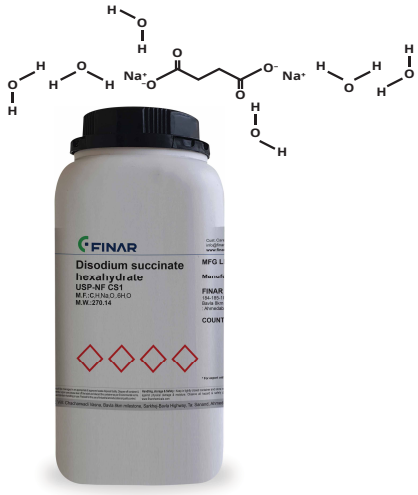
Technical Data Sheet

Disodium succinate hexahydrate

USP-NF, HP, CDMF



Applications

Disodium Succinate hexahydrate is used as pH modifier/Buffering agent in Parenteral, Semisolid and Solid oral preparations in pharmaceutical formulations.

General Information

Pharmacopeia Status	: USP-NF
CAS No.	: 6106-21-4
EC No.	: 205-778-7
Appearance/Description	: White crystals/crystalline powder
Molecular Formula	: $C_4H_{16}Na_2O_{10}$
Molecular Mass	: 270.14 g/mol

Marketed Formulation

Amphoterecin B 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 on Pathogens
- Control on Chloride (Cl), Sulphate (SO4), Phosphate (PO4), Nitrogen (N)

Pack Mode

500 gm, 1 kg plastic containers

DMF (Drug Master File)

- US DMF registered product (DMF # 31178)
- CDMF registered product (CDE # F20200000141)

Stability and Storage Conditions

Keep container dry. Keep container tightly closed in a well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.

Safety and Handling Information

Keep away from heat and sources of ignition. Evaporate the residue under a fume hood as empty containers pose a fire risk. Do not breathe dust and avoid contact with the eyes. Wear suitable protective clothing in case of insufficient ventilation and wear suitable respiratory equipment. If you feel unwell, seek medical attention.

Pharmaceutical Specifications

Appearance/Description	White crystals/crystalline powder (USP-NF/In- house)
Solubility	Freely soluble in water (USP-NF)
Identification A (By IR)	IR spectra of the sample should be concomitant with the IR spectra of the respective standard (USP-NF /In-house)
Identification B (By Chromatographic identity)	The retention time of the major peak of the sample solution corresponds to that of the standard solution (USP-NF)
Identification C (for Sodium)	Dense white precipitate should form (USP-NF /In-house)
Assay (by HPLC on dried basis)	98.0% - 102.0% (USP-NF)
Limit of Sodium Acetate	NMT 0.2% (USP-NF)
Limit of Sodium Maleate	NMT 0.1% (USP-NF)
Limit of Sodium Fumarate	NMT 0.1% (USP-NF)
Acidity & alkalinity	7.0 - 9.0 (USP-NF)
Acidity & alkalinity /PH	7.5 - 9.0 (In-house)
Loss on drying,120°C	37.0% to 41.0% (USP-NF /In-house)
Chloride (Cl)	0.005% max. (In-house)
Sulphate (SO4)	0.01% max. (In-house)
Phosphate (PO4)	0.001% max. (In-house)
Nitrogen (N)	0.001% max. (In-house)
Arsenic (As)	1.5ppm max. (In-house)
Cadmium (Cd)	0.2ppm max. (In-house)
Lead (pb)	0.5ppm max. (In-house)
Mercury (Hg)	0.3ppm max. (In-house)
Calcium (Ca)	0.005% max. (In-house)
Copper (Cu)	0.0005% max. (In-house)
Iron (Fe)	0.002% max. (In-house)
Potassium (K)	0.05% max. (In-house)
Nickel (Ni)	2ppm max. (In-house)
UV absorbance profile (10mm cell) @260nm	0.08 max. (In-house)
UV absorbance profile (10mm cell) @280nm	0.045 max. (In-house)
Total aerobic microbial count (Bioburden)	NMT 100 CFU/gm (In-house)
Total combined yeasts and moulds count (Bioburden)	NMT 50 CFU/gm (In-house)
E.coli	Absent/gm (In-house)
Salmonella	Absent/10gm (In-house)
Pseud. aeruginosa	Absent/gm (In-house)
Staphylococcus aureus	Absent/gm (In-house)
Bile-tolerant gram negative bacteria	Absent/gm (In-house)
Bacterial endotoxins	NMT 6 EU/gm (In-house)

Shipping Information

By Sea, Air and Road
Nature: Non Hazardous

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

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