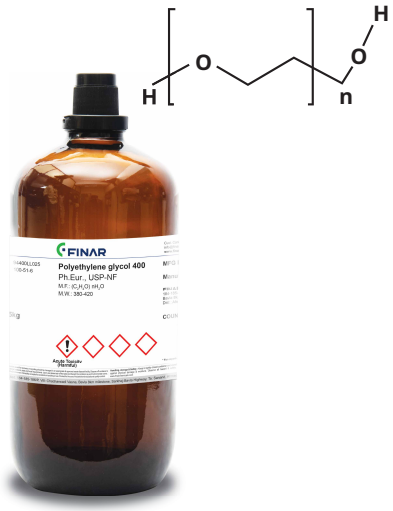
Technical Data Sheet

Polyethylene glycol 400

Ph.Eur., USP-NF



Applications

Polyethylene glycol 400 is used as solubilizing agent, solvent vehicle, ointment base, emulsion stabilizer, suspending agent and a plasticizer. Its application is in almost all dosage forms including Solid oral, Semi-solid, Topical and Parenteral formulations.

General Information

Pharmacopeia Status	:	Ph.Eur., USP-NF
CAS No.	:	25322-68-3
EC No.	:	500-038-2
Appearance/Description	:	Clear to slightly hazy, colourless or practically colourless, slightly hygroscopic, viscous liquid having a slight characteristic odour and specific gravity at 25°C of about 1.12
Molecular Formula	:	$(C_2H_4O)\ nH_2O$
Molecular Mass	:	380-420 g/mol

Marketed Formulations

- Vancomycin injection
- Busulfan injection
- Amprenavir capsule/oral solution
- Etoposide capsule and more...
- Bexarotene capsule
- Digoxin capsule

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
- Control of Hydroxyl value, Formaldehyde, Ethylene glycol & Diethylene glycol, Ethylene oxide & Dioxane

Pack Mode

- 2.5 ltr, 2.5 kg, glass bottle
- 25 kg HDPE container

Stability and Storage Conditions

Polyethylene glycol is chemically stable in air and in solution, although grades with a molecular weight less than 2000 are hygroscopic. Polyethylene glycol does not support microbial growth and does not become rancid. Polyethylene glycol and aqueous polyethylene glycol solutions can be sterilized by autoclaving, filtration, or gamma irradiation.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection is recommended.

Pharmaceutical Specifications

Description	Clear to slightly hazy, colourless or practically colourless, slightly hygroscopic, viscous liquids, having a slight, characteristic odour and a specific gravity at 25°C of about 1.12 (Ph.Eur, USP-NF)
Solubility	Miscible with water, soluble in acetone, alcohol, chloroform, ethylene glycol, monoethyl ether, ethyl acetate and toluene. Insoluble in ether, fatty oils, in mineral oils and in hexane (USP-NF, Ph.Eur)
Assay	95.0% - 105.0% (average molecular weight) (USP-NF)
Identification (by Viscosity)	To comply the test (Ph.Eur)
Identification (by Chemical test)	An abundant white, crystalline precipitate should form (Ph.Eur)
Identification by Chemical test)	The liquid phase should become blue (Ph.Eur)
Appearance of solution	The solution should be clear and not more intensely colored than reference solution BY6 (Ph.Eur)
Acidity or Alkalinity	Passes test (Ph.Eur)
Kinematic Viscosity	94 - 116 mm2.s-1 (Ph.Eur)
Dynamic Viscosity	105 - 130 mPa.s (Ph.Eur)
Hydroxyl value	264 - 300 (Ph.Eur)
Reducing substances	Passes test (Ph.Eur)
Formaldehyde	30ppm max. (Ph.Eur)
Ethylene glycol and Diethylene glycol	0.4% max. (Ph.Eur)
Ethylene glycol and Diethylene glycol	0.25% max. (Sum of ethylene glycol & diethylene glycol) (USP-NF)
Ethylene oxide	1ppm max. (Ph.Eur)
Limit of free ethylene oxide	10 µg/g max. (USP-NF)
Dioxan	10ppm max. (Ph.Eur)
Limit of 1,4-Dioxane	10 µg/g max. (USP-NF)
pH	4.5 - 7.5 (USP-NF)
Completeness and colour of solution	Passes test (USP-NF)
Viscosity	6.8 - 8.0 Centistokes (USP-NF)
Water	2.0% max. (Ph.Eur)
Sulphated ash	0.2% max. (Ph.Eur)
Residue on ignition	0.1% max. (USP-NF)
Total aerobic microbial count	NMT 100 cfu/ml
Total Yeast & mold count	NMT 10 cfu/ml
E.coli	Absent/ml
Staphylococcus aureus	Absent/ml
Pseud. aeruginosa	Absent/ml
Bile-tolerant gram negative bacteria	Absent/ml

Regulatory Information

Included in the FDA Inactive Ingredients Database (dental preparations; IM and IV injections; ophthalmic preparations; oral capsules, solutions, syrups, and tablets; rectal, topical, and vaginal preparations). Included in non-parenteral medicines licensed in the UK and the Canadian list of Acceptable Non-medicinal Ingredients.

Shipping Information

By Sea, Air and Road
Nature: Non-Hazardous

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

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