PHARMACOSMOS A/S

Batch Release Certificate

Product name: **Dextran 60 EP**

Specification No.: **40013**

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 10000578, DK API-V 10000639
FDA establishment No.: FEI 3002807874
FDA facility classification: Acceptable
EDQM certificate No.: R1-CEP 1999-064-Rev 03

Method:	Parameter:	Results of analysis:		Limits:
Visual	Appearance of powder:	Complies	*	White or almost white powder
EP	Appearance of solution:	Complies		Clear and colorless
EP	Specific rotation, (+/-) °:	+x		+195 – +201
EP	Acidity or Alkalinity:	Complies		Complies
EP	Infrared Absorption:	Complies	**	Complies
EP	Average molecular mass, Mw:	x,xxx		54,000 – 66,000
EP	Mw of 10% high fraction:	x,xxx		≤180,000
EP	Mw of 10% low fraction:	x,xxx		≥14,000
EP	Nitrogen containing substances, ppm N:	x		≤110
EP	Residual solvent % by GC:	Complies	***	Methanol ≤0.05 Ethanol & other solvents ≤0.5
EP	Loss on drying (105°C, 5h), % w/w:	x.x		≤7.0
EP	Sulphated ash, % w/w:	x.x		≤0.3
EP	Bacterial endotoxins, IU/g:	x	¤	<16
EP	Microbial contamination (TAMC), cfu/g:	Complies		≤100

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'

*) Very soluble in water, very slightly soluble in ethanol (96%).

**) Test is not carried out routinely. The identification of the product is assured througt strict adherence to established GMP rules throughout the manufacturing procedure.

***) Test is not carried out according to approval from EDQM. No class 1, class 2 and class 3 solvent, cf. ICH Q3C and VICH GL 18, 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. EP 5.4 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

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