

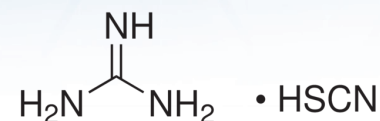
# GUANIDINE THIOCYANATE, GMP Excipient Grade

### INTENDED FOR USE AS AN EXCIPIENT

Guanidine Thiocyanate is a chaotropic agent. As one of the strongest protein denaturants, it inactivates nucleases more than twice as fast as Guanidine Hydrochloride. Guanidine Thiocyanate is preferred for the purification of RNA because it dissociates the RNA into its nucleic acids and protein forms. Higher molarity solutions of Guanidine Thiocyanate irreversibly inactivate RNase. Guanidine Thiocyanate causes proteins to dissolve readily, thus disintegrating cellular structures.

**Lead Time: 3-months**

**Minimum Order Quantity: 100kg**



**CAS #:** 593-84-0

**Molecular Formula:** C<sub>2</sub>H<sub>6</sub>N<sub>4</sub>S

**Solubility in Water (g/L):** 1,600

**F.W.:** 118.16 g/mol

**pH @ 20°C:** 5.0 - 7.0

**BIO EXCIPIENT GRADE | Product Code: GTHI-3220** | Previously: GT3220


NH<sub>2</sub>C(NH)NH<sub>2</sub>·HSCN · F.W. 118.16 g/mol · CAS#: 593-84-0



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

ANALYSIS		SPECIFICATIONS
Absorbance	280 nm	0.300 a.u. maximum
	300 nm	0.050 a.u. maximum
	340 nm	0.030 a.u. maximum
Appearance and Color		White / Crystals
Assay		99.5% minimum
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identity (IR)		Passes Test
Loss on Drying		0.5% maximum
Melting Range		115-121°C
pH (5% solution)		5.0-7.0
Solubility (35%)		Passes Test
Trace Metals	Arsenic (As)	5 ppm maximum
	Copper (Cu)	5 ppm maximum
	Iron (Fe)	5 ppm maximum
	Lead (Pb)	5 ppm maximum



 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.
<b>Bio Excipient Grade:</b> Intended for use as ICH-Q7 Compliant Excipient
<b>LBLE:</b> 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.

## Storage and Shipping Conditions:

Ship and Store in ambient temperature.

## Package Sizes:

10kg, 25kg and 50kg pails.



## General Product Description:

- BioSpectra manufactures Bio Excipient Grade Guanidine Thiocyanate GTHI-3220 in its Bangor, PA facility. Guanidine Thiocyanate is packaged, stored, tested, and released at BioSpectra's Bangor, PA facility.
- Guanidine Thiocyanate is a White Crystalline product.
- Molecular Formula:  $C_2H_6N_4S$ .
- Molecular Weight: 118.16 g/mol.
- CAS Number: 593-84-0.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Guanidine Thiocyanate GTHI-3220 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Guanidine Thiocyanate manufactured at BioSpectra and any raw materials used in the manufacture of Guanidine Thiocyanate at BioSpectra are not subject to genetic modification.
- Synonyms: Guanidine Hydrothiocyanate, Guanidine Isothiocyanate, Guanidine Monothiocyanate.

## GMP Compliance:

Bio Excipient Grade Guanidine Thiocyanate GTHI-3220 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Guanidine Thiocyanate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

### Pictogram:



**Signal word:** Danger

### Hazardous Statements:

- H302 – Harmful if swallowed
- H312 – Harmful in contact with skin
- H314 – Causes severe skin burns and eye damage
- H332 – Harmful if inhaled
- H412 – Harmful to aquatic life with long lasting effects
- EUH032 – Contact with acids liberates very toxic gas
- EUH071 – Corrosive to the respiratory tract

### Retest Date:

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