

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 10001351, DK API-V 10001349

FDA establishment No.: FEI 3002807874

FDA facility classification: Acceptable

EDQM certificate No.: R1-CEP 1999-063-Rev 03

Method:	Parameter:	Results of analysis:	Limits:
Visual	Appearance of powder:	Complies	White amorphous powder.
JP	Identification:	Complies	* Solution does not change in color
EP/USP	Identification A: Infrared Absorption:	Complies	** Absorption maxima corresponds with Dextran 40 RS
USP	Identification B: Viscosity, intrinsic, mL/g:	x	18 – 23
USP	Identification C: Meets the requirements of the tests for Mw distribution and Weight and Number Average Molecular Weights:	Complies	Complies
JP	Assay (dextran after drying, % w/w):	x.x	98.0 – 102.0
EP/JP	Appearance of solution:	Complies	Clear and colorless
USP	Color of solution (Absorbance at 375 nm, 10% sol., 4 cm):	x.xx	≤0.20
EP	Specific rotation, (+/-) °:	+x	+195 – +201
USP	Specific rotation, (+/-) °:	+x	+195 – +203
EP	Acidity or Alkalinity:	Complies	Meets EP requirement
USP	pH (10% solution):	x.x	4.5 – 7.0
JP	pH (10% solution):	x.x	5.0 – 7.0
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
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 N:	x.xxx	□ ≤0.010
EP	Nitrogen containing substances, ppm N:	x	□ ≤110
USP	Sulfate, % w/w:	Complies	≤0.03
USP	Alcohol and related impurities:	Complies	** Sum of peak areas of impurities in test solution does not exceed the peak area of n-propyl alcohol
EP	Residual solvent, % by GC:	Complies	# ≤0.05
JP	Chloride, % w/w:	Complies	≤0.018
JP	Reducing substances per g:	Complies	≤15 (mg glucose)

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

Method:	Parameter:	Results of analysis:	Limits:
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:	x.x	≤2.5
EP	Microbial contamination (TAMC), cfu/g:	Complies	≤100
JP	Antigenicity:	Not tested	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'

*) Test is not carried out. 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 performed according to modified method that is correlated to Mw.

#) Test is not carried out. No class 1, class 2 and class 3 solvent, cf. USP <467> Residual solvents, is used in the manufacturing of this product.

▫) Determined by sulfuric acid digestion (Kjeldahl), a slightly modified compendial method.

▫▫) Determined by turbidimetric kinetic method.

We 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 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