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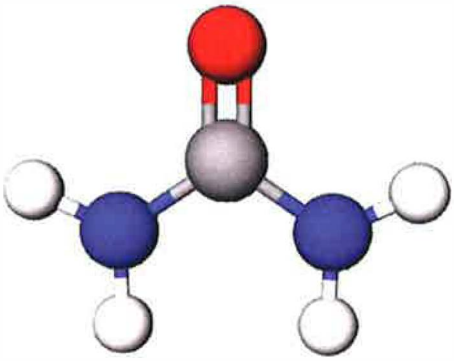
Premium Pharmaceutical Ingredients

UREA 6M SOLUTION



BIO EXCIPIENT GRADE REGULATORY PACKET

Signature/Date:

BIOSPECTRA
Premium Pharmaceutical Ingredients

TABLE OF CONTENTS

BIOSPECTRA
Premium Pharmaceutical Ingredients

1. UREA 6M SOLUTION, BIO EXCIPIENT GRADE:

1.1. General Product Information

1.1.1. Product Name:
1.1.1.1. Urea 6M Solution
1.1.2. Product Code:
1.1.2.1. UREA-3120
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 Urea 6M Solution manufactured by and at the BioSpectra, Bangor, PA facility.
1.1.4. Molecular Formula:
1.1.4.1. CH_4N_2O
1.1.5. Molecular Weight:
1.1.5.1. Urea: 60.06 g/mol
1.1.6. Urea and Water for Injection Packaged in a 1200L Tote, 360 Grams per Liter Urea: 360g/L

1.2. Manufacturing, Packaging, Release Site and Supplier Information

1.2.1. General Information:BioSpectra manufactures Urea 6M Solution in its Bangor, PA facility. Urea 6M Solution is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.
1.2.2. Manufacturing:
1.2.2.1. The manufacturing of Urea 6M Solution is performed at BioSpectra's Bangor, PA facility utilizing multi-use equipment. Equipment used in the manufacturing of Urea 6M Solution is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.
1.2.3. Packaging:
1.2.3.1. The packaging of Urea 6M Solution occurs 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 and release of Urea 6M Solution is performed at the BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013
1.2.5. GMP Compliance Statement:
1.2.5.1. Bio Excipient Grade Urea 6M Solution is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. This grade of Urea 6M Solution is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

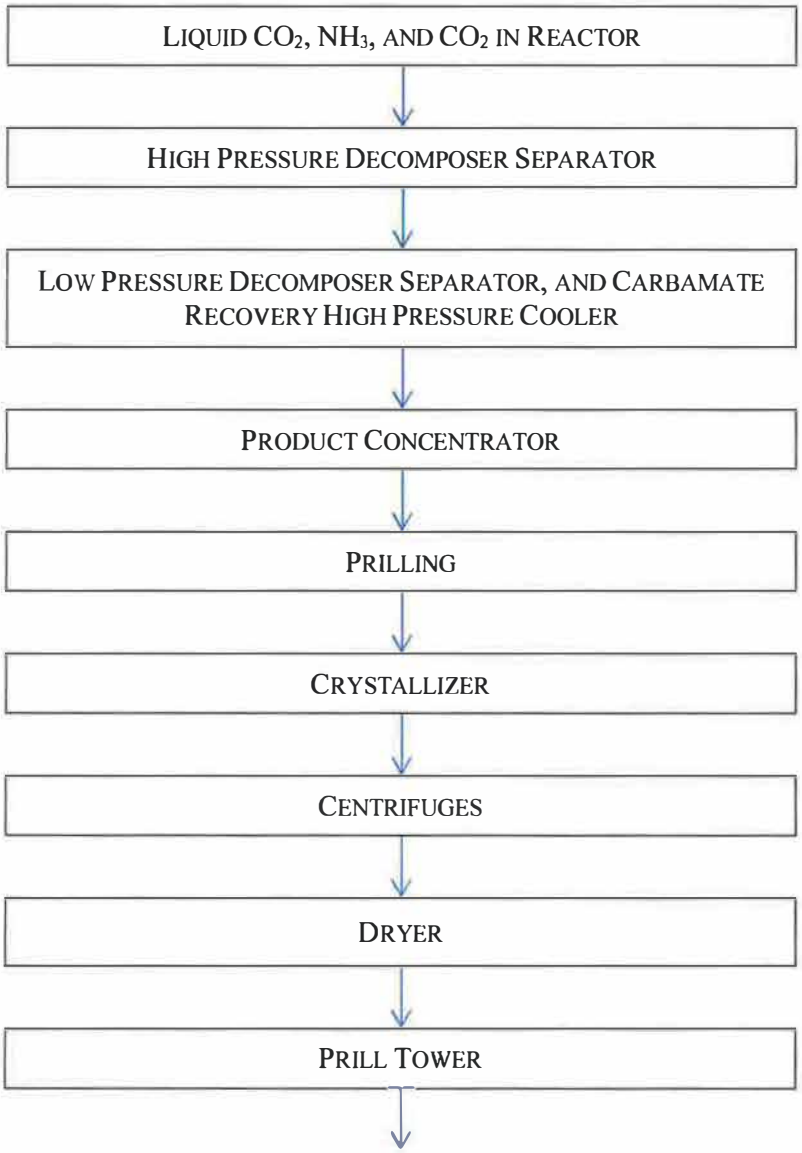
1.3. Physico-Chemical Information

1.3.1. CAS Number:
1.3.1.1. CAS# 57-13-6
1.3.2. Origin:
1.3.2.1. The origin of Urea 6M Solution is through synthetic chemical manufacturing using approved raw materials, which are further purified in accordance with ICH Q7 guidelines. Only raw materials of synthetic origin are used in the synthesis and purification of Urea.

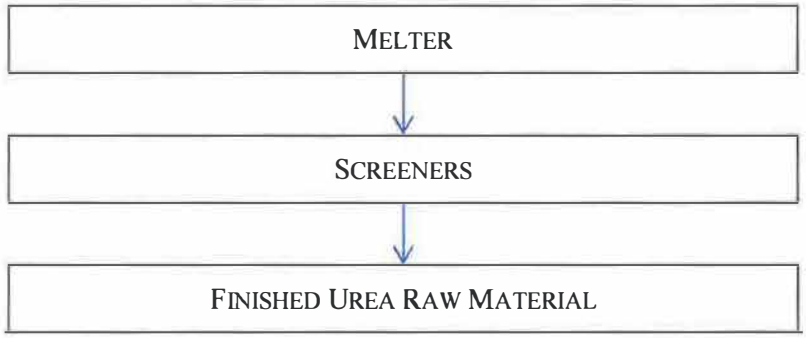
BIOSPECTRA
Premium Pharmaceutical Ingredients

1.3.3. Synonyms:
1.3.3.1. Carbamide Solution
1.3.3.2. Carbonyl Diamide Solution
1.3.4. Morphological Form:
1.3.4.1. Colorless Liquid
1.3.5. Manufacturing Process:
1.3.5.1. The manufacturing process for Urea 6M Solution, Bio Excipient Grade is by performed by the following:

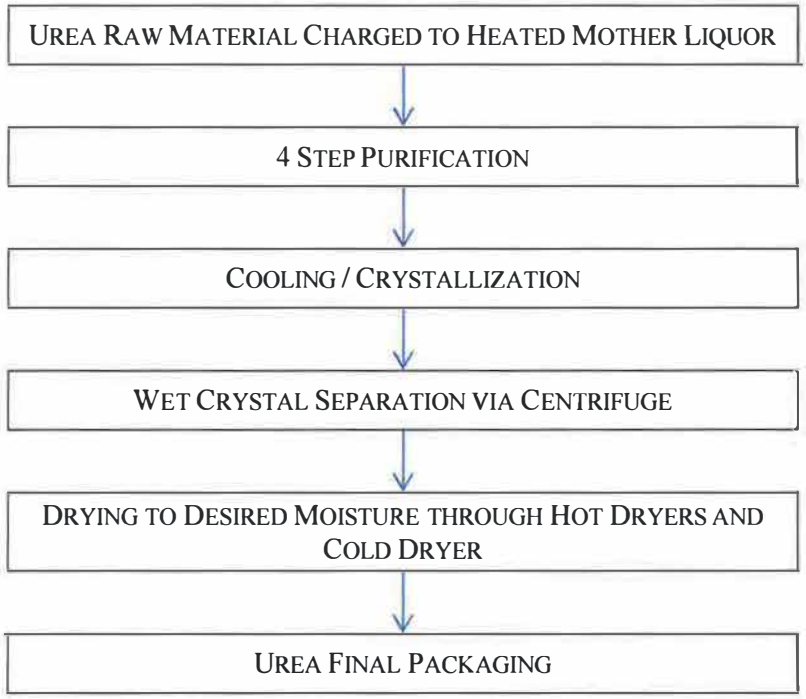
Approved Supplier Raw Material Synthesis



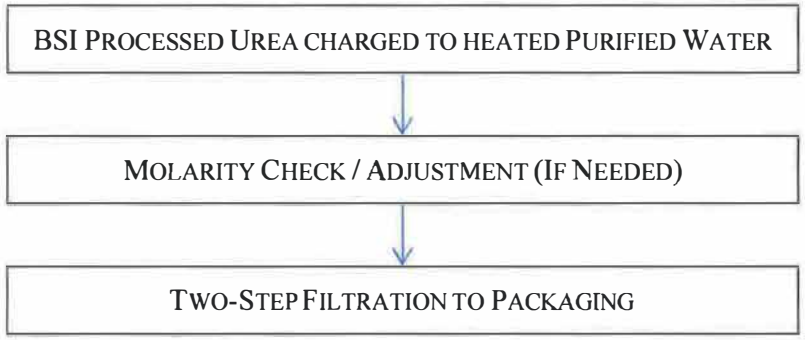
BIOSPECTRA
Premium Pharmaceutical Ingredients



BioSpectra Urea Excipient Manufacturing Process



BioSpectra Urea 6M Solution Excipient Manufacturing Process



BIOSPECTRA
Premium Pharmaceutical Ingredients

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 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 Urea 6M Solution 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. Urea 6M Solution, 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. Urea 6M Solution, Bio Excipient Grade manufactured by BioSpectra and its raw materials are not manufactured with or using any of the following substances: Casein, Corn, Fish, Lactose, Tartrazine, Crustaceans, Soy Protein, Vanillin, Yeast, Wheat, Celery, Nuts, Beef, Cocoa, Peanuts, Chicken, Benzoic Acid, Sesame, Shell Fish, Lupin, Glutamate, Mollusk, Gluten, Azo Dyes, Legumes, Chicken's Egg, Cinnamon, Nut Oil, Soya Oil, Coriander, Peanut Oil, Rye, Mustard, Sesame Oil, Pork, Sulfite, Barley, Oats, Milk, Kamut, Spelt, and Soybeans. BioSpectra has evaluated the Raw Material Supply through the Supplier Qualification Program.
1.4.6. Genetically Modified Organisms (GMO) Statement:
1.4.6.1. Urea 6M Solution, 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 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 Urea 6M Solution, Bio Excipient Grade manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4. BioSpectra does not intentionally add or use any solvents in the manufacturing process of Urea 6M Solution, Bio Excipient Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that no solvents are used in the manufacture of the Urea raw material supplied to BioSpectra.
1.4.8. Metal Catalyst and Metal Reagent Residues Statement:
1.4.8.1. Urea 6M Solution, Bio Excipient Grade 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.

BIOSPECTRA
Premium Pharmaceutical Ingredients

1.4.9. Pallet Statement:

1.4.9.1. BioSpectra can state that all wooden pallets used in the packaging and shipping of Urea 6M Solution manufactured at BioSpectra are ISPM 15 compliant.

1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra's Urea 6M Solution, 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. Urea 6M Solution, 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 melamine is not a concern based on this evaluation. BioSpectra additionally analyzes Urea Bio Excipient Grade manufactured by BioSpectra, which is used in the manufacture of Urea 6M Solution, 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 Urea 6M Solution 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 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: UREA-0123-00001

1.5.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where UREA represents Urea. 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 Urea 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 Urea 6M Solution, 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.

BIOSPECTRA
Premium Pharmaceutical Ingredients

1.5.4. Storage and shipping conditions:
1.5.4.1. Store in a tightly closed container. Store in a dry, well-ventilated area with temperature between 15-30°C. Store away from incompatible substances.
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