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Colistimethate for Injection

» Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin.

Packaging and storage—Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging](#), [Packaging for constitution](#), [USP REFERENCE STANDARDS \(11\)](#)—[USP Colistimethate Sodium RS](#)

Constituted solution—At the time of use, it meets the requirements for [Injections and Implanted Drug Products \(1\)](#), [Specific Tests, Completeness and clarity of solutions](#).

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 2.0 USP Endotoxin Units per mg of colistin.

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

Other requirements—It responds to the *Identification* test and meets the requirements for *pH*, *Loss on drying*, and [Free colistin](#) under [Colistimethate Sodium](#). It meets also the requirements for [Uniformity of Dosage Units \(905\)](#) and for [Injections and Implanted Drug Products \(1\)](#), [Specific Tests, Completeness and clarity of solutions](#) and for [Labeling \(7\)](#), [Labels and Labeling for Injectable Products](#).

Assay—

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Colistimethate for Injection in a volume of water, accurately measured, corresponding to the volume of diluent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and quantitatively dilute with *Buffer B.6* to obtain a solution having a convenient concentration.

Assay preparation 2 (where the label states the quantity of colistin equivalent in a given volume of constituted solution)—Constitute Colistimethate for Injection in a volume of water, accurately measured, corresponding to the volume of diluent specified in the labeling. Quantitatively dilute an accurately measured volume of the constituted solution with *Buffer B.6* to obtain a solution having a convenient concentration.

Procedure—Proceed as directed for Colistimethate Sodium under [Antibiotics—Microbial Assays \(81\)](#), using an accurately measured volume of *Assay preparation* diluted quantitatively with *Buffer B.6* 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
COLISTIMETHATE FOR INJECTION	Julie Zhang Associate Science & Standards Liaison	BI042020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

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