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Clindamycin Hydrochloride Oral Solution

DEFINITION

Clindamycin Hydrochloride Oral 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 clindamycin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

Buffer: 6.8 g/L of monobasic potassium phosphate in water. Adjust with 8 N potassium hydroxide to a pH of 7.5.

Mobile phase: Acetonitrile and *Buffer* (450:550). Increasing the proportion of acetonitrile in the *Mobile phase* decreases the retention time, and decreasing it increases the resolution between 7-epiclindamycin and clindamycin.

▲**Peroxide solution:** Transfer 7 mL of hydrogen peroxide to a 100-mL volumetric flask and dilute with water to volume.

System suitability solution: 2 mg/mL of USP Clindamycin Hydrochloride RS prepared as follows. Transfer a weighed amount of USP Clindamycin Hydrochloride RS to a suitable volumetric flask and add *Peroxide solution* to fill 10% of the final volume. Dilute with *Mobile phase* to volume. [Note—Clindamycin when treated with *Peroxide solution* generates two degradation products. Peroxide degradation product 1 has a relative retention time of 0.36 and peroxide degradation product 2 has a relative retention time of 0.41.]▲ (USP 1-Aug-2019)

Standard solution: 1 mg/mL of USP Clindamycin Hydrochloride RS in *Mobile phase*

Sample solution: Nominally equivalent to 0.85 mg/mL of clindamycin from Oral Solution in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between the peroxide degradation product 1 and peroxide degradation product 2 peaks, *System suitability solution*

Tailing factor: NMT 1.2, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*▲ (USP 1-Aug-2019)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲the labeled amount of▲ (USP 1-Aug-2019) clindamycin ($C_{18}H_{33}ClN_2O_5S$) in ▲the portion▲ (USP 1-Aug-2019) of Oral Solution taken:

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

r_U = peak area response from the *Sample solution*

r_S = peak area response from the *Standard solution*

C_S = concentration of USP Clindamycin Hydrochloride 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 Hydrochloride RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩**

For Oral Solution packaged in single-unit containers: Meets the requirements

• **Deliverable Volume ⟨698⟩:** Meets the requirements

IMPURITIES

Add the following:

▲• **Organic Impurities**

Buffer, Mobile phase, Peroxide solution, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.05 mg/mL of USP Clindamycin Hydrochloride RS in *Mobile phase*

Sensitivity solution: 0.005 mg/mL of USP Clindamycin Hydrochloride RS in *Mobile phase* from *Standard solution*

Sample solution: Nominally 5 mg/mL of clindamycin in *Mobile phase* prepared as follows. Transfer an appropriate volume of Oral Solution to a suitable volumetric flask. Dilute with *Mobile phase* to volume.

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between the peroxide degradation product 1 and peroxide degradation product 2 peaks, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Oral Solution taken:

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

r_U = peak response of each degradation product from the *Sample solution*

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

C_S = concentration of USP Clindamycin Hydrochloride 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 Hydrochloride RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: See *Table 1*. The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Lincomycin[a]	0.32	—
Clindamycin B[b]	0.65	2.0
7-Epiclindamycin[c]	0.80	4.0

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Clindamycin	1.0	—
Any other individual impurity	—	1.0
Total impurities[d]	—	6.0▲ (USP 1-Aug-2019)

[a] Lincomycin is controlled in the total of all related compounds. There is no individual acceptance criterion for this compound.

[b] Methyl 7-chloro-6,7,8-trideoxy-6-[(2*S*,4*R*)-1-methyl-4-ethylpyrrolidine-2-carboxamido]-1-thio-L-*threo*-α-D-*galacto*-octopyranoside.

[c] Methyl 7-chloro-6,7,8-trideoxy-6-[(2*S*,4*R*)-1-methyl-4-propylpyrrolidine-2-carboxamido]-1-thio-D-*erythro*-α-D-*galacto*-octopyranoside.

[d] Total of all related compounds including lincomycin.

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 2.5–6.0

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight containers. ▲Store at controlled room temperature.▲ (USP 1-Aug-2019)

• **Labeling:** Label Oral Solution to indicate that it is intended for veterinary use only.

• **USP Reference Standards** ⟨11⟩

USP Clindamycin Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
CLINDAMYCIN HYDROCHLORIDE ORAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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