BIOSPECTRA
Premium Pharmaceutical Ingredients

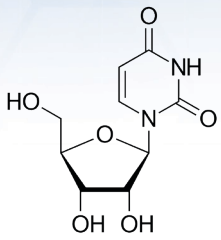
Excipient
ICH-Q7 GMP Manufactured Product

URIDINE, LBLE*, GMP, Excipient Grade

***Low Bioburden, Low Endotoxin**

INTENDED USE FOR CRITICAL BIOPHARMA APPLICATIONS

Uridine is a glycosylated pyrimidine-analog containing uracil attached to a ribose ring via a β-N_1-glycosidic bond. It is one of the five standard nucleosides which make up nucleic acid. Uridine is used as a nutrient, an intermediate in pharmaceutical preparations with other GMP pharmaceutical applications.



Lead Time: 3-6 months
Minimum Order Quantity: If Stock-10kg/ No Stock-100kg

CAS #: 58-96-8
Molecular Formula: $C_9H_{12}N_2O_6$
F.W.: 244.20 g/mol.
Density: 933 kg/m^3
Solubility in Water: (50g/L)

BIO PHARMA GRADE | Product Code: URID-3250

$C_9H_{12}N_2O_6$ · F.W. 244.20 g/mol. · CAS# 58-96-8

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 almost white powder
Bioburden TAMC	≤ 100 CFU/g
Bioburden TYMC	≤ 100 CFU/g
Endotoxin	≤ 0.5 EU/mg
Heavy Metals	≤ 10 ppm
HPLC Assay	98.0 - 102.0%
HPLC Purity	≥ 99.0%
Identification (IR)	Conforms to Spectrum of Reference Standard
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Transparency	≥ 98.0%
UV Assay	≥ 98.0%

BIOSPECTRA **Key Compliance Attributes of BioSpectra Grades**	**Bio Excipient Grade** **ICH-Q7 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	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

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

Bio Excipient Grade: Intended for use as ICH-Q7 Compliant Excipient

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 Bio Pharma Grade Uridine URID-3250 is performed at BioSpectra's Bangor, PA facility utilizing multi-use equipment. Equipment used in the manufacturing of URID-3250 is cleaned in accordance with BioSpectra's Process Cleaning Validation Master Plan.
- Uridine is a White to almost white powder.
- Molecular Formula: $C_9H_{12}N_2O_6$
- Molecular Weight: 244.20 g/mol.
- CAS Number: 58-96-8
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Uridine, URID-3250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Uridine manufactured at BioSpectra and any raw materials used in the manufacture of Uridine at BioSpectra are not subject to genetic modification.
- Synonyms: 1-β-D-Ribofuranosyluracil, Uracil-1-β-D-ribofuranoside

GMP Compliance:

Bio Excipient Grade Uridine, URID-3250 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.

Retest Date:

The recommended retest period for Uridine is two years from the date of manufacture.

Storage and Shipping Conditions:

Store at ambient temperature.

Package Sizes:

10kg, 25 kg and 50 kg pails.