

URIDINE, LBLE, GMP Excipient Grade

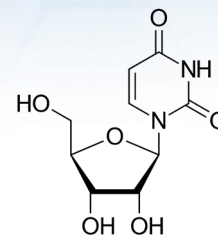
Low Bioburden, Low Endotoxin, GMP Manufactured

INTENDED USE FOR CRITICAL BIOPHARMA APPLICATIONS

Uridine is a glycosylated pyrimidine-analog containing uracil attached to a ribose ring via a β -N₁-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: C₉H₁₂N₂O₆

F.W.: 244.20 g/mol.

Density: 933 kg/m³

Solubility in Water: (50g/L)

BIO PHARMA GRADE | Product Code: URID-3250


C₉H₁₂N₂O₆ · F.W. 244.20 g/mol. · CAS# 58-96-8



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
	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%



 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.