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Benzocaine Lozenges

DEFINITION

Benzocaine Lozenges contain NLT 85.0% and NMT 120.0% 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

Buffer: 1.0 M monobasic potassium phosphate, adjusted with phosphoric acid to a pH of 3.0

Mobile phase: Acetonitrile, water, and *Buffer* (250:700:50)

Diluent A: 0.1 N hydrochloric acid

Diluent B: Acetonitrile and water (1:1)

Standard solution A: 0.01 mg/mL of [USP Benzocaine RS](#) in *Diluent A*

Standard solution B: 0.01 mg/mL of [USP Benzocaine RS](#) in *Diluent B*

Sample stock solution A: Transfer the equivalent of 40 mg of benzocaine from powdered Lozenges (NLT 20) to a 200-mL volumetric flask. Add 150 mL of *Diluent A*, and stir for NLT 2 h. Dilute with *Diluent A* to volume.

Sample stock solution B: Transfer the equivalent of 40 mg of benzocaine from powdered Lozenges (NLT 20) to a 200-mL volumetric flask. Add 150 mL of *Diluent B*, and stir for NLT 30 min. Dilute with *Diluent B* to volume.

Sample solution A: Nominally 0.01 mg/mL of benzocaine in *Diluent A* from *Sample stock solution A*

Sample solution B: Nominally 0.01 mg/mL of benzocaine in *Diluent B* from *Sample stock solution B*

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; packing L7

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution A* and *Standard solution B*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Sample solution A*, and *Sample solution B*

Calculate the percentage of the total labeled amount of benzocaine ($C_9H_{11}NO_2$) in the portion of Lozenges taken:

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

r_U = peak response from *Sample solution A*

r_S = peak response from *Standard solution A*

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

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

Calculate the percentage of free benzocaine ($C_9H_{11}NO_2$) in the portion of Lozenges taken:

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

r_U = peak response from *Sample solution B*

r_s = peak response from *Standard solution B*

C_s = concentration of [USP Benzocaine RS](#) in *Standard solution B* (mg/mL)

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

Acceptance criteria

Total labeled amount of benzocaine: 85.0%–120.0%

Free benzocaine: 85.0%–120.0%

IMPURITIES

• ORGANIC IMPURITIES

Solution A: Dissolve 9.1 g of monobasic potassium phosphate in 1000 mL of water. Adjust with phosphoric acid to a pH of 3.0.

Solution B: Acetonitrile

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	60	40
10	45	55
10.1	60	40
13	60	40

Diluent: Acetonitrile and water (10:90)

Standard stock solution: 0.03 mg/mL each of [USP Benzocaine RS](#), [USP Aminobenzoic Acid RS](#), and [USP Ethyl 4-Nitrobenzoate RS](#) in *Diluent*.
Sonicate for 2–5 min to dissolve before diluting to final volume.

Standard solution: 0.3 µg/mL each of [USP Benzocaine RS](#), [USP Aminobenzoic Acid RS](#), and [USP Ethyl 4-Nitrobenzoate RS](#) in *Diluent* from the *Standard stock solution*

Sample solution: Nominally 150 µg/mL of benzocaine in *Diluent* prepared as follows. Transfer 10 Lozenges to an appropriate volumetric flask to obtain a nominal benzocaine concentration of 0.15 mg/mL. Dissolve Lozenges in *Diluent* 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: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 10 between benzocaine and aminobenzoic acid; NLT 10 between ethyl 4-nitrobenzoate and benzocaine

Relative standard deviation: NMT 2.0% 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 Lozenges 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 the corresponding Reference Standard from the *Standard solution*

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

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

Calculate the percentage of each unspecified degradation product in the portion of Lozenges taken:

$$\text{Result} = (r_U/r_s) \times (C_s/C_U) \times 100$$