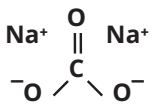
Technical Data Sheet

Sodium carbonate

IP, BP, USP-NF



Applications

Sodium carbonate is used as an alkalizing agent in injectable, ophthalmic, oral, and rectal formulations. In effervescent tablets or granules, sodium carbonate is used in combination with an acid, typically citric acid or tartaric acid.

General Information

Pharmacopeia Status	:	IP, BP, USP-NF
CAS No.	:	497-19-8
EC No.	:	207-838-8
Appearance/Description	:	A white or almost white, slightly granular powder, hygroscopic.
Molecular Formula	:	Na_2CO_3
Molecular Mass	:	105.99 g/mol

Marketed Formulation

- Atorvastatin calcium tablets
- Alendronate tablets
- Pantoprazole sodium delayed release tablets and capsules
- Pravastatin sodium 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
- Control of elemental impurities as per ICH Q3D
- Control on Chloride (Cl), Sulphate (SO4), Iron (Fe)
- Control of different Particle size
  (100% of the material should pass through 60 mesh)
  (Not less than 95% pass through 80#)
  (100% of the material should pass through 40#)

Pack Mode

500 gm, 5 kg, 25 kg, 50 kg HDPE container

Stability and Storage Conditions

Keep container tightly closed in a cool, dry and well-ventilated place.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of the material handled. When heated to decomposition it emits toxic fumes of sodium oxide. Eye protection and gloves are recommended. Respiratory protection is also recommended if inhalable dust is present.

Pharmaceutical Specifications

Description	A white or almost white, slightly granular powder, hygroscopic (IP, BP, USP-NF)
Solubility	Very soluble in boiling water, Freely soluble in water; practically insoluble in ethanol (95%) and ethanol (96%) (IP, BP, USP-NF)
Assay (on dried basis)	99.5% - 100.5% (IP, BP)
Assay (Anhydrous basis)	99.5% - 100.5% (USP-NF)
Identification (By Chemical test)	The solution should be strongly alkaline (IP, BP)
Identification (By Chemical test)	A dense precipitate should form (USP-NF)
Identification (carbonate)	A white precipitate that dissolves on addition of excess dilute hydrochloric acid should form (IP, BP)
Identification (Sodium A)	A dense white precipitate should form (IP, BP)
Identification (Carbonate)	Effervesce with acids, evolves a colorless gas that when pass into calcium hydroxide solution produces white precipitate immediately (USP-NF)
Identification (Carbonate)	A cold solution should be colored red by phenolphthalein solution (USP-NF)
Identification (Sodium B)	No precipitate should form (IP)
Identification (By Loss on drying)	1.0% max. (BP)
Appearance of solution	The solution should be clear and not more intensely colored than reference solution YS6 (IP, BP)
Alkali hydroxides and bicarbonates	The solution remains clear (IP, BP)
Heavy metals	NMT 50ppm (IP)
Arsenic (As)	NMT 5ppm (BP)
Iron (Fe)	NMT 50ppm (IP, BP)
Chlorides	NMT 125ppm (IP, BP)
Sulfates	NMT 250ppm (IP, BP)
Loss on drying,300°C	NMT 1.0% (IP, BP)
Water	NMT 0.5% (USP-NF)
Particle size	100% of the material should pass through 60 mesh (In-house)
Particle size	Not less than 95% pass through 80# (In-house)
Particle size	100% of the material should pass through 40# (In-house)

Regulatory Information

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (injections; ophthalmic solution; oral capsules and tablets; rectal suspensions). Included in the Canadian List of Acceptable Non-medicinal Ingredients. Included in parenteral (powder for solution for injection) and non-parenteral medicines (oral effervescent tablets, soluble tablets, granules, lozenges, chewing gums) licensed in the UK.

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