

## **GMP BIOTECH PRODUCT**

## **GUANIDINE HYDROCHLORIDE**

**BIOTECH, NF, GMP** 

CAS #: 50-01-1

Formula: CH<sub>5</sub>N<sub>3</sub> HCl

F.W.: 95.53 g/mol

### **GHCL-4223**

## **BIO PHARMA GRADE**

**Intended for Use in Biopharmaceutical &** 

G.1101 1110		
Analysis		SPECIFICATIONS
Acidity (NF)		< 0.01%
Appearance and Color		White/Crystals
Assay, Dried Basis (NF)		99.5 - 101.0%
Chloride and Sulfate, Sulfate (NF)		≤ 50 ppm
DNase		None Detected
Enzymes	Protease	None Detected  None Detected
	RNase	None Detected
Identification A, IR (NF)		Conforms to Reference
		Standard
Identification B,	230 nm	<u>&lt;</u> 0.2000 a.u.
Absorbance (NF)	260 nm	≤ 0.0300 a.u.
7100015dilloc (1117)	275 nm	<u>&lt;</u> 0.0300 a.u.
Identification C, Chloride (NF)		Meets the
		Requirements of Test A
Limit of Nitrate (NF)		≤ 50 ppm
Loss on Drying (NF)		<u>&lt;</u> 0.5%
Melting Range (NF)		184 - 188°C
pH (6M)		4.5 - 6.0
Residue on Ignition (NF)		<u>&lt;</u> 0.05%
Solubility (6M)		Passes Test
Trace Metals	Aluminum (Al)	<u>&lt;</u> 5 ppm
	Arsenic (As)	<u>&lt;</u> 5 ppm
	Barium (Ba)	≤ 5 ppm
	Bismuth (Bi) Calcium (Ca)	<u>&lt;</u> 5 ppm <u>&lt;</u> 10 ppm
	Cadmium (Cd)	<u>&lt; 5 ppm</u>
	Cobalt (Co)	<u>≤</u> 5 ppm
	Chromium (Cr)	<u>_</u> 5 ppm ≤ 5 ppm
	Copper (Cu)	
	Iron (Fe)	<u>&lt;</u> 5 ppm
	Potassium (K)	<u>&lt;</u> 50 ppm
	Lithium (Li)	≤ 5 ppm
	Magnesium (Mg) Manganese (Mn)	<u>&lt;</u> 5 ppm <u>&lt;</u> 5 ppm
	Molybdenum (Mo)	<u>&lt; 5 ppm</u> ≤ 5 ppm
	Sodium (Na)	_ 5 pp ≤ 150 ppm
	Nickel (Ni)	<u>_</u> ≤ 5 ppm
	Lead (Pb)	<u>&lt;</u> 5 ppm
	Strontium (Sr)	<u>&lt;</u> 5 ppm
Zinc (Zn)		<u>&lt;</u> 5 ppm
Water, KF		<u>&lt;</u> 0.3%
Water Insoluble (NF)		<u>&lt;</u> 0.05%

**Country of Origin: USA** 

Biotechnological Applications and Products
This is a high purity, GMP, Reagent Grade product, purified under full cGMP conditions. Guanidine
Hydrochloride Buffer 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. It is commonly used in the purification of RNA by dissociating the RNA into its nucleic acids and protein forms. At higher concentrations, Guanidine HCl Buffer decreases enzyme activity. It is also used to increase the solubility of hydrophobic molecules.

#### **General Product Description**

- Appears as a white crystalline product
- Manufactured under an ICH-Q7 Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- 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/derivatives.
- · Is not subject to genetic modification
- Synonyms: Guanidine Monohydrochloride, Guanidinium Chloride, Guanidinium Hydrochloride Buffer
- Visit the product page on our website (<u>www.biospectra.us</u>) for additional information, supporting regulatory documents, and CofAs.

# **Storage and Shipping Conditions** Refer to SDS.

**Standard Shelf Life Policy** 

Each Certificate of Analysis will contain a 2-year retest/recertification date supported by a 3-year ICH Q1 Stability Study (if one is completed).

#### **Package Sizes**

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg

#### **Standard Lead Time**

1-2 weeks