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Clindamycin Phosphate Gel

DEFINITION
Clindamycin Phosphate Gel 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 clindamycin phosphate 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, and mix.

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

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

Sample solution: Nominally 0.2 mg/mL of clindamycin in *Mobile phase* from Gel. Shake by mechanical means for 30 min. Centrifuge a portion of the solution, and if necessary, filter a portion of the supernatant. Use the clear filtrate.

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 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*

Calculate as follows:

$$\text{Result} = (t_r/W_{h/2})^2 \times 5.545$$

t_r = retention time

$W_{h/2}$ = 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 Gel 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*

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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 GEL	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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