Valid from: HSA/LC 07-11-2016
Replaces: HSA/LC 30-10-2015

Batch Release Certificate

Product name: **DEAE-Dextran 500**

Specification No.: **60006**

Batch No.: xxxxxx
Manufacturing date: mmmm_yyyy
Retest date (2 years): mmmm_yyyy

Manufacturing sites: Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark

Method:	Parameter:	Results of analysis:		Limits:
Pharmacosmos	Appearance of powder:	Complies		White or almost white powder
EP	Appearance of solution (5% solution):	Complies		Clear and colourless
USP	Infrared Absorption:	Complies	*	Complies
USP	Absorbance (at 375 nm, 5% sol., 4	x.x		≤0.1
EP	pH (1%w/v in 1M KCl):	x.x		4 – 7
EP	Specific rotation, (+/-) °:	+x	**	+135 – +155
EP	Loss on drying (105°C, 5h), % w/w:	x		≤7
Pharmacosmos	Lead, ppm:	Complies		≤5
Pharmacosmos	Nitrogen content, %w/w:	x.x	***	2.5 – 4.0
EP/USP	Residue on ignition, % w/w:	x.x		≤1.0
EP/USP	Microbial contamination, cfu/g:	x		≤100

DEAE-dextran 500 is a polycationic derivative of dextran, produced from GMP manufactured dextran with an average molecular weight >500,000 Da.
This DEAE-Dextran is supplied in its HCl form.
Due to the hygroscopic nature of the powder, loss on drying may change over time. Keep container well closed and protected from moisture.
We hereby confirm that no class 1, class 2 and class 3 solvent, cf. ICH Q3C Guideline for Residual solvents, is used in the manufacturing of this product.

*) Not rutinely tested. The identification is ensured through strict control of the manufacturing process.
**) Determined on 6%w/v solution and calculated on the dried substance.
***) Calculated on dried substance.

I hereby certify that the above information is authentic and accurate. This batch of DEAE-dextran has been manufactured, including packaging and quality control in full compliance with the above mentioned specifications.

Date (dd.mm.yyyy):

Heidi Skjødt Andersen, M.Sc. Pharm, Quality Control

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