REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Ravimiamet
Estonian State Agency of Medicines

CERTIFICATE NUMBER: IN-2-14/17/4-*6* (H,IMP-Mf)

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [2]

Part 1

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

The competent authority of Estonia confirms the following:

The manufacturer ***PharmaEstica Manufacturing (PharmaEstica Manufacturing OÜ) ****

Site address ***Vanapere tee 3, Pringi, Viimsi, 74011 Harju county, ESTONIA***

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 inspection of this manufacturer, the latest of which was conducted on ***2017-02-28*** *(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.
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.

* Administrative change in the name of the manufacturer.
Initial certificate following the inspection 2017-02-28 at this site was issued for the company named at that time as **Vitale-XD**; the manufacturing authorisation holder subsequently changed their name to PharmaEstica Manufacturing OÜ and the site name to **PharmaEstica Manufacturing**. The authorisation holder has the same identification code in the national business register. Manufacturing authorisation issued by the Estonian State Agency of Medicines maintains the number 673. Conclusion of the inspection 2017-02-28 was not changed.

(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

2017-08-28

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

Ms Hille Kask
chief inspector
Ravimiamet
hille.kask@ravimiamet.ee
Tel: *+372 7 374 140*
Fax: *+372 7 374 142*