Valid from: HSA/LC 01-10-2012
Replaces: HSA/LC 21-10-2011

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 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:
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.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	Heavy metals, ppm lead:	Complies	≤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:	Complies	≤100
USP	Molds and yeast, Total:	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'.

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.

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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