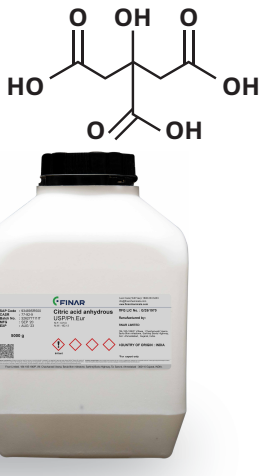
Technical Data Sheet

Citric acid anhydrous

IP, Ph.Eur., USP



Applications

Citric acid anhydrous is a commonly used excipient as an antioxidant and pH modifier. The preferred route of application is through Solid oral, Semi-solid, Topical and Parenteral dosage forms.

General Information

Pharmacopeia Status	:	IP, Ph.Eur., USP
CAS No.	:	77-92-9
EC No.	:	201-069-1
Appearance/Description	:	Colorless, translucent crystals or white, granular to fine crystalline powder
Molecular Formula	:	$C_6H_8O_7$
Molecular Mass	:	192.13 g/mol

Marketed Formulation

- Risperidone injection
- Dexamethasone injection
- Paliperidone palmitate injection
- Buprenorphine Hydrochloride (Sublingual) 8 mg tablets
- Ezetimibe, Simvastatin 10 mg/20 mg tablets & many more
- Paclitaxel injection
- Alendronate tablets

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
- Control on Chloride (Cl), Sulphate (SO4), Iron (Fe), Calcium (Ca), Oxalic acid

Pack Mode

500 gm, 5 kg, 25 kg plastic container

Stability and Storage Conditions

Keep container tightly closed in a dry and well-ventilated place.

Safety and Handling Information

Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

Pharmaceutical Specifications

Description	Colourless translucent crystals or a white granular to fine powder; slightly hygroscopic in moist air. Melts at about 153°, with decomposition (USP, IP ,Ph.Eur)
Assay (Anhydrous basis)	Not less than 99.0% and Not more than 101.0% (IP)
	99.5%-100.5% (USP, Ph.Eur)
Solubility	Very soluble in water, freely soluble in alcohol, ethanol (95%), ethanol (96%) sparingly soluble in ether (IP, USP, Ph.Eur)
Melting point	About 153°C, with decomposition (Ph.Eur)
Identification (By IR)	IR spectra of the sample should be concomitant with IR spectra of the standard (USP, IP, Ph.Eur)
Identification (By Chemical test)	The solution should be strongly acidic (Ph.Eur ,IP)
	It gives reaction (A) of citrates (IP)
	A red color should develop (Ph.Eur)
	A white precipitate should form (Ph.Eur)
Identification (By Water)	1.0% max (Ph.Eur)
Appearance of Solution	The solution is clear and not more intensely coloured than reference solution YS7, BYS7 or GY7 (IP, Ph.Eur)
Residue on ignition/Sulphated ash	Not more than 0.1% (USP, IP, Ph.Eur)
Arsenic (As)	1ppm max. (IP)
Barium (Ba)	Any opalescence produced is not more intense than that of mixture of 5ml of solution A and 5ml of distilled water (IP)
Calcium (Ca)	200ppm max. (IP)
Heavy metals	10ppm max. (IP)
Iron (Fe)	50ppm max. (IP)
Chlorides	50ppm max. (IP)
Sulphate (SO4)	150ppm max. (IP, USP, Ph.Eur)
Oxalic acid	Any pink colour produced is not more intense than that produced by carrying out the test using 0.2mg of oxalic acid dissolved in 4ml of water (IP)
Limit of oxalic acid	0.036% max. (USP, Ph.Eur)
Readily carbonizable substances	Any colour produced is not more intense than that of a mixture of 1.0 ml of CCS and 9.0 ml of FCS (USP, Ph.Eur)
Clarity of solution	The sample solution should show the same clarity as that of water or its opalescence should not be more pronounce than standard suspension (USP)
Colour of solution	The sample solution should not more intensely colored than standard solutions (USP)
Water	Not more than 1.0% (IP, USP, Ph.Eur)
Total aerobic microbial count	NMT 100 cfu/gm max. (In-house)
Total combined yeast & molds count	NMT 10 cfu/gm max. (In-house)
E.coli	Absent/g (In-house)
Pseud. aeruginosa	Absent/g (In-house)
Staphylococcus aureus	Absent/g (In-house)
Bile-tolerant gram negative bacteria	Absent/g (In-house)
Bacterial endotoxins	NMT 0.5 EU/mg max. (In-house)

Regulatory Information

GRAS listed. The anhydrous form is accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (inhalations; IM, IV, and other injections; ophthalmic preparations; oral capsules, solutions, suspensions, and tablets; topical and vaginal preparations), non-parenteral and parenteral medicines licensed in Japan and the UK and in the Canadian List of Acceptable Non-medicinal Ingredients.

Shipping Information

By Sea, Air and Road
Nature: Non Hazardous

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

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