PHARMACOSMOS A/S

Batch Release Certificate

Product name:	**Dextran 6 Pharmaceutical Quality**
Specification No.:	**40184**
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:
Visual	Description:	Complies		White or almost white powder
LI030-1	Average molecular mass, Mw:	x.xxx	*	5,000 – 7,000
EP	Loss on drying (105°C, 5h), % w/w:	x.x		≤7.0
DF005	Acidity or Alkalinity (10%):	Complies		Complies
DF009	Specific rotation, (+/-) °:	+x		+189 – +199
DF019	Nitrogen containing impurities, ppm N:	x	**	<100
EP	Bacterial endotoxins IU/g (Method C):	x	¤	<25
EP	Microbial contamination, cfu/g:	x		≤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. ICH Q3C and VICH GL 18, 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.

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):

Heidi Skjødt Andersen, M.Sc. Pharm, Quality Control

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