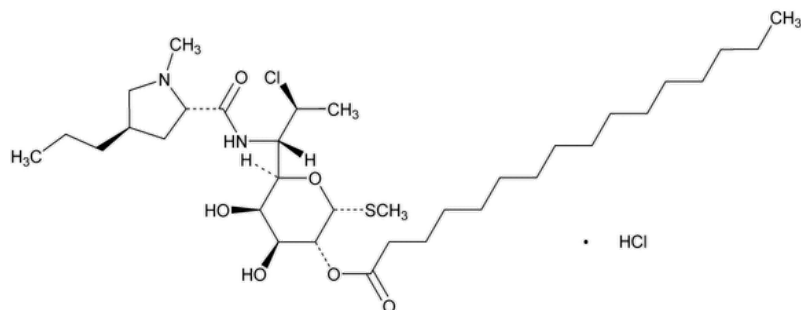


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## Clindamycin Palmitate Hydrochloride



$C_{34}H_{63}ClN_2O_6S \cdot HCl$  699.85

*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-hexadecanoate, monohydrochloride, (2*S-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-palmitate monohydrochloride CAS RN<sup>®</sup>: 25507-04-4; UNII: VN9A8JM7M7.

### DEFINITION

Clindamycin Palmitate Hydrochloride has a potency equivalent to NLT 540 µg of clindamycin ( $C_{18}H_{33}ClN_2O_5S$ )/mg.

### IDENTIFICATION

**Change to read:**

- ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#)▲ (CN 1-MAY-2020)

### ASSAY

#### PROCEDURE

**Mobile phase:** Dissolve 2 g of docusate sodium and 1.54 g of ammonium acetate in a mixture of 2 mL of glacial acetic acid and 75 mL of water. Dilute with methanol to 1 L. Pass through a suitable filter, and degas.

**Standard solution:** 14 mg/mL of [USP Clindamycin Palmitate Hydrochloride RS](#) in *Mobile phase*

**Sample solution:** 14 mg/mL of Clindamycin Palmitate Hydrochloride in *Mobile phase*

#### Chromatographic system

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

**Mode:** LC

**Detector:** Refractive index

**Column:** 3.9-mm × 30-cm; 10-µm packing L1

**Flow rate:** 1.2 mL/min

**Injection size:** 20 µL

#### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Relative standard deviation:** NMT 2.0%

#### Analysis

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

Calculate the potency in µg/mg of  $C_{18}H_{33}ClN_2O_5S$  in the portion of Clindamycin Palmitate Hydrochloride taken:

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

- $r_U$  = peak response of clindamycin palmitate from the *Sample solution*
- $r_S$  = peak response of clindamycin palmitate from the *Standard solution*
- $C_S$  = concentration of [USP Clindamycin Palmitate Hydrochloride RS](#) in the *Standard solution* (mg/mL)
- $C_U$  = nominal concentration of Clindamycin Palmitate Hydrochloride in the *Sample solution* (mg/mL)
- P = potency of clindamycin in [USP Clindamycin Palmitate Hydrochloride RS](#) (µg/mg)

**Acceptance criteria:** NLT 540 µg/mg

**IMPURITIES**

**INORGANIC IMPURITIES**

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

**SPECIFIC TESTS**

- [pH \(791\)](#): 2.8–3.8, in a 10 mg/mL solution
- [WATER DETERMINATION, Method I \(921\)](#): NMT 3.0%

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- [USP REFERENCE STANDARDS \(11\)](#)  
[USP Clindamycin Palmitate Hydrochloride RS](#)

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

| Topic/Question                      | Contact                                       | Expert Committee          |
|-------------------------------------|-----------------------------------------------|---------------------------|
| CLINDAMYCIN PALMITATE HYDROCHLORIDE | <a href="#">Documentary Standards Support</a> | SM12020 Small Molecules 1 |

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

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