Technical Data Sheet

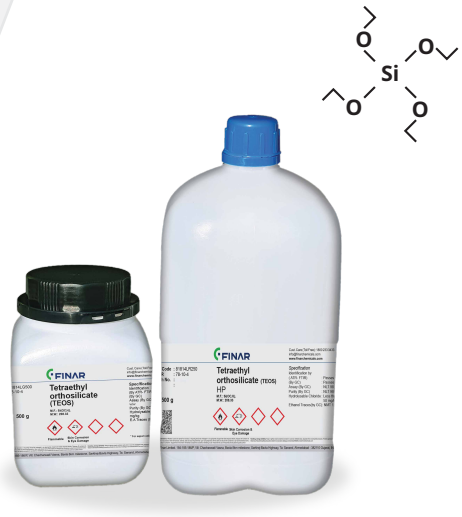
Tetraethyl Orthosilicate

HP, USDMF

Applications

Tetraethyl Orthosilicate is widely used in the pharmaceutical industry and specially for application in Topical products (i.e. Transdermal patches). Following are few of the major applications,

- Cross linking agent
- Release controlling polymer
- Use as a precursor to prepare silica xerogel (which is used as a drug carrier in NDDS formulations)



General Information

Pharmacopeia Status	:	In-house product
CAS No.	:	78-10-4
EC No.	:	201-083-8
Appearance / Description	:	Clear colorless liquid
Molecular Formula	:	Si-$C_8H_{20}O_4$
Molecular Mass	:	208.33g/mol

Marketed Formulation

Multiple formulations are under R&D stage

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
- High purity
- Low alcohol content

Pack Mode

500 gm, 2.5 Kg in HDPE container

DMF (Drug Master File)

USDMF registered product (DMF # 034762)

Stability and Storage Conditions

Stable under recommended conditions. Storage should be in accordance with all current regulations and standards. Keep container tightly closed in a cool & dry area under inert atmosphere. Keep away from incompatible substances.

Safety and Handling Information

Handling of the product should be in accordance with all current regulations and standards Use spark-proof tools and explosion-proof equipment. Avoid breathing dust, vapour, mist or gas. Avoid contact with skin, eyes and take precautionary measures against static discharges.

Product Specifications (In-house)

Appearance	Clear colorless liquid
Identification by (ATR – FTIR)	Infrared spectrum of test preparation should be concurrent with that of the TEOS reference standard or working standard preparation
Identification (By GC)	The retention time of the main peak of the sample solution corresponds to that of the reference solution and exhibit only one major peak corresponding to TEOS
Assay (By GC)	Not less than 98.0% w/w
Purity (By GC)	Not less than 98.0%
Hydrolysable Chloride	Less than 50 mg/kg
Ethanol Traces (by GC)	Not more than 1.0%

Shipping Information

By Sea, Air and Road
Nature: Hazardous
UN Number: 1292
Class: 3
Packaging group: III

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

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