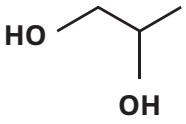
Technical Data Sheet

Propylene glycol

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



Applications

Propylene glycol is used as a humectant, plasticizer, solvent and water miscible co solvent in the pharmaceutical industry. It's application is in almost all dosage forms including Solid oral, Semi-solid, Topical and Parenteral formulations.

General Information

Pharmacopeia Status	:	BP, Ph.Eur., USP-NF, IP
CAS No.	:	57-55-6
EC No.	:	200-338-0
Appearance/Description	:	Clear colourless, viscous liquid having a slight, characteristic taste. Is practically odourless and absorbs moisture when exposed to moist air
Molecular Formula	:	$C_3H_8O_2$
Molecular Mass	:	76.0 g/mol

Marketed Formulation

- Liraglutide injection
- Triptorelin injection
- Triptorelin injection
- Dexamethasone injection
- Diclofenac gel & 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 sub-visible particles
- Control of elemental impurities as per ICH Q3D
- Control of Chloride (Cl) & Sulphate (SO4)

Pack Mode

- 2.5 Litre, 2.5 kg glass bottle
- 25 Litre, 25 kg plastic container

Stability and Storage Conditions

Propylene glycol is stable in a well-closed container in a cool temperature. At high temperatures, and in the open, it tends to oxidize, giving rise to products such as propionaldehyde, lactic acid, pyruvic acid, and acetic acid. Propylene glycol is chemically stable when mixed with ethanol (95%), glycerin, or water; aqueous solutions may be sterilized by autoclaving.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Propylene glycol should be handled in a well-ventilated environment; eye protection is recommended.

Pharmaceutical Specifications

Description/ Appearance	Clear colourless, viscous liquid having a slight characteristic taste. It is practically odourless and absorbs moisture (USP-NF, BP, Ph.Eur)
Solubility	Miscible with water, ethanol (96%), acetone and chloroform
	Soluble in ether and will dissolve many essential oils but is immiscible with fixed oils (USP-NF, BP, Ph.Eur)
Identification A (By IR)	To comply the test (USP-NF)
Identification A (By Relative density, 20°C)	1.035 - 1.040 (BP, Ph.Eur)
Identification B (Diethylene glycol)	NMT 0.10% (USP-NF)
Identification B (Ethylene glycol)	NMT 0.10% (USP-NF)
Identification B (By Refractive index, 20±0.5°C)	1.431 - 1.433 (BP, Ph.Eur)
Identification C (By GC Chromatogram)	The retention time of the propylene glycol peak of the sample solution corresponds to that of the standard solution (USP-NF)
Identification C (By Boiling Point)	184° - 189°C (BP, Ph.Eur)
Identification D (By Melting point)	Crystals should melt between 121 °C to 128 °C. (BP, Ph.Eur)
Assay	NLT 99.5% (USP-NF)
Residue on ignition	The weight of the residue is NMT 3.5 mg (0.007% max) (USP-NF)
Chloride (Cl)	70ppm max. (USP-NF)
Sulphate (SO4)	60ppm max. (USP-NF)
Specific gravity, 25°C	1.035 - 1.037 (USP-NF)
Relative density, 20°C	1.035 - 1.040 (BP, Ph.Eur)
Refractive index (20°C ± 0.5°C)	1.431 - 1.433 (BP, Ph.Eur)
Acidity	NMT 0.20 mL of 0.1N sodium hydroxide required to change the colour of the indicator to pink (USP-NF)
Acidity	Not more than 0.05 mL of 0.1 M sodium hydroxide should be required to change the colour of the indicator to blue (BP, Ph.Eur)
Oxidising substances	Not more than 0.2 mL of 0.05 M sodium thiosulfate should be required (BP, Ph.Eur)
Reducing substances	The solution does not change its appearance (BP, Ph.Eur)
Water	NMT 0.2% (BP, Ph.Eur.,USP-NF)
Sulphated ash	NMT 0.01% (Residue weight should not be more than 5 mg (BP, Ph.Eur)
Bacterial Endotoxin	NMT 0.012 EU/mg (In-house)

Regulatory Information

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (dental preparations; IM and IV injections; inhalations; ophthalmic, oral, optic, percutaneous, rectal, topical, and vaginal preparations). Included in non-parenteral and parenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

Shipping Information

By Sea, Air and Road
Nature: Hazardous

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

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