Valid from: 28-01-2022
Replaces: 19-02-2021

Batch Release Certificate

Product name: **Dextran T1**

Specification No.: **40036**

Batch No.: ABxxx

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:
–	Description:	Complies		White or almost white powder
LI030-1	Average molecular mass, Mw:	xx,100		800 – 1,200
DF001	Loss on drying (105°C, 5h), % w/w:	x	**	≤7
DF030	Color of solution (Absorbance at 375 nm, 6% sol., 1 cm):	<0.01		≤0.12
DF009	Specific rotation (+/-) °:	+x		+140 – +170
DF019	Nitrogen containing impurities, ppm N:	x		≤100

*) EDQM refers to 'European Directorate for the Quality of Medicines and Healthcare'. DKMA refers to 'Danish Medicines Agency'

**) Due to the hygroscopic nature of the powder, loss on drying may change during storage. We recommend keeping small container well closed and protected against moisture.

Confidential information. Molecular mass distribution more narrow than EP/USP requirement for Dextran 1.

We 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