Valid from: 15-12-2023
Replaces: 01-09-2023

Batch Release Certificate

Product name: **Dextran 70 EP/JP**

Specification No.: **40004**

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 amorhpous powder
JP	Assay (dextran after drying, % w/w):	x		98 – 102
JP	Identification:	Complies	*	Complies
EP	Infrared Absorption:	Complies		Complies
EP/JP	Appearance of solution:	Complies		Complies
JP	pH (6% solution):	x.x		5.0 – 7.0
EP	Acidity or Alkalinity:	Complies		Complies
EP	Specific rotation, (+/-) °:	+x		+195 – +201
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
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	x		≤100
EP	Nitrogen containing substances, ppm	x		≤110
EP	Residual solvent, % by GC:	Complies	#	Complies
JP	Chloride, % w/w:	x.xxx		≤0.018
JP	Reducing substances per g:	Complies		≤10 (mg glucose)
EP	Sulphated ash, % w/w:	x.x		≤0.3
JP	Loss on drying (105°C, 6h), % w/w:	x.x		≤5.0
JP	Residue on ignition, % w/w:	x.xx		≤0.10
EP	Bacterial endotoxins, IU/g:	Complies	¤	≤16
EP	Microbial contamination, cfu/g:	Complies		≤100
JP	Antigenicity:	Not tested		Complies
JP	Pyrogenes (groups of 3 rabbits):	Not tested		Complies

References to official monographs are to be considered as current editions.

We hereby 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.

EDQM refers to 'European Directorate for the Quality of Medicines and Healthcare'. DKMA refers to 'Danish Medicines Agency'

*) Test is not carried out routinely.

**) Test is performed acoording to modifed method that is correlated to Mw.

#) 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.

¤) Determined by turbidimetric kinetic method.

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

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