Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-F90DAB96-6913-457D-876F-D43812B54A43_3_en-US
DOI: https://doi.org/10.31003/USPNF_M18289_03_01
DOI Ref: 9ln4i

Clindamycin Injection

DEFINITION

Clindamycin Injection contains an amount of Clindamycin Phosphate in Water for Injection equivalent to NLT 90.0% and NMT 120.0% of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$). It may be frozen.

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Dissolve 10.54 g of monobasic potassium phosphate in 775 mL of water, and adjust with phosphoric acid to a pH of 2.5. Add 225 mL of acetonitrile, mix, and filter. Ensure that the concentration of acetonitrile in the *Mobile phase* is NLT 22% and NMT 25% to retain the correct elution order.

System suitability stock solution: 0.1 mg/mL of USP Benzyl Alcohol RS in *Mobile phase*

System suitability solution: 25 µg/mL of USP Benzyl Alcohol RS from *System suitability stock solution* and 0.25 mg/mL of USP Clindamycin Phosphate RS, in *Mobile phase*

Standard solution: 0.24 mg/mL of USP Clindamycin Phosphate RS in *Mobile phase*

Sample stock solution: Nominally 3 mg/mL of clindamycin from Injection in *Mobile phase*

Sample solution: 0.21 mg/mL of clindamycin from *Sample stock solution* in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; packing L7

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for clindamycin phosphate and benzyl alcohol are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between clindamycin phosphate and benzyl alcohol, *System suitability solution*

Relative standard deviation: NMT 2.5, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$) in the portion of the Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times F \times 100$$

r_U = peak response of clindamycin phosphate from the *Sample solution*

r_S = peak response of clindamycin phosphate from the *Standard solution*

C_S = concentration of USP Clindamycin Phosphate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of clindamycin in the *Sample solution* (mg/mL)

P = potency of clindamycin in USP Clindamycin Phosphate RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 5.5–7.0
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.58 USP Endotoxin Unit/mg of clindamycin
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections
- **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, or in suitable plastic containers.
- **Labeling:** Meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*. Where it is maintained in the frozen state, the label states that it is to be thawed just before use, describes the conditions for proper storage of the resultant solution, and directs that the solution is not to be refrozen.
- **USP Reference Standards ⟨11⟩**

  USP Benzyl Alcohol RS

  USP Clindamycin Phosphate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CLINDAMYCIN INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 44(2)

Current DocID: GUID-F90DAB96-6913-457D-876F-D43812B54A43_3_en-US
Previous DocID: GUID-F90DAB96-6913-457D-876F-D43812B54A43_1_en-US
DOI: https://doi.org/10.31003/USPNF_M18289_03_01
DOI ref: 9ln4i