BIOSPECTRA
Premium Pharmaceutical Ingredients

GMP Process Chemical

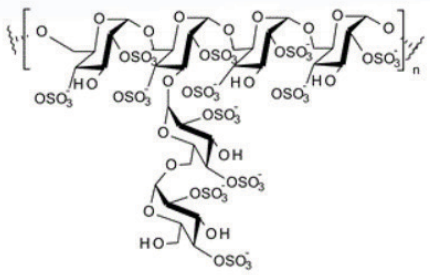
GMP Manufactured Product

DEXTRAN SULFATE Sodium Salt, MW 8000, LBLE*, GMP Grade

***Low Bioburden, Low Endotoxin**

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

Dextran Sulfate 8000 Na is a polyanionic derivative of dextran, produced by the esterification of the glucose polymer (glucan polysaccharide) with chlorosulphonic acid. Dextran fractions are characterized by their average MW and MW distribution with predominantly 1-6 glycosidic bones and 5% or less of 1-3 branching. Each base dextran polymer has characteristics unique to the specific strain of bacteria from which is was derived. In addition to variables in molecular weight and branching, the level of sulfonation adds to the unique character and performance of the finished product in terms of its intended end use. Dextran Sulfate 8000 Na, 8000 MW is used in the solubilization and purification process of protein molecules intended for use in a final drug product. Dextran is neutral in pH and soluble in water. It is easily filtered and biodegradable.



CAS #: 9011-18-1
Molecular Formula: $(C_6H_7Na_3O_{14}S_3)n$
M.W.: 8000 g/mol
pH @ 20°C: 5.0 – 7.5

BIO PHARMA GRADE | Product Code: DXSE-4250 | Previously: DS4250

$(C_6H_7Na_3O_{14}S_3)n$ M.W. 8000 g/mol. CAS# 9011-18-1

Made in the USA

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

ANALYSIS	SPECIFICATIONS
Appearance	Off White to light yellow powder
Clarity (20% solution) Absorbance at 360nm	≤ 0.9 OD unit
Chloride	≤ 1000 ppm
Endotoxin	≤0.012 EU/mg
Free Sulfate	≤ 0.2%
Glucose	35 - 48%
Identification (colorimetric)	Passes Test
Insoluble Iron	≤ 2%
Loss on Drying	≤ 10%
Manganese (As Reported)	≤ 1ppm
pH (1% Solution)	5.0 to 7.5
Residue on Ignition	35 - 50%
Pyridine	≤ 2%
Specific Rotation $[\alpha]_D^{20}$	+75° to 105°
Specific Viscosity (In 1.0M NaCl at 25°C)	0.018 – 0.032
Total Bioburden	≤100CFU/g
Sulfur	17 - 20%

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.

Lead Time: 6-12 months (depends on RM supply)
Minimum Order Quantity: 10kg

General Product Description:

- The manufacturing of Dextran Sulfate 8000 Na, DXSE-4250 is performed at BioSpectra's Bangor, PA facility utilizing multi-use equipment. Equipment used in the manufacturing of DXSE-4250 is cleaned in accordance with BioSpectra's Process Cleaning Validation Master Plan.
- Dextran Sulfate 8000 Na is an off white to light yellow powder
- Molecular Formula: $(C_6H_7Na_3O_{14}S_3)n$
- Molecular Weight: 8000 g/mol.
- CAS Number: 9011-18-1
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Dextran Sulfate 8000 Na, DXSE-4250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Dextran Sulfate 8000 Na manufactured at BioSpectra and any raw materials used in the manufacture of Dextran Sulfate 8000 Na at BioSpectra are not subject to genetic modification.
- Synonyms: Dextran, Hydrogen Sulfate, Sodium Salt

GMP Compliance:

Bio Pharma Grade Dextran Sulfate 8000 Na, DXSE-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 Dextran Sulfate 8000 Na is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Retest Date:

The recommended expiration period for Dextran Sulfate 8000 Na is two years from the date of manufacture.

Storage and Shipping Conditions:

Store at Room Temperature

Package Sizes:

10kg, 25kg and 50kg pails.