

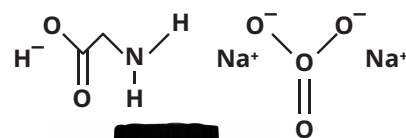


Monosodium glycine carbonate

HP

Applications

Monosodium glycine carbonate is widely used in pharmaceutical industry for solid oral dosage forms. It is mainly used in effervescent dosage forms as alkaline agent and solubilizer for insoluble acidic drugs.



General Information

Pharmacopeia Status	: In-house product
CAS No.	: 50610-34-9
Appearance/Description	: A white crystalline powder.
Molecular Formula	: C ₃ H ₃ NO ₄ Na ₂
Molecular Mass	: 163.05 g/mol

Marketed Formulation

- Paracetamol effervescent tablets
- Ascorbic acid effervescent 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

Pack Mode

5 kg HDPE container

DMF (Drug Master File)

US DMF registered product (DMF # 26697)

Stability and Storage Conditions

Store in a tightly closed container. Store in well-ventilated area away from incompatible substances.

Safety and Handling Information

Wash thoroughly after handling and use with adequate ventilation. Avoid ingestion and inhalation. Minimize dust generation and accumulation. Avoid breathing dust, vapor, mist, or gas. Avoid contact with eyes, skin, and clothing. Keep container tightly closed.

Product Specifications (In-house)

Description	A white crystalline powder
Identification (By IR)	To comply test
Sodium (Na)	Between 27.0 - 29.0%
Nitrogen (N)	Between 8.0 - 9.0%
Loss on drying	Not more than 0.5%
pH(5% aq soln), at 25°C	Between 9.6 - 10.6
Arsenic (As)	0.15 ppm max.
Cadmium(Cd)	0.5 ppm max.
Lead (Pb)	0.5 ppm max.
Mercury(Hg)	1.5 ppm max.
Methanol as Residual solvent impurity	Not more than 0.3%

Shipping Information

By Sea, Air and Road

Nature: Hazardous

UN Number: UN3259

Transport Hazard Class: 8

Packaging group: III

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

Note: The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantees since the conditions of use are beyond our control. Finar disclaims any liability incurred with the use of this data or suggestions.

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