Ravimiamet
State Agency of Medicines

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Estonian State Agency of Medicines

CERTIFICATE NUMBER:

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The competent authority of Estonia confirms the following:

The manufacturer

Site address

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 , transposed in the following national legislation:
National legislation – Medicinal Products Act requires ManA for manufacture of API in Estonia. § 16 subsection (3)

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 of GMP for active substances (3) referred to in Article 47 of Directive 2001/83/EC and 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 with the issuing authority or in EudraGMDP http://eudragmp.ema.europa.eu. If it does not appear, please contact the issuing authority.

(3) These requirements fulfil the GMP recommendations of WHO.

Part 2

Manufacture of active substance. Names of substances subject to inspect on :

[1] (en)
[3] (en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance :

3.1 Manufacture of Active Substance by Chemical Synthesis

- 3.1.1 Manufacture of active substance intermediates
- 3.1.2 Manufacture of crude active substance
- 3.1.3 Salt formation / Purification steps :
  Crystallisation

3.5 General Finishing Steps

- 3.5.1 Physical processing steps :
  Drying
- 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
- 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

3.6 Quality Control Testing

- 3.6.1 Physical / Chemical testing

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3.1 Manufacture of Active Substance by Chemical Synthesis

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- 3.5.1 Physical processing steps
  Drying etc
- 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
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3.6 Quality Control Testing

- 3.6.1 Physical / Chemical testing

Any restrictions related to the scope of this certificate:
Clarifying remarks

2013-10-21

Name and signature of the authorised person
of the competent authority of Estonia

Tel:
Fax: