

Batch Release Certificate

Product name: Dextran 750 Pharmaceutical Quality

Specification No.: 40090

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 00083617, DK API-V 00083617

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:
–	Identification:	Complies	** Complies
EP	Appearance of solution:	Complies	Complies
EP	Acidity or Alkalinity:	Complies	Complies
EP	Specific rotation, (+/-) °:	+x	+195 – +201
LI030-1	Viscosity, intrinsic, ml/g:	x	49 – 55
EP	Loss on drying (105°C, 5h), % w/w:	x	≤7
EP	Sulphated ash, % w/w:	x.x	≤0.3
EP	Nitrogen containing impurities, ppm N:	x	≤110
DF012	Heavy metals, ppm lead:	x	≤10
EP	Bacterial endotoxins, IU/g:	Complies	<25
EP	Microbial contamination, cfu/g:	Complies	≤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'

**) The identification of the product is assured through strict adherence to established GMP rules throughout the manufacturing procedures.

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 hereby confirm that no metal catalysts or metal reagents, cf. EMEA/CHMP/4446/2000 and Ph. Eur. 5.20 are used in the manufacturing of this product.

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