



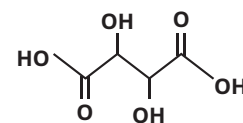
## Technical Data Sheet

# Tartaric acid

IP, Ph.Eur., USP-NF

### Applications

Tartaric acid is a commonly used excipient as a stabilizer and effervescent agent. The preferred route of application is through Solid oral and Parenteral dosage forms.



### General Information

Pharmacopeia Status	: IP, Ph.Eur., USP-NF
CAS No.	: 87-69-4
EC No.	: 201-766-0
Appearance/Description	: Colorless or translucent crystals or white, fine granular, crystalline powder. Is odorless and stable in air
Molecular Formula	: C <sub>4</sub> H <sub>6</sub> O <sub>6</sub>
Molecular Mass	: 150.09 g/mol

### Marketed Formulations

- Epinephrine injection
- Paracetamol effervescent tablets & many more

### Quality and Regulatory Support

- GMP and ISO certification
- EXCI PACT 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
- Control of elemental impurities as per ICH Q3D.
- Control of Chloride (Cl) & Sulphate (SO<sub>4</sub>), Calcium (Ca), and Oxalate

### Pack Mode

500 gm, 5 kg, 25 kg plastic container

### DMF (Drug Master File)

CDMF registered product (CDE # F20200000007)

### Stability and Storage Conditions

The material is stable and should be stored in a well-closed container in a cool & dry place.

### Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Tartaric acid may be an irritant to the eyes; eye protection and rubber or plastic gloves are recommended. When heated to decomposition, tartaric acid emits acid smoke and fumes.

## Pharmaceutical Specifications

Description	Colourless or translucent crystals or a white or almost white crystalline powder. It is odorless and stable in air (IP, Ph.Eur, USP-NF)
Solubility	Very soluble in water, freely soluble in ethanol (95%) and alcohol (IP, Ph.Eur, USP-NF)
Assay (Dried substance)	99.5% - 101.0% (Ph.Eur) 99.7% - 100.5% (USP-NF)
Identification (By Chemical test)	On ignition gradually decomposes giving off an odour resembling that of burnt sugar (IP) Solution should be strongly acidic (Ph.Eur) A reddish pink color should produce within 15 min (USP-NF) Solution should be strongly acidic (IP) Should give reactions of tartrates (Ph.Eur)
Identification (By IR)	IR spectra of the sample should be concomitant with IR spectra of the standard (USP-NF)
Residue on ignition	NMT 0.1% (USP-NF)
Identification (Tartrate A)	After charring, when ignited carbon monoxide which burns with blue flame should evolve (IP)
Identification (Tartrate B)	An intense blue colour should produce. (IP)
Appearance of solution	Solution should be clear, and not more intensely coloured than reference solution YS6 (IP, Ph.Eur)
Specific optical rotation	+12.0° to +12.8° (IP, Ph.Eur, USP-NF)
Arsenic (As)	NMT 2ppm (IP)
Heavy metals	NMT 10ppm (IP)
Chlorides	NMT 125ppm (IP)
Chlorides	NMT 100ppm (Ph.Eur)
Sulphate (SO <sub>4</sub> )	NMT 150ppm (IP, Ph.Eur)
Calcium (Ca)	NMT 200ppm (Ph.Eur)
Oxalate	No opalescence should produce within 20 minutes (IP)
Oxalic acid	NMT 350ppm (Ph.Eur)
Limit of Oxalate	No turbidity should produce (USP-NF)
Sulphated ash	NMT 0.1% (IP, Ph.Eur)
Loss on drying	NMT 0.2% (IP, Ph.Eur, USP-NF)

## Regulatory Information

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (IM and IV injections; oral solutions, syrups and tablets; sublingual tablets; topical films; rectal and vaginal preparations). Included in non-parenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

See the Material Safety Data Sheet on [www.finarchemicals.com](http://www.finarchemicals.com)

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## Shipping Information

### By Sea, Air and Road

Nature: Hazardous

## Finar Limited

### CORPORATE OFFICE & WORKS

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**passion &  
innovation**  
our commitment !