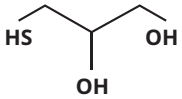
Technical Data Sheet

Monothioglycerol

IP, USP-NF, CDMF



Applications

Monothioglycerol is widely used as a pharmaceutical excipient for various Parenteral applications (i.e. Microspheres, Suspension, Solution, Lyophilized injection) as an antimicrobial preservative and an antioxidant.

General Information

Pharmacopeia Status	:	IP, USP-NF
CAS No.	:	96-27-5
EC No.	:	202-495-0
Appearance/Description	:	A colourless or pale yellow, viscous liquid, having a slight sulfidic odor. Is hygroscopic
Molecular Formula	:	$C_3H_8O_2S$
Molecular Mass	:	108.16 g/mol

Marketed Formulations

- Thiamine injection
- Diclofenac injection
- Pemetrexed injection & 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 pathogens
- Control of sub-visible particles
- Control of elemental impurities as per ICH Q3D

Pack Mode

250gm, 500gm & 1kg glass bottle

DMF (Drug Master File)

CDMF registered product (CDE # F20180001740)

Stability and Storage Conditions

Monothioglycerol is unstable in alkaline solutions. Monothioglycerol should be stored in a well-closed container in a cool and dry place.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Monothioglycerol is flammable when exposed to heat or flame; when heated to decomposition it emits toxic fumes of SOx.

Pharmaceutical Specifications

Description	A colourless or pale yellow viscous liquid, having a slight sulfidic odor and is hygroscopic (USP-NF, IP, CDMF)
Solubility	Miscible with alcohol, freely soluble in water and insoluble in ether (USP-NF, CDMF)
Specific gravity (25°C)	1.241 - 1.250 (IP, USP-NF, CDMF)
Refractive index (25°C)	1.521 - 1.526 (USP-NF, IP, CDMF)
Heavy Metals	20 ppm max. (IP)
Sulphated ash	Not more than 0.1% (IP)
pH (10% aq soln)	3.5 - 7.0 (USP-NF, IP, CDMF)
Water	NMT 5.0% (USP-NF, IP, CDMF)
Residue on ignition	NMT 0.1% (USP-NF, CDMF)
Selenium	NMT 30 µg/g (USP-NF, CDMF)
Assay (Anhydrous basis)	97.0% - 101.0% (USP-NF, IP, CDMF)
Colour of solution	The absorbance of 1% solution in water at 420nm should not be more than 0.10AU (In-house)
Clarity of solution	The % T of 1% solution in water at 650nm should not be less than 97.0% (In-house)
Total aerobic microbial count	NMT 100 cfu/ml (In-house)
Total combined yeast and molds count	NMT 10 cfu /ml (In-house)
Bacterial endotoxins	NMT 6.0 EU/ml (In-house)
E.coli	Absent/ml (In-house)
Pseud. aeruginosa	Absent/ml (In-house)
Staphylococcus aureus	Absent/ml (In-house)
Bile-tolerant gram negative bacteria	Absent/ml (In-house)
Salmonella	Absent/10ml (In-house)

Regulatory Information

Included in the FDA Inactive Ingredients Database (IM, IV and other injections) and the Canadian List of Acceptable Non-medicinal Ingredients.

Shipping Information

By Sea, Air and Road
Nature: Hazardous
UN No: UN2810
Transport Hazard class: 6.1
Packing group: II

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

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