Batch Release Certificate

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

Specification No.: **40165**

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 powder:	Complies		White, amorphous powder
JP	Identification:	Complies	**	Solution does not change in color
USP	Infrared Absorption:	Complies	**	Complies
USP	Specific rotation, (+/-) °:	+x		+195 – +203
JP	Appearance of solution:	Complies		Clear and colorless
USP	Color of solution (Absorbance at 375 nm, 10% sol., 4 cm):	x.xx		≤0.15
USP	pH (10% solution):	x.x		5.0 – 7.0
USP	Average molecular mass, Mw:	x,xxx		35,000 – 45,000
USP	Mw of 10% high fraction:	x,xxx		≤120,000
USP	Mw of 10% low fraction:	x,xxx		≥5,000
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
JP	Assay (dextran after drying, % w/w):	x.x		98.0 – 102.0
JP	Viscosity, intrinsic, dL/g:	x.x		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	Chloride, % w/w:	Complies		≤0.018
JP	Nitrogen containing impurities, % w/w	x.xxx		≤0.010
USP	Nitrogen containing substances, ppm	x		≤100
USP	Sulfate, % w/w:	Complies		≤0.03
JP	Reducing substances per g:	Complies		≤0.15 (mg glucose)
JP	Loss on drying (105°C, 6h), % w/w:	x.x		≤5.0
USP	Loss on drying (105°C, 5h), % w/w:	x.x		≤7.0
JP	Residue on ignition, % w/w:	x.x		≤0.1
USP	Bacterial endotoxins (10% sol.) EU/ml:	x.x		≤1.0
JP	Bacterial endotoxins, IU/g:	x.x		<2.5
JP	Antigenicity:	Not tested		Complies
USP	Antigenic impurities:	Complies	***	Complies
USP	Safety:	Complies		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 performed. The identification of the product is assured througt strict adherence to established GMP rules throughout the manufacturing procedure.
**) Test is not carried out routinely.
We hereby 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

PHARMACOSMOS A/S
ROERVANGSVEJ 30
DK-4300 HOLBAEK
DENMARK

TELEPHONE: +45 59 48 59 59
E-MAIL: info@pharmacosmos.com
WEB-SITE: www.pharmacosmos.com

CVR NO.: DK15517085
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