Valid from: HSA/LC 05-05-2015
Replaces: HSA/LC 09-12-2014

Batch Release Certificate

Product name: **Dextran T500**

Specification No.: **40030**
Batch No.: ABxxx

Manufacturing sites: Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark
DKMA* No.: 254629
GMP certificate No.: N/A
FDA establishment No.: N/A
FDA facility classification: N/A
EDQM* certificate No.: N/A

Method:	Parameter:	Results of analysis:	Limits:
–	Description:	Complies	White powder
LI030-1	Average molecular mass, Mw:	xx,000	450,000 – 550,000
DF001	Loss on drying (105°C, 5h), % w/w:	x	≤7
DF030	Color of solution (Absorbance at 375 nm, 10% sol., 1 cm):	x.xx	≤0.05
DF004	pH (10% solution):	x.x	4.5 – 7.0
DF009	Specific rotation (+/-) °:	+x	+195 – +201
DF012	Heavy metals, ppm lead:	x	≤20
DF019	Nitrogen containing impurities, ppm N:	x	≤100

*) EDQM refers to 'European Directorate for the Quality of Medicines and Healthcare'. DKMA refers to 'Danish Health and Medicines Authority'
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.
This certificate of analysis is applicable for supplies of code No. 5510 0500 90xx where xx is varying with pack size.

I hereby certify that the above information is authentic and accurate. This batch of technical quality dextran has been manufactured, including packaging and quality control in full compliance with the above mentioned specifications.

Date (dd.mm.yyyy):

Heidi Skjødt Andersen, M.Sc. Pharm., Quality Control

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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VAT NO. EXPORT: DK29127204