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Clindamycin Phosphate Topical Suspension

DEFINITION

Clindamycin Phosphate Topical Suspension contains the equivalent of NLT 90.0% and NMT 110.0% 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*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Dissolve 10.54 g of monobasic potassium phosphate in 775 mL of water, and adjust with phosphoric acid to a pH of 2.5. Add 225 mL of acetonitrile, mix, and filter.

System suitability solution: 0.6 mg/mL each of USP Clindamycin Phosphate RS and USP Clindamycin Hydrochloride RS, in the *Mobile phase*

Standard solution: 0.25 mg/mL of USP Clindamycin Phosphate RS in the *Mobile phase*

Sample solution: Equivalent to 0.2 mg/mL of clindamycin from Topical Suspension in *Mobile phase*. Prepare as follows. Using a suitable hypodermic needle and syringe, transfer a suitable aliquot of Topical Suspension to a suitable volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; packing L7

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for clindamycin phosphate and clindamycin are about 1.0 and 1.5, respectively.]

Suitability requirements

Resolution: NLT 6.0 between the clindamycin phosphate and clindamycin peaks, *System suitability solution*

Column efficiency: NLT 1700 theoretical plates, *System suitability solution*, calculated from the peak width at half height

Tailing factor: NMT 1.3, *System suitability solution*

Relative standard deviation: NMT 2.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$) in the portion of the Topical Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Minimum Fill ⟨755⟩:** Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩:** 4.5–6.5

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Clindamycin Hydrochloride RS

USP Clindamycin Phosphate RS

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

Topic/Question	Contact	Expert Committee
CLINDAMYCIN PHOSPHATE TOPICAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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