

# 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 Protease RNase	None Detected None Detected None Detected	
Identification A, IR (NF)	Conforms to Reference Standard		
Identification B, Absorbance (6M) (NF)	230 nm 235 nm 260 nm 275 nm 280 nm	< = 0.20 a.u. < = 0.20 a.u. < = 0.03 a.u. < = 0.03 a.u. < = 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 TYMC Bile-tolerant gram-negative bacteria Candida albicans Escherichia coli Pseudomonas aeruginosa Salmonella Staphylococcus aureus	< = 100 CFU/g < = 10 CFU/g Absent/g Absent/g Absent/g Absent/10g 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) Copper (Cu) Iron (Fe) Lead (Pb)	< = 5 ppm < = 5 ppm < = 5 ppm < = 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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