European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R1-CEP 1999-063 - Rev 03

Name of the substance:
DEXTRAN 40 FOR INJECTION

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

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 1999-063 - REV 02

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **DEXTRAN 40 FOR INJECTION** no. 999 of the European Pharmacopoeia, current edition including supplements.

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

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

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

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

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.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

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 **22 December 2004** according to the provisions of Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has one annex of 1 page.
This certificate has:
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 1999-063 - Rev 03 for Dextran 40 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*)

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*):

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Annex 1 : Site(s) of production for R1-CEP 1999-063 - Rev 03

Production of Dextran 40 for injection:

PHARMACOSMOS A/S
Roervangsvej 30
Denmark-4300 Holbaek