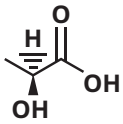
Technical Data Sheet

L -(+) -Lactic Acid

IP, BP, Ph.Eur., JP, USP



Applications

Lactic acid is widely used excipient in pharmaceutical industry for topical, solid orals, aerosol and parenteral preparations. It is mainly used as pH modifier, preservative agent or acidulants.

General Information

Pharmacopeia Status	:	IP, BP, Ph.Eur., JP, USP
CAS No.	:	79-33-4
EC No.	:	201-196-2
Appearance/Description	:	Colorless or yellowish, practically odorless, syrupy liquid.
Molecular Formula	:	$C_3H_6O_3$
Molecular Mass	:	90.08 g/mol

Pack Mode

- 500 ml, 2.5 Litre, 2.5 kg glass bottle
- 25 Litre, 25 kg HDPE container

Marketed Formulation

- Irinotecan hydrochlorine injection
- Sodium lactate injection & many 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 sub-visible particles
- Control of elemental impurities as per ICH Q3D
- Control on Chloride (Cl), Sulphate (SO4), Iron (Fe), Calcium (Ca)
- Control of Residual solvent

Stability and Storage Conditions

Lactic acid is hygroscopic and will form condensation products such as polylactic acids on contact with water. The equilibrium between the polylactic acids and lactic acid is dependent on concentration and temperature. At elevated temperatures lactic acid will form lactide, which is readily hydrolyzed back to lactic acid. Lactic acid should be stored in a well-closed container in a cool & dry place.

Safety and Handling Information

Lactic acid is caustic in concentrated form and can cause burns on contact with the skin and eyes. It is harmful if swallowed, inhaled, or absorbed through the skin. Observe precautions appropriate to the circumstances and quantity of material handled. Eye protection, rubber gloves, and respirator are recommended. It is advisable to handle the compound in a chemical fume hood and to avoid repeated or prolonged exposure. Spillages should be diluted with copious quantities of water. In case of excessive inhalation, move the patient to a well-ventilated environment and seek medical attention. Lactic acid presents no fire or explosion hazard but emits acrid smoke and fumes when heated to decomposition.

Pharmaceutical Specifications

Description /Appearance	A colourless or slightly yellow, viscous liquid; almost odourless or has faint, unpleasant odor; hygroscopic (IP, JP)
	Colourless or slightly yellow, syrupy liquid and not more intensely colored than reference solution Y6 (BP, Ph.Eur USP)
Assay	88.0% - 92.0% w/w (IP, USP, BP, Ph.Eur)
	85.0% to 92.0% (JP)
Identification A (By Chemical test)	Aldehyde should evolve (IP)
	The solution should strongly acidic (BP, Ph.Eur, JP)
Identification (Lactate)	A blue color should produce (USP)
Identification B (By Chemical test)	A dark green ring appears at the interface of the two liquids (IP)
	Give reaction of lactates (JP)
Identification B (By Relative density, 20°C)	1.20 - 1.21 (BP, Ph.Eur)
Identification C (By Chemical test)	Solution should be strongly acidic (IP)
	A dark green ring should appear at the junction of the two liquids (BP, Ph.Eur)
Arsenic (As)	1ppm max (IP)
Heavy metals	10ppm max (IP, JP)
Citric, oxalic and phosphoric acids	Any opalescence in the solution is not more intense than that in a mixture of 5 mL of the test solution and 1 mL of water (IP, BP, Ph.Eur)
Limit of citric, oxalic, phosphoric or tartaric acid	No change occurs (JP, USP)
Ether insoluble substances	The solution is not more opalescent than the solvent used for the test (IP, BP, Ph.Eur)
Volatile fatty acids	No unpleasant odour resembling that of lower fatty acids is recognizable immediately after opening the flask (IP, JP)
Glycerin or mannitol	No turbidity produced (JP)
Methanol and methyl esters	Any color in the solution is not more intense than that of 1 mL of reference solution (IP)
Reducing sugars	No red or greenish precipitate should produce (IP, BP, Ph.Eur, JP, USP)
Readily carbonizable substances	No dark color should develop at the interface of the two acid within 15 min (USP, JP)
Sulphated ash / Residue on ignition	Not more than 0.1% (IP, BP, Ph.Eur, JP)
	0.05% max. (USP)
Chloride (Cl)	0.036% max. (JP)
	No opalescence should produce immediately (USP)
Iron (Fe)	5ppm max. (JP)
Sulphate (SO4)	200ppm max. (BP, Ph.Eur)
	0.010% max. (JP)
	No turbidity should produce (USP)
Calcium (Ca)	200ppm max. (BP, Ph.Eur)
Cyanide	Passes test (JP)
Bacterial endotoxins test	NMT 5.0 EU/g (USP)

Regulatory Information

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

Shipping Information

By Sea, Air and Road
Nature: Hazardous
UN Number: UN3265
Transport Hazard Class: 8
Packaging group: III

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

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