

# Batch Release Certificate

**Product name:** Dextran 1.5 Pharmaceutical Quality

**Specification No.:** 40110

**Batch No.:** xxxxxx

**Manufacturing date:** mmmm\_yyyy

**Retest date (3 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:
EP	Description:	Complies	White or almost white powder
EP	Appearance of solution:	Complies	Clear and colorless
EP	Specific rotation, (+/-) °:	+x	+155 – +182
EP	Acidity or Alkalinity:	Complies	Complies
LI030-1	Average molecular mass, Mw:	x,xxx	1,200 – 1,800
EP	Nitrogen containing substances, ppm	x	≤110
EP	Residual solvent % by GC:	Complies	** Complies
EP	Loss on drying (105°C, 5h), % w/w:	x.x	*** ≤7.0
EP	Sulphated ash, % w/w:	x.x	≤0.3
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'

\*\*) Test for Residual solvents is not carried out according to approval from EDQM.

\*\*\*) 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. EP 5.4 and USP <467> Residual solvents, is used in the manufacturing of this product.

We hereby confirm that no metal catalysts or metal reagents are used in the manufacturing of this product. Elemental impurities, cf. ICH Q3D are unlikely to be present.

## 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