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Lincomycin Oral Solution

» Lincomycin Oral Solution contains an amount of lincomycin hydrochloride ($C_{18}H_{34}N_2O_6S \cdot HCl \cdot H_2O$) equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of lincomycin ($C_{18}H_{34}N_2O_6S$), and one or more suitable colors, flavors, preservatives, and sweeteners in water.

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11)—
[USP Lincomycin Hydrochloride RS](#)

UNIFORMITY OF DOSAGE UNITS (905)—

FOR ORAL SOLUTION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

DELIVERABLE VOLUME (698): meets the requirements.

pH (791): between 3 and 5.5.

Assay—

Mobile phase, Standard preparation, and Chromatographic system—Proceed as directed in the Assay under [Lincomycin Hydrochloride](#).

Assay preparation—Transfer an accurately measured volume of Oral Solution, freshly mixed and free of air bubbles, equivalent to about 100 mg of lincomycin, to a suitable container. Add 0.5 mL of sodium carbonate solution (3 in 10), and swirl for 30 seconds, noting that a precipitate forms. Add 1.0 mL of 0.2 N sodium hydroxide, swirl for 30 seconds, add 10.0 mL of chloroform, and shake by mechanical means for 10 minutes. Centrifuge, and remove the upper aqueous layer by suction. Transfer 1.0 mL of the clear chloroform layer to a suitable container, and evaporate under a stream of nitrogen to dryness. Add 10.0 mL of *Mobile phase* to the residue, and dissolve by swirling, sonicating if necessary.

Procedure—Proceed as directed in the Assay under [Lincomycin Hydrochloride](#), recording the chromatogram over a period seven times the retention time of lincomycin. Calculate the quantity, in mg, of lincomycin ($C_{18}H_{34}N_2O_6S$) in each mL of the Oral Solution taken by the formula:

$$(CP/10V)(r_U/r_S)$$

in which V is the volume, in mL, of Oral Solution taken; and the other terms are as defined therein.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
LINCOMYCIN ORAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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