



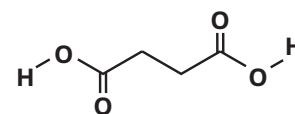
Succinic Acid

USP-NF

Applications

Succinic acid is used as pH modifier in pharmaceutical formulations.

It is used in Parenteral and Solid oral formulations.



General Information

Pharmacopeia Status	: USP-NF
CAS No.	: 110-15-6
EC No.	: 203-740-4
Appearance/Description	: White, odorless crystals.
Molecular Formula	: C ₄ H ₆ O ₄
Molecular Mass	: 118.09 g/mol

Marketed Formulation

- Ciprofloxacin extended release 500 mg tablets
- Ibuprofen (Chewable) 100 mg tablets
- Methylphenidate hydrochloride extended-Release 27 mg tablets 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

Pack Mode

500 gm, 50 kg HDPE containers

Stability and Storage Conditions

The product is chemically stable under standard ambient conditions (room temperature). Keep containers tightly closed in a dry, cool and well-ventilated place.

Safety and Handling Information

Wear personal protective equipment and avoid contact with eyes, skin or clothing. Ensure adequate ventilation. Avoid ingestion and inhalation. Avoid dust formation.

Pharmaceutical Specifications

Description	White, odorless crystals (USP-NF)
Solubility	Soluble in water, in alcohol, and in Glycerine, freely soluble in boiling water (USP-NF)
Identification A (By IR)	IR spectra of the sample should be concomitant with IR spectra of the standard (USP-NF)
Identification B (By Chromatographic identity)	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay (USP-NF)
Assay	99.0% - 100.5% (USP-NF)
Residue on ignition	NMT 0.025% (USP-NF)
Melting range	185.0°C - 190.0°C (USP-NF)
Total aerobic microbial count	NMT 100 cfu/g (In-house)
Total Yeast and mold count	NMT 10 cfu/g (In-house)
Bacterial endotoxin test	NMT 2.5 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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