Valid from: 14-10-2024
Replaces: 15-12-2023

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 10000578, DK API-V 10000639
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	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,xxx		+195 – +201
EP/USP	Average molecular mass, Mw:			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
JP	Reducing substances per g:	Complies		≤15 (mg glucose)
USP	Sulfate, % w/w:	Complies		≤0.03

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

Valid from: 14-10-2024
Replaces: 15-12-2023

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
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'

*) Test is not carried out. 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 performed acoording to modifed 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 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

PHARMACOSMOS A/S
ROERVANGSVEJ 30
DK-4300 HOLBAEK
DENMARK

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