

Batch Release Certificate

Product name: Dextran T1

Specification No.: 40036

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,100	800 – 1,200
DF001	Loss on drying (105°C, 5h), % w/w:	x	≤7
DF030	Color of solution (Absorbance at 375 nm, 6% sol., 1 cm):	x.xx	≤0.12
DF005	Acidity or Alkalinity:	Complies	Complies
DF009	Specific rotation (+/-) °:	+x	+140 – +170
DF012	Heavy metals, ppm lead:	x	≤10
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'

**) Due to the hygroscopic nature of the powder, loss on drying may change during storage. We recommend keeping small packs (100g and 500g) well closed and protected against moisture.

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