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Lidocaine Topical Aerosol

Change to read:

DEFINITION

Lidocaine Topical Aerosol is a solution of Lidocaine in a suitable flavored vehicle with suitable propellants in a pressurized container. ▲ (USP 1-May-2022) It contains NLT 90.0% and NMT 110.0% of the labeled amount of lidocaine ($C_{14}H_{22}N_2O$).

▲[NOTE—This monograph may not be sufficient for products defined under 21 CFR Part 348.3(a).]▲ (USP 1-May-2022)

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197K▲ (USP 1-May-2022)

Sample: ▲Collect 10 mL of Topical Aerosol in a separator, add 10 mL of [1 N hydrochloric acid](#), and wash with 10 mL of [hexane](#). Allow the two layers to completely separate. Discard the bead-like globules and the hexane wash. Collect the aqueous layer. Add 5 mL of [ammonium hydroxide](#) to the collected aqueous layer, and extract with 10 mL of [hexane](#). Filter the hexane extract through a pledget of cotton previously moistened with [hexane](#). Evaporate the extract to dryness under ambient conditions over molecular sieves.

Standard: Dissolve 10 mg of [USP Lidocaine RS](#) with about 2 mL of [hexane](#). Evaporate to dryness under ambient conditions.▲ (USP 1-May-2022)

Acceptance criteria: ▲The attenuated total reflection or▲ (USP 1-May-2022) a potassium bromide dispersion of the ▲*Sample*▲ (USP 1-May-2022) exhibits maxima only at the same wavelengths as those of ▲the *Standard*.▲ (USP 1-May-2022)

Change to read:

- B. ▲The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2022)

Delete the following:

- ▲. C.

Analysis: To 2 mL of Aerosol spray, collected in a test tube, add 5 mL of water, 1 mL of 2 N nitric acid, and 3 mL of mercuric nitrate TS.
Acceptance criteria: A light yellow color develops (lidocaine).▲ (USP 1-May-2022)

ASSAY

Change to read:

- PROCEDURE

▲**Solution A:** 0.1% (v/v) [phosphoric acid](#) in [water](#)
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
2	90	10
30	10	90
30.1	90	10
35	90	10

Diluent: [Acetonitrile](#) and [water](#) (25:75)
Standard solution: 0.04 mg/mL of [USP Lidocaine RS](#) in *Diluent*. Sonicate to dissolve if necessary.

Sample solution: Nominally 0.04 mg/mL of lidocaine in *Diluent* from a portion of Topical Aerosol. Sonicate to dissolve if necessary.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 28°

Flow rate: 0.8 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

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 Topical Aerosol taken:

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

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

r_S = peak response of lidocaine 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: 90.0%–110.0% ▲ (USP 1-May-2022)

PERFORMANCE TESTS

Change to read:

• ▲ (USP 1-May-2022) [TOPICAL AEROSOLS \(603\)](#): Meets the requirements

▲ (USP 1-May-2022)

IMPURITIES

Add the following:

▲ • ORGANIC IMPURITIES

Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.

Sensitivity solution: 0.1 μg/mL of [USP Lidocaine RS](#) and 0.13 μg/mL of [USP Ropivacaine Related Compound A RS](#) (equivalent to 0.1 μg/mL of 2,6-dimethylaniline) in *Diluent*

Standard solution: 0.2 μg/mL of [USP Lidocaine RS](#) and 0.26 μg/mL of [USP Ropivacaine Related Compound A RS](#) (equivalent to 0.2 μg/mL of 2,6-dimethylaniline) in *Diluent*

Sample solution: Nominally 0.1 mg/mL of lidocaine in *Diluent* from Topical Aerosol. Sonicate to dissolve if necessary.

System suitability

Samples: *Sensitivity solution* and *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for lidocaine and 2,6-dimethylaniline, *Standard solution*

Relative standard deviation: NMT 5.0% for lidocaine and 2,6-dimethylaniline, *Standard solution*

Signal-to-noise ratio: NLT 10 for lidocaine and 2,6-dimethylaniline, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 2,6-dimethylaniline (ropivacaine related compound A free base) in the portion of Topical Aerosol taken:

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

r_U = peak response of 2,6-dimethylaniline from the *Sample solution*

r_S = peak response of 2,6-dimethylaniline from the *Standard solution*

C_S = concentration of [USP Ropivacaine Related Compound A RS](#) in the *Standard solution* (μg/mL)

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

