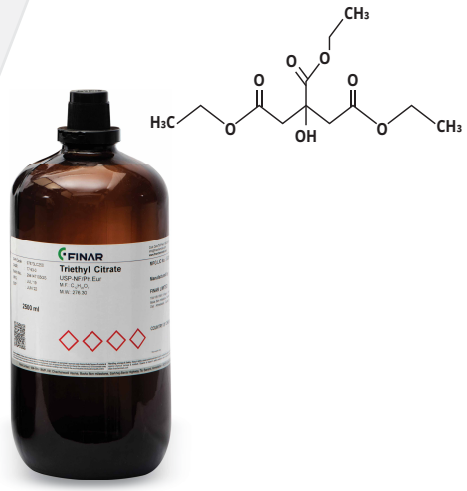
Technical Data Sheet

Triethyl citrate

IP, Ph.Eur., USP-NF



Applications

Triethyl citrate is used as plasticizer in the pharmaceutical industry. Its application is in almost all dosage forms including pharmaceutical pellet coating, soft gel capsules, tablet coating, hard gelatine capsules and all type of films (including transdermal & buccal films).

General Information

Pharmacopeia Status	:	IP, Ph.Eur., USP-NF
CAS No.	:	77-93-0
EC No.	:	201-070-7
Appearance/Description	:	A clear, viscous, colourless or almost colourless, hygroscopic liquid
Molecular Formula	:	$C_{12}H_{20}O_7$
Molecular Mass	:	276.29 g/mol

Marketed Formulation

- Cetirizine and pseudoephedrine tablets
- Lansoprazole enteric coated tablets and capsules
- Omeprazole pellets & 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
- Control of sub-visible particles
- Control of elemental impurities as per ICH Q3D

Pack Mode

- 2.5 Litre, 2.5 kg glass bottle
- 25 kg HDPE drum

Stability and Storage Conditions

Triethyl citrate should be stored in a closed container in a cool & dry location. When stored in accordance with these conditions, triethyl citrate is a stable product.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Triethyl citrate is irritating to the eyes and may irritate the skin. It is irritating to the respiratory system as a mist or at elevated temperatures. Gloves, eye protection, and a respirator are recommended.

Pharmaceutical Specifications

Description/ Appearance	Clear, viscous, colourless or almost colourless (not more intensely coloured than reference solution BY6), oily liquid, hygroscopic liquid (Ph.Eur, USP-NF)
Solubility	Slightly soluble in water, in fatty oils, miscible with alcohol, ethanol (96%) and ether (USP-NF, IP, Ph.Eur)
Assay	98.50% - 101.0% (anhydrous substance) (IP, Ph.Eur)
Identification A (By IR)	IR spectra of the sample should be concomitant with IR spectra of the corresponding standard (USP-NF)
Identification(By Refractive index, 20±0.5°C)	1.440 - 1.446 (Ph.Eur)
Identification (By IR)	To comply the test (IP, Ph.Eur)
Identification (By GC Chromatogram)	The retention time of the major peak of the sample solution corresponds to that of a similar preparation of triethyl citrate standard as obtained in the assay (USP-NF)
Identification (By Chemical test)	Gives reactions of citrates (IP)
Identification (Reaction of esters)	A bluish-red or red color should produce (Ph.Eur)
Identification (By Chemical test)	Gives reactions of esters (IP)
Identification (Reaction of citrates)	Violet color turning to violet-blue should produce (Ph.Eur)
Appearance of Solution	The substance should be clear and not more intensely coloured than reference solution BYS6 (IP)
Assay (By GC) On anhydrous basis	99.0% - 100.5% (USP-NF)
Specific gravity, 25°C	1.135 - 1.139 (USP-NF)
Refractive index, 25°C	1.439 - 1.441 (USP-NF)
Refractive index (20°C ± 0.5°C)	1.440 - 1.446 (IP, Ph.Eur)
Acidity	NMT 1.0ml of 0.1 N Sodium hydroxide should be required to change the color of the indicator to blue (USP-NF) Not more than 0.3ml of 0.1 M Sodium hydroxide should be required to change the color of the indicator to blue (IP, Ph.Eur)
Related substances (Any impurity)	0.2% max. (IP, Ph.Eur)
Related substances (Total impurity)	0.5% max. (IP, Ph.Eur)
Heavy metals	5ppm max. (IP)
Water	NMT 0.25% (IP, USP-NF, Ph.Eur)
Sulfated ash	0.1% max. (IP, Ph.Eur)

Regulatory Information

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (oral capsules and tablets). 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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