BIOSPECTRA
Bulk cGMP Fine Chemical Manufacturer

EXCIPIENT

DEXTRAN POWDER, MW 10,000

GMP, Excipient Grade

CAS #: 9004-54-0 **Formula: $C_6H_{10}O_5$** **M.W.: 10,000**

D010-3201

BIO EXCIPIENT GRADE

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

ANALYSIS	SPECIFICATIONS
Appearance and Color	White to slightly off-white powder
Ash Content	≤ 2.0%
Chloride	≤ 1%
Cold Water Solubility (1% Solution)	Passes Test
Color of Solution (10%) 375 nm	≤ 0.20 OD Units
Heavy Metals (as Pb)	≤ 20 ppm
Intrinsic Viscosity (1% Solution) @ 37°C	0.08 – 0.11
Loss on Drying	≤ 7.0%
pH (10% Solution)	4.5 – 7.0
Specific Rotation (2% Solution) @ 20°C	≥ + 148°

Country of Origin: USA

Intended for Use as an Intermediate (substrate) or Excipient in downstream parenteral drug applications.

General Product Description

GMP, Excipient Grade of Dextran, 10,000 MW is a more refined and purified version of hydrolyzed, higher molecular weight, Dextran Polymer (Powders). Dextran Powder, MW 10,000 is a glucose polymer made by the fermentation of sugar by the Leuconostroc Mesenteroides bacteria. It is defined as a "branched poly-α-d-glucoside having predominant C-1 to C-6 bonds. Dextran polymers are freely soluble in water and other solvents, biodegradable and biocompatible, and have a wide range of applications in the Life Sciences. Our Dextran Powers are produced, refined and purified at our plant in Scarborough, Ontario, Canada and then further purified under full cGMP at our FDA Registered, cGMP plant in Bangor, PA, USA. Visit the product page on our website (www.biospectra.us) for additional information, supporting regulatory documents, and CofAs.

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf Life Policy

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

Package Sizes

5, 10, 25 and 50kg Poly Pails with Poly Liner.