

ANALYTICAL SPECIFICATION

Issued by: G.Jandikova

Edition no: 0433AC

Approved by: C. de Belder Tesséus

Supersedes: 0433AB

Valid from: 05-2023

Dextran sulfate 8 HS, Ph. grade

Catalogue No. DS8 HS PG

Description: A polyanionic derivative of dextran with a weight average molecular weight of approximately 8000. Supplied as the sodium salt as a white to off white powder which is readily soluble in water.

TEST/CHARACTERISTIC	LIMITS	TEST METHOD
Appearance, colour	White to off white	02037
Appearance, form	Powder	02037
Weight average molecular weight (Mw)	6500–9000	02030
Number average molecular weight (Mn)	To be noted	02030
Sulphur content	16–20 %	02011
pH	5.0–7.5	02009
Free sulfate	≤ 0.2 %	02013
Loss on drying	≤ 7 %	02018
Specific optical rotation	+75° to +105°	02008
Turbidity	< 5 NTU	02021
Residual solvents		
EtOH	To be noted (According to ICH Q3C)	Ph.Eur. 2.4.24
Formamide	To be noted (According to ICH Q3C)	Ph.Eur. 2.4.24
Total aerobic microbial count (TAMC)	≤ 10 ³ CFU/g	Ph.Eur. 2.6.12
Total combined yeasts/mould count (TYMC)	≤ 10 ² CFU/g	Ph.Eur. 2.6.12
Bacterial endotoxins (BET)	< 5 IU/mg	Ph.Eur. 2.6.14

We hereby confirm that no metal catalysts or metal reagents are used in the manufacturing of this product. Therefore, elemental impurities, classified according to ICH Q3D, are unlikely to be present.

We hereby confirm that no class 1 solvent, classified according to Ph.Eur. 5.4 and USP <467> Residual solvents, is used in the manufacturing of this product.