Valid from: HSA/LC 14-01-2021
Replaces: HSA/LC N/A

Batch Release Certificate

Product name: **Dextran 70 Ultra**

Specification No.: **50013**

Batch No.: xxxxxx

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
DF001	Loss on drying (105°C, 5h), % w/w:	x.x	**	≤7.0
DF030	Absorbance (at 375 nm, 10% sol., 1 cm)	x.xx		≤0.12
DF009	Specific rotation, (+/-) °:	+x		+195 – +201
DF019	Nitrogen, ppm:	x		<110
DF034	Average molecular mass, Mw:	x,xxx		64,000 – 76,000
DF034	Mw/Mn:	x.x		≤1.5
DF007	Sulphated ash, % w/w:	x.x		≤0.3
DF022	Microbial contamination, cfu/g:	Complies		≤100

We hereby confirm that no class 1, class 2 and class 3 solvent, cf. EP 5.4 and USP <467> Residual solvents is used in the manufacturing of this product.

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

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

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