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

Name of the substance:
DEXTAN 1 FOR INJECTION

Name of holder:
PHARMACOSMOS A/S
Roervangsvej 30
Denmark-4300 Holbaek

Site(s) of production:
PHARMACOSMOS A/S
Roervangsvej 30
Denmark-4300 Holbaek

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

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

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

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

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

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

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.
Failure to comply with these provisions will render this certificate void.

This certificate is renewed from 17 September 2009 according to the provisions of Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has:

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

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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):

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