

## **GMP BIOTECH PRODUCT**

## DEXTRAN SULFATE SODIUM SALT, MW 8,000

LOW BIOBURDEN, GMP

CAS #: 9011-18-1

Formula: (C<sub>6</sub>H<sub>7</sub>Na<sub>3</sub>O<sub>14</sub>S<sub>3</sub>)n

F.W.: 8,000 g/mol

## **DXSE-4252**

## **BIO PHARMA GRADE**

Analysis	SPECIFICATIONS
Appearance and Color	Off White to Light Yellow Powder
Chloride	< = 1000 ppm
Absorbance (20%) 360 nm	< = 0.9 OD Unit
DNase - NICKase Enzymes DNase - Exonuclease Protease	None Detected None Detected None Detected
Free Inorganic Sulfate	<= 0.2%
Glucose	35 - 48%
Identification, Colorimetric	Passes Test
Insoluble Iron	< = 2.0%
Loss on Drying	< = 10.0%
Microbial Content TAMC TYMC	< = 10 CFU/g < = 10 CFU/g
pH (1%)	5.0 - 7.5
Residue on Ignition	35 - 50%
Pyridine	<= 2.0%
Specific Rotation, 20°C	+75° to +105°
Sulfur	17.0 - 20.0%
Specific Viscosity (In 1.0M NaCl, 25°C)	0.018 - 0.032

## **Country of Origin: USA**

### **Standard Shelf Life Policy**

Each Certificate of Analysis (CofA) will contain a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

#### **Package Sizes**

1kg, 5kg, 10kg, 25kg, 50kg

# Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

This is a high purity, reagent grade product, purified under cGMP conditions. Dextran Sulfate Sodium Salt, MW 8,000, 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. Dextran Sulfate Sodium Salt, MW 8,000 is used in the solubilization and purification process of protein molecules intended for use in a final drug product. Dextran is soluble in water, easily filtered and biodegradable.

#### **General Product Description**

- Appears as an off-white to light yellow powder
- Manufactured in accordance with IPEC
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: Dextran Hydrogen Sulfate, Sodium Salt
- Visit the product page on our website (<u>www.biospectra.us</u>) for additional information, supporting regulatory documents, and CoAs.

## **Storage and Shipping Conditions**

Refer to SDS.

#### **Standard Lead Time**

2-4 weeks

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