Batch Release Certificate

Product name: **Dextran 3.5 Pharmaceutical Quality**

Specification No.: **40109**

Batch No.: xxxxxx
Manufacturing date: mmmm_yyyy
Retest date # (3 years): mmmm_yyyy

Manufacturing sites: Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark
DKMA* No.: 254629
GMP certificate No.: DK API-H 00010511, DK API-V 00010511
FDA establishment No.: FEI 3003233785
FDA facility classification: Acceptable
EDQM* certificate No.: Certificates for Dextran 1, 40, 60 & 70 Ph.Eur. available

Method:	Parameter:	Results of analysis:		Limits:
EP	Description:	Complies		White or almost white powder
EP	Appearance of solution:	Complies		Clear and colorless
EP	Specific rotation, (+/-) °:	+x.x		+170 – +198
EP	Acidity or Alkalinity:	Complies		Complies
LI030-1	Average molecular mass, Mw:	x,xxx		3,000 – 4,000
EP	Nitrogen containing substances, ppm N:	x		≤110
EP	Residual solvent % by GC:	Complies	**	Complies
EP	Loss on drying (105°C, 5h), % w/w:	x.x		≤7.0
EP	Heavy metals, ppm lead:	x		<10
EP	Sulphated ash, % w/w:	x.x		≤0.3
EP	Bacterial endotoxins, IU/g:	Complies		<25
EP	Microbial contamination, cfu/g:	Complies		≤100

Retest date is 2 years for small pack sizes: 100 g and 500 g pack
References to official monographs are to be considered as current editions.
*) EDQM refers to 'European Directorate for the Quality of Medicines and Healthcare'. DKMA refers to 'Danish Health and Medicines Authority'
**) Test for Residual solvents is not carried out routinely according to approval from EDQM.
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.
We hereby confirm that no metal catalysts or metal reagents, cf. EMEA/CHMP/4446/2000 and Ph. Eur. 5.20 are used in the manufacturing of this produc

I hereby certify that the above information is authentic and accurate. This batch of Active Pharmaceutical Ingredient has been manufactured, including packaging and quality control at the above mentioned site in full 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, Kim Nordfjeld, Ph.D., Pharmacy

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