PHARMACOSMOS

Batch Release Certificate

Product name: **DEAE-Dextran 500 Pharmaceutical Quality**

Specification No.: **60009**

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

Description: **DEAE-Dextran 500 Pharmaceutical Quality is a GMP manufactured polycationic derivative of dextran, produced from dextran with an average molecular weight > 500,000 Da. DEAE-Dextran 500 Pharmaceutical Quality is supplied in its HCl form, suitable for use as an API or in pharmaceutical preparations.**

Method:	Parameter:	Results of analysis:		Limits:
Visual	Appearance of powder:	Complies		White or almost white powder
EP	Appearance of solution (6% sol.):	Complies		Clear and colourless
EP	Infrared Absorption:	Complies	a)	Complies
EP	Absorbance (at 375 nm, 6% sol., 4 cm):	x.x		≤0.1
EP	pH (1%w/v in 1M KCl):	x.x		4 – 7
EP	Specific rotation, (+/-) °:	+x	b)	+135 – +155
EP	Loss on drying (105°C, 5h), % w/w:	x		≤7
EP	Lead, ppm:	Complies		≤5
DDF008	Nitrogen content, %w/w:	x.x	c)	2.5 – 4.0
DDF008	Degree of substitution:	x.xx		0.40 – 0.72
DDF009	Specific viscosity:	x.x		0.5 – 1.0
EP	Residue on ignition, % w/w:	x.x		≤1.0
EP	Microbial contamination (TAMC), cfu/g:	x		≤100
EP	Microbial contamination (TYMC), cfu/g:	x		≤100
EP	Bacterial endotoxins, IU/mg:	Complies		≤10

Additional information:

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.
Retest date may be extended in light of on-going stabiliy studies.
* DKMA refers to "Danish Medicines Agency".

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

CERTIFICATE OF CONFORMITY
I hereby certify that this batch of Active Pharmaceutical Ingredient (API) has been manufactured at the above mentioned site in compliance with the detailed guideline on good manufacturing practice (GMP) for active substances, i.e. EU GMP Part II, ICH Q7 guidelines and the GMP recommendations of WHO. By signature, I confirm that the above is authentic and accurate and that this batch complies with the above mentioned specification.

Date (dd.mm.yyyy):

Qualified Person, Heidi Skjødt Andersen, M.Sc. Pharm

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