REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Ravimiamet
Estonian State Agency of Medicines

CERTIFICATE NUMBER: ***JV-16/23/5***

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

Part 1

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

The competent authority of Estonia confirms the following:

The manufacturer ***PharmaEstica Manufacturing OÜ***

Site address ***Vanapere tee 3, Pringi küla, Viimsi vald, Harju maakond 74011, Estonia***

OMS Organisation Id. / OMS Location Id.: **ORG-100002475 / LOC-100009659**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***673*** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC transposed in the following national legislation:
Medicinal Products Act (public. ref: RT I 2005, 2, 4; RT = Riigi Teataja = State Gazette) § 16 subsection (1), (3); § 16 subsection (6), § 18 subsection (3) - import

From the knowledge gained during the latest general GMP inspection of this manufacturer, which was conducted on ***2023-02-10*** (inspection end date), 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 Art. 15 of Directive 2001/20/EC and Art. 111(5) of Directive 2001/83/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 HUMAN INVESTIGATIONAL MEDICINAL PRODUCTS

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets *1.2.2 Batch certification*
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.13 Tablets *1.5.2 Secondary packing*
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

1.2.2 - in the scope of dosage forms indicated under 1.2.1

2023-05-22

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

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