

GUANIDINE HYDROCHLORIDE

NF, LBLE, GMP, Excipient

CAS #: 50-01-1

Formula: $\text{NH}_2\text{C}(\text{NH})\text{NH}_2 \cdot \text{HCl}$

F.W.: 95.53 g/mol

GHCL-3253

BIO EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Acidity (NF)		< = 0.01%
Appearance and Color		White Crystals
Appearance of Solution (6M)		Clear and Colorless
Assay, Dried Basis (NF)		99.5 – 101.0%
Chloride		36.5 – 37.5%
Endotoxin		< = 2.5 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification A, IR (NF)		Conforms to Reference Standard
Identification B, Absorbance (6M) (NF)	230 nm	< = 0.20 a.u.
	235 nm	< = 0.20 a.u.
	260 nm	< = 0.03 a.u.
	275 nm	< = 0.03 a.u.
	280 nm	< = 0.10 a.u.
Identification C, Chloride (NF)		Passes Test
Limit of Nitrate (NF)		< = 50 ppm
Loss on Drying (NF)		< = 0.5%
Melamine		< = 0.01%
Melting Range (NF)		184 – 188°C
Microbial Content	TAMC	< = 100 CFU/g
	TYMC	< = 10 CFU/g
	Bile-tolerant gram-negative bacteria	Absent/g
	Candida albicans	Absent/g
	Escherichia coli	Absent/g
	Pseudomonas aeruginosa	Absent/g
	Salmonella	Absent/10g
	Staphylococcus aureus	Absent/g
pH (6M)		4.5 – 6.0
pH (0.5M)		5.0 – 6.5
Residue on Ignition (NF)		< = 0.05%
Solubility (6M)		Passes Test
Sulfate (NF)		< = 50 ppm
Trace Metals	Arsenic (As)	< = 5 ppm
	Copper (Cu)	< = 5 ppm
	Iron (Fe)	< = 5 ppm
	Lead (Pb)	< = 5 ppm
Water Insoluble Substances (NF)		< = 0.05%
Water, KF		< = 0.5%

General Product Overview

Guanidine Hydrochloride is a strong protein denaturant that functions as a chaotropic agent. As a denaturant, it unfolds proteins and turns them into their original polypeptide chains. As a chaotropic agent, it breaks down the structure of proteins. Guanidine Hydrochloride is commonly used in the purification of RNA by dissociating the RNA into its nucleic acids and protein forms. At higher concentrations, Guanidine Hydrochloride decreases enzyme activity and increases the solubility of hydrophobic molecules.

Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

Key Product Features

- The manufacturing of Guanidine HCl, GHCL-3253 is performed at BioSpectra's Stroudsburg, PA facility.
- Appears as white crystals
- Manufactured in accordance with ICH Q7
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives
- Is not subject to genetic modification
- Synonyms: Guanidine Monohydrochloride; Guanidinium Chloride; Guanidinium Hydrochloride.

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

10kg, 25kg and 50kg pails

[Click here to view SDS, CoAs and other supporting regulatory documents on our website.](#)

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