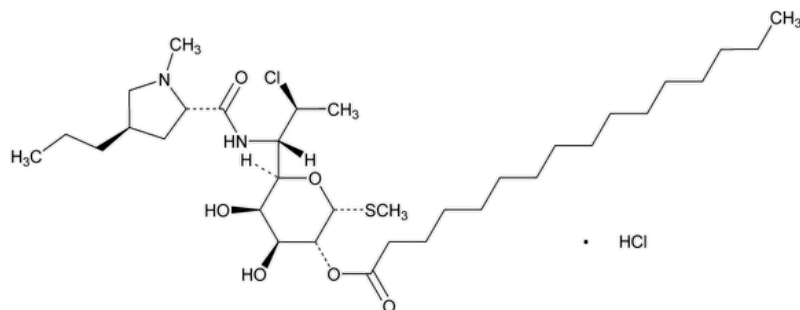


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Clindamycin Palmitate Hydrochloride



$C_{34}H_{63}ClN_2O_6S \cdot HCl$ 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, (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-palmitate monohydrochloride CAS RN®: 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	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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