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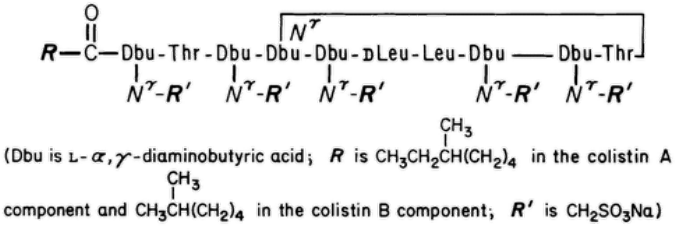
Colistimethate Sodium



$C_{58}H_{105}N_{16}Na_5O_{28}S_5$ (colistin A component) 1749.82
$C_{57}H_{103}N_{16}Na_5O_{28}S_5$ (colistin B component) 1735.79

Colistimethate sodium.

Pentasodium colistinmethanesulfonate CAS RN®: 8068-28-8; 21362-08-3; UNII: XW0E5YS77G.

» Colistimethate Sodium has a potency equivalent to not less than 390 µg of colistin per mg.

Packaging and storage—Preserve as described in *Packaging and Storage Requirements* ⟨659⟩, *Injection Packaging, Packaging for constitution*.

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 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*.

Change to read:

Identification, ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

pH ⟨791⟩: between 6.5 and 8.5, in a solution containing 10 mg per mL.

Loss on drying ⟨731⟩—Dry about 100 mg, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 7.0% of its weight.

Free colistin—Dissolve 80 mg in 3 mL of water, and add 0.05 mL of silicotungstic acid solution (1 in 10): no immediate precipitate is formed.

Other requirements—Where the label states that Colistimethate Sodium is sterile, it meets the requirements for *Sterility* and *Bacterial endotoxins* under *Colistimethate for Injection*. Where the label states that Colistimethate Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Colistimethate for Injection*.

Assay—

Assay preparation—Dissolve a suitable quantity of Colistimethate Sodium, accurately weighed, in 2.0 mL of water, add a sufficient accurately measured volume of *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 SODIUM	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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