Technical Data Sheet

Potassium chloride

IP, BP, Ph.Eur, USP

Cl ---------- K^+

Applications

Potassium chloride is widely used in a variety of parenteral and non-parenteral pharmaceutical formulations. Its primary use is in parenteral and ophthalmic preparations to produce isotonic solutions. Many solid-dosage forms of potassium chloride exist including tablets prepared by direct compression and Granulation, Effervescent tablets, Coated, Sustained-release tablets, Microcapsules, Pellets and Osmotic pump formulations.

General Information

Pharmacopeia Status	: IP, BP, Ph.Eur, USP
CAS No.	: 7447-40-7
EC No.	: 231-211-8
Appearance/Description	: Colorless, elongated, prismatic, or cubical crystals, or white, granular powder, stable in air. Its solutions are neutral to litmus.
Molecular Formula	: KCl
Molecular Mass	: 74.55 g/mol

Marketed Formulation

- Bupropion hydrochloride tablets
- Nifedipine tablets
- Propoxyphene hydrochloride 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 for parenteral application
- Control of TAMC & TYMC
- Control of pathogens
- Control of elemental impurities as per ICH Q3D
- Control of Arsenic (As), Barium (Ba), Calcium (Ca), Magnesium (Mg), Iron (Fe), Bromide (Br), Iodine (I), Sulphate (SO4), aluminium (Al), Sodium (Na)

Pack Mode

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

Stability and Storage Conditions

Potassium chloride is stable and 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.

Product Specifications (In-house)

Description/Appearance	Colorless, elongated, prismatic or cubical crystals or white granular powder. Is odorless, has a saline taste, and is stable in air. Its solutions are neutral to litmus (IP, BP, Ph.Eur, USP)
Solubility	Freely soluble in water, practically insoluble in ethanol and in ether (IP, BP, Ph.Eur, USP)
Identification (Potassium A)	A yellow or orange yellow precipitate should produce immediately (IP)
Identification A (Chloride a)	A white curdled precipitate which dissolves easily in ammonia should form (BP, Ph.Eur)
Identification A (Chloride b)	The paper should turn violet-red (BP, Ph.Eur)
Identification A (Potassium)	A white crystalline precipitate that soluble in 6 N ammonium hydroxide and solutions of alkali hydroxides and carbonates should form (USP)
Identification (Potassium B)	A white, crystalline precipitate should produce (IP)
Identification B (Potassium a)	A white crystalline precipitate should form (BP, Ph.Eur)
Identification B (Potassium b)	A yellow or orange-yellow precipitate should form immediately (BP, Ph.Eur)
Identification B (Chloride)	A curdy precipitate that insoluble in nitric acid but soluble in a slight excess of 6 N ammonium hydroxide should form (USP)
Identification (Potassium C)	A yellow crystalline precipitate should produce which on ignition leaves a reside of potassium chloride and platinum (IP)
Identification (Chloride A)	A curdy white precipitate which should insoluble in nitric acid but soluble in ammonia solution should form (IP)
Identification (Chloride B)	A filter-paper moistened with diphenyl carbazide solution should turn violet red (IP)
Appearance of solution	Clear and colorless solution (IP, BP, Ph.Eur)
Acidity & alkalinity	Not more than 0.5ml of 0.01M hydrochloric acid or of 0.01M sodium hydroxide for neutralization to bromothymol blue solution (IP, BP, Ph.Eur)
Acidity & alkalinity	A pink color should produce (USP)
Arsenic (As)	1ppm max. (IP)
Barium (Ba)	Any opalescence in the solution should not be more intense than reference solution (BP, Ph.Eur, IP)
Heavy metals	10ppm max. (IP)
Calcium (Ca) & Magnesium (Mg)	The solution remains clear (IP ,USP)
Magnesium and alkaline earth metals	200ppm max. (BP, Ph.Eur)
Iron (Fe)	20ppm max. (IP, BP, Ph.Eur)
Bromide (Br)	0.1% max. (IP, BP, Ph.Eur, USP)
Iodide (I)	The substance shows no blue colour after 5 minutes (IP, BP, Ph.Eur)
	NMT 0.005% (USP)
Sulphate (SO4)	300ppm max. (IP, BP, Ph.Eur)
Loss on drying,105°C	Not more than 1.0% (IP, BP, Ph.Eur, USP)
Assay (on dried basis)	99.00% - 100.50% (IP, USP, BP, Ph.Eur)
Aluminium (Al)	1 ppm max. (IP, BP, Ph.Eur, USP)
Sodium (Na)	NMT 0.1% (IP ,BP, Ph.Eur)
Sodium (Na)	Sample solution tested on a platinum wire does not impart a pronounced yellow color to a nonluminous flame (USP)
Total aerobic microbial count	NMT 100 cfu/g (In-house)
Total Yeast and mold count	NMT 10 cfu/g (In-house)
Bacterial endotoxin test	NMT 2.5 EU/g (In-house)

Product Specifications (In-house)

E.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)

Regulatory Information

GRAS listed. Accepted as a food additive in Europe. Included in the FDA Inactive Ingredients Database (injections, ophthalmic preparations, oral capsules, and tablets). 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