



European Directorate for the  
Quality of Medicines & HealthCare



Certification of Substances Division

## Certificate of suitability No. R1-CEP 1999-064-Rev 02

1 *Name of the substance:*  
2 **DEXTRAN 60 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 **R1-CEP 1999-064-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 60 FOR INJECTION**  
17 no. 1000 of the European Pharmacopoeia, current edition including supplements.

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

19 The test for residual solvents described in the monograph can be omitted since no  
20 other solvent than water is used during the synthesis.

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


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

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



- 27 Manufacture of the substance shall take place in accordance with the Good  
28 Manufacturing Practice and in accordance with the dossier submitted.
- 29 Failure to comply with these provisions will render this certificate void.
- 30 This certificate is renewed from **22 December 2004** according to the provisions of  
31 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive  
32 2001/82/EC and any subsequent amendment, and the related guidelines.
- 33 This certificate has:  
34 lines.



  
On behalf of the  
Director of EDQM

Strasbourg, 15 October 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 1999-064-Rev 02 for DEXTRAN 60 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):