Dihydrostreptomycin Injection

» Dihydrostreptomycin Injection contains an amount of Dihydrostreptomycin Sulfate equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of dihydrostreptomycin (C₂₁H₄₁N₇O₁₂). It contains one or more suitable preservatives.

Packaging and storage—Preserve in single-dose or multiple-dose containers.

Labeling—Label it to indicate that it is intended for veterinary use only.

USP REFERENCE STANDARDS (11)-

USP Dihydrostreptomycin Sulfate RS

Identification—It responds to the *Identification* tests under <u>Dihydrostreptomycin Sulfate</u>.

BACTERIAL ENDOTOXINS TEST (85). —It contains not more than 0.5 USP Endotoxin Unit per mg of dihydrostreptomycin.

<u>STERILITY TESTS (71)</u>. —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

PH (791): between 5.0 and 8.0.

Assay-

Assay preparation 1 (where it is represented as being in a single-dose container)—Withdraw all of the withdrawable contents of Injection, using a suitable hypodermic needle and syringe, and dilute quantitatively with water to obtain a solution containing a convenient quantity of dihydrostreptomycin in each mL.

Assay preparation 2 (where the label states the quantity of dihydrostreptomycin in a given volume of solution)—Dilute an accurately measured volume of Injection quantitatively with water to obtain a solution containing a convenient quantity of dihydrostreptomycin in each mL. Procedure—Proceed as directed for the turbidimetric assay of dihydrostreptomycin under <u>Antibiotics—Microbial Assays (81)</u>, using an accurately measured volume of Assay preparation diluted quantitatively with water to yield a Test Dilution having a concentration assumed to

be equal to the median dose level of the Standard.

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

Topic/Question	Contact	Expert Committee
DIHYDROSTREPTOMYCIN INJECTION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:

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