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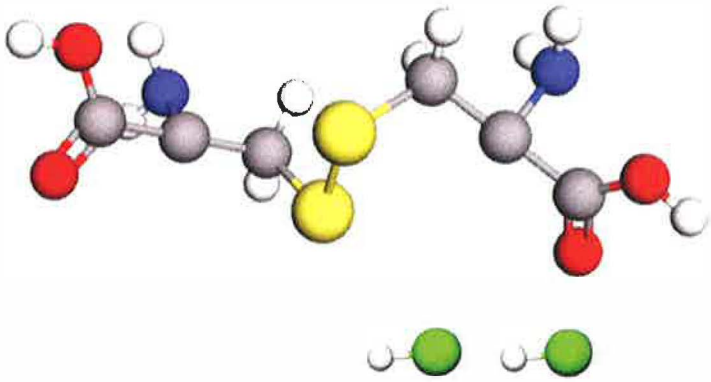
L-CYSTINE DIHYDROCHLORIDE



BIO PHARMA GRADE FOR BIOBUFFER SOLUTIONS PRODUCT LINE REGULATORY PACKET

Signature/Date:

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1. L-CYSTINE DIHYDROCHLORIDE BIO PHARMA GRADE FOR BIOBUFFER SOLUTIONS PRODUCT LINE:

1.1. General Product Information:

1.1.1. Product Name:

1.1.1.1. L-Cystine DiHydrochloride

1.1.2. Product Code:

1.1.2.1. Historic Code: CY4250 and CY4251

1.1.2.2. Current Code: LCYS-4250 and LCYS-4251

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 Pharma Grade for BioBuffer Solutions Product Line L-Cystine DiHydrochloride supplied by BioSpectra.

1.1.4. Molecular Formula:

1.1.4.1. $C_6H_{12}N_2O_4S_2$ 2HCl

1.1.5. Molecular Weight:

1.1.5.1. 313.22 g/mol

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

1.2.1. General Information:

1.2.1.1. L-Cystine DiHydrochloride is manufactured and tested by BioSpectra's approved Supplier in India.

1.2.1.2. L-Cystine DiHydrochloride is stored, tested in accordance with the BioBuffer Solutions Testing Program, BSI-SOP-0576, released, and shipped at BioSpectra's Bangor, PA facility.

1.2.1.3. L-Cystine DiHydrochloride 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 L-Cystine DiHydrochloride is performed by BioSpectra's approved Supplier utilizing multiuse equipment.

1.2.3. Packaging:

1.2.3.1. The packaging of L-Cystine DiHydrochloride occurs at BioSpectra's approved Supplier's facility, and may also occur in the following BioSpectra site: BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013

1.2.4. Testing for Release:

1.2.4.1. Testing for release of material is performed in accordance with the BioBuffer Solutions Testing Program BSI-SOP-0576.

1.2.5. GMP Compliance Statement:

1.2.5.1. Bio Pharma Grade for BioBuffer Solutions Product Line L-Cystine DiHydrochloride is suitable for use as a process chemical. It is GMP manufactured by the approved supplier in accordance with the approved supplier's ISO 9001:2015 certified management system. This grade of L-Cystine DiHydrochloride is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

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1.3. Physico-Chemical Information:

1.3.1. CAS Number:
- 1.3.1.1. CAS# 30925-07-6

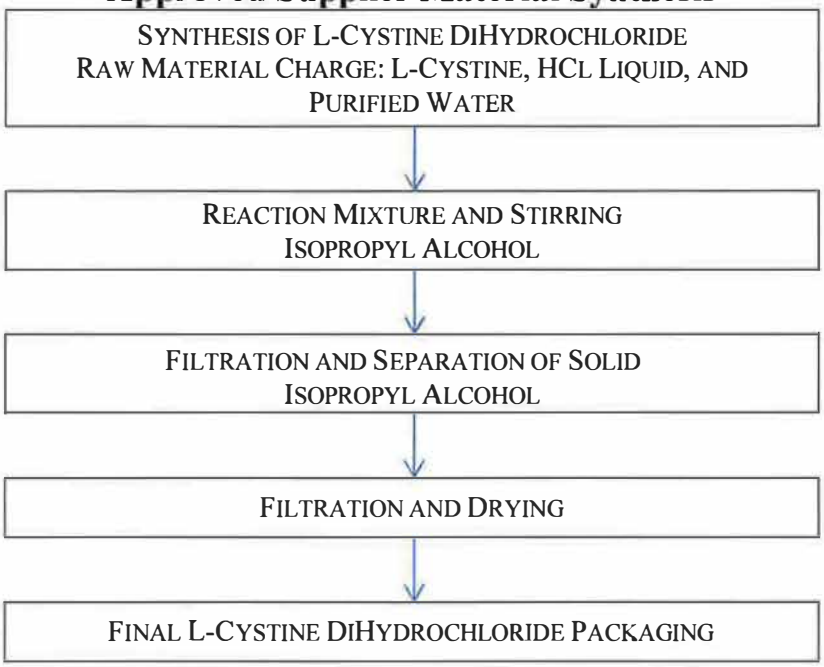
1.3.2. Origin:
- 1.3.2.1. The origin of L-Cystine DiHydrochloride is through synthetic chemical manufacturing.

1.3.3. Synonyms:
- 1.3.3.1. (2R)-2-amino-3-{[(2R)-2-amino-2-carboxyethyl]disulfanyl}propanoic acid dihydrochloride

1.3.4. Morphological Form:
- 1.3.4.1. White to Slightly Yellow Crystalline Powder

1.3.5. Manufacturing Process:
- 1.3.5.1. The manufacturing process for L-Cystine DiHydrochloride is performed by the following:

Approved Supplier 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.

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1.4.3. REACH:

1.4.3.1. Refer to the L-Cystine DiHydrochloride 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. L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product Line 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. L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product Line does not contain, and has not been derived from or commingled with the following allergens: 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 sulfites at >10 mg/kg as SO, Nuts, i.e., Almonds (*Amygdalus communis* L.), Hazelnuts (*Corylus avellana*), Walnuts (*Juglans regia*), Cashews (*Anacardium occidentale*), Pecan nuts (*Carya illinoinensis* (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 material supply through the Supplier Qualification Program.

1.4.6. Genetically Modified Organisms (GMO) Statement:

1.4.6.1. L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product Line is a synthetic chemical and has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. There are no raw materials, source materials, or reagents used in the L-Cystine DiHydrochloride manufacturing process that are genetically modified or derived from GMO sources. BioSpectra can state that genetic modification is not a concern based on this evaluation.

1.4.7. Residual Solvents Statement:

1.4.7.1. L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product Line is manufactured using the solvent Isopropyl Alcohol, and is stated to comply with the ICH Q3C required concentration limit of 5000ppm for a Class 3 residual solvent. BioSpectra has evaluated the material supply through the Supplier Qualification Program.

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1.4.8. Metal Catalyst and Metal Reagent Residues Statement:

1.4.8.1. L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product Line is manufactured without the use of metal catalysts, metal reagents, or metal residues. BioSpectra has evaluated the material supply through the Supplier Qualification Program.

1.4.9. Pallet Statement:

1.4.9.1. BioSpectra can state that all pallets used in the packaging of L-Cystine DiHydrochloride are ISPM 15 compliant.

1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra has evaluated the material supply through the Supplier Qualification Program, and can state that none of the elemental impurities listed in ICH Q3D, USP <232>, and USP <233> are anticipated to be present in L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product Line.

1.4.11. Melamine Statement:

1.4.11.1. BioSpectra has evaluated the material supply through the Supplier Qualification Program, and can state that L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product Line does not contain Melamine based on this evaluation. BioSpectra does not specifically analyze L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product Line for Melamine.

1.5. Miscellaneous Product Information:

1.5.1. Description of Batch:

1.5.1.1. The L-Cystine DiHydrochloride process is a batch process where each batch size is determined based on order requirements.

1.5.2. Lot/batch numbering system:

1.5.2.1. The lot numbering system at BioSpectra employs the following format: 4 alphanumerical digits followed by a hyphen, 4 numerical digits followed by a hyphen, and finally 5 numerical digits. A sample lot number would appear as: LCYS-0123-00001

1.5.2.1.1. The first four digits are alpha digits which indicate the material, where LCYS represents L-Cystine DiHydrochloride. The fifth and sixth digits are numeric digits which indicate the site of final packaging, where 01 represents the Bangor, 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 L-Cystine DiHydrochloride 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.

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

1.5.3.1. The current recommended Retest or Expiration Date for L-Cystine DiHydrochloride, Bio Pharma 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 locked up. Store in a well-ventilated place. Keep cool. Store in original container or corrosive resistant and/or lined container.

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