



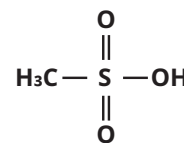
Methane Sulphonic Acid

HP, CDMF, USDMF

Applications

Methane Sulphonic Acid is widely used in the pharmaceutical industry.

- Buffering agents
- pH Modifier
- Stabilizing agent
- Intermediate in preparation of API



General Information

Pharmacopeia Status	: In-house product
CAS No.	: 75-75-2
EC No.	: 200-898-6
Appearance/Description	: Clear colourless to pale yellow, pale brown or pale brownish yellow clear liquid
Molecular Formula	: CH ₄ O ₃ S
Molecular Mass	: 96.10 g/mol

Marketed Formulation

- Dihydroergotamine injection
- Ziprasidone mesylate injection and 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

Pack Mode

- 500 gm glass bottle

DMF (Drug Master File)

- USDMF registered product (DMF # 32834)
- CDMF registered product (CDE # F20190000136)

Stability and Storage Conditions

Store in a segregated and approved area which is cool and well-ventilated. Keep container tightly closed and sealed until ready for use. Avoid all possible sources of ignition.

Safety and Handling Information

Keep container dry. Do not ingest or inhale the gas / fumes or vapour. Do not add water to the product. In case of insufficient ventilation always wear suitable respiratory equipment. If ingested, seek medical advice immediately. Avoid contact with skin and eyes.

Product Specifications (In-house)

Description	Clear colourless to pale yellow, pale brown or pale brownish yellow clear liquid
Solubility	Miscible with water, slightly soluble in toluene, practically insoluble in hexane
Identification A (By IR)	IR absorption spectrum of the test preparation should exhibit the maxima only at the same wave number as that of the standard preparation of Methane Sulphonic Acid
Assay	98.0% - 102.0%
Sulphate (SO ₄)	50ppm max
Chloride (Cl)	10ppm max
Residue on ignition	0.1% max
Density, 20°C	1.478 - 1.482
Cadmium (Cd)	0.2ppm max
Lead (Pb)	0.5ppm max
Arsenic (As)	1.5ppm max
Mercury (Hg)	3.0ppm max
Bacterial endotoxins test	0.5 EU/mg max
Total aerobic microbial count	100 CFU/ml max
Total combined yeast and molds count	100 CFU/ml max

Shipping Information

By Sea, Air and Road

Nature: Hazardous

UN Number: 3265

Class: 8

Packaging group: II

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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