fimea

Lääkealan turvallisuus- ja kehittämiskeskus
Säkerhets- och utvecklingscentret
för läkemedelsområdet
Finnish Medicines Agency

Certificate No:

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1,2]

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC or Art. 80(5) of Directive 2001/82/EC as amended and Art. 15 of Directive 2001/20/EC

The competent authority of Finland confirms the following:

The manufacturer:

Site address:

Has been inspected under national inspection programme in connection with manufacturing authorisation no. 2957/11.01.02./2012 in accordance with Art. 40 of Directive 2001/83/EC, Art. 44 of Directive 2001/82/EC and Art. 13 of Directive 2001/20/EC transposed in the following national legislation: Medicines Act and Medicines Decree, Finland

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on it is considered that it complies with The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[3] The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC[3] and The principles of GMP for active substances[3] referred to in Article 47 of Directive 2001/83/EC/ Article 51 of Directive 2001/82/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact issuing authority.

Turku 8th May 2014

Senior Inspector,
Finnish Medicines Agency, Inspectorate
Tel. · Fax. ·

[1]The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, is also applicable to importers.
[2] Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database
[3]These requirements fulfil the GMP recommendations of WHO

Part 2

☒ Human Medicinal Products

☒ Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS

1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of: 1.4.1.3 Others: Manufacture of non-sterile solid, powder or liquid Active substances:
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate: This certificate is requested by for USA

Turku 8th May 2014

Senior Inspector,
Finnish Medicines Agency, Inspectorate
Tel. Fax. +

Proceeding fee, Fermion Oy