Finnish Medicines Agency

CERTIFICATE NUMBER: ***001997/06.08.02.00/2014***

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 as amended

The competent authority of Finland confirms the following:
The manufacturer: ***Hankintatukku Oy***
Site address: ***Lehtolankatu 18, Karkkila, FI-03600, Finland***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***002065/06.08.00.04/2014*** in accordance with Art. 40 of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2014-10-14*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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 the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[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

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products Special Requirements 7 Other: Solids: tablets, capsules(en)
	1.4.3 Other: Storage for finished products(en)
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

1.4.3 Storage for finished products address: Yrittäjäntie 64, 03600, Karkkila, Finland

2014-12-18

Name and signature of the authorised person of the Competent Authority of Finland

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Confidential
Finnish Medicines Agency
Tel: ***Confidential***
Fax: ***Confidential***

Lohjan kaupunki

CERTIFICATE OF THE MANUFACTURER

Manufacturer: Hankintatukku Oy

Factory address: Lehtolankatu 18
03600 Karkkila
Finland

We hereby certify that Hankintatukku Oy's factory at Karkkila has the licence to industrially manufacture health food products (The City of Karkkila 26.8.1983) and pharmaceuticals (Finnish Medicines Agency Dnro 001997/06.08.02.00/2014).

We also certify that in production Hankintatukku Oy follows the guidelines of European GMP and the factory is inspected regularly by authorities from the City of Karkkila and Finnish Medicines Agency.

The products fulfil the requirements of the Finnish and EU food legislation.

This certificate is valid two (2) years from the date of signature.

THE CITY OF LOHJA

27.1.2015

Päivi Kohonen
Municipal Health Inspector

Länsi-Uudenmaan ympäristöterveys
Västra Nylands miljöhälsa
Lohja Lojo

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