BIOSPECTRA
Premium Pharmaceutical Ingredients

GMP Process Chemical

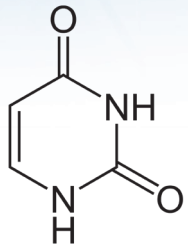
GMP Manufactured Product

URACIL, LBLE, ≥98%, GMP Grade

Low Bioburden, Low Endotoxin, GMP Manufactured

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

Uracil is important for the detoxification of many carcinogens and is also used to detoxify many drugs such as cannabinoids and opioids. Uracil can be used for drug delivery and as an intermediate to compounds used in anticancer drugs. Other derivatives are used in pesticides and antiphotosynthetic herbicides as well as in the synthesis of caffeine. Uracil is used as a coenzyme and allosteric regulator during biochemical reactions and for polysaccharide biosynthesis and transportation of sugars containing aldehydes.



CAS #: 66-22-8
Molecular Formula: $C_4H_4N_2O_2$
F.W.: 112.09 g/mol

BIO PHARMA GRADE | Product Code: URAC-4250 | Previously: UC4250

$C_4H_4N_2O_2$ · F.W. 112.09 g/mol. · CAS# 66-22-8

Made in the USA

These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

ANALYSIS	SPECIFICATIONS
Appearance and Color	White to Slightly Yellow Powder
Assay	≥ 98%
Chlorides	≤ 100 ppm
Endotoxin content	< 3 EU/g
Heavy Metals	≤ 20 ppm
Identification (IR)	Passes Test
Loss on Drying	≤ 0.50%
Melting Point	≥ 300 °C (Target 335 °C)
Reaction	Passes Test
Residue on Ignition	≤ 0.10%
Solubility	Passes Test
Sulphates	≤ 400 ppm
TAMC	≤ 100 CFU/g

Lead Time: Stock or 3-months
Minimum Order Quantity: Stock- 5kg / No Stock- 20kg

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

BIOSPECTRA Key Compliance Attributes of BioSpectra Grades	Bio Pharma Grade IPEC GMP Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Pharma Grade: Intended for use as IPEC cGMP Compliant Chemical

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).
LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

General Product Description:

- The manufacturing of Uracil URAC-4250 is performed at BioSpectra's Bangor, PA facility utilizing multi-use equipment. Equipment used in the manufacturing of URAC-4250 is cleaned in accordance with BioSpectra's Process Cleaning Validation Master Plan.
- Uracil is a white to slightly yellow powder.
- Molecular Formula: $C_4H_4N_2O_2$
- Molecular Weight: 112.09 g/mol.
- CAS Number: 66-22-8.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Uracil URAC-4250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Uracil manufactured at BioSpectra and any raw materials used in the manufacture of Uracil at BioSpectra are not subject to genetic modification.
- Synonyms: 2,4-Dihydroxypyrimidine; 2,4(1H,3H)-Pyrimidinedione; 2,4-Pyrimidinediol.

GMP Compliance:

Bio Pharma Grade Uracil URAC-4250 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.

Retest Date:

The recommended expiration period for Uracil is three years from the date of manufacture.

Storage and Shipping Conditions:

Ship and Store in ambient temperature.

Package Sizes:

10kg, 25kg and 50kg pails.