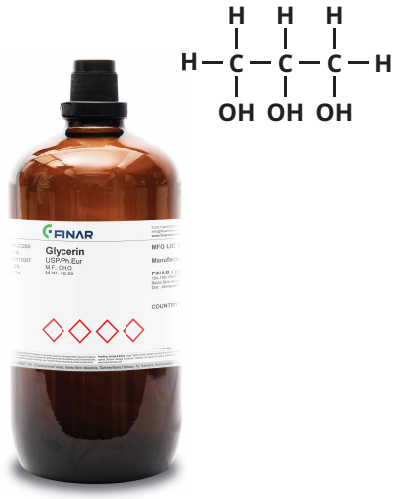
Technical Data Sheet

Glycerin (Glycerol)

IP, BP, Ph.Eur, JP, USP



Applications

Glycerin is used in a wide variety of pharmaceutical formulations including oral, otic, ophthalmic, topical and parenteral preparations. Glycerin is used as humectant, emollient, solvent, co-solvent, sweetening agent and viscosity-increasing agent. It is also used as a plasticizer and in film coatings and production of soft-gelatin capsules and gelatin suppositories.

General Information

Pharmacopeia Status	:	IP, BP, Ph.Eur., JP, USP
CAS No	:	56-81-5
EC No.	:	200-289-5
Appearance/Description	:	Syrupy liquid, unctuous to the touch, colourless or almost colourless, clear and hygroscopic.
Molecular Formula	:	$C_3 H_8 O_3$
Molecular Mass	:	92.09 g/mol

Marketed Formulations

- Ibuprofen 200 mg / phenylephrine 10 mg tablet
- Atenolol 50 mg and 100 mg tablet
- Benzonatate 100 mg tablet
- Dexamethasone injection
- Conjugated estrogens tablets & 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
- Control on Chloride (Cl), Sulphate (SO4), Iron (Fe)
- Low Benzaldehyde

Stability and Storage Conditions

Glycerin is hygroscopic. Pure glycerin is not prone to oxidation by the atmosphere under ordinary storage conditions, but it decomposes on heating with the evolution of toxic acrolein. Mixtures of glycerin with water, ethanol (95%), and propylene glycol are chemically stable.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. In the UK, the recommended long-term workplace exposure limit for glycerin mist is 10 mg/m³.

Pharmaceutical Specifications

Description	Clear, colorless, syrupy liquid, having a sweet taste. Has not more than a slight characteristic odor, which is neither harsh nor disagreeable. Is hygroscopic. Solution is neutral to litmus (USP, BP, Ph.Eur, JP, IP)
Solubility	Miscible with water, ethanol (96%), ethanol (95%) and with alcohol. Slightly soluble in acetone, insoluble in chloroform, in ether, and in fixed and volatile oils. Practically insoluble in fatty oils and in essential oils (USP, BP, Ph.Eur, JP, IP)
Assay (Anhydrous basis)	99.0% - 101.0% (USP, BP, Ph.Eur, JP, IP)
Identification (By IR)	IR spectra of the sample solution should be concomitant with the reference spectrum of glycerin (85%) (IP, BP, Ph.Eur, USP, JP)
Identification (By Refractive index, 20±0.5°C)	1.470 - 1.475 (BP, Ph.Eur, JP ,IP)
Identification (Diethylene glycol)	NMT 0.10% (USP, BP, Ph.Eur, JP)
Identification (Ethylene glycol)	NMT 0.10% (USP)
Identification (By Chemical test)	The blue color should not be diffuse into the lower layer
Identification (By GC Chromatogram)	The retention time of the glycerin peak of the sample solution corresponds to that obtained in the standard solution (USP)
	To comply the test (JP)
Identification (By Chemical test)	Irritant vapours should evolve which blackens filter paper moistened with alkaline potassium mercuric-iodide solution (IP)
	To comply the test (JP)
Identification (By Relative density)	1.258 - 1.268 (BP, Ph.Eur)
Appearance of solution	Solution is clear and colourless (JP ,IP)
Chloride (Cl)	NMT 10ppm (USP, BP, Ph.Eur, JP)
	25ppm max. (IP)
Sulphate (SO4)	NMT 20ppm (USP)
	30ppm max. (IP)
Residue on ignition	0.01% max. (USP)
Related compounds : Individual impurity	NMT 0.1% (USP)
Related substances (Any impurity with a retention time less than the retention time of glycerol)	0.1% max. (BP, Ph.Eur)
Related compounds: Total impurities	NMT 1.0% (USP)
Related substances: Total of all impurities with retention times greater than the retention time of glycerol	0.5% max. (BP, Ph.Eur)
Related substances (Any impurity)	0.1% max. (JP)
Related substances (Total impurity)	0.5% max. (JP)
Ethylene glycol, diethylene glycol and related substances	The area of any secondary peak in the chromatogram obtained with the test solution should be less than the area of the peak corresponding to diethylene glycol in the chromatogram obtained with the reference solution
Chlorinated compounds	NMT 30ppm of Cl (USP)
Halogenated compounds	35ppm max. (BP, Ph.Eur, JP)
Fatty acids and esters	NMT 1.0ml of 0.5N sodium hydroxide shall consume (USP)
Color	Color of the sample should not be darker than the color of the standard (USP)
Sugars	The solution remains blue and no precipitate should form (BP, Ph.Eur, JP, IP)
Specific gravity, 25°C	NLT 1.249 (USP)
Water	NMT 5.0% (USP)

Pharmaceutical Specifications

Water	2.0% max. (BP, Ph.Eur, JP, IP)
Appearance of solution	Clear and colorless solution (BP, Ph.Eur)
Acidity or Alkalinity	Not more than 0.2ml of 0.1M sodium hydroxide is required to change the color of the indicator to pink (BP, Ph.Eur, JP, IP)
Refractive index,20° C	1.470 - 1.475 (BP, Ph.Eur, JP)
Aldehydes	10ppm max. (BP, Ph.Eur, JP)
Aldehydes and reducing substances	Any color produce should not be more intense than that obtained in a standard preparation (IP)
Ester	Not less than 8.0 ml of 0.1M hydrochloric acid should be required to the change the colour of the indicator (BP, Ph.Eur, JP, IP)
Sulphated ash	0.01% max. (BP, Ph.Eur, JP, IP)
Heavy metals	5ppm max. (JP, IP)
Iron (Fe)	4ppm max. (IP)
Total aerobic microbial count	NMT 100 cfu/g (In-house)
Total combined yeast and molds count	NMT 10 cfu/g (In-house)
Bacterial endotoxin test	NMT 5.0 EU/g (In-house)

Regulatory Information

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (dental pastes; buccal preparations; inhalations; injections; nasal and ophthalmic preparations; oral capsules, solutions, suspensions and tablets; otic, rectal, topical, transdermal, and vaginal preparations). Included in non-parenteral and parenteral medicines licensed in the UK and in 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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