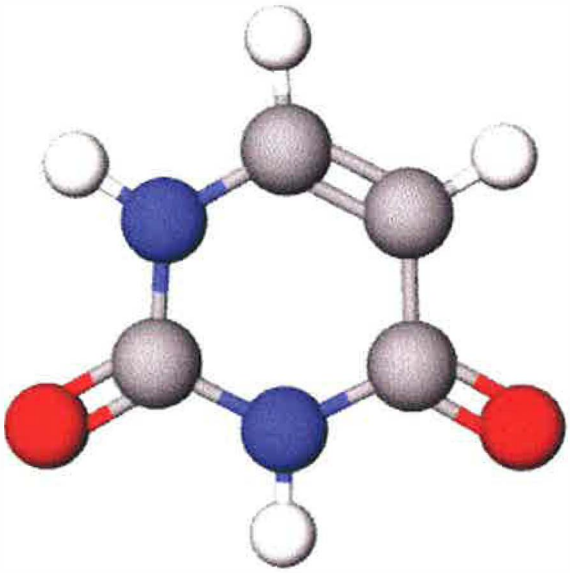
BIOSPECTRA
Premium Pharmaceutical Ingredients

URACIL



BIO PHARMA GRADE FOR BIOSPECTRA PRODUCT LINE REGULATORY PACKET

Signature/Date:

BIOSPECTRA
Premium Pharmaceutical Ingredients

TABLE OF CONTENTS

BIOSPECTRA
Premium Pharmaceutical Ingredients

1. URACIL BIO PHARMA GRADE FOR BIOSPECTRA PRODUCT LINE:

1.1. General Product Information

1.1.1. Product Name:
1.1.1.1. Uracil
1.1.2. Product Code:
1.1.2.1. Historic Code: UC4201, UC4202, UC4250, UC4301
1.1.2.2. Current Code: URAC-4201, URAC-4202, URAC-4250, URAC-4301
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 Uracil manufactured by and at the BioSpectra, Bangor, PA facility.
1.1.4. Molecular Formula:
1.1.4.1. $C_4H_4N_2O_2$
1.1.5. Molecular Weight:
1.1.5.1. 112.09 g/mol

1.2. Manufacturing, Packaging, Release Site and Supplier Information

1.2.1. General Information:
1.2.1.1. BioSpectra manufactures Uracil in its Bangor, PA facility. Uracil is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.
1.2.1.2. Uracil 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 Uracil is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Uracil is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.
1.2.3. Packaging:
1.2.3.1. The packaging of Uracil 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 Uracil 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 Pharma Grade Uracil is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. This grade of Uracil is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

1.3. Physico-Chemical Information

1.3.1. CAS Number:
1.3.1.1. CAS# 66-22-8
1.3.2. Origin:
1.3.2.1. The origin of Uracil is through chemical manufacturing using approved raw materials, which are further purified in accordance with the validated manufacturing process. Raw materials of synthetic origin are used in the synthesis and purification of Uracil.

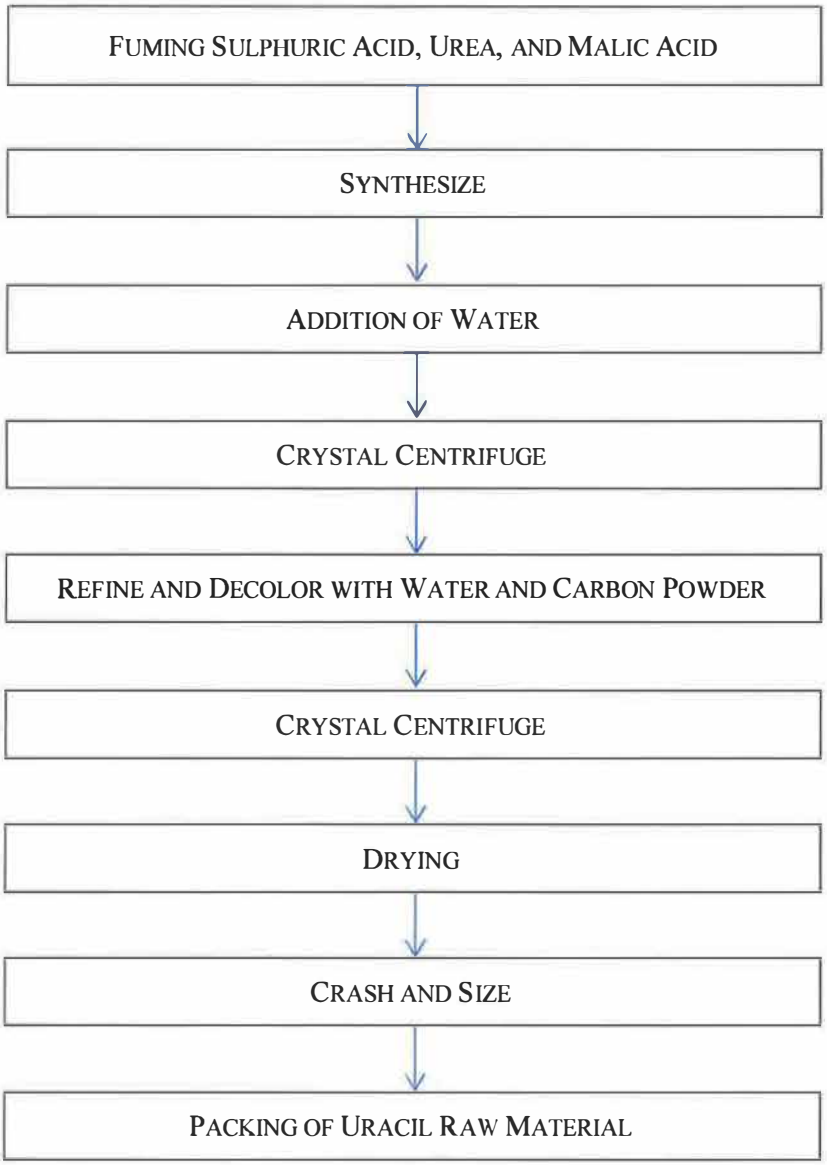
BIOSPECTRA
Premium Pharmaceutical Ingredients

1.3.3. Synonyms:
- 1.3.3.1. 2,4-Dihydroxypyrimidine
- 1.3.3.2. 2,4-Pyrimidinediol
- 1.3.3.3. 2,4(1H,3H)-Pyrimidinedione

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

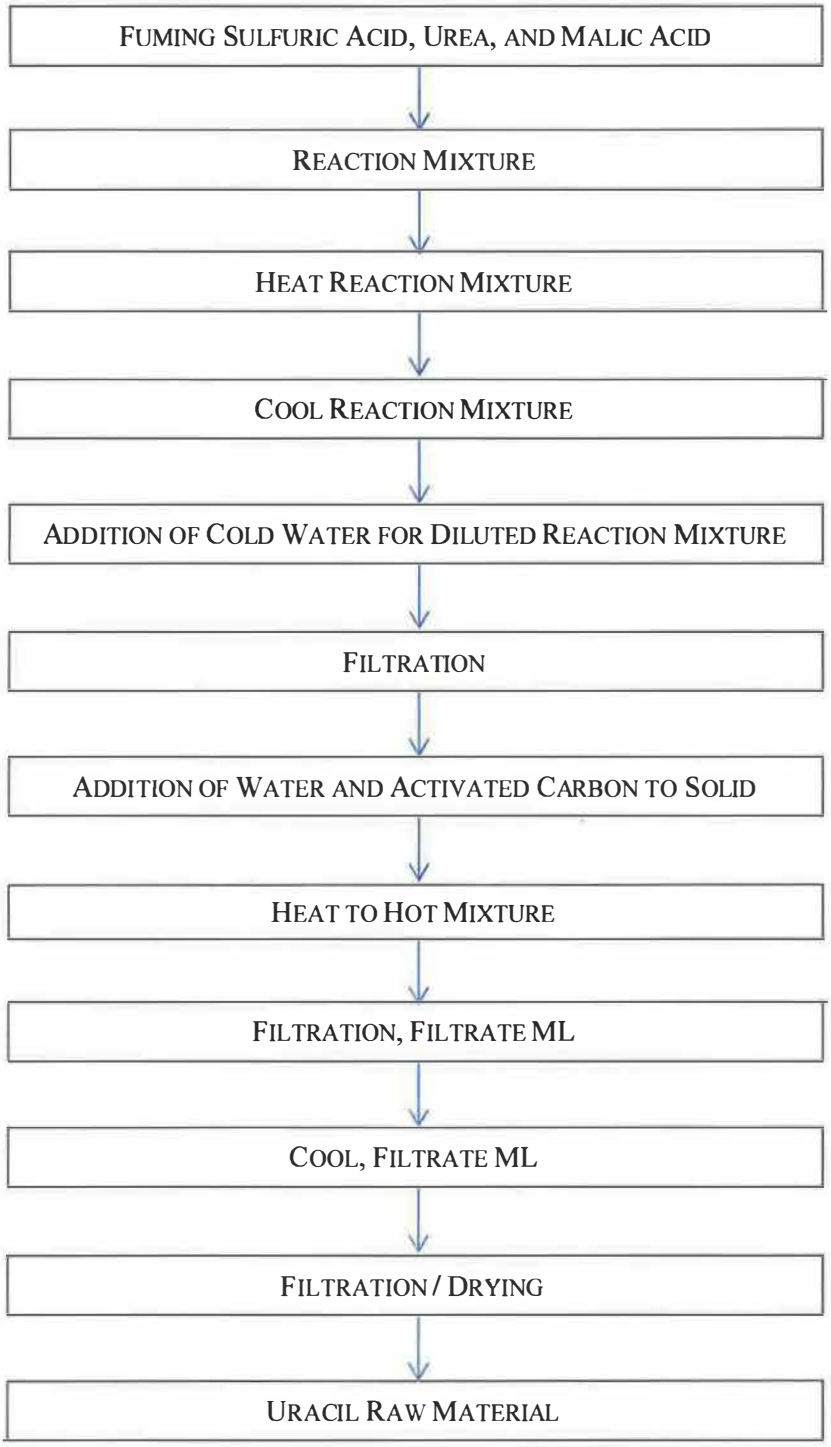
1.3.5. Manufacturing Process:
- 1.3.5.1. The manufacturing process for Uracil is performed by the following:

Approved Supplier Raw Material Synthesis



BIOSPECTRA
Premium Pharmaceutical Ingredients

Approved Supplier Raw Material Synthesis



BIOSPECTRA
Premium Pharmaceutical Ingredients

BioSpectra Chemical Manufacturing Process

URACIL RAW MATERIAL CHARGED TO HEATED MOTHER LIQUOR

↓

3 STAGE PURIFICATION

↓

TRANSFER TO FINAL COOLING STAGE

↓

WET CRYSTAL SEPARATION VIA CENTRIFUGE OR FUNNEL FILTER

↓

TRAY DRIED TO DESIRED MOISTURE

↓

URACIL FINAL PACKAGING

BioSpectra Additional Wash Process, as Required

FINISHED GOOD URACIL TO BE RE-WASHED

↓

CRYSTAL WASH VIA FUNNEL FILTER

↓

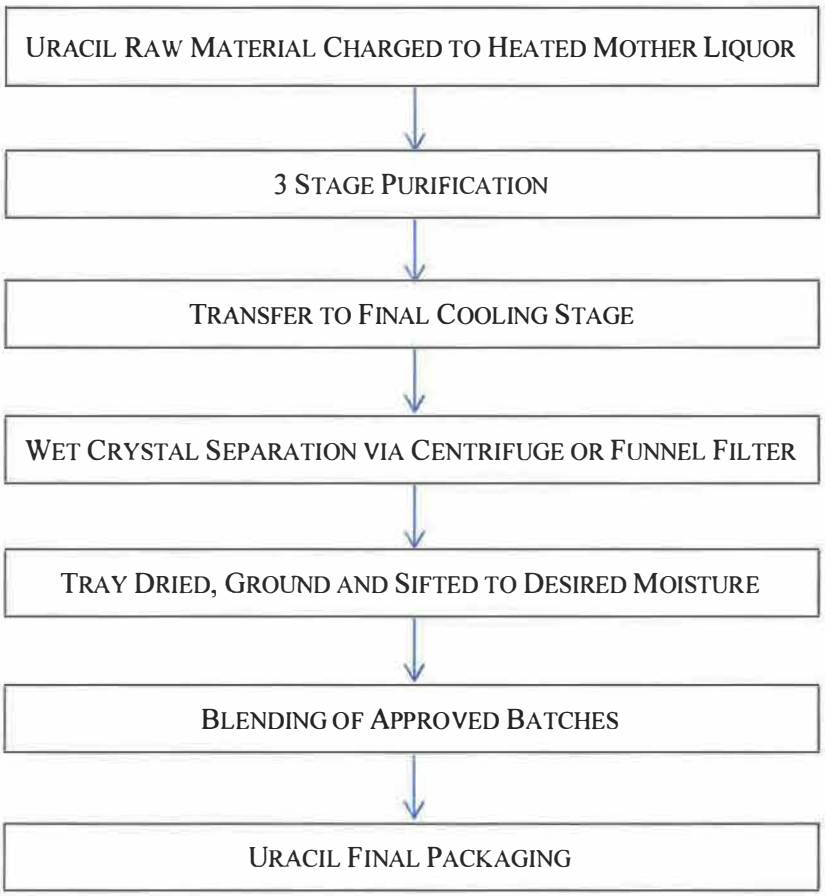
TRAY DRIED TO DESIRED MOISTURE

↓

URACIL FINAL PACKAGING

BIOSPECTRA
Premium Pharmaceutical Ingredients

BioSpectra Chemical Manufacturing Process (Blend)



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 Uracil 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. Uracil, Bio Pharma 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. Uracil, Bio Pharma Grade and its raw materials are not of animal origin.

BIOSPECTRA
Premium Pharmaceutical Ingredients

1.4.5. Allergens Statement:

1.4.5.1. Uracil, Bio Pharma Grade manufactured by 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 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 raw material supply through the Supplier Qualification Program.

1.4.6. Genetically Modified Organisms (GMO) Statement:

1.4.6.1. Uracil, Bio Pharma 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 Uracil manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4. There are no class 1, 2, 3, or other solvents used in the manufacture of Uracil, Bio Pharma Grade or its raw materials. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program.

1.4.8. Metal Catalyst and Metal Reagent Residues Statement:

1.4.8.1. Uracil, Bio Pharma 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.

1.4.9. Pallet Statement:

1.4.9.1. BioSpectra can state that all wooden pallets used in the packaging and shipping of Uracil manufactured by BioSpectra are ISPM 15 compliant.

1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra's Uracil, Bio Pharma 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.

BIOSPECTRA
Premium Pharmaceutical Ingredients

1.4.11. Melamine Statement:

1.4.11.1. BioSpectra does not intentionally add or use melamine in the BioSpectra manufacturing process of Uracil, Bio Pharma Grade. Bio Spectra 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 additionally analyzes Uracil for melamine annually, 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 Uracil 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: URAC-0123-00001.

1.5.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where URAC represents Uracil. 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 Uracil 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 Uracil, 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 in a tightly closed container in a dry, well-ventilated area 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