

DEXTRAN SULFATE SODIUM SALT, MW 8,000 BIOTECH LBLE, GMP DXSE-4252

(C<sub>6</sub>H<sub>7</sub>Na<sub>3</sub>O<sub>14</sub>S<sub>3</sub>)n ★ F.W. 8000 g/mol ★ CAS# 9011-18-1

#### Intended for Use in Biopharmaceutical, Biotechnological Applications and Products

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. 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 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 neutral in pH and soluble in water. It is easily filtered and biodegradable.

Analysis	SPECIFICATIONS
Appearance (Color)	Off White to Light Yellow
Appearance (Form)	Powder
Chloride Content	<u>&lt;</u> 1000 ppm
DNase-Endo/Exonuclease	Pass
DNase – Nickase	Pass
Free Inorganic Sulfate	$\leq$ 0.2 %
Glucose	35 - 48%
Identity (colorimetric)	Pass
Insoluble Iron	$\leq$ 2.0 %
Loss on Drying	$\leq$ 10.0 %
Microbial Contamination	$\leq 10 \text{ CFU/g}$
pH 1% aqueous	5.0 - 7.5
Protease Detection	Pass
Residue on Ignition	35 - 50%
Residue Pyridine	<u>≤2.0%</u>
Specific Rotation 20°C	75 – 105°
Total Sulfur Content	17.0 - 20.0%
UV Absorbance 360nm 20% aqueous	$\leq$ 0.9 Abs UN
Viscosity 1.0M NaCl / 25°C	0.018 - 0.032

#### SPECIFICATIONS

Page 1 of 2

100 Majestic Way | Bangor, PA 18013 | www.BioSpectra.us | 1.610.599.3400

# SPFC1 Bulk cGMP Fine Chemical Manufacturer

# **General Product Description:**

Molecular Formula: (C<sub>6</sub>H<sub>7</sub>Na<sub>3</sub>O<sub>14</sub>S<sub>3</sub>)n Molecular Weight: 8000 g/mol CAS Number: 9011-18-1

#### Dextran Sulfate Sodium Salt, MW 8,000 Biotech

- Appears as an off-white to light yellow powder
- Is manufactured under an ICH-Q7 Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- Has no known major food allergens (as defined by FDA and WHO)
- The final product nor its raw materials are not derived from nor come into contact with animals, animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: Dextran Hydrogen Sulfate, Sodium Salt

# **GMP** Biotech Product

### **Shelf Life Policy:**

Three-year expiry from the date of manufacture.

# **Storage and Shipping Conditions:**

Please refer to the SDS for storage and shipping conditions.

#### Package Size:

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg