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Clindamycin Hydrochloride Capsules

DEFINITION

Clindamycin Hydrochloride Capsules contain the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$).

IDENTIFICATION

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

ASSAY

• **Procedure**

Mobile phase: Add 2 g of *dl*-10-camphorsulfonic acid, 1 g of ammonium acetate, and 1 mL of glacial acetic acid to 200 mL of water in a 500-mL volumetric flask, and mix to dissolve. Dilute with methanol to volume, and mix. Adjust, if necessary, with hydrochloric acid or a sodium hydroxide solution (1 in 2) to a pH of 6.0 ± 0.1.

Internal standard solution: Add 0.5 mL of phenylethyl alcohol to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Standard solution: 18 mg/mL of USP Clindamycin Hydrochloride RS in *Internal standard solution*

Sample solution: Equivalent to 15 mg/mL of clindamycin, from the contents of NLT 20 Capsules, in *Internal standard solution*; shake for 30 min; centrifuge or filter, if necessary, to obtain a clear solution.

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 4-mm × 30-cm stainless steel; packing L1

Flow rate: 1 mL/min

Injection size: 25 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for the internal standard and clindamycin are 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 5.0 between the analyte and internal standard

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

R_U = peak response ratio of clindamycin to the internal standard from the *Sample solution*

R_S = peak response ratio of clindamycin to the internal standard from the *Standard solution*

C_S = concentration of USP Clindamycin Hydrochloride 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 Hydrochloride RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: pH 6.8 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*); 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Mobile phase: Dissolve 16 g of *dl*-10-camphorsulfonic acid, 8 g of ammonium acetate, and 8 mL of glacial acetic acid in 1600 mL of water. Add 2400 mL of methanol, and adjust with hydrochloric acid or 5 N sodium hydroxide to a pH of 6.0 ± 0.05.

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.

Standard solution: Prepare a solution of USP Clindamycin Hydrochloride RS in *Medium* having a known concentration similar to that expected in the *Sample solution*.

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 3-µm packing L1

Flow rate: 2 mL/min

Injection size: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$) dissolved.

Tolerances: NLT 80% (*Q*) of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** NMT 7.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Clindamycin Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
CLINDAMYCIN HYDROCHLORIDE CAPSULES	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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