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Benzethonium Chloride Tincture

DEFINITION

Benzethonium Chloride Tincture contains, in each 100 mL, NLT 190 mg and NMT 210 mg of benzethonium chloride ($C_{27}H_{42}ClNO_2$).

Prepare Benzethonium Chloride Tincture 2 mg/mL as follows.

Benzethonium Chloride	2 g
Alcohol	685 mL
Acetone	100 mL
Purified Water, a sufficient quantity to make	1000 mL

Dissolve the *Benzethonium Chloride* in a mixture of *Alcohol* and *Acetone*. Add sufficient *Purified Water* to make 1000 mL. [NOTE—Benzethonium Chloride Tincture may be colored by the addition of any suitable color or combination of colors certified by the FDA for use in drugs.]

IDENTIFICATION

• **A. PROCEDURE**

Sample: 50 mL

Analysis: To the residue obtained by evaporating the *Sample* on a steam bath, add 2 mL of alcohol, 0.5 mL of 2 N nitric acid, and 1 mL of silver nitrate TS.

Acceptance criteria: A white precipitate, which is insoluble in 2 N nitric acid but soluble in 6 N ammonium hydroxide, is formed.

• **B. PROCEDURE**

Sample: 50 mL

Analysis: Evaporate the *Sample* on a steam bath.

Acceptance criteria: The residue obtained forms precipitates with 2 N nitric acid and with mercuric chloride TS, both of which dissolve upon the addition of alcohol.

ASSAY

• **PROCEDURE**

Sample: 50 mL

Analysis: Transfer the *Sample* to a 150-mL beaker, and add, with continuous stirring, 10 mL of 25 mg/mL of sodium tetraphenylboron solution. Cover, and allow to stand for 16 h. Decant the supernatant into a tared sintered-glass crucible, applying vacuum filtration. Suspend the precipitate in 20 mL of water. Transfer the precipitate to the crucible, washing well with water. Dry the precipitate and the crucible at 105° for 1 h, cool, and weigh. The weight of the precipitate so obtained, multiplied by 0.6122, represents its equivalent of benzethonium chloride ($C_{27}H_{42}ClNO_2$).

Acceptance criteria: 190–210 mg

OTHER COMPONENTS

• **ALCOHOL AND ACETONE CONTENT**

Standard solution A (alcohol low standard solution): Add 5.0 mL of methanol and 11.0 mL of dehydrated alcohol to a 100-mL volumetric flask, and dilute with water to volume.

Standard solution B (alcohol high standard solution): Add 5.0 mL of methanol and 14.0 mL of dehydrated alcohol to a 100-mL volumetric flask, and dilute with water to volume.

Standard solution C (acetone low standard solution): Add 5.0 mL of methanol and 1.7 mL of acetone to a 100-mL volumetric flask, and dilute with water to volume.

Standard solution D (acetone high standard solution): Add 5.0 mL of methanol and 2.2 mL of acetone to a 100-mL volumetric flask, and dilute with water to volume.

Sample solution: Transfer 20 mL of Tincture to a 100-mL volumetric flask, add 5.0 mL of methanol as the internal standard, and dilute with water to volume.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 120-cm × 4-mm packed with a suitable type of support, such as 80- to 100-mesh S3

Carrier gas: Dry helium

Temperature

Injector port: 240°

Detector block: 240°

Column: 120°

Flow rate: 90 mL/min

Injection size: 0.8 µL

Analysis

Samples: *Standard solutions A, B, C,* and *D*, and *Sample solution*

From the respective chromatograms obtained as described previously, calculate the ratios of peak areas for alcohol to internal standard and for acetone to internal standard.

Calculate the percentage of alcohol and of acetone in the portion of Tincture taken:

$$\text{Result} = [A(Y - Z) + B(Z - X)]/(Y - X)$$

A = percentage of alcohol, or of acetone, in *Standard solution A* and *Standard solution C*, respectively

Y = ratio of the alcohol peak areas, or the acetone peak areas, to the internal standard peak areas for *Standard solution B* and *Standard solution D*, respectively

Z = ratio of the alcohol peak areas, or the acetone peak areas, to the internal standard peak areas for the *Sample solution*

B = percentage of alcohol, or of acetone, in *Standard solution B* and *Standard solution D*, respectively

X = ratio of the alcohol peak areas, or the acetone peak areas, to the internal standard peak areas for *Standard solution A* and *Standard solution C*, respectively

Acceptance criteria

Alcohol (C_2H_5OH): 62.0%–68.0%

Acetone (C_3H_6O): 9.0%–11.0%

SPECIFIC TESTS

• **Specific Gravity ⟨841⟩:** 0.868–0.876

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers.

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

Topic/Question	Contact	Expert Committee
BENZETHONIUM CHLORIDE TINCTURE	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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