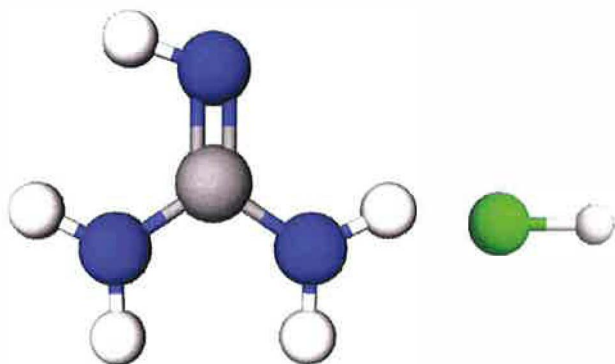




GUANIDINE HYDROCHLORIDE



BIO EXCIPIENT GRADE REGULATORY PACKET

Signature/Date:



TABLE OF CONTENTS

I. GUANIDINE HYDROCHLORIDE, BIO EXCIPIENT GRADE: 3

 1.1. GENERAL PRODUCT INFORMATION: 3

 1.2. MANUFACTURING, PACKAGING, RELEASE SITE, AND SUPPLIER INFORMATION: 3

 1.3. PHYSICO-CHEMICAL INFORMATION: 4

 1.4. REGULATORY INFORMATION:..... 5

 1.5. MISCELLANEOUS PRODUCT INFORMATION:..... 7

 1.6. CONTACT INFORMATION:..... 8



1. GUANIDINE HYDROCHLORIDE, BIO EXCIPIENT GRADE:

1.1. General Product Information:

- 1.1.1. Product Name:
 - 1.1.1.1. Guanidine Hydrochloride
- 1.1.2. Product Code:
 - 1.1.2.1. Historic Code: GH3202, GH3220, GH3221, GH3224, GH3225, GH3250, GH3251, GH3253
 - 1.1.2.2. Current Code: GHCL-3202, GHCL-3220, GHCL-3221, GHCL-3224, GHCL-3225, GHCL-3250, GHCL-3251, GHCL-3253
- 1.1.3. Scope:
 - 1.1.3.1. This regulatory packet will provide the quality and regulatory information regarding the manufacturing, testing, packaging, storage, release, shipping and handling of Bio Excipient Grade Guanidine Hydrochloride manufactured by and at the BioSpectra Stroudsburg, PA facility.
- 1.1.4. Molecular Formula:
 - 1.1.4.1. $\text{NH}_2\text{C}(\text{NH})\text{NH}_2 \cdot \text{HCl}$
- 1.1.5. Molecular Weight:
 - 1.1.5.1. 95.53 g/mol

1.2. Manufacturing, Packaging, Release Site, and Supplier Information:

- 1.2.1. General Information:
 - 1.2.1.1. BioSpectra manufactures Guanidine Hydrochloride in its Stroudsburg, PA facility. Guanidine Hydrochloride is manufactured, packaged, stored, tested and released at BioSpectra's Stroudsburg, PA facility.
 - 1.2.1.2. Guanidine Hydrochloride is additionally stored and shipped at BioSpectra's Supply Chain Center: 51 North 3rd Street, Stroudsburg, PA 18360.
- 1.2.2. Manufacturing:
 - 1.2.2.1. The manufacturing of Guanidine Hydrochloride is performed at BioSpectra's Stroudsburg, PA facility utilizing product-dedicated equipment. Equipment used in the manufacturing of Guanidine Hydrochloride is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.
- 1.2.3. Packaging:
 - 1.2.3.1. The packaging of Guanidine Hydrochloride may occur in the following BioSpectra sites: BioSpectra Stroudsburg, PA Facility: 1474 Rockdale Lane, Stroudsburg, PA 18360, and BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013
- 1.2.4. Testing for Release:
 - 1.2.4.1. Testing and release of Guanidine Hydrochloride may be performed at: BioSpectra Stroudsburg, PA Facility: 1474 Rockdale Lane, Stroudsburg, PA 18360, and BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013
- 1.2.5. GMP Compliance Statement:
 - 1.2.5.1. Bio Excipient Grade Guanidine Hydrochloride 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.

**1.3. Physico-Chemical Information:**

1.3.1. CAS Number:

1.3.1.1. CAS# 50-01-1

1.3.2. Origin:

1.3.2.1. The origin of Guanidine Hydrochloride is through chemical manufacturing using approved raw materials, which are further purified in accordance with ICH Q7 guidelines. Raw materials of synthetic origin are used in the synthesis and purification of Guanidine Hydrochloride.

1.3.3. Synonyms:

1.3.3.1. Guanidine Monohydrochloride

1.3.3.2. Guanidinium Chloride

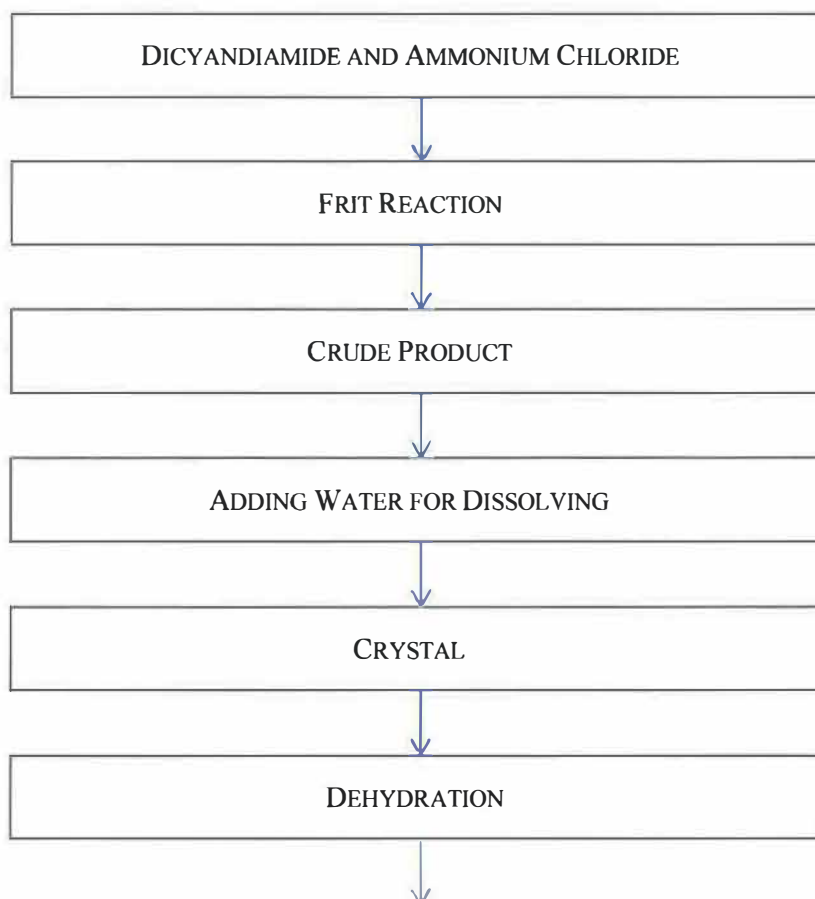
1.3.3.3. Guanidinium Hydrochloride

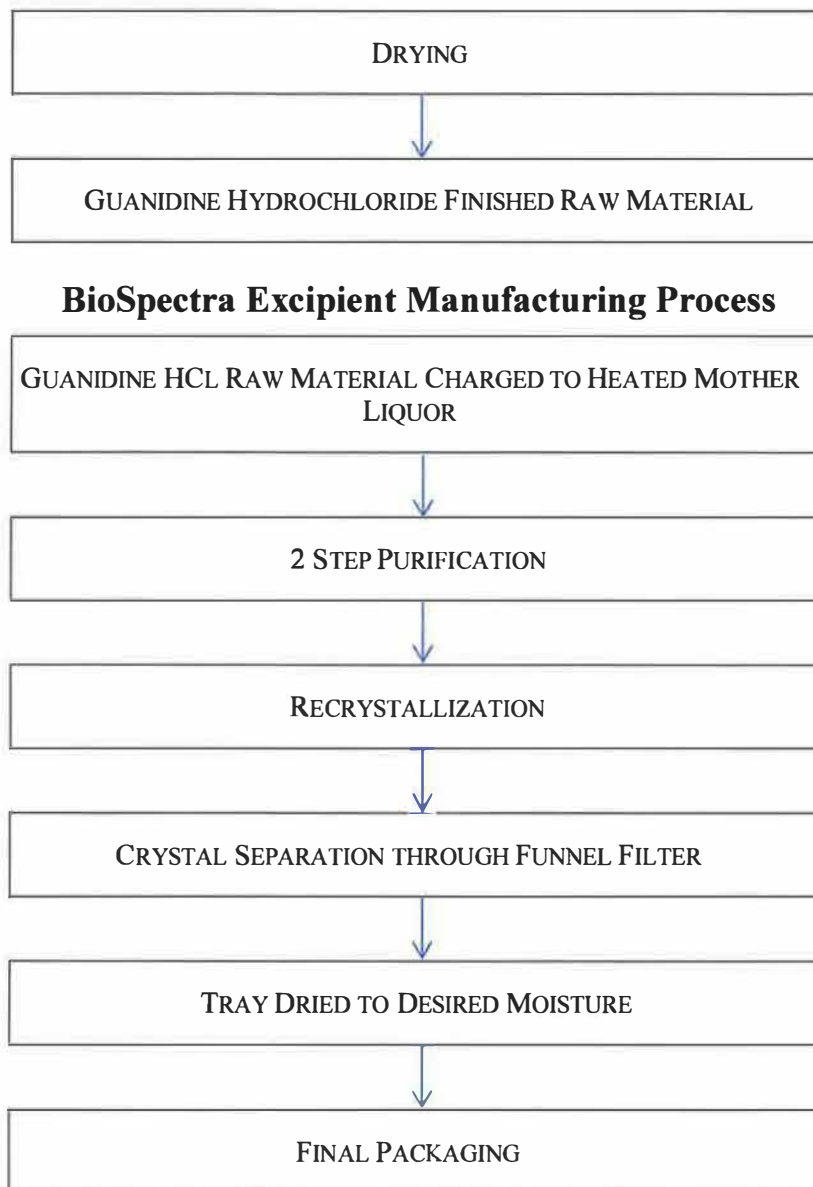
1.3.4. Morphological Form:

1.3.4.1. White Crystals

1.3.5. Manufacturing Process:

1.3.5.1. The manufacturing process for Guanidine Hydrochloride is performed by the following:

Approved Supplier Raw Material Synthesis



1.3.6. Specifications:

1.3.6.1. Available upon request.

1.4. Regulatory Information:

1.4.1. Compendial Compliance:

1.4.1.1. Not Applicable

1.4.2. Master File:

1.4.2.1. Drug Master File (DMF) is currently not available for this product.

1.4.2.2. EDQM Certificate of Suitability is currently not available for this product.

- 1.4.3. REACH:
- 1.4.3.1. Refer to the Guanidine Hydrochloride Safety Data Sheet for the REACH Number or contact your Commercial Team Representative for further information.
- 1.4.4. BSE/TSE Statement:
- 1.4.4.1. Guanidine Hydrochloride, Bio Excipient Grade is a synthetic chemical and has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that BSE/TSE is not a concern based on this evaluation.
- 1.4.5. Allergens Statement:
- 1.4.5.1. Guanidine Hydrochloride, Bio Excipient Grade manufactured at BioSpectra and its raw materials are not manufactured with or using any of the following substances: Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof, Crustaceans and products thereof, Eggs and products thereof, Fish and products thereof, Peanuts and products thereof, Soybeans and products thereof, Milk and products thereof (including lactose), Celery and products thereof, Mustard and products thereof, Sesame seeds and products thereof, Lupin and products thereof, Molluscs and products thereof, Sulphur dioxide and sulphites at >10 mg/kg as SO₂, Nuts, i.e., Almonds (*Amygdalus communis* L.), Hazelnuts (*Corylus avellana*), Walnuts (*Juglans regia*), Cashews (*Anacardium occidentale*), Pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), Pistachio nuts (*Pistacia vera*), Macadamia or Queensland nuts (*Macadamia ternifolia*) and products thereof, Beef, Chicken, Pork, Azo Dyes, Benzoic Acid, Tartrazine, Vanillin, Cocoa, Cinnamon, Coriander, Yeast, Glutamate, Legumes, and Corn. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program.
- 1.4.6. Genetically Modified Organisms (GMO) Statement:
- 1.4.6.1. Guanidine Hydrochloride, Bio Excipient Grade has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that genetic modification is not a concern based on this evaluation.
- 1.4.7. Residual Solvents Statement:
- 1.4.7.1. BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product, that the Guanidine Hydrochloride manufactured at BioSpectra complies with the requirements of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents. There are no Class 1, 2, 3 or other solvents used or produced in the manufacturing or purification of Guanidine Hydrochloride.
- 1.4.8. Metal Catalyst and Metal Reagent Residues Statement:
- 1.4.8.1. Guanidine Hydrochloride manufactured by BioSpectra is manufactured without the use of metal catalysts and metal reagents. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program.



1.4.9. Pallet Statement:

1.4.9.1. BioSpectra can state that all wooden pallets used in the packaging of Guanidine Hydrochloride manufactured at BioSpectra are ISPM 15 compliant.

1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra's Guanidine Hydrochloride, Bio Excipient Grade material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D. The results are reported in the associated Elemental Impurity Profile and are available upon request.

1.4.11. Melamine Statement:

1.4.11.1. BioSpectra does not intentionally add or use melamine in the BioSpectra manufacturing process of Guanidine Hydrochloride. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the raw materials are not expected to contain melamine based on this evaluation. BioSpectra analyzes Guanidine Hydrochloride annually for Melamine with a specification of 2.5 mg/kg max.

1.5. Miscellaneous Product Information:

1.5.1. Description of Batch:

1.5.1.1. The Guanidine Hydrochloride process is a batch process where expected batch yields are established during validation in accordance with the Manufacturing Process Validation Master Plan. Individual batch yield is additionally determined for each manufactured batch and documented in the respective batch record.

1.5.2. Lot/batch numbering system:

1.5.2.1. The lot numbering system at BioSpectra employs the following format: 4 alphanumeric digits followed by a hyphen, 4 numerical digits followed by a hyphen, and finally 5 numerical digits. A sample lot number would appear as: GHCL-0223-00001

1.5.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where GHCL represents Guanidine Hydrochloride. The fifth and sixth digits are numeric digits which indicate the site of final packaging, where 02 represents the Stroudsburg, PA facility. The seventh and eighth digits are numeric digits which indicate the year the batch record was issued, where 23 represents 2023. The final five digits are numeric digits which indicate the sequential batch number, where 00001 represents the first Guanidine Hydrochloride batch of 2023 that is automatically generated by the ERP system. The sequential batch number automatically resets on the first of the new calendar year.

1.5.3. Expiration date and/or recommended re-evaluation interval:

1.5.3.1. The current recommended Retest or Expiration Date for Guanidine Hydrochloride, Bio Excipient Grade is available in the BioSpectra Product Retest and Expiration Date List, DCN: BSI-LST-0239, and is based on current available stability data in accordance with BioSpectra's Stability Testing Program. Additionally, the recommended Retest or Expiration Date will be available on the Product Specific Certificate of Analysis, as applicable.



1.5.4. Storage and shipping conditions:

1.5.4.1. Store in a cool, dry, well-ventilated area away from incompatible and combustible substances. Keep containers tightly closed. Do not store in metal containers.

1.5.5. Packaging:

1.5.5.1. Packaging information is available through the following:
<https://Biospectra.us/packaging>

1.6. Contact Information:

1.6.1. <https://www.biospectra.us/about-us/commercial-marketing-team>