Batch Release Certificate

Product name: **Dextran 1 USP**

Specification No.: **40017**

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 00083617, DK API-V 00083617
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:
USP	Infrared Absorption:	Complies	**	Complies
USP	Color of solution (Absorbance at 375 nm, 15% sol., 1 cm):	x.xx		≤0.12
USP	pH (15% solution):	x.x		4.5 – 7.0
USP	Specific rotation, (+/-) °:	+x		+148 – +164
USP	Average molecular mass, Mw:	x		850 – 1,150
USP	<3 glucose units fraction, % w/w:	x		<15
USP	>9 glucose units fraction, % w/w:	x		<20
USP	Nitrogen containing impurities, ppm N:	x		≤110
USP	Alcohol and related impurities:	Complies	**	Complies
USP	Sodium chloride, % w/w:	x.x		≤1.5
USP	Loss on drying (100°C to 105°C, 5h), % w/w:	x.x	***	≤5.0
USP	Bacterial endotoxins EU/g:	x.x		≤25.0
Microbial contamination, cfu/g:				
USP	Aerobic microbial count (TAMC), cfu/g:	Complies		≤100
USP	Yeast and mold (TYMC), cfu/g:	Complies		≤10

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 Medicines Agency'

**) Test is not carried out routinely.

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

We hereby confirm that no class 1, class 2 and class 3 solvent, cf. USP <467> Residual solvents, 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. Elemental impurities, cf. ICH Q3D are unlikely to be present.

CERTIFICATE OF CONFORMITY

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, Heidi Skjødt Andersen, M.Sc. Pharm

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