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Benzocaine and Menthol Topical Aerosol

DEFINITION

Benzocaine and Menthol Topical Aerosol is a solution of Benzocaine and Menthol with suitable propellants in a pressurized container. It contains NLT 90.0% and NMT 110.0% of the labeled amounts of benzocaine (C₉H₁₁NO₂) and menthol (C₁₀H₂₀O).

IDENTIFICATION

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The retention time of the major peak for benzocaine of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** The retention time of the major peak for menthol of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **BENZOCAINE**

Solution A: Dilute 1.0 mL of trifluoroacetic acid with water to 1 L.

Solution B: Acetonitrile

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
15	72	28
18	50	50
18.1	90	10
20	90	10

Diluent: *Solution A* and *Solution B* (1:1)

Standard solution: 0.1 mg/mL of [USP Benzocaine RS](#) in *Diluent*. Sonicate for 2–5 min to dissolve before diluting to final volume.

Sample solution: Nominally 0.1 mg/mL of benzocaine in *Diluent* prepared as follows. Spray the contents of the Topical Aerosol into a flask with a stopper. Heat and stir the sprayed Topical Aerosol at 100° for 30 min in an oil bath to obtain a viscous liquid sample. Cool the sample to room temperature. Transfer an amount of Topical Aerosol equivalent to 10 mg of benzocaine to a 100-mL volumetric flask. Dissolve the sample in *Diluent* and dilute with *Diluent* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm. For *Identification* test A, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing L7

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of benzocaine ($C_9H_{11}NO_2$) in the portion of Topical Aerosol 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 Benzocaine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

• **MENTHOL**

Internal standard solution: 1 mg/mL of decanol in isopropyl alcohol

Standard stock solution: 1 mg/mL of [USP Menthol RS](#) in isopropyl alcohol

Standard solution: 0.5 mg/mL each of [USP Menthol RS](#) and decanol in isopropyl alcohol from *Internal standard solution* and *Standard stock solution*

Sample solution: Nominally 0.5 mg/mL of menthol prepared as follows. Spray the contents of the Topical Aerosol into a flask. Transfer an amount of Topical Aerosol equivalent to 5 mg of menthol to a 10-mL volumetric flask and add 5.0 mL of *Internal standard solution*. Dilute with isopropyl alcohol to volume.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m; fused-silica capillary column bonded with a 1.0-μm film of phase G16

Carrier gas: Hydrogen

Temperatures

Injection port: 250°

Detector: 250°

Column: See [Table 2](#).

Table 2

Initial Temperature (°)	Hold Time at 130° (min)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
130	7.5	35	240	1.0

Flow rate: 10 mL/min

Injection volume: 1 μL

Injection type: Split, split ratio 10:1

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for menthol and decanol are 1.0 and 1.6, respectively.]

Suitability requirements

Resolution: NLT 2.5 between the menthol and decanol peaks

Relative standard deviation: NMT 1.0% of the ratio of the peak response of menthol to that of decanol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of menthol ($C_{10}H_{20}O$) in the portion of Topical Aerosol taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of menthol to decanol from the *Sample solution*

R_S = peak response ratio of menthol to decanol from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%