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Clindamycin for Injection

DEFINITION
Clindamycin for Injection contains an amount of Clindamycin Phosphate equivalent to NLT 758 µg/mg of clindamycin (C₁₈H₃₃ClN₂O₅S), calculated on the anhydrous basis.

IDENTIFICATION
Change to read:
• A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#) ▲ (CN 1-May-2020)
Sample: Undried specimen
Acceptance criteria: Meets the requirements

ASSAY
• **PROCEDURE**
Buffer: Add 14 mL of phosphoric acid to 4000 mL of HPLC grade water. Add 10 mL of ammonium hydroxide, and adjust with ammonium hydroxide to a pH of 3.90 ± 0.05.
Solution A: Acetonitrile and methanol (9:1)
Diluent: *Solution A* and *Buffer* (1:4)
Solution B: *Solution A* and *Buffer* (2:23)
Solution C: *Solution A* and *Buffer* (12:13)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	95	5
40	5	95
41	95	5
46	95	5

Standard solution: 2.2 mg/mL of [USP Clindamycin Phosphate RS](#) in *Diluent*, prepared as follows. Shake briefly, and sonicate for 5 min to dissolve. Allow to cool to ambient temperature.
Sample solution: Nominally 2.2 mg/mL of clindamycin phosphate in *Diluent* from Clindamycin for Injection, prepared as follows. Shake briefly, and sonicate for 5 min to dissolve. Allow to cool to ambient temperature.
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: UV 214 nm
Column: 4.6-mm × 25-cm; packing L7
Column temperature: 40°
Flow rate: 1.2 mL/min
Injection volume: 25 µL
System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 1.0 between clindamycin phosphate and its nearest related compound. Calculate the resolution using peak widths at half height.

Peak-to-valley ratio: NLT 2.5

Calculate the peak-to-valley ratio:

$$\text{Result} = H_p/H_v$$

H_p = height above the baseline of the nearest related compound peak

H_v = height above the baseline of the valley between clindamycin phosphate and its nearest related compound

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity of clindamycin ($\text{C}_{18}\text{H}_{33}\text{ClN}_2\text{O}_5\text{S}$), in $\mu\text{g}/\text{mg}$, in the portion of Clindamycin for Injection taken:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of [USP Clindamycin Phosphate RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of clindamycin phosphate in the *Sample solution* (mg/mL)

P = potency of clindamycin in the [USP Clindamycin Phosphate RS](#) ($\mu\text{g}/\text{mg}$)

Acceptance criteria: NLT 758 $\mu\text{g}/\text{mg}$ on the anhydrous basis

SPECIFIC TESTS

- [BACTERIAL ENDOTOXINS TEST \(85\)](#): Contains NMT 0.58 USP Endotoxin Unit/mg of clindamycin
- [STERILITY TESTS \(71\)](#)

Sample solution: 6 g of Clindamycin for Injection aseptically dissolved in 200 mL of *Fluid A*

Acceptance criteria: Meets the requirements when tested as directed in [Test for Sterility of the Product to Be Examined](#), Membrane Filtration

- [pH \(791\)](#)

Sample solution: Nominally 10 mg/mL of clindamycin in water from Clindamycin for Injection

Acceptance criteria: 3.5–4.5

- [WATER DETERMINATION, Method I \(921\)](#): NMT 6.0%
- [CRYSTALLINITY \(695\)](#): Meets the requirements
- **OTHER REQUIREMENTS:** It responds to the *Identification* test in *Clindamycin Phosphate*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging](#), [Packaging for constitution](#).
- [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 FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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