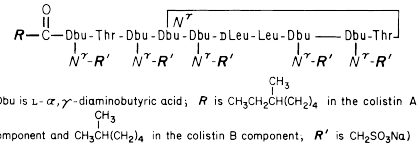
number of Tablets taken to prepare the *Test preparation;* and *L* is the labeled amount of colestipol hydrochloride, in g per Tablet.

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) 1735.80
Colistimethate sodium.
Pentasodium colistinmethanesulfonate [8068-28-8; 21362-08-3].

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

Packaging and storage—Preserve in *Containers for Sterile Solids* as described under *Injections* ⟨1⟩.

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
USP Endotoxin RS

Constituted solution—At the time of use, it meets the requirements for *Constituted Solutions* under *Injections* ⟨1⟩.

Identification, *Infrared Absorption* ⟨197K⟩**.**

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.

Heavy metals, *Method II* ⟨231⟩: not more than 0.003%.

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 No. 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 No. 6* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

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 in *Containers for Sterile Solids* as described under *Injections* ⟨1⟩.

USP Reference standards ⟨11⟩**—**
USP Colistimethate Sodium RS
USP Endotoxin RS

Constituted solution—At the time of use, it meets the requirements for *Constituted Solutions* under *Injections* ⟨1⟩.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 2.0 USP Endotoxin Units per mg of colistin.

Sterility ⟨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*, *Heavy metals*, and *Free colistin* under *Colistimethate Sodium*. It meets also the requirements for *Uniformity of Dosage Units* ⟨905⟩ and for *Constituted Solutions* and *Labeling* under *Injections* ⟨1⟩.

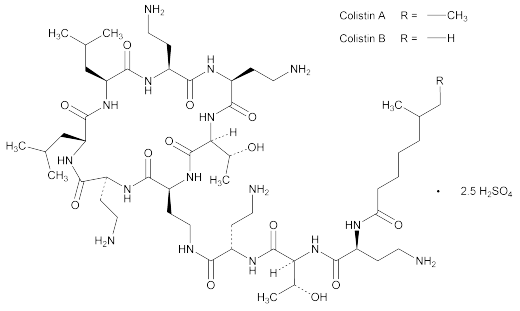
Assay—

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 No. 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 No. 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 No. 6* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Colistin Sulfate



Colistin, sulfate.
Colistins sulfate [1264-72-8].

» Colistin Sulfate is the sulfate salt of an antibacterial substance produced by the growth of *Bacillus polymyxa* var. *colistinus.* It has a potency