

Batch Release Certificate

Product name: DEAE-Dextran 500

Specification No.: 60006

Batch No.: xxxxxx

Manufacturing date: mmmm_yyyy

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

Description: DEAE-Dextran 500 is a polycationic derivative of dextran, produced from dextran with an average molecular weight >500,000 Da. This DEAE-Dextran is supplied in its HCl form.

Method:	Parameter:	Results of analysis:	Limits:
Visual	Appearance of powder:	Complies	White or almost white powder
DDF002	Appearance of solution (6% sol.):	Complies	Clear and colourless
DDF006	Infrared Absorption:	Complies	Complies
DDF004	Absorbance (at 375 nm, 6% sol., 4 cm):	x.x	≤0.1
DDF003	pH (1%w/v in 1M KCl):	x	4 – 7
DDF007	Specific rotation, (+/-) °:	+x	+135 – +155
DDF005	Loss on drying (105°C, 5h), % w/w:	x	≤7
DDF012	Lead, ppm:	Complies	≤5
DDF008	Nitrogen content, %w/w:	x.x	2.5 – 4.0
DDF009	Specific viscosity:	x.x	0.5 – 1.0
DDF010	Residue on ignition, % w/w:	x.x	≤1.0
DDF011	Microbial contamination, cfu/g:	x	≤100

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.

a) Not routinely 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.

I hereby certify that the above information is authentic and accurate. This technical batch of DEAE-Dextran has been manufactured in full compliance with the above mentioned specifications.

Date (dd.mm.yyyy):

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