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Benzocaine Topical Aerosol

DEFINITION
Benzocaine Topical Aerosol is a solution of Benzocaine in a pressurized container. It contains NLT 90.0% and NMT 110.0% of the labeled amount of benzocaine ($C_9H_{11}NO_2$).

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 of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- PROCEDURE**
Solution A: 0.1% Trifluoroacetic acid, prepared by diluting 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
34	50	50
35	90	10
38	90	10

Diluent: *Solution A* and *Solution B* (1:1)
System suitability solution: 1 µg/mL each of [USP Benzocaine RS](#), [USP Aminobenzoic Acid RS](#), and [USP Ethyl 4-Nitrobenzoate RS](#) in *Diluent*
Standard solution: 0.1 mg/mL of [USP Benzocaine RS](#) in *Diluent*
Sample composite: Spray a portion of Topical Aerosol into a beaker or glass tube, and heat on a steam bath or a heating module at 100° for a few min to expel residual propellant. Use the resulting benzocaine solution.
Sample solution: Nominally 0.1 mg/mL of benzocaine in *Diluent* prepared as follows. Transfer a known quantity of benzocaine solution from a portion of *Sample composite* to an appropriate volumetric flask, dissolve, 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
Samples: *System suitability solution* and *Standard solution*
[NOTE—See [Table 2](#) for relative retention times.]
Suitability requirements
Resolution: NLT 6 between aminobenzoic acid and benzocaine; NLT 6 between benzocaine and ethyl 4-nitrobenzoate, *System suitability solution*
Tailing factor: NMT 1.5, *Standard solution*
Relative standard deviation: NMT 1.0%, *Standard solution*
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 of benzocaine from the *Sample solution*

r_S = peak response of benzocaine 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%

IMPURITIES

• ORGANIC IMPURITIES

Solution A: 0.1% Trifluoroacetic acid, prepared by diluting 1.0 mL of trifluoroacetic acid with water to 1 L

Solution B: Acetonitrile

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

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

Standard solution: 1 µg/mL each of [USP Benzocaine RS](#), [USP Aminobenzoic Acid RS](#), and [USP Ethyl 4-Nitrobenzoate RS](#) in *Diluent*

Sample composite: Spray a portion of the Topical Aerosol into a beaker or a glass tube, and heat on a steam bath or a heating module at 100° for a few min to expel residual propellant. Use the resulting benzocaine solution.

Sample solution: Nominally 0.5 mg/mL of benzocaine in *Diluent* prepared as follows. Transfer 50 mg of benzocaine from a portion of *Sample composite* to a 100-mL volumetric flask, dissolve, and dilute with *Diluent* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 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*

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 6 between aminobenzoic acid and benzocaine; NLT 6 between benzocaine and ethyl 4-nitrobenzoate

Relative standard deviation: NMT 3% for each peak corresponding to benzocaine, aminobenzoic acid, and ethyl 4-nitrobenzoate

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of aminobenzoic acid and ethyl 4-nitrobenzoate 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 aminobenzoic acid or ethyl 4-nitrobenzoate from the *Sample solution*

r_S = peak response of aminobenzoic acid or ethyl 4-nitrobenzoate from the *Standard solution*

C_S = concentration of [USP Aminobenzoic Acid RS](#) or [USP Ethyl 4-Nitrobenzoate RS](#) in the *Standard solution* (mg/mL)

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

Calculate the percentage of any other individual, unspecified impurity 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 any other individual, unspecified impurity from the *Sample solution*

r_S = peak response of benzocaine 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: See [Table 2](#). Disregard peaks less than 0.05%.

Table 2