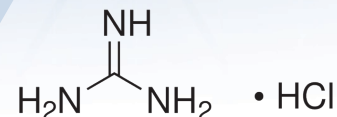


GUANIDINE HCL, NF, LBLE*, GMP, Excipient Grade

*Low Bioburden, Low Endotoxin

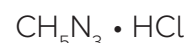
INTENDED FOR CRITICAL BIOPHARMA APPLICATIONS

Guanidine Hydrochloride is a strong protein denaturant that functions as a chaotropic agent. As a denaturant, it acts to unfold proteins and turn 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. It is also used to increase the solubility of hydrophobic molecules.



CAS #: 50-01-1

Molecular Formula:



Solubility in Water (g/L): 573

F.W.: 95.53 g/mol

pH @ 20°C: 4.5 - 6.0

BIO EXCIPIENT GRADE | Product Code: GHCL-3253

$\text{CH}_5\text{N}_3 \cdot \text{HCl}$ • F.W. 95.53 g/mol. • CAS# 50-01-1



These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

ANALYSIS		SPECIFICATIONS
Acidity		≤ 0.01%
Appearance and Color		White / Crystals
Appearance of Solution (6 mol/l; water)		Clear and Colorless
Assay (Dried Basis)		99.5% - 101.0%
Bacterial Endotoxins		≤ 2.5 IU/g
Chloride (Cl) (Argentometric)		36.5 – 37.5%
Chloride and Sulfate, Sulfate		≤ 0.005%
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Heavy Metals (as Pb)		≤ 10 ppm
Identification A (IR)		Passes Test
Identification B, Absorbance	280 nm, 6 mol/l, 1 cm, water	≤ 0.10 a.u.
	275 nm, 6 mol/l, 1 cm, water	≤ 0.03 a.u.
	260 nm, 6 mol/l, 1 cm, water	≤ 0.03 a.u.
	235 nm, 6 mol/l, 1 cm, water	≤ 0.20 a.u.
	230 nm, 6 mol/l, 1 cm, water	≤ 0.20 a.u.
Identification C – Chloride		Meets the Requirements of test A
Limit of Nitrate		≤ 0.005%
Loss on Drying		≤ 0.5 %
Melamine (HPLC)		≤ 0.01 %
Melting Range		184°C–188°C
pH (6M)		4.5 – 6.0
pH (0.5 mol/l, water)		5.0 – 6.5
Residue on Ignition		≤ 0.05%


ANALYSIS		SPECIFICATIONS
Solubility (6M)		Passes Test
Sulfated Ash (600 °C)		≤ 0.05 %
TAMC		≤ 100 CFU/g
TYMC		≤ 10 CFU/g
Bile-tolerant gram-negative bacteria (absent in 1 g)		Passes Test
Candida albicans (absent in 1 g)		Passes Test
Escherichia coli (absent in 1 g)		Passes Test
Pseudomonas aeruginosa (absent in 1 g)		Passes Test
Salmonella (absent in 10 g)		Passes Test
Staphylococcus aureus (absent in 1 g)		Passes Test
Trace Metals	Arsenic (As)	≤ 5 ppm
	Copper (Cu)	≤ 5 ppm
	Iron (Fe)	≤ 5 ppm
	Lead (Pb)	≤ 5 ppm
Water (according to Karl Fischer)		≤ 0.5 %
Water Insoluble		≤ 0.05 %

NOTES:

Residual solvents (ICH (Q3C)) excluded by manufacturing process. Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

RESIDUAL SOLVENTS:

Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

 Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH-Q7 Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Excipient Grade: Intended for use as ICH-Q7 Compliant Excipient

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).

LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

(If No Stock) Lead Time: 1-month
Minimum Order Quantity: 500kg

General Product Description:

- The manufacturing of Guanidine Hydrochloride GHCL-3253 is performed at BioSpectra's Stroudsburg, PA facility and is conducted in a dedicated processing area using only dedicated equipment.
- Guanidine HCl is a White Crystalline product.
- Molecular Formula: $\text{CH}_5\text{N}_3 \cdot \text{HCl}$
- Molecular Weight: 95.53 g/mol.
- CAS Number: 50-01-1.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Guanidine Hydrochloride GHCL-3253 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Guanidine Hydrochloride manufactured at BioSpectra and any raw materials used in the manufacture of Guanidine Hydrochloride at BioSpectra are not subject to genetic modification.
- Synonyms: Guanidine Monohydrochloride, Guanidinium Chloride, Guanidinium Hydrochloride.

GMP Compliance:

Bio Excipient Grade Guanidine Hydrochloride, GHCL-3253 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Guanidine Hydrochloride is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for Guanidine Hydrochloride is two years from the date of manufacture.

Storage and Shipping Conditions:

Ship and store in ambient temperature. Store in a clean and dry area. Store in the original container.

Package Sizes:

10kg, 25 kg and 50 kg pails.