

# Benzethonium chloride

Meets USP-NF, EP, BP and JP testing specifications

**Product Code: TC554M**

## Product Description :

Molecular weight: 448.09

Molecular formula:  $C_{27}H_{42}ClNO_2$

CAS No.: 121-54-0

## Quality Control:

### Appearance (USP)

White crystals

### Appearance (JP)

Colourless or white crystals.

### Appearance (BP, EP)

White or yellowish-white powder

### Solubility (JP)

Very soluble in ethanol (95%), freely soluble in water, and practically insoluble in diethyl ether.

### Solubility (USP)

Soluble in water, in alcohol, and in chloroform; slightly soluble in ether

### Solubility (BP, EP)

Very soluble in water and in ethanol (96%), freely soluble in methylene chloride

### Identification 1 : (JP)

Develops a red color.

### Identification A : (BP, EP)

158 - 164°C (after drying at 105°C for 4 h)

### Identification A : (USP)

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

### Identification 2 : (JP)

The chloroform layer turns colorless.

### Identification B, TLC (BP, EP)

The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution

### Identification B, FTIR (USP)

Matches with the standard pattern

### Identification 3, UV (JP)

Both spectra exhibit similar intensities of absorption at the same wavelengths.

### Identification C (BP, EP)

A blue colour develops in the lower layer

### Identification C (USP)

The retention time of the major peak of the sample solution corresponds to the standard solution, as obtained in the assay

### Identification 4 (JP)

A white precipitate is produced. This precipitate does not dissolve on addition of dilute nitric acid, but dissolves on addition of ammonia TS.

### Identification D : chlorides (BP, EP)

The solution gives reaction (a) of chlorides

### Melting point (JP)

158 - 164°C (after drying)

### Appearance of solution (BP, EP)

Solution S (10% solution) is clear and not more intensely coloured than reference solution Y6

### Ammonium (JP)

The evolving gas does not change moistened red litmus paper to blue.

### Loss on drying (at 105°C, 4h) : (JP, BP, EP, USP)

$\leq 5.00\%$

### Residue on ignition (JP, USP)

$\leq 0.10\%$

### Acidity or alkalinity (BP, EP)

Complies

**Volatile bases and salts of volatile bases (EP, BP)**

<= 0.0050%

**Sulfated ash (BP, EP)**

<= 0.10%

**Residue on ignition (USP)**

<= 0.10%

**Organic impurities, system suitability, HPLC : RSD (USP)**

<= 5.0%

**Organic impurities, HPLC : total impurities (USP)**

<= 1.0%

**Assay, system suitability, HPLC : Resolution (USP)**

>= 7.0 between the benzethonium and methylbenzethonium peak

**Assay, system suitability, HPLC : RSD**

<= 1.0% for the benzethonium peak

**Assay (HPLC, on dried basis) : (USP)**

97.0 - 103.0%

**Assay (KIO3 Titration, dried substance) : (BP, EP)**

97.0 - 103.0%

**Assay (Tetraphenylboron Titration, dried substance) : (JP)**

min. 97.0%

**Storage and Shelf Life:**

Store below 30°C.

Shelf life is 48 months.

Use before expiry date given on the product label.

Revision : 02/2024

**Disclaimer :**

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