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Benzocaine, Butamben, and Tetracaine Hydrochloride Ointment

DEFINITION

Benzocaine, Butamben, and Tetracaine Hydrochloride Ointment is Benzocaine, Butamben, and Tetracaine Hydrochloride in a suitable ointment base. It contains NLT 90.0% and NMT 110.0% of the labeled amounts of benzocaine ($C_9H_{11}NO_2$), butamben ($C_{11}H_{15}NO_2$), and tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$).

IDENTIFICATION

• **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Diluent: Methanol and water (60:40)

Mobile phase: Methanol, water, and 0.25 M sodium 1-heptanesulfonate (500:500:20)

Standard solution: Transfer 140 mg of USP Benzocaine RS to a 100-mL volumetric flask with the aid of 25 mL of methanol, and swirl. Transfer 140*J* mg of USP Butamben RS to the same volumetric flask with the aid of 25 mL of water, *J* being the ratio of the labeled amount, as a percentage, of butamben to the labeled amount, as a percentage, of benzocaine in the Ointment. Transfer 140*J'* mg of USP Tetracaine Hydrochloride RS to the same volumetric flask with the aid of 25 mL of water, *J'* being the ratio of the labeled amount, as a percentage, of tetracaine hydrochloride to the labeled amount, as a percentage, of benzocaine in the Ointment. Sonicate for about 1 min, and dilute with *Diluent* to volume.

Sample stock solution: Nominally 14 mg/mL of benzocaine, prepared as follows. Transfer a portion of Ointment, equivalent to 1400 mg of benzocaine, to a 100-mL volumetric flask. Add 75 mL of methanol, and mix. Sonicate for about 1 min, and dilute with methanol to volume.

Sample solution: Nominally 1.4 mg/mL of benzocaine in *Diluent* from the *Sample stock solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 313 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for benzocaine, butamben, and tetracaine are about 0.3, 0.8, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2 between benzocaine and butamben, and between butamben and tetracaine

Relative standard deviation: NMT 2.0% for each of the three analyte peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amounts of benzocaine ($C_9H_{11}NO_2$), butamben ($C_{11}H_{15}NO_2$), and tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$) in the portion of Ointment taken:

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

r_U = peak response of the corresponding analyte from the *Sample solution*

r_S = peak response of the corresponding analyte from the *Standard solution*

C_S = concentration of the corresponding Reference Standard in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

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PERFORMANCE TESTS

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and avoid freezing.

• **USP Reference Standards ⟨11⟩**

USP Benzocaine RS
USP Butamben RS
USP Tetracaine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BENZOCAINE, BUTAMBEN, AND TETRACAINE HYDROCHLORIDE OINTMENT	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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