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# Clindamycin Phosphate Topical Solution

**DEFINITION**

Clindamycin Phosphate Topical Solution 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. Ensure that the concentration of acetonitrile in the *Mobile phase* is NLT 22% and NMT 25% to retain the correct elution order.

**System suitability stock solution 1:** 4 mg/mL of 4'-hydroxyacetophenone in acetonitrile

**System suitability stock solution 2:** 0.04 mg/mL of 4'-hydroxyacetophenone from *System suitability stock solution 1* in *Mobile phase*

**Standard solution:** 0.24 mg/mL of USP Clindamycin Phosphate RS in *Mobile phase*

**System suitability solution:** Mix 1 part of *System suitability stock solution 2* with 3 parts of *Standard solution*.

**Sample solution:** Equivalent to 0.2 mg/mL of clindamycin from Topical Solution in *Mobile phase*

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

[Note—The relative retention times for clindamycin phosphate and 4'-hydroxyacetophenone are about 1.0 and 1.2, respectively.]

**Suitability requirements**

**Resolution:** NLT 2.0 between clindamycin phosphate and 4'-hydroxyacetophenone, *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 Solution 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%

**SPECIFIC TESTS**

• **pH** ⟨791⟩**:** 4.0–7.0

**ADDITIONAL REQUIREMENTS**

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

• **USP Reference Standards** ⟨11⟩

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 SOLUTION | Documentary Standards Support | SM12020 Small Molecules 1 |

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