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

Batch Release Certificate

Product name: **Dextran 40 USP**

Specification No.: **40018**

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 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, 10% sol., 4 cm):	x.xx	≤0.20
USP	pH (10% solution):	x.x	4.5 – 7.0
USP	Specific rotation (+/-) °:	x.x	+195 – +203
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.xx	1.4 – 1.9
USP	Mn:	x,xxx	16,000 – 30,000
USP	Viscosity, intrinsic, ml/g:	x.x	18 – 23
USP	Nitrogen containing impurities, ppm N:	x	≤100
USP	Alcohol and related impurities:	Complies	Complies
USP	Heavy metals, ppm lead:	Complies	≤5
USP	Sulfate, % w/w:	Complies	≤0.03
USP	Loss on drying (105°C, 5h), % w/w:	x.x	≤7.0
USP	Bacterial endotoxins (10% sol.) EU/ml:	x.x	≤1.0
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'.
This certificate of analysis is applicate for suppliers of Code No. 5510 0040 20xx, where xx i varying with pack size.
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

PHARMACOSMOS A/S
ROERVANGSVEJ 30
DK-4300 HOLBAEK
DENMARK

TELEPHONE: +45 59 48 59 59
TELEFAX: +45 59 48 59 60
E-MAIL: info@pharmacosmos.com
WEB-SITE: www.pharmacosmos.com

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