

# Batch Release Certificate

**Product name:** Dextran 70 EP

**Specification No.:** 40014

**Batch No.:** xxxxxx

**Manufacturing date:** mmmm\_yyyy

**Retest date (5 years):** mmmm\_yyyy

**Manufacturing sites:** Pharmacosmos A/S, Roervangvej 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.:** R1-CEP 1999-065-Rev 02

Method:	Parameter:	Results of analysis:	Limits:
EP	Appearance of powder:	Complies	White or almost white
EP	Solubility:	Complies	Very soluble in water, very slightly soluble in ethanol (96%)
EP	Specific rotation, (+/-) °:	+x	+195 – +201
EP	Infrared Absorption:	Complies	Complies
EP	Appearance of solution:	Complies	Clear and colorless
EP	Acidity or Alkalinity:	Complies	Complies
EP	Average molecular mass, Mw:	x,xxx	64,000 – 76,000
EP	Mw of 10% high fraction:	x,xxx	≤185,000
EP	Mw of 10% low fraction:	x,xxx	≥15,000
EP	Nitrogen containing substances, ppm N:	x	≤110
EP	Residual solvent % by GC:	Complies	Methanol ≤0.05 Ethanol & other solvents ≤0.5
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	<16
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 is not carried out routinely. The identification of the product is assured through strict adherence to established GMP rules throughout the manufacturing procedure.

\*\*\*) Test is not carried out according to approval from EDQM. No class 1, class 2 and class 3 solvent, cf. EP 5.4. Residual solvent, 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

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