BIOSPECTRA
Premium Pharmaceutical Ingredients

Excipient

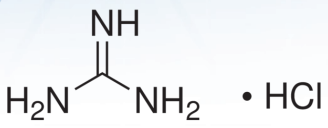
ICH-Q7 GMP Manufactured Product

GUANIDINE HCl, LBLE, GMP Excipient Grade

Low Bioburden, Low Endotoxin, GMP Manufactured

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:
CH_5N_3 • HCl
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-3250 | Previously: GH3250

CH_5N_3 • HCl • F.W. 95.53 g/mol. • CAS# 50-01-1

Made in the USA

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

ANALYSIS		SPECIFICATIONS
Absorbance (6M)	230 nm	0.1500 a.u. max.
	260 nm	0.0300 a.u. max.
	275 nm	0.0300 a.u. max.
Appearance and Color		White / Crystals
Assay		99.5% min.
Endotoxin		≤ 50 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification (FTIR)		Passes Test
Identification (Chloride)		Passes Test
Insoluble Matter		0.15% max.
Loss on Drying		0.5% max.
Melting Range		184-188°C
Microbial Content	TAMC	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
Nitrate		0.01% max.
pH (6M)		4.5-6.0
Residue on Ignition		0.05% max.
Solubility (6M)		Passes Test
Sulfate		0.01% max.

ANALYSIS		SPECIFICATIONS
Trace Metals	Arsenic (As)	5 ppm max.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.

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BIOSPECTRA **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.

Lead Time: 1-month
Minimum Order Quantity: 500kg

General Product Description:

- The manufacturing of Guanidine Hydrochloride GHCL-3250 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: $CH_5N_3 \cdot HCl$
- 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-3250 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-3250 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.

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.