



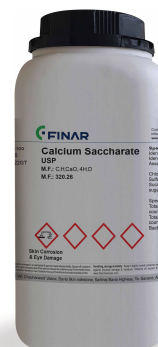
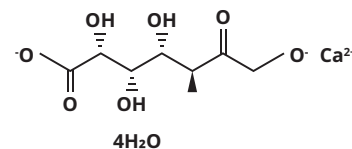
Technical Data Sheet

Calcium D-Saccharate Tetrahydrate

USP, CDMF

Applications

Calcium D-Saccharate Tetrahydrate is a commonly used excipient as a stabilizer and the preferred route of application is through Solid oral and Parenteral dosage forms.



General Information

| | |
|------------------------|--|
| Pharmacopeia Status | : USP |
| CAS No. | : 5793-89-5 |
| EC No. | : 227-334-1 |
| Appearance/Description | : White, odorless, tasteless crystalline powder |
| Molecular Formula | : C ₆ H ₈ CaO ₈ · 4H ₂ O |
| Molecular Mass | : 320.26 g/mol |

Marketed Formulation

- Calcium gluconate injection
- Calcium carb + calcium gluconate 500 mg + Vitamin D2 200 unit tablet & 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
- Control of Chlorides (Cl) & Sulphate (SO₄)

Pack Mode

100 gm, 1 kg, 5 kg plastic container

DMF (Drug Master File)

CDMF registration product (CDE # F2020000092)

Stability and Storage Conditions

Keep container tightly closed in a dry and well-ventilated cool place. Storage class (TRGS 510): 13: Non-Combustible Solids.

Safety and Handling Information

Wear protective clothing and avoid contact with skin and eye. Wash hands thoroughly after handling. Provide adequate ventilation. Avoid generation and spreading of dust.

Pharmaceutical Specifications

| | |
|-------------------------------|---|
| Description | White, odorless, tasteless crystalline powder (USP) |
| Solubility | Soluble in dilute mineral acids; slightly soluble in boiling water; practically insoluble in alcohol, in cold water, in ether and in chloroform |
| Identification A (Calcium) | A white precipitate, which is insoluble in 6N acetic acid but soluble in hydrochloric acid should form (USP) |
| Identification B (By IR) | IR spectra of the sample should be concomitant with IR spectra of the corresponding standard (USP) |
| Assay | 98.5% w/w - 102.0% w/w (USP) |
| Chloride (Cl) | NMT 0.07% (USP) |
| Sulfate | NMT 0.12% (USP) |
| Sucrose and reducing sugars | No red precipitate should form immediately (USP) |
| Optical Rotation | +18.5° to + 22.5° (USP) |
| Total aerobic microbial count | NMT 1000 cfu/g max (In-house) |
| Total Yeast and mold count | NMT 100 cfu/g max (In-house) |
| Bacterial endotoxins | NMT 5 EU/g (In-house) |

Shipping Information

By Sea, Air and Road

Nature: Non Hazardous

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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