



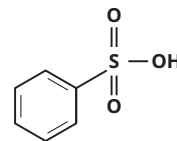
Benzene Sulphonic Acid

HP, CDMF, USDMF

Applications

Benzene Sulphonic Acid is widely used in the pharmaceutical industry. Following is a list of key applications.

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



General Information

Pharmacopeia Status	: In-house product
CAS No.	: 98-11-3
EC No.	: 202-638-7
Appearance/Description	: Off-white to white waxy crystalline solid
Molecular Formula	: C ₆ H ₆ O ₃ S
Molecular Mass	: 158.18 g/mol

Marketed Formulation

- Cisatracurium Besilate injection
- Atracurium Besilate injection and more...

Quality and Regulatory Support

- GMP and ISO certification
- EXCI PACT 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
- Control of residual solvent

Pack Mode

100 gm and 500 gm in HDPE containers

DMF (Drug Master File)

- USDMF registered product (DMF # 30281)
- CDMF registered product (CDE # F20180001463)

Stability and Storage Conditions

Keep container tightly closed in a cool (between 15°C–25°C), dry and well-ventilated place. Store under inert gas.

Safety and Handling Information

Wear personal protective equipment/face protection. Do not get in eyes, skin or on clothing. Use only under a chemical fume hood. Do not inhale or ingest. If swallowed, seek immediate medical assistance.

Product Specifications (In-house)

Description	Off-white to white waxy crystalline solid
Solubility	Soluble in water & alcohol
Identification by IR	To comply the test
Melting point	59°C - 61°C
Chloride (Cl)	Not more than 0.05%
Moisture	1.0% max
Assay (HPLC)	Min. 98.0% (Anhydrous basis)
Residue on ignition	0.1% max
Organic impurities; Diphenyl sulfone	Not more than 2.0%
Organic impurities; Total impurities	Not more than 2.0%
Iron (Fe)	0.002% max
Arsenic (As)	0.15ppm max
Lead (Pb)	0.5ppm max
Mercury (Hg)	0.15ppm max
Cadmium (Cd)	0.2ppm max
Total aerobic microbial count	100 cfu/gm max
Total combined yeast and molds count	10 cfu/gm max
E.coli	Absent/gm
Salmonella	Absent/10 gm
Staphylococcus aureus	Absent/gm
Pseud. aeruginosa	Absent/gm
Bile-tolerant gram negative bacteria	Absent/gm
Bacterial endotoxins	2.5 EU/mg max
Cyclohexane as residual solvent	2000ppm max
Benzene	2ppm max

Shipping Information

By Sea, Air and Road

Nature: Hazardous

UN Number: 3261

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.

For more information contact : deepaklodhiya@finarchemicals.com

Finar Limited

CORPORATE OFFICE & WORKS

184-185-186/P, Vill:Chacharwadi Vasna, Bavla 8km milestone, Sarkhej

Bavla Highway, Sanand, Ahmedabad - 382110. Gujarat, INDIA.

t: +91-2717-616717 | e: sales@finarchemicals.com

www.finarchemicals.com

Chemistry is our
**passion &
innovation**
our commitment !