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

Clindamycin Tablets

General Notices

Action and use

Lincosamide antibacterial.

DEFINITION

Clindamycin Tablets contain Clindamycin Hydrochloride.

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

Content of clindamycin, $C_{18}H_{33}ClN_2O_5S$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing the equivalent of 30 mg of clindamycin with 50 mL of *dichloromethane*, filter and evaporate the filtrate to dryness. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of clindamycin hydrochloride *(RS 064)*.

TESTS

Dissolution

Comply with the dissolution test for tablets and capsules, *Appendix XII B1*.

TEST CONDITIONS

(a) Use Apparatus 1, rotating the basket at 100 revolutions per minute.
(b) Use 900 mL of a solution containing 0.68% w/v of *potassium dihydrogen phosphate* and 0.063% w/v of *sodium hydroxide* at a temperature of 37° as the medium.

PROCEDURE

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) After 30 minutes withdraw a sample of the medium and filter. Use the filtered sample, diluted with the dissolution medium if necessary, to produce a solution expected to contain 0.0028% w/v of clindamycin.
(2) 0.003% w/v of *clindamycin hydrochloride EPCRS* in the dissolution medium.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil BDS 5 µm is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 210 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

45 volumes of *acetonitrile R1* and 55 volumes of a 0.68% w/v solution of *potassium dihydrogen orthophosphate* adjusted to pH 7.5 with a 25% w/v solution of *potassium hydroxide*.

When the chromatograms are recorded under the prescribed conditions, the retention time of clindamycin is about 10 minutes.

DETERMINATION OF CONTENT

Calculate the total content of clindamycin, $C_{18}H_{33}ClN_2O_5S$ in the medium from the chromatograms obtained and using the declared content of $C_{18}H_{33}ClN_2O_5S$,HCl in *clindamycin hydrochloride EPCRS*. Each mg of $C_{18}H_{33}ClN_2O_5S$,HCl is equivalent to 0.9209 mg of $C_{18}H_{33}ClN_2O_5S$.

LIMITS

The amount of clindamycin released is not less than 80% (Q) of the stated amount.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Shake a quantity of the powdered tablets containing the equivalent of 0.1 g of clindamycin with 100 mL of the mobile phase for 15 minutes and filter (Whatman GF/C filter is suitable).
(2) Dilute 1 volume of solution (1) to 50 volumes with the mobile phase.
(3) 0.1% w/v of *clindamycin hydrochloride EPCRS* in the mobile phase.
(4) Dilute 1 volume of solution (2) to 20 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Dissolution may be used. For solution (1), allow the chromatography to proceed for at least twice the retention time of the principal peak.

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to clindamycin (retention time, about 10 minutes) are: impurity B, about 0.7 and impurity C, about 0.8.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3):

the *resolution* between the peaks due to impurity B and impurity C is at least 3.0 and;

the *resolution* between the peaks due to impurity C and clindamycin is at least 2.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity C is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (4%);

the area of any peak corresponding to impurity B is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (2%);

the area of any other *secondary peak* is not greater than half the area of the principal peak in the chromatogram obtained with solution (2) (1%);

the sum of the areas of all the *secondary peaks* is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (6%).

Disregard any peak with an area less than 3 times the area of the principal peak in the chromatogram obtained with solution (4) (0.3%).

Water

The tablets contain not more than 6.0% w/w, Appendix IX C. Use 0.1 g.

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Shake a quantity of the powdered tablets containing the equivalent of 0.2 g of clindamycin in 160 mL of the mobile phase for 15 minutes, dilute to 200 mL and filter (Whatman GF/C filter is suitable).
(2) 0.11% w/v of *clindamycin hydrochloride EPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Dissolution may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{18}H_{33}ClN_2O_5S$ in the tablets using the declared content of $C_{18}H_{33}ClN_2O_5S,HCl$ in *clindamycin hydrochloride EPCRS*. Each mg of $C_{18}H_{33}ClN_2O_5S,HCl$ is equivalent to 0.9209 mg of $C_{18}H_{33}ClN_2O_5S$.

LABELLING

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

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Clindamycin Hydrochloride.