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Lidocaine Hydrochloride Jelly

DEFINITION

Lidocaine Hydrochloride Jelly is Lidocaine Hydrochloride in a suitable, water-soluble, sterile, viscous base. It contains NLT 95.0% and NMT 105.0% of the labeled amount of lidocaine hydrochloride ($C_{14}H_{22}N_2O \cdot HCl$).

IDENTIFICATION

Change to read:

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

Standard: Prepare as directed in ▲*Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020), using USP Lidocaine RS.

Sample: Place in a separator containing 10–15 mL of water a quantity of Jelly, equivalent to 300 mg of lidocaine hydrochloride. Mix to assure thorough dilution of the Jelly, and add 4 mL of 6 N ammonium hydroxide. Extract with four 15-mL portions of chloroform. Combine the chloroform extracts, and evaporate with the aid of a current of warm air to dryness. Redissolve the crystals in solvent hexane, evaporate with the aid of warm air, and dry the residue in vacuum over silica gel for 24 h.

Acceptance criteria: The residue 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 0.12 mg/mL of lidocaine hydrochloride in *Diluent* from a portion of Jelly. Sonicate the solution for about 10 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 of 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 hydrochloride ($C_{14}H_{22}N_2O \cdot HCl$) in the portion of Jelly taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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 hydrochloride in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of lidocaine hydrochloride, 270.80

M_{r2} = molecular weight of lidocaine, 234.34

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Minimum Fill ⟨755⟩:** Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩:** 6.0–7.0

• **Sterility Tests ⟨71⟩:** Meets the requirements

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 HYDROCHLORIDE JELLY	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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