PHARMACOSMOS A/S

Batch Release Certificate

Product name:	**Dextran 40 USP**
Specification No.:	**40018**
Batch No.:	xxxxxx
Manufacturing date:	mmmm_yyyy
Retest date (5 years):	mmmm_yyyy
Manufacturing sites:	Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark
DKMA No.:	254629
GMP certificate No.:	DK API-H 10001351, DK API-V 10001349
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:
Visual	Appearance of powder:	Complies		White or almost white powder
USP	Identification A: Infrared Absorption:	Complies	*	Complies
USP	Identification B: Viscosity, intrinsic, mL/g:	x		18 – 23
USP	Identification C: Meets the requirements of the tests for Mw distribution and Weight and Number Average Molecular Weights:	Complies		Complies
USP	Color of solution (Absorbance at 375 nm, 10% sol., 4 cm):	x.xx		≤0.20
USP	pH (10% solution):	x.x		4.5 – 7.0
USP	Specific rotation (+/-) °:	+x		+195 – +203
USP	Average molecular mass, Mw:	x.xxx		35,000 – 45,000
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	Nitrogen containing impurities, ppm N:	x	¤	≤100
USP	Alcohol and related impurities:	Complies	*	Complies
USP	Sulfate, % w/w:	Complies		≤0.03
USP	Loss on drying (105°C, 5h), % w/w:	x.x		≤7.0
USP	Bacterial endotoxins (10% sol.) EU/ml:	x.x	¤¤	≤1.0

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.

¤) Determined by sulfuric acid digestion (Kjeldahl), a slighly modified compendial method.

¤¤) Determined by turbidimetric kinetic method.

We confirm that no class 1, class 2 and class 3 solvent, cf. USP <467> Residual solvents, 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

Valid from: 01-05-2026
Replaces: 01-01-2026

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VAT NO. EXPORT: DK29127204