

Batch Release Certificate

Product name: Dextran 40 JP

Specification No.: 40010

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 00083617, DK API-V 00083617

FDA establishment No.: FEI 3002807874

FDA facility classification: Acceptable

EDQM* certificate No.: Certificates for Dextran 1, 40, 60 & 70 Ph.Eur. available

Method:	Parameter:	Results of analysis:	Limits:
JP	Appearance of solution:	Complies	Clear and colorless
JP	Identification:	Complies	** Solution does not change in color
JP	Assay (dextran after drying, % w/w):	x.x	98.0 – 102.0
JP	Average molecular mass, Mw:	x,xxx	app. 40,000
JP	Viscosity, intrinsic, dL/g:	x.xx	0.16 – 0.19
JP	Viscosity, intrinsic, high fraction, dL/g:	x.xx	≤0.27
JP	Viscosity, intrinsic low fraction, dL/g:	x.xx	≥0.09
JP	pH (10% solution):	x.x	5.0 – 7.0
JP	Nitrogen containing impurities, % w/w N:	x.xxx	≤0.010
JP	Chloride, % w/w:	Complies	≤0.018
JP	Reducing substances per g:	Complies	≤15 (mg glucose)
JP	Heavy metals, ppm lead:	Complies if tested	≤20
JP	Arsenic, ppm:	Complies if tested	≤1.3
JP	Loss on drying (105°C, 6h), % w/w:	x.x	≤5.0
JP	Residue on ignition, % w/w:	x.x	≤0.1
JP	Bacterial endotoxins, IU/g:	Complies	<2.5
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 routinely.

We hereby 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 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.

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