

**Certification of Substances Department**

**Certificate of suitability  
No. R1-CEP 2003-165 - Rev 01**

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 **SEE ANNEX 1**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
10 **R1-CEP 2003-165 - REV 00**

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

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

17 No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of  
18 the substance.

19 The substance is packed in either double polyethylene bags in an aluminium bag placed in a  
20 fibre drum or double polyethylene bags placed in a polyethylene container.

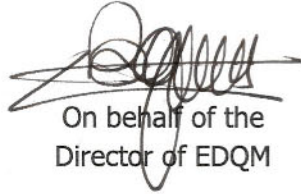
21 The holder of the certificate has declared the absence of use of material of human or animal  
22 origin in the manufacture of the substance.

23 Compliance with the statements of the Production Section of the monograph is to be considered  
24 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 quality,  
26 safety or efficacy of the substance.

27 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice  
28 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 **17 September 2009** according to the provisions of Resolution  
31 AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent  
32 amendment, and the related guidelines.
- 33 This certificate has one annex of 1 page.
- 34 This certificate has:  
35 lines.

  
On behalf of the  
Director of EDQM



Strasbourg, 3 January 2022

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 01 for Dextran 1 for injection**

hereby authorises .....  
*(name of the pharmaceutical company)*

to use the above-mentioned certificate of suitability in support of their application(s) for the following  
Marketing Authorisation(s): *(name of product(s) and marketing number(s), if known)*



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**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)*:

**Certification of Substances Department**

**Annex 1: Site(s) of production for R1-CEP 2003-165 - Rev 01**

**Production of Dextran 1 for injection:**

PHARMACOSMOS A/S  
Roervangsvej 30  
Denmark-4300 Holbaek