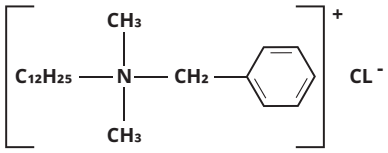
Technical Data Sheet

Benzalkonium chloride

IP, BP, Ph.Eur., USP-NF



Applications

Benzalkonium chloride is widely used as a pharmaceutical excipient in various formulations as an antimicrobial preservative. The preferred route of application is Parenteral, Ophthalmic, Nasal and Semi-solid dosage forms.

General Information

Pharmacopeia Status	:	IP, BP, Ph.Eur., USP-NF
CAS No.	:	8001-54-5
EC No.	:	264-151-6
Appearance/Description	:	Clear liquid; colorless or slight yellow unless a color has been added. Has an aromatic odor and a bitter taste.
Molecular Formula	:	$C_{22}H_{40}ClN$
Molecular Mass	:	372.028 g/mol

Marketed Formulations

- Diphenhydramine injection
- Betamethasone injection
- Lorazepam gel
- Prednisolone eye drops & many more

Quality and Regulatory Support

- GMP and ISO certification
- EXCiPACT certification
- Nitrosamine impurity risk assessment
- Elemental impurity risk assessment
- Residual solvent declaration
- Genotoxic impurity declaration
- Vendor questionnaire and site audit
- CMC documentation
- Regulatory queries

Key Product Attributes

- Manufacturing and packing under GMP environment
- Low Endotoxin suitable for parenteral application
- Control of TAMC & TYMC
- Control of sub-visible particles
- Control of elemental impurities as per ICH Q3D

Pack Mode

500 ml, 1 Litre, 2.5 kg plastic container

Stability and Storage Conditions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Benzalkonium chloride is an irritant to the skin and eyes and repeated exposure to the skin may cause hypersensitivity. Concentrated benzalkonium chloride solutions accidentally spilled on the skin may produce corrosive skin lesions with deep necrosis and scarring, and should be washed immediately with water, followed by soap solutions applied freely. Gloves, eye protection, and suitable protective clothing should be worn.

Safety and Handling Information

The bulk material should be stored in an airtight container, protected from light and contact with metals, in a cool, dry place.

Pharmaceutical Specifications

Description/ Appearance	A clear, colourless or slightly yellow, syrupy liquid with an aromatic odour and a bitter taste (IP, BP, Ph.Eur, USP-NF)
Solubility	Miscible with water and with ethanol. It froths when shaken with ethanol (IP, BP, Ph.Eur)
Assay	Not less than 49.0% and Not more than 51.0% w/v (IP)
Assay	Not less than 475 g/l and Not more than 525 g/l (BP, Ph.Eur)
Assay (Total Alkylbenzyldimetylammonium chlorides)	Not less than 47.5% w/v and Not more than 52.5% w/v (USP-NF)
Identification (By Chemical test)	A white precipitate is produced which is soluble in ethanol (95%) (IP)
Identification (By UV spectrophotometry)	To comply the test (BP, Ph.Eur)
Identification (By Chemical test)	A white precipitate should form, and it should dissolve after adding 5 mL of alcohol (USP-NF)
Identification (By Chemical test)	An orange red colour is produced (IP, USP-NF)
Identification (By Liquid Chromatography)	The principal peaks in the chromatogram obtained with the test solution are similar in retention time to the principal peaks in the chromatogram obtained with the reference solution (BP, Ph.Eur)
Identification (By Chemical test)	A solution should yield a white, curdy precipitate which should be insoluble in nitric acid but soluble in slight excess of 6 N ammonium hydroxide (USP-NF)
Identification (By Chemical test)	A curdy white precipitate is formed (IP)
Identification (By Chemical test)	To comply the test (BP, Ph.Eur)
Identification D (By Chemical test)	The methylene chloride layer becomes blue (BP, Ph.Eur)
Identification (By Liquid Chromatography)	The retention times of the major peaks for benzalkonium chloride in the sample solution correspond to those of the standard solution, as obtained in the test for ratio of Alkyl components (USP-NF)
Identification (By Chemical test)	The solution gives reaction (a) of chlorides (BP, Ph.Eur)
Appearance of Solution	Solution S is clear and not more intensely coloured than reference solution Y6 (BP, Ph.Eur)
Acidity or Alkalinity	Not more than 0.1ml of 0.1M hydrochloric acid or 0.1M sodium hydroxide is required to change the colour of the indicator (BP, Ph.Eur. IP)
Acidity or Alkalinity	NMT 0.5 ml of 0.1N hydrochloric acid or 0.1N sodium hydroxide should require to change the color sodium hydroxide should require to change the color of the indicator (USP-NF)
Average relative molecular mass and ratio of Alkyl components (C12 homologue)	Min. 40.0% (BP, Ph.Eur)
Ratio of Alkyl components (n-C12H25 homolog)	NLT 40.0% (On the solid basis) (USP-NF)
Average relative molecular mass and ratio of Alkyl components (C14 homologue)	Min. 20.0% (BP, Ph.Eur)
Ratio of Alkyl components (n-C14H29 homolog)	NLT 20.0% (On the solid basis) (USP-NF)
Average relative molecular mass and ratio of Alkyl components (Sum of C12 and C14 homologue)	Min. 70.0% (BP, Ph.Eur)
Ratio of Alkyl components (The amount of the n-C12H25 and n-C14H29 homolog components together)	NLT 70.0% (On the solid basis) (USP-NF)

Pharmaceutical Specifications

Impurities A (Benzyl alcohol) / Limit of Benzyl alcohol, Benzaldehyde and (chloromethyl) Benzene) : Benzyl alcohol	Not more than 0.5% (BP, Ph.Eur ,USP-NF)
Impurities B (Benzaldehyde) / Limit of Benzyl alcohol, Benzaldehyde and (chloromethyl) Benzene): Benzaldehyde	Not more than 0.15% (BP, Ph.Eur , USP-NF)
Impurities C (chloromethyl) benzene / Limit of Benzyl alcohol, Benzaldehyde and (chloromethyl) Benzene): (Chloromethyl) Benzene	Not more than 0.05% (BP, Ph.Eur, USP-NF)
Ammonia compounds	No odour of ammonia is produced (IP)
Foreign amines	No precipitate is formed. Heat to boiling; the odour of amines is not perceptible (IP)
Amine & amine salts	Not greater than 5.0ml 0.1M tetrabutylammonium hydroxide solution required between two points of inflexion (BP, Ph.Eur, USP-NF)
Ethanol (C2H5OH)	Not more than 16.0% v/v (IP)
Other components Alcohol content (If added)	Not more than 10.0% v/v (USP-NF)
Sulphated ash	Not more than 0.2% (IP)
Sulphated ash	0.1% max. (BP, Ph.Eur)
Total aerobic microbial count (Bioburden)	NMT 1000 cfu/ml (In-house)
Total combined yeasts and molds count (Bioburden)	NMT 100 cfu/ml (In-house)
Bacterial endotoxins	NMT 0.5 EU/mg (In-house)

Regulatory Information

Included in the FDA Inactive Ingredients Database (inhalations, IM injections, nasal, ophthalmic, optic, and topical preparations). Included in non-parenteral medicines licensed in the UK. It is also included in the Canadian List of Acceptable Non-medicinal Ingredients.

Shipping Information

By Sea, Air and Road
Nature: Hazardous
UN No.: UN2922
Transport Hazard class: 8 (6.1)
Packing group: III

See the Material Safety Data Sheet on www.finarchemicals.com

For more information contact : deepaklodhiya@finarchemicals.com

Finar Limited
CORPORATE OFFICE & WORKS
184-185-186/P, Vill:Chacharwadi Vasna, Bavla 8km milestone, Sarkhej Bavla Highway, Sanand, Ahmedabad – 382110. Gujarat, INDIA.
t: +91-2717-616717 | e: sales@finarchemicals.com
www.finarchemicals.com