Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-F6CBAFC1-6AFD-4269-90FE-D60FCE32E2A3_2_en-US
DOI: https://doi.org/10.31003/USPNF_M18304_02_01
DOI Ref: 0dk7m

Clindamycin Phosphate Vaginal Inserts

DEFINITION

Clindamycin Phosphate Vaginal Inserts contain the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (CN 1-May-2020)

Sample: Transfer a Vaginal Insert into a suitable container, add 120 mL of methylene chloride, insert a stopper, and shake until the Vaginal Insert is completely dissolved. Using a vacuum, pass through a methylene chloride-compatible filter having a 0.45-µm pore size. Rinse the filter with several portions of methylene chloride, and allow the filter to air-dry. Use the white residue to prepare the mineral oil dispersion for the test.

Acceptance criteria: The IR absorption of the *Sample* exhibits maxima at the same wavelengths as that of a similar preparation of USP Clindamycin Phosphate RS.

• **B.** 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**

Buffer: 10.54 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 2.5.

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: 0.24 mg/mL of USP Clindamycin Phosphate RS and 6 µg/mL of USP Clindamycin Hydrochloride RS, in *Buffer*

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

Sample solution: Transfer 1 Vaginal Insert to a suitable 100-mL container. Add 40 mL of isooctane, and seal the container tightly with a teflon-lined septum and crimp cap. Shake vigorously for about 15 min until all of the Vaginal Insert is dissolved. Add 40.0 mL of *Buffer*. Recap the container tightly, and shake vigorously for NLT 30 min, taking care to avoid leakage. Allow the layers to separate, and remove a volume of the lower aqueous layer sufficient to perform the following steps. Pass the aqueous solution through a filter having a 5-µm or finer pore size, discarding the first 2 mL of the filtrate. Collect the remaining filtrate, and prepare a solution equivalent to 0.2 mg/mL of clindamycin with *Buffer*.

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: 35 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between clindamycin phosphate and clindamycin hydrochloride, *System suitability solution*

Calculate as follows.

$$\text{Result} = [(t_2 - t_1)/(w_{h1} + w_{h2})] \times 1.177$$

t_2 = retention time of the second peak

t_1 = retention time of the first peak

w_{h1} = height at half width of the first peak

w_{h2} = height at half width of the second peak

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$) equivalent in the Vaginal Insert 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 the USP Clindamycin Phosphate RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–110.0%. Use as the *Assay* value the average of the determinations obtained in the test for *Uniformity of Dosage Units* ⟨905⟩, *Content Uniformity*.

PERFORMANCE TESTS

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, at controlled room temperature, or in a cool place.

• **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 INSERTS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 44(2)

Current DocID: GUID-F6CBAFC1-6AFD-4269-90FE-D60FCE32E2A3_2_en-US

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