Valid from: 18-08-2023
Replaces: 06-01-2022

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		Complies
JP	Assay (dextran after drying, % w/w):	x		98 – 102
JP	Identification:	Complies	**	Complies
EP/USP	Infrared Absorption:	Complies	***	Complies
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)

PHARMACOSMOS A/S
ROERVANGSVEJ 30
DK-4300 HOLBAEK
DENMARK

TELEPHONE: +45 59 48 59 59
E-MAIL: info@pharmacosmos.com
WEB-SITE: www.pharmacosmos.com

CVR NO.: DK15517085
VAT NO. EXPORT: DK29127204

PHARMACOSMOS A/S

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:
USP	Sulfate, % w/w:	Complies		≤0.03
EP	Sulphated ash, % w/w:	x.x		≤0.3
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 performed. The identification of the product is assured througt strict adherence to established GMP rules throughout the manufacturing procedure.

***) Test is not carried out routinely.

****) Test is not performed 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 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

PHARMACOSMOS A/S
ROERVANGSVEJ 30
DK-4300 HOLBAEK
DENMARK

TELEPHONE: +45 59 48 59 59
E-MAIL: info@pharmacosmos.com
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