

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-24156E81-ED21-4073-9FE8-B11A8434BB8F_2_en-US
DOI: https://doi.org/10.31003/USPNF_M45100_02_01
DOI Ref: co7dv

© 2025 USPC
Do not distribute

Lidocaine Ointment

DEFINITION

Lidocaine Ointment is Lidocaine in a suitable hydrophilic ointment base. It contains NLT 95.0% and NMT 105.0% of the labeled amount of lidocaine (C₁₄H₂₂N₂O).

IDENTIFICATION

Change to read:

- A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)
Sample: Stir a quantity of Ointment, equivalent to 300 mg of lidocaine, with 20 mL of water, transfer to a separator, and extract with two 30-mL portions of solvent hexane. Wash the combined hexane extracts with 10 mL of water, evaporate with the aid of a current of warm air, and dry the residue in vacuum over silica gel for 24 h.
Acceptance criteria: The crystalline precipitate so obtained meets the requirements.
- 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

- Solution A:** 0.1% phosphoric acid, prepared by adding 1.0 mL of 85% phosphoric acid to 1 L of water
- Solution B:** Acetonitrile
- Mobile phase:** See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
10	10	90
10.1	90	10
15	90	10

- Diluent:** Acetonitrile and *Solution A* (1:1)
- System suitability solution:** 0.1 mg/mL of [USP Lidocaine RS](#) and 0.04 mg/mL of [USP Ropivacaine Related Compound A RS](#) in *Diluent*
[NOTE—[USP Ropivacaine Related Compound A RS](#) is 2,6-dimethylaniline hydrochloride.]
- Standard solution:** 0.1 mg/mL of [USP Lidocaine RS](#) in *Diluent*
- Sample solution:** Nominally 0.1 mg/mL of lidocaine in *Diluent* from a portion of Ointment. Sonicate the solution for about 5 min.
- Chromatographic system**
(See [Chromatography \(621\), System Suitability](#).)

- Mode:** LC
- Detector:** UV 210 nm
- Column:** 4.6-mm × 15-cm; 5-µm packing L1
- Flow rate:** 0.8 mL/min
- Injection volume:** 5 µL

System suitability

- Samples:** *System suitability solution* and *Standard solution*
[NOTE—The relative retention times for 2,6-dimethylaniline and lidocaine are about 0.93 and 1.0, respectively.]
- Suitability requirements**
- Tailing factor:** NMT 1.5 for the lidocaine peak, *System suitability solution*
- Relative standard deviation:** NMT 2.0%, *Standard solution*
- Resolution:** NLT 1.8 between lidocaine and 2,6-dimethylaniline, *System suitability solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lidocaine ($C_{14}H_{22}N_2O$) in the portion of Ointment taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

SPECIFIC TESTS

- [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store at controlled room temperature.
- [USP REFERENCE STANDARDS \(11\)](#).

[USP Lidocaine RS](#)

[USP Ropivacaine Related Compound A RS](#)

2,6-Dimethylaniline hydrochloride.
 $C_8H_{12}ClN$ 157.64

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
LIDOCAINE OINTMENT	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 43(6)

Current DocID: GUID-24156E81-ED21-4073-9FE8-B11A8434BB8F_2_en-US

DOI: https://doi.org/10.31003/USPNF_M45100_02_01

DOI ref: [co7dv](#)