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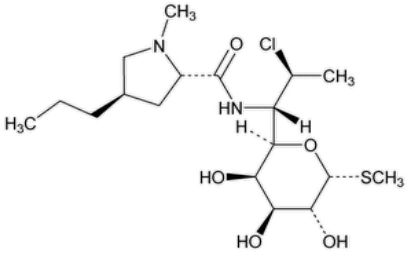
Clindamycin Hydrochloride



• HCl

$C_{18}H_{33}ClN_2O_5S \cdot HCl$ 461.44
$C_{18}H_{33}ClN_2O_5S \cdot HCl \cdot H_2O$ 479.47

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*S*-*trans*)-, monohydrochloride;
Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*-α-D-*galacto*-octopyranoside monohydrochloride CAS RN®: 21462-39-5; UNII: T20OQ1YN1W.
Monohydrate CAS RN®: 58207-19-5; UNII: ZNC153389R.

DEFINITION

Clindamycin Hydrochloride is the hydrated hydrochloride salt of clindamycin, a substance produced by the chlorination of lincomycin. It has a potency equivalent to NLT 800 µg/mg of $C_{18}H_{33}ClN_2O_5S$.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (CN 1-May-2020)

• **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**

Buffer: 6.8 g/L of monobasic potassium phosphate in water. Adjust with 8 N potassium hydroxide to a pH of 7.5.

Mobile phase: Acetonitrile and *Buffer* (9:11)

Standard solution: 1 mg/mL of USP Clindamycin Hydrochloride RS in *Mobile phase*

Sample solution: 1 mg/mL of Clindamycin Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

[Note—USP Clindamycin Hydrochloride RS contains clindamycin B and 7-epiclindamycin as minor components.]

Resolution: NLT 2.4 between clindamycin B and 7-epiclindamycin and NLT 3.0 between 7-epiclindamycin and clindamycin

Tailing factor: NMT 1.2 for the clindamycin peak

Relative standard deviation: NMT 1.0% for the clindamycin peak

Analysis

Samples: *Standard solution* and *Sample solution*

Record the chromatograms for a period of time that is twice the retention time of the clindamycin peak.

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

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

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

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

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

Acceptance criteria: NLT 800 µg/mg

IMPURITIES

Organic Impurities

• **Procedure**

Buffer and **Mobile phase:** Prepare as directed in the *Assay*.

Standard stock solution: 0.5 mg/mL of USP Lincomycin Hydrochloride RS and 1 mg/mL of USP Clindamycin Hydrochloride RS in *Mobile phase*

Standard solution: 50 µg/mL of USP Lincomycin Hydrochloride RS and 100 µg/mL of USP Clindamycin Hydrochloride RS from *Standard stock solution* in *Mobile phase*

Sample solution: 5 mg/mL of Clindamycin Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection size: 10 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Record the chromatograms for a period of time that is six times the retention time of clindamycin.

Calculate the percentage of lincomycin in the portion of Clindamycin Hydrochloride taken:

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

r_U = peak response of lincomycin from the *Sample solution*

r_S = peak response of lincomycin from the *Standard solution*

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

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

P = potency of USP Lincomycin Hydrochloride RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Calculate the percentage of all other related compounds in the portion of Clindamycin Hydrochloride taken:

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

r_U = peak response of each individual related compound, other than lincomycin, from the *Sample solution*

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

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

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

P = potency of USP Clindamycin Hydrochloride RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Lincomycin[a]	0.4	—
Clindamycin B	0.65	2.0
7-Epiclindamycin	0.8	4.0
Clindamycin	1.0	—
Any other individual related compound	—	1.0
Total related compounds[b]	—	6.0

[a] Lincomycin is controlled in the total of all related compounds. There is no individual acceptance criterion for this compound.

[b] Total of all related compounds including lincomycin.

SPECIFIC TESTS

- **Crystallinity ⟨695⟩:** Meets the requirements
- **pH ⟨791⟩:** 3.0–5.5, in a 100-mg/mL solution
- **Water Determination, *Method I*⟨921⟩:** 3.0%–6.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards ⟨11⟩**

USP Clindamycin Hydrochloride RS

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*S*-*trans*)-, monohydrochloride.

$C_{18}H_{33}ClN_2O_5S \cdot HCl$ 461.45

USP Lincomycin Hydrochloride RS

D-*erythro*-α-D-*galacto*-Octopyranoside, methyl 6,8-dideoxy-6-[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-, monohydrochloride, monohydrate, (2*S*-*trans*)-.

$C_{18}H_{34}N_2O_6S \cdot HCl \cdot H_2O$ 461.02

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

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

Chromatographic Database Information: Chromatographic Database

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