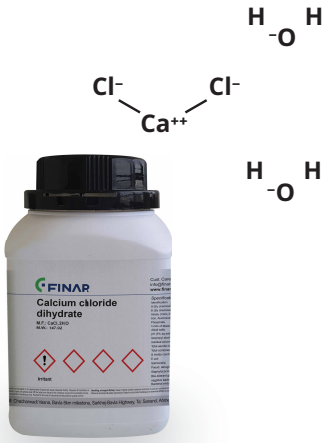
Technical Data Sheet

Calcium chloride dihydrate

IP, BP, Ph.Eur, USP



Applications

The main applications of calcium chloride as an excipient relate to its dehydrating properties and therefore, it has been used as an antimicrobial preservative, desiccant and as an astringent in formulations. It is widely used in Solid orals and Parenteral preparations.

General Information

Pharmacopeia Status	:	IP, BP, Ph.Eur, USP
CAS No.	:	10035-04-8
EC No.	:	233-140-8
Appearance/Description	:	White, hard, odorless fragments or granules. Is deliquescent.
Molecular Formula	:	$CaCl_2.2H_2O$
Molecular Mass	:	147.02 g/mol

Marketed Formulation

- Bisacodyl 5 mg tablets
- Desipramine 25 mg 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 elemental impurities as per ICH Q3D
- Control of Arsenic (As), Barium (Ba), Aluminium (Al)
- Control of Iron (Fe), Phosphate (PO4)
- Control of Sulphate (SO4), Chloride (Cl)

Pack Mode

500 gm HDPE container

Stability and Storage Conditions

Calcium chloride is chemically stable. Store in a cool and dry place protected from moisture in an airtight container.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of the material handled. Calcium chloride is irritating to eyes, the respiratory system and skin. Gloves, eye protection, respirator, and other protective clothing should be worn.

Pharmaceutical Specifications

Description/Appearance	A white, crystalline powder or fragments or granules; odourless; hygroscopic (IP, BP, Ph.Eur, USP)
Solubility	Freely soluble in water, ethanol and in boiling alcohol (95%) (IP, BP, Ph.Eur, USP)
Identification A (Calcium1)	A white, crystalline precipitate should form (IP)
Identification A (Calcium 2)	A white precipitate that sparingly soluble in dilute acetic acid but soluble in hydrochloric acid should form (IP)
Identification A (Chloride)	A curdled, white precipitate should form which dissolves in ammonia (BP, Ph.Eur)
Identification A (Calcium)	Precipitate should insoluble in 6N acetic acid while soluble in hydrochloric acid (USP)
Identification B (Chloride)	A curdy white precipitate insoluble in dilute nitric acid but soluble in dilute ammonia should form (IP)
Identification B (Calcium 1)	The chloroform layer should coloured red (BP, Ph.Eur)
Identification B (Calcium 2)	A white, crystalline precipitate should form (BP, Ph.Eur)
Identification B (Chloride)	A curdy white precipitate should insoluble in nitric acid but soluble in 6N ammonium hydroxide (USP)
Identification C (By Assay)	97.0 % - 103.0 % (BP, Ph.Eur)
Appearance of solution	Solution should be clear and not more intensely coloured than the reference solution YS6 (IP, BP, Ph.Eur)
Acidity or Alkalinity	Not more than 0.2 mL of 0.01M sodium hydroxide or 0.01M of hydrochloric acid should require (IP, BP, Ph.Eur)
Arsenic	3 ppm max. (IP)
Aluminium and phosphate	No turbidity or precipitate should form (IP)
Iron, Aluminum & Phosphate	No turbidity or precipitate should produce (USP)
Aluminium (Al)	1 ppm max. (BP, Ph.Eur)
Aluminum	NMT 1 ppm (USP)
Barium (Ba)	A solution should not be more opalescent than standard (IP)
	Any opalescence in the solution is not more intense than reference solution (BP, Ph.Eur)
Heavy metals	10ppm max. (IP)
Iron (Fe)	10ppm max. (BP, Ph.Eur, IP)
Magnesium & alkali metals	0.5% max. (BP, Ph.Eur, IP, USP)
Sulfates	300 ppm max. (IP)
Assay	97.0% - 103.0% (IP, BP, Ph.Eur)
Assay	99.0% - 107.0% of $CaCl_2.2H_2O$ (USP)
pH (5% aq soln)	4.5 - 9.2 (USP)
Total aerobic bacterial count	NMT 100 cfu/gm (In-house)
Total combined yeast and molds count	NMT 10 cfu/gm (In-house)
Bacterial endotoxins	NMT 2.5 EU/gm (In-house)

Regulatory Information

GRAS listed and included in the FDA Inactive Ingredients Database (injections, ophthalmic preparations, suspensions, creams). Included in medicines licensed in the UK (eye drops; intraocular irrigation; vaccines; injection powders for reconstitution; nebulizer solution; oral suspension).

Shipping Information

By Sea, Air and Road
Nature: Non Hazardous

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

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