



**STATEMENT ON GOOD MANUFACTURING PRACTICES FOR
PHARMACEUTICAL STARTING MATERIALS (API)**

This one-page certificate conforms to the format recommended
by the World Health Organization

On the basis of an inspection carried out by the Danish Medicines Agency on
27th - 28th March 2008

we certify that the site indicated on this certificate complies with Good Manufacturing Practices for active pharmaceutical ingredients according to The Rules governing Medicinal Products in the European Union, Volume 4, Part II (ICH Q7) for the dosage forms, categories and activities listed in Table 1.

Name and address of site:

**Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek
Denmark**

Manufacturer's DKMA authorisation number:

254629

Table 1

Product / Product category:

**Dextran 1, Ph. Eur.
Dextran 40, Ph. Eur.
Dextran 60, Ph. Eur.
Dextran 70, Ph. Eur.**

Dosage form(s):

Active Pharmaceutical Ingredient

Activity(ies):

Manufacture, control, release and distribution

The responsibility for the purity and quality of the individual batches of the active pharmaceutical ingredients manufactured through the process lies with the manufacturer.

This certificate remains valid for three years from the date of last inspection.

This certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

Danish Medicines Agency
Axel Heides Gade 1
DK-2300 Copenhagen S
Tel: +45 44 88 95 95
Fax: +45 44 88 91 95
E-mail: dkma@dkma.dk
Internet: www.dkma.dk

Direct E-mail:
LI-exportcertificates
@dkma.dk

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