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Lincomycin Hydrochloride Capsules

» Lincomycin Hydrochloride Capsules contain an amount of $C_{18}H_{34}N_2O_6S \cdot HCl \cdot H_2O$ equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of lincomycin ($C_{18}H_{34}N_2O_6S$).

Packaging and storage—Preserve in tight containers.

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

DISSOLUTION (711).—

Medium: water; 500 mL.
Apparatus 1: 100 rpm.
Time: 45 minutes.

Procedure—Filter a portion of about 20 mL of the solution under test. Transfer about 5 mL of the eluant into a small test tube, and add 250 µL of 0.01 M sodium sulfate internal standard solution. Evaporate until dry using a vacuum centrifuge. Add 10.0 µL of water to the precipitate and place on a vortex mixer until all solid material is dissolved. Transfer this solution to a capillary tube, place it in a Raman spectrometer, and obtain the Raman spectrum using suitable instrumental conditions . Integrate the Raman intensity, applying baseline corrections, between 660 cm^{-1} and 720 cm^{-1} . Divide this result by the integrated intensity between 966 cm^{-1} and 994 cm^{-1} . Determine the amount of $C_{18}H_{34}N_2O_6S$ dissolved in comparison with an aqueous Standard solution having a known concentration of [USP Lincomycin Hydrochloride RS](#).

Tolerances—Not less than 75% (Q) of the labeled amount of $C_{18}H_{34}N_2O_6S$ is dissolved in 45 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

WATER DETERMINATION, Method I (921): not more than 7.0%.

Assay—

Mobile phase, Standard preparation, and Chromatographic system—Proceed as directed in the Assay under [Lincomycin Hydrochloride](#).
Assay preparation—Remove, as completely as possible, the contents of not less than 10 Capsules, taking care to prevent capsule shell fragments from being combined with the capsule contents and to remove any shell fragments from the contents. Weigh and mix the combined contents, and transfer an accurately weighed portion of the powder, equivalent to about 50 mg of lincomycin, to a suitable container. Add 50.0 mL of *Mobile phase*, and shake by mechanical means for 5 minutes. Use the solution thus obtained as the Assay preparation.
Procedure—Proceed as directed for *Procedure* in the Assay under [Lincomycin Hydrochloride](#). Calculate the quantity, in mg, of lincomycin ($C_{18}H_{34}N_2O_6S$) in the portion of Capsule contents taken by the formula:

$$(CP/20)(r_U/r_S)$$

in which the terms are as defined therein.

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

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

Most Recently Appeared In:

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