Batch Release Certificate

Product name: **Dextran 500 Pharmaceutical Quality**

Specification No.: **40016**

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 10000578, DK API-V 10000639
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:
EP	Appearance of solution (6%):	Complies		Complies
DF005	Acidity or Alkalinity (10%):	Complies		Complies
EP	Specific rotation, (+/-) °:	+x		+195 – +201
DF046	Average molecular mass, Mw (laser):	x,xxx	*	450,000 – 550,000
DF019	Nitrogen containing substances, ppm N:	x	**	≤110
EP	Loss on drying (105°C, 5h), % w/w:	x.x		≤7.0
EP	Sulphated ash, % w/w:	x.x		≤0.3
EP	Bacterial endotoxins, IU/g:	x	¤	<25
EP	Microbial contamination (TAMC), cfu/g:	Complies		≤100

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'
*) Determined by size-exclusion chromatography (GPC).
**) Determined by sulfuric acid digestion (Kjeldahl).
¤) Determined by turbidimetric kinetic method.

We 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 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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