

DEXTRAN 70, LBLE, USP/ EP, GMP EXCIPIENT GRADE

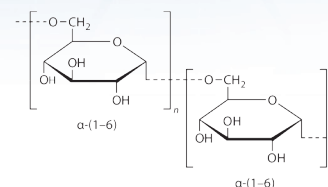
Low Bioburden, Low Endotoxin, GMP Manufactured

INTENDED FOR USE AS AN EXCIPIENT

Dextrans are used in diverse applications ranging from Vaccines, Ophthalmic, Protein Stabilization and Bulking Agent, to Cryopreservation, Organ Preservation, Blood Cell Separation and Blood Volume Expander.

Lead Time: 3-6 months (depends on RM supply)

Minimum Order Quantity: 10kg



CAS #: 9004-54-0

Molecular Formula: $(C_6H_{10}O_5)_n$

Molecular Weight: 63000 - 77000

pH in aqueous solution: 4.5 - 7.5%

BIO EXCIPIENT GRADE | Product Code: DX70-3250

$(C_6H_{10}O_5)_n$ • F.W. 63000 - 77000 CAS# 9004-54-0



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

EP Compendia

ANALYSIS	SPECIFICATIONS
Appearance of powder	White or almost white powder
Appearance of solution	Complies
Acidity or Alkalinity	Complies
Specific Rotation (+/-)	+195° to +201°
Average molecular mass	64,000 – 76,000 Mw
Mw of 10% high fraction	≤185,000 Mw
Mw of 10% low fraction	≥15,000 Mw
Residual solvent, % by GC	Complies
Sulphated ash	≤ 0.3 % w/w
Loss on drying (105°C, 5h)	≤7.0 % w/w
Total viable aerobic count (TAMC)	≤100 CFU/g



DEXTRAN 70 Bio Excipient

USP Compendia

ANALYSIS	SPECIFICATIONS
Infrared Absorption	Complies
Color of Solution (Absorbance at 375 nm, 6% sol., 4 cm)	≤ 0.15 a.u.
pH (6% solution)	4.5 – 7.0
Specific Rotation (+/-)	+195° to +203°
Mn	34,000 – 48,000
Mw/Mn	1.4 – 1.9
Viscosity, intrinsic	24 – 29 ml/g
Nitrogen containing impurities	≤100 ppm N
Alcohol and related impurities	Complies
Sulfate	≤0.03 % w/w
Loss on drying (105°C, 5h)	≤7.0 % w/w
Bacterial endotoxins (6% sol.)	≤0.5 EU/ml
Antigenic impurities	Complies
Safety	Complies

General Product Description:

- The manufacturing of Dextran 70, DX70-3250 is performed at BioSpectra's Rensselaer, NY facilities utilizing multi-use equipment. Equipment used in the manufacturing of DX70-3250 is cleaned in accordance with BioSpectra's Process Cleaning Validation Master Plan.
- Dextran 70 is a White Crystalline Product.
- Molecular Formula: $(C_6H_{10}O_5)_n$
- Molecular Weight: 63000 - 77000
- CAS Number: 9004-54-0
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Dextran 70, DX70-3250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Dextran 70 manufactured at BioSpectra and any raw materials used in the manufacture of Dextran 70 at BioSpectra are not subject to genetic modification.
- Synonyms: Dextran

GMP Compliance:

Bio Excipient Grade Dextran 70, DX70-3250 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Dextran 70 is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for Dextran 70 is two years from the date of manufacture.

Storage and Shipping Conditions:

Ship and store in ambient temperature. Store in a clean and dry area. Store in the original container.

Package Sizes:

1kg, 5kg, 10kg, 25kg