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

**Colistimethate Sodium**

![Chemical structure of colistimethate sodium](image)

C18H105N16Na5O28S5 (colistin A component) 1749.82
C25H28N16Na5O28S5 (colistin B component) 1735.80
Colistimethate sodium.

Pentasodium colistimethanesulfonate [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**—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 yield a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.

**Colistin Sulfate**

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

Colistin Sulfate for Oral Suspension is a dry mixture of Colistin Sulfate with or without one or more suitable buffers, colors, diluents, dispersants, and flavors. It contains the equivalent of not less than 90.0 per cent and not more than 120.0 per cent of the labeled amount of colistin.

Packaging and storage—Preserve in tight containers, protected from light.

USP Reference standards (11)—
USP Colistin Sulfate RS

Uniformity of dosage units (905)—
For solid packaged in single-unit containers: meets the requirements.

Deliverable volume (698): meets the requirements.

pH (791): between 5.0 and 6.0, in the suspension constituted as directed in the labeling.

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 °C for 3 hours: it loses not more than 3.0% of its weight.

Assay—Constitute Colistin Sulfate for Oral Suspension as directed in the labeling. Proceed as directed under Antibiotics—Microbial Assays (81) using an accurately measured volume of this suspension, freshly mixed and free from air bubbles, 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 and Neomycin Sulfates and Hydrocortisone Acetate Otic Suspension

Colistin and Neomycin Sulfates and Hydrocortisone Acetate Otic Suspension is a sterile suspension containing the equivalent of not less than 90.0 per cent and not more than 135.0 per cent of the labeled amount of colistin, not less than 90.0 per cent and not more than 125.0 per cent of the labeled amount of neomycin, and not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of hydrocortisone acetate (C23H32O6). It contains one or more suitable buffers, detergents, dispersants, and preservatives.

NOTE—Where Colistin and Neomycin Sulfates and Hydrocortisone Acetate Otic Suspension is prescribed, without reference to the quantity of colistin, neomycin, or hydrocortisone acetate contained therein, a product containing 3.0 mg of colistin, 3.3 mg of neomycin, and 10 mg of hydrocortisone acetate per mL shall be dispensed.

Packaging and storage—Preserve in tight containers.

USP Reference standards (11)—
USP Colistin Sulfate RS
USP Neomycin Sulfate RS
USP Hydrocortisone Acetate RS

Sterility (71): meets the requirements, 0.25 mL from each container being transferred directly to 90 mL of each medium.

pH (791): between 4.8 and 5.2.

Assay for colistin—Proceed as directed under Antibiotics—Microbial Assays (81), using a freshly mixed, accurately measured volume of Otic Suspension diluted quantitatively and stepwise with Buffer No. 6 to yield a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.

Assay for neomycin—Proceed as directed under Antibiotics—Microbial Assays (81), using a freshly mixed, accurately measured volume of Otic Suspension diluted quantitatively and stepwise with Buffer No. 3 to yield a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.

Assay for hydrocortisone acetate—
Reagent blank—Dilute 200 mL of 22 N sulfuric acid with 100 mL of dehydrated alcohol.
Phenylhydrazine reagent—Dissolve 43.33 mg of phenylhydrazine hydrochloride in 100 mL of Reagent blank.

Standard preparation—Dissolve a suitable quantity of USP Hydrocortisone Acetate RS, accurately weighed, in chloroform, and dilute quantitatively and stepwise with chloroform to obtain a solution having a known concentration of about 10 µg per mL.