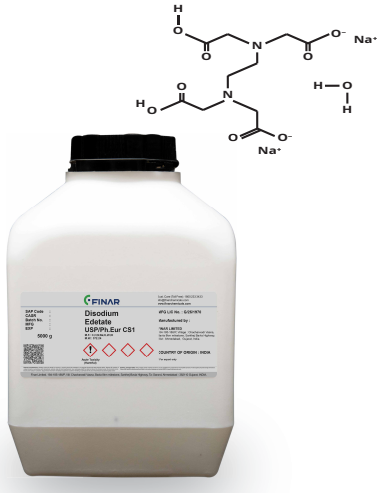
Technical Data Sheet

Disodium Edetate

IP, Ph.Eur, USP



Applications

Disodium edetate is used as a chelating agent in a wide range of pharmaceutical preparations, including Mouthwashes, Ophthalmic preparations, Solid orals and Topical preparations.

General Information

Pharmacopeia Status	:	IP, Ph.Eur, USP
CAS No.	:	6381-92-6
EC No.	:	205-358-3
Appearance/Description	:	White, crystalline powder.
Molecular Formula	:	$C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$
Molecular Mass	:	372.23 g/mol

Marketed Formulation

- Risedronate sodium tablets
- Bromocriptine Mesylate tablets
- Methyldopa tablets
- Phenelzine sulfate tablets & 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 TAMC & TYMC
- Control of pathogens
- Control of elemental impurities as per ICH Q3D
- Calcium (Ca), Iron (Fe)

Pack Mode

100 gm, 500 gm, 1 kg, 5 kg, 25 kg HDPE container

Stability and Storage Conditions

It should be stored in a well-closed container in a cool and dry place.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Disodium edetate and its derivatives are mild irritants to the mucous membranes. Eye protection, gloves and dust masks are recommended.

Pharmaceutical Specifications

Description/Appearance	A white, crystalline powder, odourless (IP, Ph.Eur, USP)
Solubility	Soluble in water, practically insoluble in ethanol (96%) (IP, Ph.Eur, USP)
Identification A (By IR)	IR spectra of the sample should be concomitant with IR spectra of the standard (IP, Ph.Eur, USP)
Identification B (By Chemical test)	No precipitate should produce (IP, Ph.Eur)
	The red color should discharge, leaving a yellowish solution (USP)
Identification C (By Chemical test)	No precipitate should produce (IP, Ph.Eur)
	A dense white precipitate should form (USP)
Identification D (Sodium 1)	A dense white precipitate should form (IP, Ph.Eur)
Identification D (Sodium 2)	No precipitate should form (IP)
Appearance of solution	A 5% w/v solution in carbon dioxide free water should be clear and colourless (IP)
	Solution should be clear and colourless (Ph.Eur)
pH of 5%w/v solution	4.0 - 5.5 (IP, Ph.Eur,USP)
Impurity A (Nitrilotriacetic acid)	0.1% max. (IP, Ph.Eur ,USP)
Heavy metals	20ppm max. (IP)
Iron (Fe)	80ppm max. (IP, Ph.Eur)
Assay (on dried basis)	99.0% - 101.0% (IP, Ph.Eur. USP)
Calcium (Ca)	No precipitate should form (USP)
Loss on drying at 150° for 6 Hr	8.7%-11.4% (USP)
Particle size	NLT 95% Passes through 100 mesh (In-house)
Total aerobic microbial count	NMT 100 cfu/g (In-house)
Total Yeast & mold count	NMT 10 cfu /g (In-house)
Escherichia coli	Absent/g (In-house)
Pseud. aeruginosa	Absent/g (In-house)
Staphylococcus aureus	Absent/g (In-house)
Bile-tolerant gram negative bacteria	Absent/g (In-house)
Salmonella	Absent/10g (In-house)
Bacterial endotoxins	NMT 30 EU/g (In-house)

Regulatory Information

GRAS listed. Included in the FDA Inactive Ingredients Database (inhalations, injections, ophthalmic preparations, oral capsules, solutions, suspensions, syrups and tablets, rectal topical and vaginal preparations). Included in non-parenteral and parenteral medicines licensed in 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

For more information contact : deepaklodhiya@finarchemicals.com

Finar Limited
CORPORATE OFFICE & WORKS
184-185-186/P, Vill:Chacharwadi Vasna, Bavla 8km milestone, Sarkhej Bavla Highway, Sanand, Ahmedabad – 382110. Gujarat, INDIA.
t: +91-2717-616717 | e: sales@finarchemicals.com
www.finarchemicals.com