

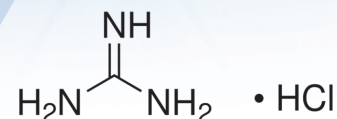
## Guanidine HCl 6M, GMP Excipient Grade

### INTENDED FOR CRITICAL BIOPHARMA APPLICATIONS

Guanidine Hydrochloride 6M solution can be used to denature proteins which become randomly coiled with no residual structure. This concentration is also used to decrease enzyme activity. The denatured proteins can be modified or analyzed using mass spectrometry, electrophoresis and enzymatic digests. As a chaotropic agent, Guanidine Hydrochloride solution is also used to break the hydrogen bonds in the structure of proteins and increase the solubility of hydrophobic molecules.

**Lead Time: 3-months**

**Minimum Order Quantity: 4000-liters**



**CAS #:** 50-01-1

**Molecular Formula:**

$\text{CH}_5\text{N}_3 \cdot \text{HCl}$

**Solubility in Water (g/L):**

573 @ 20°C

**F.W.:** 95.53 g/mol

**pH @ 20°C:** 4.5 - 6.5

**BIO EXCIPIENT GRADE | Product Code: GHCL-3101 | Previously: GH3101**

$\text{CH}_5\text{N}_3 \cdot \text{HCl}$  • 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          |
|----------------------|-------|-------------------------|
| Absorbance           | 260nm | 0.1 a.u. max.           |
| Appearance and Color |       | Clear, Colorless Liquid |
| Cyanide              |       | Passes Test             |
| Heavy Metals         |       | ≤ 10 ppm                |
| Identification (IR)  |       | Passes Test             |
| Iron                 |       | ≤ 3 ppm                 |
| Molarity             |       | 5.8 – 6.2M              |
| pH                   |       | 4.5 – 6.5               |

### GMP Compliance:

Bio Excipient Grade Guanidine HCl 6M, GHCL-3101 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Guanidine HCl 6M is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.



| <br>Key Compliance Attributes of<br>BioSpectra Grades | Bio Excipient Grade<br>ICH-Q7 Compliant<br>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.

## General Product Description:

- The manufacturing of Bio Excipient Grade Guanidine Hydrochloride 6M, GHCL-3101 is performed at BioSpectra's Bangor, PA facility and is conducted in a dedicated processing area using only dedicated equipment. Cleaning verification is performed on the dedicated manufacturing equipment.
- Molecular Formula:  $\text{CH}_5\text{N}_3 \cdot \text{HCl}$
- Molecular Weight: 95.53 g/mol.
- CAS #: 50-01-1
- Guanidine Hydrochloride 6M is a clear colorless solution.
- 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 6M, GHCL-3101 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- Guanidine Hydrochloride 6M manufactured at BioSpectra and any raw materials used in the manufacture of Guanidine Hydrochloride 6M at BioSpectra are not subject to genetic modification.
- Synonyms: Guanidine Monohydrochloride, Guanidinium Chloride, Guanidinium Hydrochloride.
- Manufactured with USP grade purified water.

## Retest Date:

The recommended retest period for Guanidine Hydrochloride 6M solution is two years from the date of manufacture.

## Storage and Shipping Conditions:

Ship and store in ambient temperature.

## Package Sizes:

200L drums and 1135L totes.