# STATEMENT ON GMP COMPLIANCE

# FOR NON-EC/EEA COUNTRIES

This one-page certificate conforms to the format recommended

by the World Health Organization

On the basis of the 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 according to the Rules governing Medicinal Products in the European Union, Volume 4, 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 quality of the individual batches of the pharmaceutical products 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.