Batch Release Certificate

Product name: **Dextran 40 JP**

Specification No.: **40010**

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 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:
JP	Appearance of solution:	Complies		Clear and colorless
JP	Identification:	Complies	*	Solution does not change in color
JP	Assay (dextran after drying, % w/w):	x.x		98.0 – 102.0
DF034	Average molecular mass, Mw:	x,xxx		app. 40,000
JP	Viscosity, intrinsic, dL/g:	x.xx	**	0.16 – 0.19
JP	Viscosity, intrinsic, high fraction, dL/g:	x.xx	**	≤0.27
JP	Viscosity, intrinsic low fraction, dL/g:	x.xx	**	≥0.09
JP	pH (10% solution):	x.x		5.0 – 7.0
JP	Nitrogen containing impurities, % w/w N:	x.xxx		≤0.010
JP	Chloride, % w/w:	Complies		≤0.018
JP	Reducing substances per g:	Complies		≤15 (mg glucose)
JP	Loss on drying (105°C, 6h), % w/w:	x.x		≤5.0
JP	Residue on ignition, % w/w:	x.x		≤0.1
JP	Bacterial endotoxins, IU/g:	x.x	¤	<2.5
JP	Antigenicity:	Not tested	***	Complies

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.
**) Test is performed acoording to modifed method that is correlated to Mw.
***) Test is not carried out. The manufacturing process produces no impurities having a possible antigenicity.
¤) 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. 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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