



Technical Data Sheet

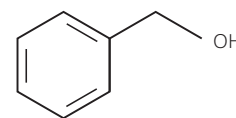
Benzyl Alcohol USP-NF, Ph.Eur., BP

Applications

Benzyl Alcohol is used as an excipient (preservative, solubilising agent) and as an active principal (antiseptic, local anaesthetic).

- Preservative (in oral, parenteral pharmaceutical preparations and cosmetics)
- Local anaesthetic (in certain injections, cough remedies, ophthalmic solutions, ointments, dermatological aerosols)
- Solubilising agent

The most common routes of administration are parenteral and to a lesser extend topical



General Information

Pharmacopeia Status	: USP-NF, Ph. Eur., BP
CAS No	: 100-51-6
EC No.	: 202-859-9
Appearance / Description	: Clear, colourless, oily liquid
Molecular Formula	: C ₇ H ₈ O
Molecular Mass	: 108.14 g/mol

Marketed Formulation

- Diazepam injection
- Diclofenac Sodium gel
- Piroxicam gel
- B Complex injection
- Methylcarbylamine injection and more...

Quality and Regulatory Support

- GMP and ISO certifications
- EXCI PACT 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 peroxide value
- Low Benzaldehyde
- Low Cyclohexyl Methanol

Pack Mode

- 2.5 Litre glass bottle
- 25 Litre HDPE Jerrycan

Stability and Storage Conditions

Benzyl Alcohol oxidizes slowly in air to benzaldehyde and benzoic acid; it does not react with water. Benzyl Alcohol should be stored in an airtight container, protected from light, in a cool & dry well-ventilated environment. For long term use, storage at 2-8° temperature is recommended.

Safety and Handling Information

Benzyl Alcohol (liquid and vapor) is an irritant to the skin, eyes, and mucous membranes. Eye protection, gloves and protective clothing are recommended. Benzyl Alcohol should be handled in a well-ventilated environment. A self-contained breathing apparatus is recommended in areas with poor ventilation. Benzyl Alcohol is flammable.

Pharmaceutical Specifications

Description	Clear, colourless, oily liquid. Boils at about 206°C without decomposition. Is neutral to litmus. Specific gravity is between 1.042 and 1.047 (USP-NF)
Appearance	Clear, colourless, oily liquid (Ph.Eur., BP)
Solubility	Freely soluble in 50% alcohol; sparingly soluble in water. Miscible with alcohol, with ether and with chloroform (USP-NF)
Solubility	Soluble in water, miscible with ethanol (96%) and with fatty and essential oils (Ph.Eur., BP)
Relative density, 20°C	1.043-1.049 (Ph.Eur., BP)
Identification by IR	To comply the test (USP-NF, Ph.Eur., BP)
Appearance of solution	The solution is clear and colourless (Ph.Eur., BP)
Clarity of solution	The sample solution shows same clarity as that of water or its opalescence is not more pronounced than that of reference suspension (USP-NF)
Colour of solution	Sample solution has the colour of water (USP-NF)
Refractive index (20°C ± 0.5°C)	1.538-1.541 (USP-NF, Ph.Eur., BP)
Assay	98.0-100.5% (USP-NF, Ph.Eur., BP)
Acidity	NMT 1 mL of 0.1M sodium hydroxide is required to change the colour of the indicator to pink (USP-NF, Ph.Eur., BP)
Fats and fixed oils (peroxide value)	Not more than 5 (USP-NF, Ph.Eur., BP)
Residue on evaporation	Not more than 0.05% (USP-NF, Ph.Eur., BP)
Related substances: Impurity A (Benzaldehyde)	Not more than 0.05% (USP-NF, Ph.Eur., BP)
Related substances: Impurity B (Cyclohexylmethanol)	Not more than 0.10% (USP-NF, Ph.Eur., BP)
Related substances: Sum of the areas of other peaks with a relative retention time less than that of Benzyl Alcohol	Not more than 0.02% (USP-NF, Ph.Eur., BP)
Related substances: Sum of the areas of other peaks with a relative retention time greater than that of Benzyl Alcohol	Not more than 0.2% (USP-NF, Ph.Eur., BP)
For Injectable Application	
Total aerobic microbial count	100 CFU/ml max (In-house)
Total combined yeasts and molds count	100 CFU/ml max (In-house)
Bacterial endotoxins	NMT 2.5 EU/ml (In-house)

Regulatory Information

Included in the FDA Inactive Ingredients database, parenteral and no parenteral medicines licensed in the UK and Canadian List of Acceptable Non-medicinal Ingredients

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

Note: The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantees since the conditions of use are beyond our control. Finar disclaims any liability incurred with the use of this data or suggestions.

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Shipping Information

By Sea, Air and Road

Nature: Hazardous

UN Number: 3334

Class: 9

Packaging group: III

Finar Limited

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184-185-186/P, Vill:Chacharwadi Vasna, Bavla 8km milestone, Sarkhej
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