

# Batch Release Certificate

**Product name:** Dextran 250 Pharmaceutical Quality

**Specification No.:** 40128

**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:
EP	Appearance of solution:	Complies	Clear and colorless
EP	Acidity or Alkalinity:	Complies	Complies
EP	Specific rotation, (+/-) °:	+x	+195 – +201
LI030-1	Average molecular mass, Mw:	x,xxx	200,000 – 300,000
EP	Nitrogen containing substances, ppm N:	x	≤110
EP	Residual solvent % by GC:	Complies	** N/A
EP	Heavy metals, ppm lead:	x	<10
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.

Test is not carried out. No class 1, class 2 and class 3 solvent, cf. EP 5.4 Residual solvents, 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