



**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 a voluntary 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:

Iron dextran solution of various selected strengths

Dosage form(s):

Active Pharmaceutical Ingredient

Activity(ies):

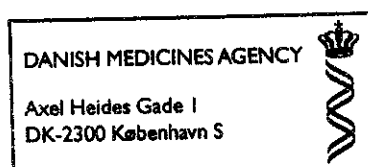
Manufacture, control, release and distribution

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.

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H5-205
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