

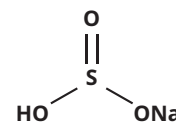


# Sodium bisulfite (Bisulphite)

JP

## Applications

Sodium bisulfite (Bisulphite) is used in the pharmaceutical industry as an antioxidant and a preservative. Its application is spread across Solid oral, Semi-solid, Topical and Parenteral formulations.



## General Information

Pharmacopeia Status	: JP
CAS No.	: 7631-90-5
EC No.	: 231-548-0
Appearance/Description	: White granules or powder, having the odour of sulfur dioxide
Molecular Formula	: NaHSO <sub>3</sub>
Molecular Mass	: 104.06 g/mol

## Marketed Formulation

Epinephrine 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 pathogens
- Control of elemental impurities as per ICH Q3D

## Pack Mode

500 gm, 1 kg, 5 kg plastic container

## Stability and Storage Conditions

The bulk material should be stored in a well-closed container, protected from light, in a cool & dry place.

## Safety and Handling Information

Use personal protective equipment and ensure adequate ventilation. Avoid dust formation. Should not be released into the environment

## Pharmaceutical Specifications

Description	White granules or powder, having the odour of sulfur dioxide (JP)
Solubility	Freely soluble in water, practically insoluble in ethanol and in ether (JP)
Identification A (By Chemical test)	Gives positive test for sodium (JP)
Identification B (By Chemical test)	Gives positive test for bisulfite (JP)
Clarity and colour of solution	The solution is clear and colorless (JP)
Thiosulfate (S <sub>2</sub> O <sub>3</sub> )	No turbidity is produced (JP)
Heavy metals	NMT 20ppm (JP)
Iron (Fe)	NMT 20ppm (JP)
Arsenic (As)	NMT 4ppm (JP)
Assay	NLT 64.0% and NMT 67.4% of SO <sub>2</sub> (JP)
Total aerobic microbial count	NMT 100 cfu/g (In-house)
Total combined yeast and molds count	NMT 100 cfu/g (In-house)
Pseud. aeruginosa	Absent/g (In-house)
Staphylococcus aureus	Absent/g (In-house)
E.coli	Absent/g (In-house)
Bile-tolerant gram negative bacteria	Absent/g (In-house)
Salmonella	Absent/10g (In-house)
Candida albicans	Absent/g (In-house)
Bacterial endotoxin test	NMT 6.0 EU/g (In-house)

## Shipping Information

### By Sea, Air and Road

Nature: Non-Hazardous

See the Material Safety Data Sheet on [www.finarchemicals.com](http://www.finarchemicals.com)

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our commitment !