Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Aug-2013
Document Type: USP Monographs
DocId: GUID-0466C50B-7B22-40AC-A91B-D4FD6B0C84EC_1_en-US
DOI: https://doi.org/10.31003/USPNF_M7965_01_01
DOI Ref: ob6wi

Benzethonium Chloride Concentrate

DEFINITION

Benzethonium Chloride Concentrate contains NLT 94.0% and NMT 106.0% of the labeled amount of benzethonium chloride ($C_{27}H_{42}ClNO_2$).

IDENTIFICATION

• **A.**

Sample: Evaporate a volume of the Concentrate, equivalent to 200 mg of benzethonium chloride, on a steam bath.

Analysis: To the residue 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.**

Sample: Evaporate a volume of the Concentrate, equivalent to 200 mg of benzethonium chloride, on a steam bath.

Analysis: To the residue add 0.1 g of potassium nitrate, and heat on a steam bath for 3 min. Cautiously dilute the solution with water to 10 mL, add 0.5 g of granulated zinc, and warm the mixture for 10 min. Cool. Add 0.2 g of sodium nitrite to 1 mL of the clear liquid, and add this mixture to 20 mg of naphthol dipotassium disulfonate or naphthol disodium disulfonate in 1 mL of ammonium hydroxide.

Acceptance criteria: The solution turns orange-red, and a brown precipitate may be formed.

ASSAY

• **Procedure**

Sample solution: Equivalent to 200 mg of benzethonium chloride from a volume of Concentrate, in a glass-stoppered flask

Analysis: Add 0.4 mL of bromophenol blue solution (1 in 2000), 10 mL of chloroform, and 1 mL of 1 N sodium hydroxide. Titrate with 0.02 M sodium tetraphenylboron VS until the blue color disappears from the chloroform layer. Add the last portions of the sodium tetraphenylboron solution dropwise, agitating vigorously after each addition. Each mL of 0.02 M sodium tetraphenylboron is equivalent to 8.962 mg of benzethonium chloride ($C_{27}H_{42}ClNO_2$).

Acceptance criteria: 94.0%–106.0% of the labeled amount of benzethonium chloride

IMPURITIES

• **Limit of Nitrites**

Sample: One drop of Concentrate on a spot plate

Analysis: To the *Sample* add one drop each of glacial acetic acid, sulfanilic acid in acetic acid solution (1 in 100), and 1-naphthylamine-acetic acid solution (prepared by boiling 30 mg of 1-naphthylamine in 70 mL of water, decanting the colorless solution from the blue-violet residue, and mixing with 30 mL of glacial acetic acid).

Acceptance criteria: No red color develops in the resulting solution within 10 min.

SPECIFIC TESTS

• **Oxidizing Substances**

Sample: 5 mL

Analysis: To the *Sample* add 0.5 mL of potassium iodide TS and a few drops of 3 N hydrochloric acid.

Acceptance criteria: The solution does not acquire a yellow color.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers. Store at room temperature.

• **Labeling:** The label states that this article is not intended for direct administration to humans or animals.

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

Topic/Question	Contact	Expert Committee
BENZETHONIUM CHLORIDE CONCENTRATE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(3)
Current DocID: GUID-0466C50B-7B22-40AC-A91B-D4FD6B0C84EC_1_en-US
DOI: https://doi.org/10.31003/USPNF_M7965_01_01
DOI ref: ob6wi