BIOSPECTRA
Premium Pharmaceutical Ingredients

API
ICH-Q7 GMP Manufactured
Active Drug Substance

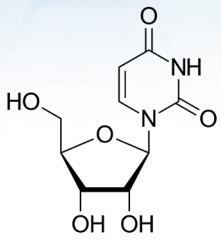
URIDINE, API, LBLE Grade

Low Bioburden, Low Endotoxin, GMP Manufactured

INTENDED FOR USE AS AN ACTIVE PHARMACEUTICAL INGREDIENT

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. Uridine is intended to be used as an Active Pharmaceutical Ingredient in oral and parenteral drug formulations.

Lead Time: MTO 3-months
Minimum Order Quantity: 10kg



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 ACTIVE GRADE | Product Code: URID-2250

$C_9H_{12}N_2O_6$ · 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
Ammonium		≤ 100 ppm
Appearance		White Crystalline Powder
Arsenicum		≤ 2 ppm
Assay (HPLC)		97 – 102% (on anhydrous)
Bacterial Endotoxins		≤ 0.5 EU/mg
Dry Substance		≥ 99.0%
Heavy Metals		≤ 10 ppm
Identification A (IR)		Positive
Identification B (HPLC)		Positive
Methanol		≤ 1000 ppm
Melting Point		167° - 170°C
pH of solution (5%, water)		4.0 – 6.0
Phosphates		≤ 1000 ppm
Purity (HPLC)		≥ 97% (main peak area %)
Related Substances (HPLC)	Uracil Pseudouridine Impurity RRT about 1.6 Each single unknown Total Impurities	≤ 0.5% ≤ 2% ≤ 0.3% ≤ 0.1% ≤ 3.0%
Transmittance of solution (5%, water)		≥ 95.0%
Water Content (KF)		≤ 1.0%

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URIDINE
API Grade

BIOSPECTRA Key Compliance Attributes of BioSpectra Grades	Bio Active 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	✓
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 II Drug Master File	✓
Suitable for use as Active Ingredient	✓

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

Bio Active Grade: Intended for use as ICH-Q7 Compliant Active Pharmaceutical Ingredient

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.

GMP Compliance:

Bio Active Grade Uridine, URID-2250 is suitable for use as a non-Sterile Active Pharmaceutical Ingredient manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Uridine is not suitable to be used as a Sterile or Injectable Active Pharmaceutical Ingredient, Drug Product or Household Item.

General Product Description:

- The Manufacturing of Bio Active Grade Uridine is performed at BioSpectra's Bangor, PA facility utilizing multi-use equipment. Equipment used in the manufacturing of Bio Active Grade Uridine is cleaned in accordance with BioSpectra's Cleaning Validation Plan.
- Uridine is a White Crystalline 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-2250 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

Retest Date:

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

Storage and Shipping Conditions:

Keep container tightly closed and store between 2-8°C, do not store above 20°C. Store in a dry and well-ventilated area.

Package Sizes:

10kg, 25 kg and 50 kg pails.