# 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 the voluntary inspection carried out by the Danish Medicines Agency on **dd.mm.yyyy,** 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:*

**Name of manufacturer**

**Address of manufacturer**

**Postcode and city**

**Country**

Table 1

*Product / Product category:*

**Product/product category**

*Dosage form(s):*

**Dosage form**

*Activity(ies):*

**Activities**

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.