Batch Release Certificate

Product name: **Dextran 10 Ultra**

Specification No.: **50001**

Batch No.: xxxxxx
Manufacturing date: mmmm_yyyy
Retest date (5 years): mmmm_yyyy

Manufacturing sites: Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark
DKMA* No.: 254629
GMP certificate No.: DK API-H 00042914, DK API-V 00042914
FDA establishment No.: FEI 3002807874
FDA facility classification: Acceptable
EDQM* certificate No.: Certificates for Dextran 1, 40, 60 & 70 Ph.Eur. available

Method:	Parameter:	Results of analysis:		Limits:
–	Description:	Complies		White or almost white powder
EP	Identification:	Complies	**	Complies
EP	Loss on drying (105°C, 5h), % w/w:	x.x	***	≤7.0
EP	Absorbance (at 375 nm, 10% sol., 1 cm)	x.xx		≤0.12
EP	Specific rotation, (+/-) °:	+x		+188 – +198
EP	Nitrogen, ppm:	x		<110
LI030-1	Average molecular mass, Mw:	x,xxx		9,000 – 11,000
LI030-1	Mw/Mn:	x.x		≤1.5
EP	Sulphated ash, % w/w:	x.x		≤0.3
EP	Bacterial endotoxins, IU/g:	x		<25
EP	Microbial contamination, cfu/g:	Complies		≤100

This is a well characterized dextran fraction suited for membrane characterization. A molecular weight distribution curve performed from size exclusion chromatography is attached to this Batch Release Certificate

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'

**) The identification of the product is assured through strict adherence to established GMP rules throughout the manufacturing processes.

***) Due to the hygroscopic nature of the powder, loss on drying may change during storage. We recommend keeping small packs (100 and 500g) well closed and protected against moisture.

Certificate of Conformity

I hereby certify that the above information is authentic and accurate. This actual batch has been manufactured, including packaging and quality control at the above mentioned site in compliance with the GMP requirements for active starting materials and with the above mentioned specifications. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Date (dd.mm.yyyy): _____

Qualified Person, Heidi Skjødt Andersen, M.Sc. Pharm

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