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Clindamycin Phosphate Vaginal Cream

DEFINITION

Clindamycin Phosphate Vaginal Cream contains an amount of clindamycin phosphate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$).

IDENTIFICATION

• **A.** The relative retention time of the major peak for clindamycin phosphate 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 Cream, prepared as follows. Transfer a suitable portion of Cream to a stoppered conical flask, and add *Mobile phase*. Add about 10 glass beads (about 10 mm in diameter). Insert the stopper securely in the flask, and shake by mechanical means at 50° for 1 h. Cool in an ice bath for 20 min, and centrifuge. Pass a portion of the cloudy lower layer through a filter of 2-µm or finer pore size, and use the 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 about 1.0 and 1.5, respectively.]

Suitability requirements

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

Column efficiency: NLT 1700 theoretical plates, *System suitability solution*

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 Cream 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)

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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⟩**:** 3.0–6.0, determined on the undiluted Cream

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed 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 VAGINAL CREAM	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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