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Add the following:

▲Clindamycin Hydrochloride Compounded Oral Solution

DEFINITION

Clindamycin Hydrochloride Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of clindamycin ($C_{18}H_{33}ClN_2O_5S$).

Prepare Clindamycin Hydrochloride Compounded Oral Solution 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Clindamycin (as Clindamycin Hydrochloride)	1 g (calculate)[a]
SuspendIt,[b] a sufficient quantity to make	100 mL

[a] Calculate the amount of clindamycin hydrochloride powder based on the salt conversion and potency obtained from the Certificate of Analysis.

[b] PCCA, Houston, TX.

Place the *Clindamycin Hydrochloride* in a suitable container and triturate to a fine powder. Add a small amount of *SuspendIt* and mix well to form a smooth paste. Add a sufficient amount of *SuspendIt* to make a liquid that is pourable. Transfer contents stepwise and quantitatively to a calibrated container using the remainder of the *SuspendIt*. Add sufficient *SuspendIt* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 50 mM monobasic sodium phosphate adjusted with phosphoric acid to a pH of 2.9

Mobile phase: Acetonitrile and *Solution A* (15:85)

Standard solution: 0.01 mg/mL of clindamycin prepared from USP Clindamycin Hydrochloride RS in *Solution A*

Sample solution: Transfer 0.01 mL of Oral Solution to a 10-mL volumetric flask, and dilute with *Solution A* to volume. Mix on a vortex mixer for 30 s.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 205 nm

Column: 2.1-mm × 10-cm; 5-µm packing L1

Flow rate: 0.8 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for clindamycin is about 3.5 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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 Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of clindamycin from the *Sample solution*

r_S = peak response of clindamycin from the *Standard solution*

C_S = concentration of clindamycin in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.7–5.7

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Clindamycin Hydrochloride RS▲ (USP 1-Aug-2019)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CLINDAMYCIN HYDROCHLORIDE COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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