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Clindamycin Injection

[General Notices](#)

Details for the public consultation of this monograph are as follows:

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Notes:	Revision to monograph Revision of Related Substances and Assay procedures. If the limits in the monograph are too tight, please provide the BP with Batch and Stability data to indicate the suitability.

Action and use

Lincosamide antibacterial.

DEFINITION

Clindamycin Injection is a sterile solution of Clindamycin Phosphate in Water for Injections.

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

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

90.0 to 105.0% of the stated amount.

CHARACTERISTICS

An almost colourless solution.

IDENTIFICATION

A. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using the following solutions.

- (1) Dilute a volume of the injection containing the equivalent of 50 mg of clindamycin to 10 mL with [methanol](#).
- (2) 0.5% w/v of [clindamycin phosphate EPCRS](#) in [methanol](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel GF₂₅₄](#).
- (b) Use the mobile phase as described below.
- (c) Apply 10 µL of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, allow it to dry in air and spray with [dilute potassium iodobismuthate solution](#).

MOBILE PHASE

1.5 volumes of 18M [ammonia](#), 30 volumes of [toluene](#) and 70 volumes of [methanol](#).

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to clindamycin phosphate in the chromatogram obtained with solution (2).

TESTS

[Acidity or alkalinity](#)

pH, 5.5 to 7.0, [Appendix V L](#).

Related substances

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions in mobile phase A.

- (1) Dilute a volume of the injection with sufficient mobile phase to produce a solution containing the equivalent of 0.25% w/v of clindamycin.
- (2) Dilute 1 volume of solution (1) to 100 volumes
- (3) 0.3 w/v of clindamycin phosphate for system suitability EPCRS
- (4) Dilute 1 volume of solution (2) to 10 volumes

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (15 cm × 4.6 mm) packed with end-capped octadecylsilyl silica gel for chromatography (5 µm) (Symmetry C18 is suitable).
- (b) Use gradient elution and the mobile phase described below.
- (c) Use a flow rate of 1.1 mL per minute.
- (d) Use a column temperature of 30 °.
- (e) Use a detection wavelength of 210 nm.
- (f) Inject 20 µL of each solution

MOBILE PHASE

mobile phase A 21 volumes of acetonitrile R1 and 79 volumes of a 13.6 g/L solution of potassium dihydrogen phosphate R previously adjusted to pH 6.0 with a 450 g/L solution of potassium hydroxide R

mobile phase B 40 volumes of a 13.6 g/L solution of potassium dihydrogen phosphate R previously adjusted to pH 6.0 with a 450 g/L solution of potassium hydroxide R, and 60 volumes of acetonitrile R1

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-13	100	0	isocratic
13-18	100→50	0→50	linear gradient
18-39	50	50	isocratic
39-40	50→100	50→0	linear gradient
40-50	100	0	re-equilibration

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to clindamycin (retention time about 12 minutes) are: impurity F, about 0.15; impurity G, about 0.19; impurity I, about 0.34; impurity B, about 0.45; impurity L, about 0.64; impurity J, about 1.20; impurity E, about 1.73; impurity K, about 1.90

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the resolution factor between the peaks due to impurities F and G is at least 2.0.

LIMITS

In the chromatogram obtained with solution (1):

The area of the peaks due to impurities B and L are not greater than the area of the principle peak obtained from solution (2) (1%);

the area of the peaks due to impurities E and F are not greater than 0.5 times the area of the principle peak obtained from solution (2) (0.5%);

the area of the peaks due to impurities G, I, J and K are not greater than 0.2 times the area of the principle peak obtained from solution (2) (0.2%);

the area of any other peak is not greater than 0.2 times the area of the principle peak obtained from solution (2) (0.2%);

the sum of the areas of any secondary peaks is not greater than 2 times the area of the principle peak obtained from solution (2) (0.2%).

Disregard all peaks with an area less than the principle peak in the chromatogram obtained with solution (3) (0.1%)

Bacterial endotoxins

Carry out the [test for bacterial endotoxins, Appendix XIV C](#). Dilute the injection in [water BET](#) to give a solution containing the equivalent of 10 mg of clindamycin per mL (solution A). The endotoxin limit concentration of solution A is 6 IU of endotoxin per mL.

ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions in mobile phase.

(1) Dilute a volume of the injection with sufficient mobile phase to produce a solution containing the equivalent of 0.125% w/v of clindamycin.

(2) 0.15% w/v of [clindamycin phosphate EPCRS](#).

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with end-capped octadecylsilyl silica gel for chromatography (5 μm) (Symmetry C18 is suitable).

(b) Use isocratic elution and the mobile phase described below.

(c) Use a flow rate of 1.1 mL per minute.

(d) Use a column temperature of 30 °.

(e) Use a detection wavelength of 210 nm.

(f) Inject 20 μL of each solution.

MOBILE PHASE

21 volumes of acetonitrile R1 and 79 volumes of a 13.6 g/L solution of potassium dihydrogen phosphate R previously adjusted to pH 6.0 with a 450 g/L solution of potassium hydroxide R.

SYSTEM SUITABILITY

The Assay is not valid unless, in the chromatogram obtained with solution (2), the symmetry factor of the peak due to clindamycin is a maximum of 3.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{18}H_{33}ClN_2O_5S$ in the injection using the declared content of $C_{18}H_{34}ClN_2O_8PS$ in [clindamycin phosphate BPCRS](#). Each mg of $C_{18}H_{34}ClN_2O_8PS$ is equivalent to 0.8416 mg of $C_{18}H_{33}ClN_2O_5S$.

STORAGE

Clindamycin Injection should be stored at a temperature not exceeding 30°. It should not be refrigerated and it should not be allowed to freeze.

LABELLING

The strength is stated in terms of the equivalent amount of clindamycin in a suitable dose-volume.