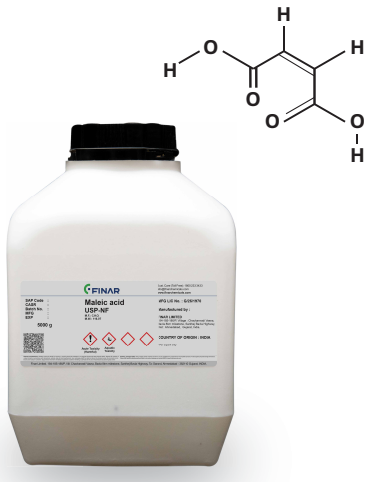
Technical Data Sheet

Maleic acid

BP, Ph.Eur., USP-NF



Applications

Maleic acid is used in the pharmaceutical industry as a pH modifier and a Buffering agent. It is mainly used for Solid oral preparations.

General Information

Pharmacopeia Status	:	BP, Ph.Eur., USP-NF
CAS No.	:	110-16-7
EC No.	:	203-742-5
Appearance/Description	:	A white or almost white, crystalline powder.
Molecular Formula	:	$C_4H_4O_4$
Molecular Mass	:	116.10 g/mol

Marketed Formulation

- Bromocriptine mesylate 2.5 mg tablets
- Enalapril maleate 2.5 mg tablets
- Enalapril maleate and hydrochlorothiazide 10 mg / 25 mg tablet 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
- Control of Iron (Fe)

Pack Mode

1 kg, 5 kg HDPE containers

Stability and Storage Conditions

Maleic acid is combustible when exposed to heat or flame and should be stored in airtight glass containers and protected from light. It is recommended not to store it above 25 °C.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of the material handled. Maleic acid is considered very hazardous in the case of eye contact, which can result in corneal damage. It is also hazardous with respect to skin contact and inhalation. Skin contact can produce inflammation and blistering, with the amount of tissue damage dependent on the length of contact. Gloves, eye protection, and approved or certified respirators should be employed.

Pharmaceutical Specifications

Description	A white or almost white, crystalline powder (BP, Ph.Eur, USP-NF)
Solubility	Freely soluble in water and in alcohol, sparingly soluble in ether (BP, Ph.Eur, USP-NF)
Identification A (By pH)	The pH of the solution should be less than 2 (BP, Ph.Eur)
Identification A (By IR)	IR Spectra of the sample should be concomitant with IR spectra of the standard (USP-NF)
Identification B (By TLC test)	The principal spot in the chromatogram obtained with test solution (b) should be similar in position and size to the principal spot in the chromatogram obtained with reference solution (a) (BP, Ph.Eur)
Identification B (By Assay)	The retention time of the maleic acid peak of the sample solution corresponds to that of the standard solution, as obtained in the assay (USP-NF)
Identification C (By Chemical test)	A violet-pink colour should develop (BP, Ph.Eur)
Appearance of solution	Solution should be clear and not more intensely coloured then reference solution Y7 (BP, Ph.Eur)
Fumaric acid	NMT 1.5% (BP, Ph.Eur)
Limit of Fumaric acid	NMT 1.0% (USP-NF)
Iron (Fe)	NMT 5ppm (BP, Ph.Eur, USP-NF)
Limit of Malic acid	NMT 0.5% (USP-NF)
Sulfated ash	NMT 0.1% (BP, Ph.Eur)
Residue on ignition	NMT 0.1% (USP-NF)
Water	NMT 2.0% (BP, Ph.Eur)
Water (By KF)	NMT 0.5% (USP-NF)
Assay (anhydrous basis)	99.0% - 101.0% on anhydrous basis (BP, Ph.Eur, USP-NF)

Regulatory Information

Included in the FDA Inactive Ingredients Database (IM and IV injections; oral tablets and capsules; topical applications). Included in non-parenteral and parenteral medicines licensed in the UK.

Shipping Information

By Sea, Air and Road
Nature: Hazardous
UN No: UN2215
Transport Hazard class: 8
Packing group: III

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

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