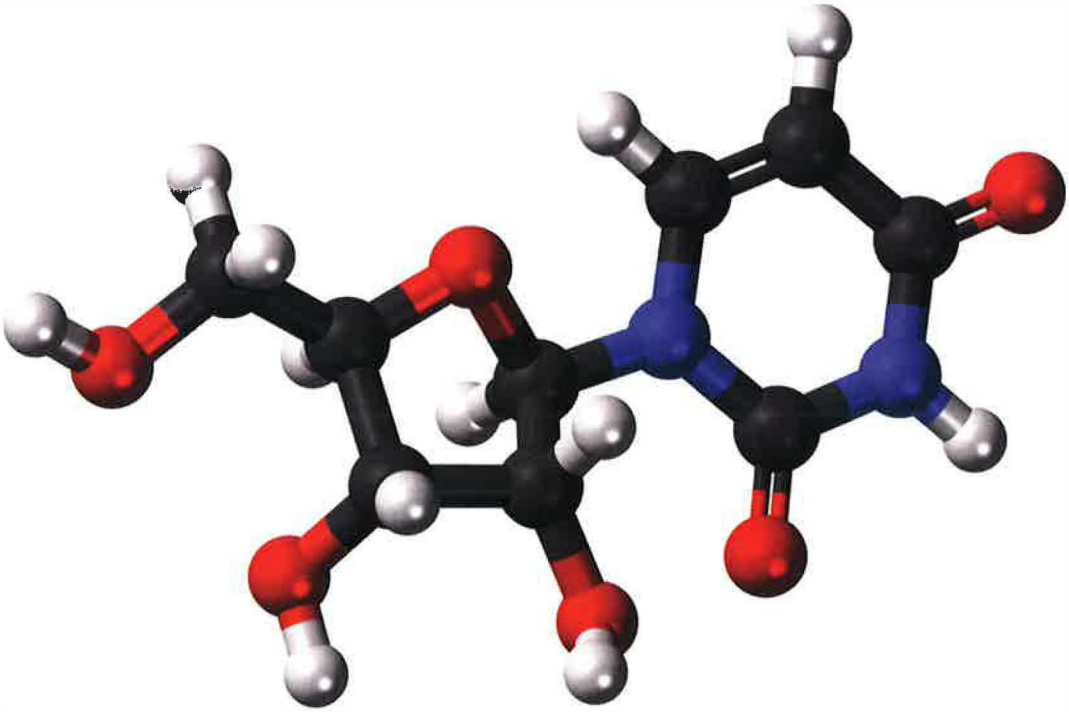
BIOSPECTRA
Premium Pharmaceutical Ingredients

URIDINE



BIO EXCIPIENT GRADE REGULATORY PACKET

Signature/Date:

BIOSPECTRA
Premium Pharmaceutical Ingredients

TABLE OF CONTENTS

BIOSPECTRA
Premium Pharmaceutical Ingredients

1. URIDINE, BIO EXCIPIENT GRADE:

1.1. General Product Information:

1.1.1. Product Name:
1.1.1.1. Uridine
1.1.2. Product Code:
1.1.2.1. Historic Code: UD3250
1.1.2.2. Current Code: URID-3250
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 Uridine manufactured by and at the BioSpectra, Bangor, PA facility
1.1.4. Molecular Formula:
1.1.4.1. $C_9H_{12}N_2O_6$
1.1.5. Molecular Weight:
1.1.5.1. 244.2 g/mol.

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

1.2.1. General Information:
1.2.1.1. BioSpectra manufactures Uridine in its Bangor, PA facility. Uridine is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.
1.2.2. Manufacturing:
1.2.2.1. The manufacturing of Uridine is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Uridine is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.
1.2.3. Packaging:
1.2.3.1. The packaging of Uridine 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 Uridine 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 Uridine is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. This Grade of Uridine is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

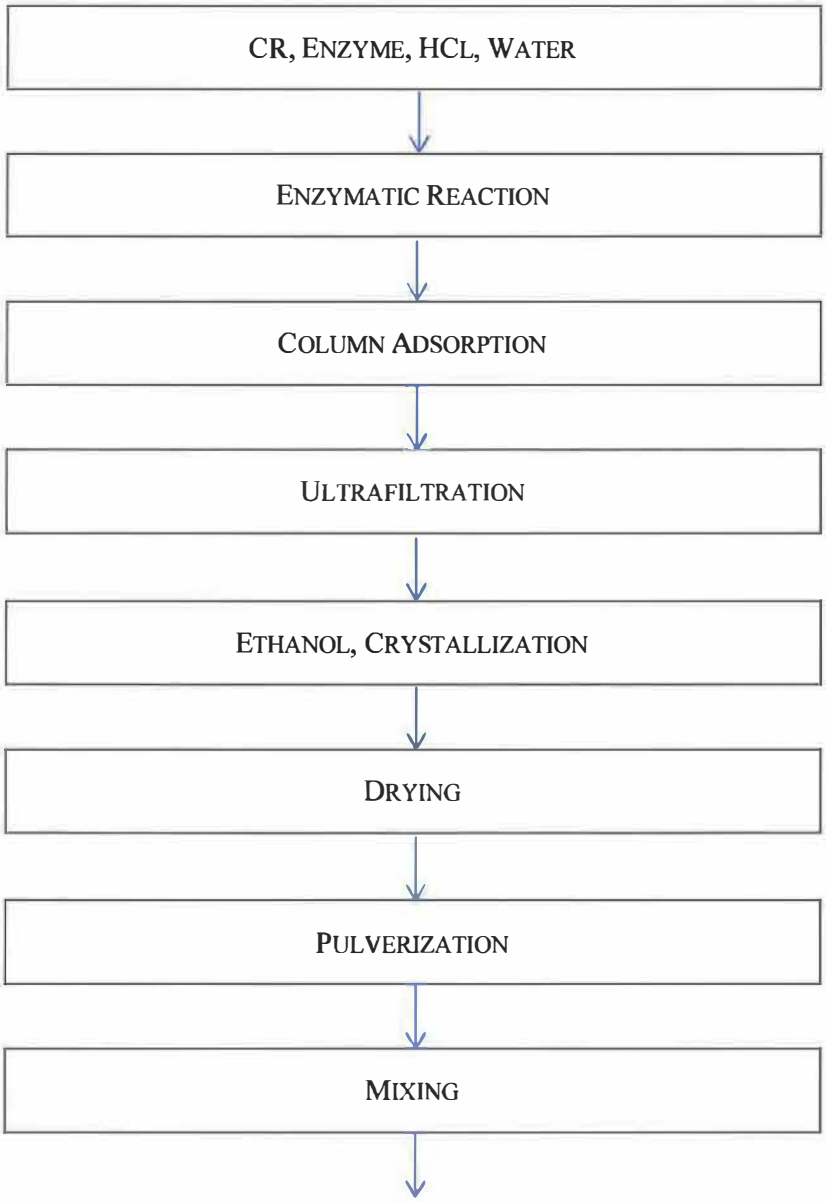
1.3. Physico-Chemical Information:

1.3.1. CAS Number:
1.3.1.1. CAS# 58-96-8
1.3.2. Origin:
1.3.2.1. The origin of Uridine is through chemical manufacturing using approved raw materials, which are further purified in accordance with ICH Q7 guidelines. Raw materials of enzymatic origin are used in the synthesis and purification of Uridine.

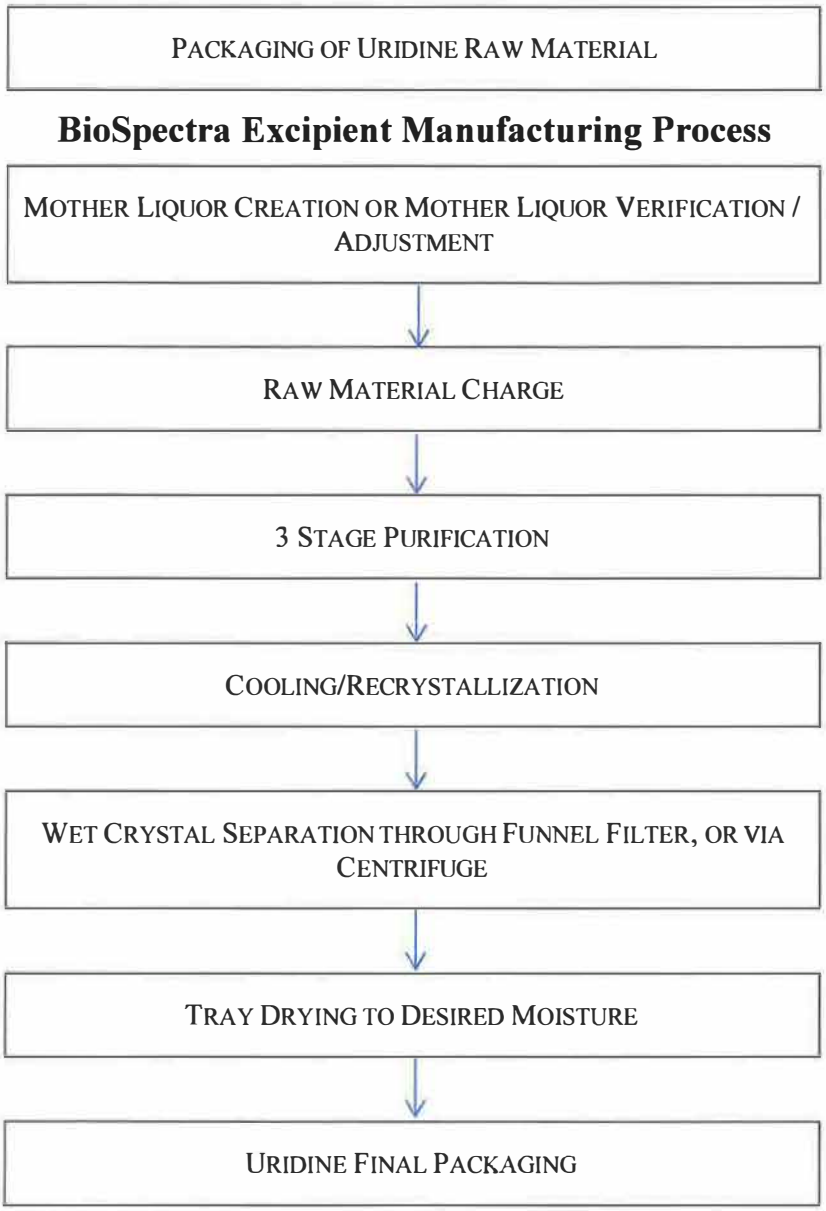
BIOSPECTRA
Premium Pharmaceutical Ingredients

1.3.3. Synonyms:
  1.3.3.1. Uracil-1-β-D-ribofuranoside
  1.3.3.2. 1-β-D-Ribofuranosyluracil
1.3.4. Morphological Form:
  1.3.4.1. White to almost White Powder
1.3.5. Manufacturing Process:
  1.3.5.1. The manufacturing process for Uridine is performed by the following:

Approved Supplier Raw Material Synthesis



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

BIOSPECTRA
Premium Pharmaceutical Ingredients

1.4.3. REACH:

1.4.3.1. Refer to the Uridine 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. Uridine, 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 BSE/TSE is not a concern based on this evaluation. Uridine, Bio Excipient Grade and its raw materials are not of animal origin.

1.4.5. Allergens Statement:

1.4.5.1. Uridine, Bio Excipient Grade manufactured at BioSpectra and its raw materials are not manufactured with or using any of the following allergenic 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 sulfites at >10 mg/kg as SO_2, 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 raw material supply through the Supplier Qualification Program.

1.4.6. Genetically Modified Organisms (GMO) Statement:

1.4.6.1. Uridine, 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.

BIOSPECTRA
Premium Pharmaceutical Ingredients

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 Uridine, 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 Uridine, Bio Excipient Grade, with the exception of Isopropyl Alcohol (2-Propanol). BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that Ethanol is used in the manufacture of the Uridine raw material supplied to BioSpectra. BioSpectra's approved Raw Material Supplier has indicated that the Uridine raw material complies with the allowed limit of 5000ppm Ethanol. BioSpectra additionally analyzes Uridine finished good for residual solvents during process validation, and has confirmed that the product complies with the limits of 5000ppm Ethanol and 2-Propanol.

1.4.8. Metal Catalyst and Metal Reagent Residues Statement:

1.4.8.1. Uridine, Bio Excipient Grade manufactured by BioSpectra and its raw materials are 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 and shipping of Uridine manufactured at BioSpectra are ISPM 15 compliant.

1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra's Uridine, 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 Uridine, Bio Excipient Grade. 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.

1.5. Miscellaneous Product Information:

1.5.1. Description of Batch:

1.5.1.1. The Uridine, Bio Excipient Grade manufacturing 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: URID-0123-00001.

1.5.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where URID represents Uridine. 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 Uridine 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 date or expiration date for Uridine, 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. Keep container tightly closed and store between 2-8°C, do not store above 20°C. Store in a dry and well-ventilated area.

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