

# ANALYTICAL SPECIFICATION

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**Approved by:** C. de Belder Tesséus

**Supersedes:** 0436AB

**Valid from:** 11-2024

## Dextran sulfate 10 HS, Ph. grade

Catalogue No. DS10 HS PG

**Description:** A polyanionic derivative of dextran with a weight average molecular weight of approximately 10000. 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)	9000-16000	02030
Number average molecular weight (Mn)	To be noted	02030
Sulphur content	16-20 %	02050
pH	5.0-7.5	02009
Free sulfate	≤ 0.2 %	02013
Loss on drying	≤ 7 %	02018
Specific optical rotation	+80° to +105°	02008
Turbidity	< 5 NTU	02021
Residual solvents: EtOH	To be noted	Ph.Eur. 2.4.24
Formamide	To be noted	Ph.Eur. 2.4.24
Total aerobic microbial count (TAMC)	≤ 10 <sup>3</sup> CFU/g	Ph.Eur. 2.6.12
Total combined yeasts/mould count (TYMC)	≤ 10 <sup>2</sup> 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.