

**Certification of Substances Division**

**Certificate of suitability  
No. R1-CEP 2003-165-Rev 00**

1 *Name of the substance:*  
2     **DEXTRAN 1 FOR INJECTION**

3 *Name of holder:*  
4     **PHARMACOSMOS A/S**  
5     Roervangsvej 30  
6     Denmark-4300 Holbaek

7 *Site(s) of production:*  
8     **PHARMACOSMOS A/S**  
9     Roervangsvej 30  
10    Denmark-4300 Holbaek

11                   **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
12                   **R0-CEP 2003-165-REV 01**

13 After examination of the information provided on the manufacturing method and  
14 subsequent processes (including purification) for this substance on the site(s) of  
15 production mentioned above, we certify that the quality of the substance is suitably  
16 controlled by the current version of the monograph **DEXTRAN 1 FOR INJECTION** no.  
17 1506 of the European Pharmacopoeia, current edition including supplements.

18     In the last steps of the synthesis water is used as solvent.

19     The holder of the certificate has declared the absence of use of material of human or  
20 animal origin in the manufacture of the substance.


21     Compliance with the statements of the Production Section of the monograph is to be  
22 considered in the context of a medicinal product containing this substance.

23     The submitted dossier must be updated after any significant change that may alter the  
24 quality, safety or efficacy of the substance.

25     Manufacture of the substance shall take place in accordance with the Good  
26 Manufacturing Practice and in accordance with the dossier submitted.



- 27 Failure to comply with these provisions will render this certificate void.
- 28 This certificate is renewed from **17 September 2009** according to the provisions of  
29 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive  
30 2001/82/EC and any subsequent amendment, and the related guidelines.
- 31 This certificate has:  
32 lines.

  
On behalf of the  
Director of EDQM



Strasbourg, 7 September 2009

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

**Pharmacosmos A/S**, as holder of the certificate of suitability  
**R1-CEP 2003-165-Rev 00 for DEXTRAN 1 FOR INJECTION**

here

to us  
Mark



**Unauthorized Copy!**  
**For illustration only**

**PHARMACOSMOS**

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been made since the granting of this version of the certificate.

Date and Signature *(of the CEP holder)*: