

Batch Release Certificate

Product name: Dextran T750

Specification No.: 40129

Batch No.: ABxxx

Manufacturing sites: Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark
DKMA* No.: 254629
GMP certificate No.: N/A
FDA establishment No.: N/A
FDA facility classification: N/A
EDQM* certificate No.: N/A

| Method: | Parameter: | Results of analysis: | Limits: |
|---------|---|----------------------|-------------------|
| – | Description: | Complies | White powder |
| DF034 | Average molecular mass, Mw (laser): | xx,000 | 600,000 – 900,000 |
| DF001 | Loss on drying (105°C, 5h), % w/w: | x | ≤7 |
| DF030 | Color of solution (Absorbance at 375 nm, 10% sol., 1 cm): | x.xx | ≤0.05 |
| DF004 | pH (10% solution): | x.x | 4.5 – 7.0 |
| DF009 | Specific rotation (+/-) °: | +x | +195 – +201 |
| DF012 | Heavy metals, ppm lead: | x | ≤20 |
| DF019 | Nitrogen containing impurities, ppm N: | x | ≤100 |

*) EDQM refers to 'European Directorate for the Quality of Medicines and Healthcare'. DKMA refers to 'Danish Medicines Agency'
We hereby confirm that no class 1, class 2 and class 3 solvent, cf. ICH Q3C and VICH GL 18, is used in the manufacturing of this product.
This certificate of analysis is applicable for supplies of code No. 5510 0500 90xx where xx is varying with pack size.

I hereby certify that the above information is authentic and accurate. This batch of technical quality 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