Valid from: HSA/LC 19-04-2018
Replaces: HSA/LC 10-11-2017

Batch Release Certificate

Product name: **Dextran T2000**

Specification No.: **40058**

Batch No.: Axxx

Manufacturing sites: Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark
DKMA* No.: 254629
GMP certificate No.: N/A
FDA establishment No.: N/A
FDA facility classification: N/A
EDQM* certificate No.: N/A

Method:	Parameter:	Results of analysis:		Limits:
Pharmacosmos	Average molecular weight, Mw (Da):	Complies	**	approx. 2,000,000
DF039	Infrared Absorption:	Complies	***	To pass test
DF034	Viscosity, intrinsic, dL/g:	x.xx		0.58 – 0.68
DF001	Loss on drying (105°C, 5h), % w/w:	x		≤7
DF030	Color of solution (Absorbance at 375 nm, 10% sol., 1 cm):	x.xx		≤0.05

*) EDQM refers to 'European Directorate for the Quality of Medicines and Healthcare'. DKMA refers to 'Danish Medicines Agency'
**) The molecular weight distribution is assured through strict adherence to established procedures and in-process control throughout the manufacturing.
***) Test is not carried out routinely.
We hereby confirm that no class 1, class 2 and class 3 solvent, cf. ICH Q3C and VICH GL 18, is used in the manufacturing of this product.
We hereby confirm that no metal catalysts or metal reagents are used in the manufacturing of this product.

I hereby certify that the above information is authentic and accurate. This batch of technical quality dextran has been manufactured, including packaging and quality control in full compliance with the above mentioned specifications.

Date (dd.mm.yyyy):

Heidi Skjødt Andersen, M.Sc. Pharm., Quality Control

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VAT NO. EXPORT: DK29127204