

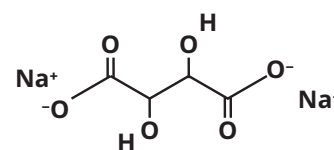


Sodium Tartrate

USP-NF

Applications

Sodium tartrate is used as pH Modifier/Buffering agent in pharmaceutical formulations. It is used in Injectable and Solid oral preparations.



General Information

| | |
|------------------------|---|
| Pharmacopeia Status | : USP-NF |
| CAS No. | : 6106-24-7 |
| EC No. | : 212-773-3 |
| Appearance/Description | : White, hard, odorless fragments or granules. Is deliquescent. |
| Molecular Formula | : C ₄ H ₄ O ₆ Na ₂ ·2H ₂ O |
| Molecular Mass | : 230.08 g/mol |

Marketed Formulation

Methylergonovine maleate 0.2mg/mL 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

Pack Mode

500 gm, 5 kg HDPE container

Stability and Storage Conditions

Keep away from heat and source of ignition. Evaporate the residue under a fume hood as empty containers pose a fire risk. Do not breathe dust.

Safety and Handling Information

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume, or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Pharmaceutical Specifications

| | |
|--------------------------------------|--|
| Description | Transparent, colorless, odourless crystals (USP-NF) |
| Solubility | Freely soluble in water; insoluble in alcohol (USP-NF) |
| Identification A (Sodium) | A dense precipitate should form (USP-NF) |
| Identification B (Tartrate) | Reddish pink color should produce within 15 min (USP-NF) |
| Assay (on dried basis) | 99.0%-100.5% (USP-NF) |
| pH (10% aq soln) | 7 – 9 (USP-NF) |
| Loss on drying, 150°C for 3 Hr. | 14.0% - 17.0% w/w (USP-NF) |
| Total aerobic microbial count | NMT 100 cfu/gm (In-house) |
| Total combined yeast and molds count | NMT 10 cfu/gm (In-house) |
| Bacterial endotoxins | NMT 2.5 EU/gm (In-house) |

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

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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