Batch Release Certificate

Product name: **Dextran 1 EP**

Specification No.: **40011**

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 00042914, DK API-V 00042914
FDA establishment No.: FEI 3002807874
FDA facility classification: Acceptable
EDQM* certificate No.: R1-CEP 2003-165-Rev 00

Method:	Parameter:	Results of analysis:		Limits:
EP	Description:	Complies		White or almost white powder
EP	Solubility:	Complies		Very soluble in water, very slightly soluble in ethanol (96%)
EP	Specific rotation, (+/-) °:	+x		+148 – +164
EP	Color of solution (Absorbance at 375 nm, 15% sol., 1 cm):	x.xx		≤0.12
EP	Infrared Absorption:	Complies	**	Complies
EP	Acidity or Alkalinity:	Complies		Complies
EP	Average molecular mass, Mw:	x,xxx		850 – 1,150
EP	<3 glucose units fraction, % w/w:	x		<15
EP	>9 glucose units fraction, % w/w:	x		<20
EP	Nitrogen containing substances, ppm N:	x		≤110
EP	Sodium chloride, % w/w:	x.x		≤1.5
EP	Heavy metals, ppm lead:	x		<10
EP	Loss on drying (105°C, 5h), % w/w:	x.x	***	≤5.0
EP	Bacterial endotoxins, IU/g:	Complies		<25
EP	Microbial contamination, 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 Health and Medicines Authority'

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

***) Due to the hygroscopic nature of the powder, loss on drying may change during storage. We recommend keeping small packs (100g and 500g) well closed and protected against moisture.

We hereby 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 hereby confirm that no metal catalysts or metal reagents, cf. EMEA/CHMP/4446/2000 and Ph. Eur. 5.20 are used in the manufacturing of this product.

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
TELEFAX: +45 59 48 59 60
E-MAIL: info@pharmacosmos.com
WEB-SITE: www.pharmacosmos.com

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