Edition: BP 2025 (Ph. Eur. 11.6 update)

Lincomycin Injection

General Notices

Action and use

Lincosamide antibacterial.

DEFINITION

Lincomycin Injection is a sterile solution of Lincomycin Hydrochloride in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of lincomycin, $C_{18}H_{34}N_2O_6S$

92.5 to 107.5% of the stated amount.

CHARACTERISTICS

A colourless or almost colourless solution.

IDENTIFICATION

A. Add *acetone* to a volume of the injection containing the equivalent of 0.2 g of lincomycin until precipitation begins and add a further 20 mL of *acetone*. Filter the precipitate, wash with two 10-mL quantities of *acetone*, dissolve the residue in the minimum of a mixture of 4 volumes of *chloroform* and 1 volume of *methanol*, evaporate to dryness and dry at 60° at a pressure not exceeding 2 kPa for 4 hours. The *infrared absorption spectrum* of the dried precipitate, Appendix II A, is concordant with the *reference spectrum* of lincomycin hydrochloride *(RS 203)*.
B. In the Assay, the chromatogram obtained with solution (2) shows a peak with the same retention time as the peak due to the trimethylsilyl derivative of lincomycin in the chromatogram obtained with solution (1).

TESTS

Acidity

pH, 3.0 to 5.5, Appendix V L.

Lincomycin B

Examine solution (3) as described under the Assay but increase the sensitivity by 8 to 10 times while recording the peak derived from lincomycin B, which is eluted immediately before that derived from lincomycin.

LIMITS

The area of the peak derived from lincomycin B, when corrected for the sensitivity factor, is not more than 5% of the area of the peak derived from lincomycin.

Bacterial endotoxins

Carry out the *test for bacterial endotoxins*, Appendix XIV C. Dilute the injection if necessary with *water BET* to give a solution containing the equivalent of 10 mg of lincomycin per mL (solution A). The endotoxin limit concentration of solution A is 5.0 IU per mL.

ASSAY

Carry out the method for *gas chromatography*, Appendix III B, using the following solutions.

(1) Add 10 mL of a 0.8% w/w solution of *dotriacontane* (internal standard) in *chloroform* to 0.1 g of *lincomycin hydrochloride BPCRS*, dilute to 100 mL with a 2% w/v solution of *imidazole* in *chloroform* and shake to dissolve. Place 4 mL of the resulting solution in a 15-mL ground-glass-stoppered centrifuge tube, add 1 mL of a mixture of 99 volumes of N,O-*bis(trimethylsilyl)acetamide* and 1 volume of *trimethylchlorosilane* and swirl gently. Loosen the glass stopper and heat at 65° for 30 minutes.
(2) Prepare in the same manner as solution (1) but omitting the internal standard and using the residue obtained by evaporating to dryness 1 mL of a solution prepared by diluting a volume of the injection containing the equivalent of 0.9 g of lincomycin to 10 mL with *methanol* in place of the *lincomycin hydrochloride BPCRS*.
(3) Prepare in the same manner as solution (1) but using the residue obtained by evaporating to dryness 1 mL of a solution prepared by diluting a volume of the injection containing the equivalent of 0.9 g of lincomycin to 10 mL with *methanol* in place of the *lincomycin hydrochloride BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a glass column (1.5 m × 3 mm) packed with *acid-washed silanised diatomaceous support* impregnated with 3% w/w of phenyl methyl silicone fluid (50% phenyl) (OV-17 is suitable) and maintained at 260°.
(b) Use *helium* as the carrier gas at a flow rate of about 45 mL per minute.
(c) Use an inlet temperature of 260° to 290°.
(d) Use a flame ionisation detector at a temperature of 260° to 290°.
(e) Inject 1 µL of each solution.

DETERMINATION OF CONTENT

Calculate the content of $C_{18}H_{34}N_2O_6S$ in the injection using the declared content of $C_{18}H_{34}N_2O_6S$ in *lincomycin hydrochloride BPCRS*.

STORAGE

Lincomycin Injection should be protected from light and stored at a temperature not exceeding 30°.

LABELLING

The strength is stated as the equivalent amount of lincomycin in a suitable dose-volume.