

Batch Release Certificate

Product name: Dextran 70 EP/JP/USP

Specification No.: 40078

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 10000578, DK API-V 10000639

FDA establishment No.: FEI 3002807874

FDA facility classification: Acceptable

EDQM certificate No.: R1-CEP 1999-065-Rev 03

Method:	Parameter:	Results of analysis:	Limits:
EP/JP	Appearance of powder:	Complies	White or almost white amorphous powder
JP	Assay (dextran after drying, % w/w):	x	98 – 102
JP	Identification:	Complies	* Complies
EP/USP	Infrared Absorption:	Complies	** Absorption maxima corresponds with Dextran 70 RS
EP/JP	Appearance of solution:	Complies	Clear and colorless
USP	Color of solution (Absorbance at 375 nm, 6% sol., 4 cm):	x.xx	≤0.15
JP	pH (6% solution):	x.x	5.0 – 7.0
USP	pH (6% solution):	x.x	4.5 – 7.0
EP	Acidity or Alkalinity:	Complies	Complies
EP	Specific rotation, (+/-) °:	+x	+195 – +201
USP	Specific rotation, (+/-) °:	+x	+195 – +203
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
USP	Average molecular mass, Mw:	x,xxx	63,000 – 77,000
USP	Mw of 10% high fraction:	x,xxx	≤195,000
USP	Mw of 10% low fraction:	x,xxx	≥13,000
USP	Mw/Mn:	x.x	1.4 – 1.9
USP	Mn:	x,xxx	34,000 – 48,000
USP	Viscosity, intrinsic, ml/g:	x	24 – 29
JP	Viscosity, intrinsic, dL/g:	x.xx	# 0.21 – 0.26
JP	Viscosity, intrinsic, high fraction:	x.xx	# ≤0.35
JP	Viscosity, intrinsic, low fraction:	x.xx	# ≥0.10
JP	Nitrogen containing substances, ppm N:	x	≤100
EP	Nitrogen containing substances, ppm N:	x	≤110
USP	Nitrogen containing impurities, ppm N:	x	≤100
EP	Residual solvent, % by GC:	Complies	*** Complies
USP	Alcohol and related impurities:	Complies	*** Complies
JP	Chloride, % w/w:	x.xxx	≤0.018
JP	Reducing substances per g:	Complies	≤10 (mg glucose)
USP	Sulfate, % w/w:	Complies	≤0.03
EP	Sulphated ash, % w/w:	x.x	≤0.3

Batch Release Certificate

Product name: Dextran 70 EP/JP/USP

Specification No.: 40078

Batch No.: xxxxxx
Manufacturing date: mmmm_yyyy
Retest date (3 years): mmmm_yyyy

Method:	Parameter:	Results of analysis:	Limits:
JP	Loss on drying (105°C, 6h), % w/w:	x.x	≤5.0
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	Residue on ignition, % w/w:	x.x	≤0.1
EP	Bacterial endotoxins, IU/g:	Complies	☐ <16
USP	Bacterial endotoxins (6% sol.) EU/ml:	<x.x	☐ ≤0.5
EP	Microbial contamination, cfu/g:	Complies	≤100
USP	Antigenic impurities:	Complies	** Complies
JP	Antigenicity:	Not tested	Complies
JP	Pyrogenes (groups of 3 rabbits):	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'

*) 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 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.

#) Test is performed according to modified method that is correlated to Mw.

☐) Determined by turbidimetric kinetic method.

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