

# Batch Release Certificate

**Product name:** Dextran 40 EP/JP/USP

**Specification No.:** 40001

**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.:** R1-CEP 1999-063-Rev 02

Method:	Parameter:	Results of analysis:	Limits:
JP	Appearance of powder:	Complies	White amorphous powder.
JP	Assay (dextran after drying, % w/w):	x.x	98.0 – 102.0
JP	Identification:	Complies	** Solution does not change in color
USP	Infrared Absorption:	Complies	Absorption maxima corresponds with Dextran 40 RS
USP	Color of solution (Absorbance at 375 nm, 10% sol., 4 cm):	x.xx	≤0.20
EP/JP	Appearance of solution:	Complies	Clear and colorless
USP	pH (10% solution):	x.x	4.5 – 7.0
JP	pH (10% solution):	x.x	5.0 – 7.0
EP	Acidity or Alkalinity:	Complies	Meets EP requirement
USP	Specific rotation, (+/-) °:	+x	+195 – +203
EP	Specific rotation, (+/-) °:	+x	+195 – +201
EP/USP	Average molecular mass, Mw:	x,xxx	35,000 – 45,000
EP	Mw of 10% high fraction:	x,xxx	≤110,000
EP	Mw of 10% low fraction:	x,xxx	≥7,000
USP	Mw of 10% high fraction:	x,xxx	≤120,000
USP	Mw of 10% low fraction:	x,xxx	≥5,000
USP	Mw/Mn:	x.x	1.4 – 1.9
USP	Mn:	x,xxx	16,000 – 30,000
USP	Viscosity, intrinsic, ml/g:	x	18 – 23
JP	Viscosity, intrinsic, dL/g:	x.xx	0.16 – 0.19
JP	Viscosity, intrinsic, high fraction:	x.xx	≤0.27
JP	Viscosity, intrinsic, low fraction:	x.xx	≥0.09
USP	Nitrogen containing impurities, ppm N:	x	≤100
JP	Nitrogen containing impurities, % w/w	x.xxx	≤0.010
EP	Nitrogen containing substances, ppm N:	x	≤110
USP	Alcohol and related impurities:	Complies	*** Total area of peaks from impurities in the test solution does not exceed the area of the n-propyl alcohol solution peak
EP	Residual solvent, % by GC:	Complies	**** ≤0.05
JP	Chloride, % w/w:	Complies	≤0.018
USP	Heavy metals, ppm lead:	Complies	≤5
EP	Heavy metals, ppm lead:	x	<10
JP	Heavy metals, ppm lead:	Not tested	≤20

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Method:	Parameter:	Results of analysis:	Limits:
JP	Arsenic, ppm:	Complies	≤1.3
JP	Reducing substances per g:	Complies	≤15 (mg glucose)
USP	Sulfate, % w/w:	Complies	≤0.03
EP	Sulphated ash, % w/w:	x.x	≤0.3
JP	Residue on ignition, % w/w:	x.x	≤0.1
EP	Loss on drying (105°C, 5h), % w/w:	x.x	≤7.0
USP	Loss on drying (105°C, 5h), % w/w:	x.x	≤7.0
JP	Loss on drying (105°C, 6h), % w/w:	x.x	≤5.0
USP	Bacterial endotoxins (10% sol.) EU/ml:	x.x	≤1.0
EP/JP	Bacterial endotoxins, IU/g:	Complies	<2.5
EP	Microbial contamination, cfu/g:	Complies	≤100
USP	Antigenic impurities:	Complies	Complies
JP	Antigenicity:	Not tested	Complies
USP	Safety:	Complies	Complies

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'

\*\*) This test is not performed. The identification of the product is assured through strict adherence to established GMP rules throughout the manufacturing procedure.

\*\*\*) Test is not carried out routinely.

\*\*\*\*) 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