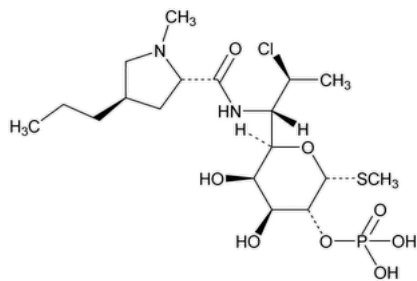


Status: Currently Official on 17-Feb-2025  
Official Date: Official as of 01-May-2020  
Document Type: USP Monographs  
DocId: GUID-9083402B-BCDD-41AB-AA01-6AFA9318ADD4\_5\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M18280\\_05\\_01](https://doi.org/10.31003/USPNF_M18280_05_01)  
DOI Ref: g9s9q

© 2025 USPC  
Do not distribute

# Clindamycin Phosphate



$C_{18}H_{34}ClN_2O_8PS$  504.96  
L-threo-α-D-galacto-Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-, 2-(dihydrogen phosphate), (2S-trans)-;  
Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo-α-D-galacto-octopyranoside 2-(dihydrogen phosphate) CAS RN®: 24729-96-2; UNII: EH6D7113I8.

**DEFINITION**

Clindamycin Phosphate has a potency equivalent to NLT 758 µg/mg of clindamycin ( $C_{18}H_{33}ClN_2O_5S$ ), calculated on the anhydrous basis.

**IDENTIFICATION**

Change to read:

- A.** **SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K** (CN 1-MAY-2020)  
**Standard:** Add 0.2 mL of water to 50 mg of [USP Clindamycin Phosphate RS](#), and heat to dissolve. Evaporate to dryness under vacuum, and dry the residue at 100°–105° for 2 h.  
**Sample:** Add 0.2 mL of water to 50 mg of Clindamycin Phosphate, and heat to dissolve. Evaporate to dryness under vacuum, and dry the residue at 100°–105° for 2 h.  
**Acceptance criteria:** Meets the requirements
- B.** 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**

- Solution A:** Add 14 mL of phosphoric acid to 4000 mL of water. Add 10 mL of ammonium hydroxide, and adjust with ammonium hydroxide to a pH of 5.6 ± 0.1.
- Solution B:** Acetonitrile and methanol (900:100)
- Solution C:** *Solution B* and *Solution A* (80:920)
- Solution D:** *Solution B* and *Solution A* (480:520)
- Diluent:** *Solution B* and *Solution A* (20:80)
- Mobile phase:** See [Table 1](#).

Table 1

| Time (min) | Solution C (%) | Solution D (%) |
|------------|----------------|----------------|
| 0          | 95             | 5              |
| 40         | 5              | 95             |
| 41         | 95             | 5              |
| 46         | 95             | 5              |

**System suitability solution:** 2.2 mg/mL of [USP Clindamycin Phosphate System Suitability RS](#) in *Diluent*, shake, and sonicate to dissolve.

**Standard solution:** 2.2 mg/mL of [USP Clindamycin Phosphate RS](#) in *Diluent*. Shake, and sonicate to dissolve.

**Sample solution:** 2.2 mg/mL of Clindamycin Phosphate in *Diluent*. Shake, and sonicate to dissolve.

#### Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

**Mode:** LC

**Detector:** UV 214 nm

**Column:** 4.6-mm × 25-cm; 5-μm packing L7

**Column temperature:** 40°

**Flow rate:** 1.2 mL/min

**Injection volume:** 20 μL

#### System suitability

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

##### Suitability requirements

**Resolution:** NLT 3.0 between clindamycin phosphate and 7-epiclindamycin phosphate, *System suitability solution*

**Tailing factor:** NMT 2.0 for clindamycin phosphate, *Standard solution*

**Relative standard deviation:** NMT 0.73%, *Standard solution*

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the quantity of clindamycin ( $C_{18}H_{33}ClN_2O_5S$ ), in μg/mg, in the portion of Clindamycin Phosphate taken:

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

$r_U$  = peak response from the *Sample solution*

$r_S$  = peak response from the *Standard solution*

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

$C_U$  = concentration of Clindamycin Phosphate in the *Sample solution* (mg/mL)

$P$  = potency of clindamycin in [USP Clindamycin Phosphate RS](#) (μg/mg)

**Acceptance criteria:** NLT 758 μg/mg on the anhydrous basis

#### IMPURITIES

##### • ORGANIC IMPURITIES

**Solution A, Solution B, Solution C, Solution D, Diluent, Mobile phase, System suitability solution, Sample solution, and Chromatographic system:** Proceed as directed in the Assay.

**Standard solution:** 14 μg/mL of [USP Clindamycin Phosphate RS](#) in *Diluent*. Shake, and sonicate to dissolve.

#### System suitability

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

##### Suitability requirements

**Resolution:** NLT 3.0 between 7-epiclindamycin phosphate and clindamycin phosphate, *System suitability solution*

**Tailing factor:** NMT 2.0 for clindamycin phosphate, *Standard solution*

**Relative standard deviation:** NMT 5.0% for clindamycin phosphate, *Standard solution*

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Clindamycin Phosphate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times (F_1/F_2) \times 100$$

$r_U$  = peak response of each impurity 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)

$C_U$  = concentration of Clindamycin Phosphate, corrected for water content, in the *Sample solution* (mg/mL)

$P$  = potency of clindamycin in [USP Clindamycin Phosphate RS](#) (μg/mg)

$F_1$  = conversion factor, 0.001 mg/μg

$F_2$  = relative response factor (see [Table 2](#))