Batch Release Certificate

Product name: **Dextran T6**

Specification No.: **40164**

Batch No.: xxxxxx

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:	x,500	5,000 – 7,000
EP	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
DF005	Acidity or Alkalinity:	Complies	Complies
DF009	Specific rotation, (+/-) °:	+x	+189 – +199
DF012	Heavy metals, ppm lead:	x	≤20
DF019	Nitrogen containing impurities, ppm N:	x	≤100

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'
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.

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

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VAT NO. EXPORT: DK29127204