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Clindamycin Palmitate Hydrochloride for Oral Solution

DEFINITION

Clindamycin Palmitate Hydrochloride for Oral Solution is a dry mixture of Clindamycin Palmitate Hydrochloride and one or more suitable buffers, colors, diluents, flavors, and preservatives. It contains the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$), the labeled amount being 15 mg/mL when constituted as directed in the labeling.

ASSAY

• **Procedure**

Solution A: 300 mg/mL of sodium carbonate

Internal standard solution: 5 mg/mL of cholesteryl benzoate in chloroform

Standard solution: Transfer 150 mg of USP Clindamycin Palmitate Hydrochloride RS to a glass-stoppered, 15-mL conical centrifuge tube. Add 5 mL of water, 5.0 mL of *Internal standard solution*, and 1 mL of *Solution A*. Insert the stopper, shake vigorously for NLT 10 min, and centrifuge. Remove the upper aqueous layer, and transfer 1.0 mL of the lower chloroform layer to a 15-mL centrifuge tube. Add 1.0 mL of pyridine and 1.0 mL of acetic anhydride. Agitate the tube to ensure complete mixing, cover the top of the centrifuge tube with a plastic cap through which a small hole has been punched, heat at 100° for 2.5 h, and allow to cool. Mix, and centrifuge if necessary. Use the clear solution.

Sample solution: Constitute the Clindamycin Palmitate Hydrochloride for Oral Solution as directed in the labeling, and transfer 5.0 mL of the constituted solution to a glass-stoppered, 15-mL conical centrifuge tube. Add 5.0 mL of *Internal standard solution* and 1 mL of *Solution A*. Insert the stopper, shake vigorously for NLT 10 min, and centrifuge. Remove the upper aqueous layer, and transfer 1.0 mL of the lower chloroform layer to a 15-mL centrifuge tube. Add 1.0 mL of pyridine and 1.0 mL of acetic anhydride. Agitate the tube to ensure complete mixing, cover the top of the centrifuge tube with a plastic cap through which a small hole has been punched, heat at 100° for 2.5 h, and allow to cool. Mix, and centrifuge if necessary. Use the clear solution.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.6-m × 3-mm glass; packing 1% phase G36 on support S1AB

Temperature

Column: 290°

Detector: 320°

Carrier gas: Dry helium

Flow rate: 60 mL/min

Injection size: 1.0 µL

System suitability

Sample: *Standard solution*

The elution order is: cholesteryl benzoate, clindamycin palmitate.

Suitability requirements: In a suitable chromatogram, the peaks are completely resolved.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$) in each mL of the solution constituted from Clindamycin Palmitate Hydrochloride for Oral Solution taken:

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

R_U = internal standard ratio (peak response of clindamycin palmitate/peak response of cholesteryl benzoate) from the *Sample solution*

R_S = internal standard ratio (peak response of clindamycin palmitate/peak response of cholesteryl benzoate) 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: 90.0%–120.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩**

For solids packaged in single-unit containers: Meets the requirements

• **Deliverable Volume ⟨698⟩:** Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩:** 2.5–5.0, in the solution constituted as directed in the labeling

• **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 FOR ORAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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