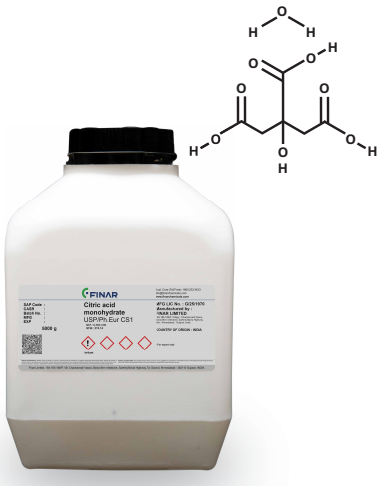
Technical Data Sheet

Citric acid monohydrate

IP, BP, Ph.Eur, USP



Applications

Citric acid is widely used in pharmaceutical formulations to adjust the pH of solutions and injections. It has also been used experimentally to adjust the pH of tablet matrices in enteric-coated formulations for colon-specific drug delivery. Citric acid monohydrate is used in the preparation of effervescent granules and tablets. Citric acid has also been shown to improve the stability of spray-dried insulin powder in inhalation formulations.

General Information

Pharmacopeia Status	: IP, BP, Ph.Eur., USP
CAS No.	: 5949-29-1
EC No.	: 201-069-1
Appearance/Description	: Colourless, translucent crystals or white granular to fine crystalline powder. Efflorescent in dry air.
Molecular Formula	: $C_6 H_8 O_7 . H_2 O$
Molecular Mass	: 210.14 g/mol

Marketed Formulation

- Bupropion hydrochloride extended-release (XL) 150 mg tablets
- Calcium carbonate antacid (Chewable) 500 mg tablets
- Simvastatin 10 mg tablets
- Tri-Buffered aspirin 325 mg 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 elemental impurities as per ICH Q3D
- Control of Chloride (Cl), Calcium (Ca), Sulphate (SO4), Oxalic acid
- Control of Particle size (Min. 80% of the material should passes through # 40)

Pack Mode

500 gm, 5 kg, 25 kg HDPE container

Stability and Storage Conditions

Citric acid monohydrate loses water of crystallization in dry air or when heated to about 40°C. It is slightly deliquescent in moist air. Dilute aqueous solutions of citric acid may ferment on standing. The material should be stored in an airtight container in a cool & dry place.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Direct contact with eyes can cause serious damage. Citric acid should be handled in a well-ventilated environment or a dust mask should be worn. It is combustible.

Pharmaceutical Specifications

Description/Appearance	Colourless crystals or a white, crystalline powder; slightly efflorescent in warm, dry air (IP, BP, Ph.Eur, USP)
Solubility	Very soluble in water, freely soluble in ethanol, Sparingly soluble in ether (IP, BP, Ph.Eur ,USP)
Identification A	To Comply the test (IP, USP)
	The solution is strongly acidic (BP, Ph.Eur)
Identification B	It gives reaction (A) of citrates (IP)
	IR spectra of the sample should be concomitant with IR spectra of the standard (BP, Ph.Eur)
Identification C	A 10.0% w/v solution is strongly acidic (IP)
	A red colour develops (BP, Ph.Eur)
Identification D (By Chemical test)	A white precipitate is formed (BP, Ph.Eur)
Identification E (By Water)	7.5% to 9.0% (BP, Ph.Eur)
Appearance of Solution	The solution is clear and not more intensely coloured than reference solution YS7, BYS7 or GYS7 (IP, BP, 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 (IP)
Chlorides	50ppm (IP)
Sulphate (SO4)	150ppm (IP,BP, Ph.Eur)
	0.015% max (USP)
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)
Readily carbonizable substances	Any colour produced is not more intensely coloured than a mixture of 1ml of red primary solution and 9ml of yellow primary solution (BP, Ph.Eur)
	Any colour produced is not more intense than that of a mixture of 1.0 ml of CCS and 9.0 ml of FCS (IP)
	The color of the acid is not darker than that of a similar volume of matching fluid K (USP)
Sulphated ash	Not more than 0.1% (IP)
Residue on ignition	Not more than 0.1% (USP)
Water	7.5% to 9.0% (IP, BP, Ph.Eur, USP)
Clarity of solution	The sample solution shows the same clarity as that of water or its opalescence is not more pronounced than standard suspension A (USP)
	The sample solution is not more intensely colored than water or standard solutions A, B and C (USP)
Assay (Anhydrous basis)	99.50%-100.50% (BP, Ph.Eur, USP, IP)
Bacterial endotoxin test	NMT 0.5 EU/mg (In-house)
Particle size	Min. 80% of the material should passes through # 40 (In-house)

Regulatory Information

GRAS listed. Included in non-parenteral and parenteral medicines licensed in Japan and the UK. Included 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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