

# Batch Release Certificate

**Product name:** Dextran 1 USP

**Specification No.:** 40017

**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

**EDQM\* certificate No.:** Certificates for Dextran 1, 40, 60 & 70 Ph.Eur. available

| Method:                                | Parameter:  | Results of analysis: | Limits:     |
|--|---|----------------------|-------------|
| USP                                    | Infrared Absorption:                                      | Complies             | ** Complies |
| USP                                    | Color of solution (Absorbance at 375 nm, 15% sol., 1 cm): | x.xx                 | ≤0.12       |
| USP                                    | pH (15% solution):  | x.x                  | 4.5 – 7.0   |
| USP                                    | Specific rotation, (+/-) °:                               | +x                   | +148 – +164 |
| USP                                    | Average molecular mass, Mw:                               | x                    | 850 – 1,150 |
| USP                                    | <3 glucose units fraction, % w/w:                         | x                    | <15         |
| USP                                    | >9 glucose units fraction, % w/w:                         | x                    | <20         |
| USP                                    | Nitrogen containing impurities, ppm N:                    | x                    | ≤110        |
| USP                                    | Alcohol and related impurities:                           | Complies             | ** Complies |
| USP                                    | Sodium chloride, % w/w:                                   | x.x                  | ≤1.5        |
| USP                                    | Heavy metals, ppm lead:                                   | Complies             | ≤5          |
| USP                                    | Loss on drying (100°C to 105°C, 5h), % w/w:               | x.x                  | *** ≤5.0    |
| USP                                    | Bacterial endotoxins EU/g:                                | x.x                  | ≤25.0       |
| <u>Microbial contamination, cfu/g:</u> |   |                      |             |
| USP                                    | Aerobic microbial count (TAMC), cfu/g:                    | Complies             | ≤100        |
| USP                                    | Yeast and mold (TYMC), cfu/g:                             | Complies             | ≤10         |

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 Medicines Agency'

\*\*) Test is not carried out routinely.

\*\*\*) 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. USP <467> 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