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

Lincomycin Tablets

General Notices

Action and use

Lincosamide antibacterial.

DEFINITION

Lincomycin Tablets contains Lincomycin Hydrochloride.

The tablets comply with the requirements stated under Tablets and with the following requirements.

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

90.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Mix a quantity of the powdered tablets containing the equivalent of 0.2 g of lincomycin with 5 mL of a mixture of 4 volumes of *chloroform* and 1 volume of *methanol*, filter and evaporate the filtrate. Dissolve the oily residue in 1 mL of *water*, add *acetone* until precipitation begins and add a further 20 mL of *acetone*. Filter, wash with two 10-mL quantities of *acetone*, dissolve the residue in the chloroform-methanol mixture, evaporate to dryness and dry at 60° at a pressure of 2 kPa for 1 hour. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of lincomycin hydrochloride (*RSV 52*).
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

Lincomycin B

Examine solution (3) as described under the Assay but increasing the sensitivity by eight to ten times while recording the peak due to the trimethylsilyl derivative of lincomycin B, which is eluted immediately before the trimethylsilyl derivative of lincomycin.

LIMITS

The area of the peak due to the trimethylsilyl derivative of lincomycin B, when corrected for the sensitivity factor, is not more than 5% of the area of the peak due to the trimethylsilyl derivative of lincomycin.

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*, shake to dissolve and filter. Place 4 mL of the filtrate 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 a quantity of the powdered tablets containing the equivalent of 90 mg of lincomycin in place of the *lincomycin hydrochloride BPCRS*.
(3) Prepare in the same manner as solution (1) but using a quantity of the powdered tablets containing the equivalent of 90 mg of lincomycin 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 tablets using the declared content of $C_{18}H_{34}N_2O_6S$ in *lincomycin hydrochloride BPCRS*.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of lincomycin.