Batch Release Certificate

Product name: **Dextran 40 EP/USP**

Specification No.: **40002**

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 00125319, DK API-V 00125319
FDA establishment No.: FEI 3002807874
FDA facility classification: Acceptable
EDQM* certificate No.: R1-CEP 1999-063-Rev 03

Method:	Parameter:	Results of analysis:		Limits:
EP	Appearance of powder:	Complies		White or almost white powder
USP	Infrared Absorption:	Complies	**	Absorption maxima corresponds with Dextran 40 RS
USP	Color of solution (Absorbance at 375 nm, 10% sol., 4 cm):	x.xx		≤0.20
EP	Appearance of solution:	Complies		Clear and colorless
USP	pH (10% solution):	x.x		4.5 – 7.0
EP	Acidity or Alkalinity:	Complies		Complies
EP	Specific rotation, (+/-) °:	+x		+195 – +201
USP	Specific rotation, (+/-) °:	+x		+195 – +203
EP/USP	Average molecular mass, Mw:	x,xxx		35,000 – 45,000
EP/USP	Mw of 10% high fraction:	x,xxx		≤110,000
EP/USP	Mw of 10% low fraction:	x,xxx		≥7,000
USP	Mw/Mn:	x.x		1.4 – 1.9
USP	Mn:	x,xxx		16,000 – 30,000
USP	Viscosity, intrinsic, ml/g:	x		18 – 23
USP	Nitrogen containing impurities, ppm N:	x		≤100
USP	Alcohol and related impurities:	Complies	**	Complies
EP	Residual solvent, % by GC:	Complies	***	Complies
USP	Sulfate, % w/w:	Complies		≤0.03
EP	Sulphated ash, % w/w:	x.x		≤0.3
EP	Loss on drying (105°C, 5h), % w/w:	x.x		≤7.0
USP	Loss on drying (105°C, 5h), % w/w:	x.x		≤7.0
EP	Bacterial endotoxins, IU/g:	Complies		<10
USP	Antigenic impurities:	Complies	**	Complies
EP	Total viable aerobic count (TAMC), cfu/g:	Complies		≤100
USP	Safety:	Complies		Complies

References to official monographs are to be considered as current editions.

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.

*) 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 not carried out. No class 1, class 2 and class 3 solvent, cf. USP <467> Residual solvents, is 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):

Qualified Person, Heidi Skjødt Andersen, M.Sc. Pharm

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