REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Ravimiamet
Estonian State Agency of Medicines

CERTIFICATE NUMBER: IN-2-14/15/8 (H, V)

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. 80 (5) of Directive 2001/82/EC,
Art. 15 of Directive 2001/20/EC.

The competent authority of Estonia confirms the following:

The manufacturer ***Tallinn Pharmaceutical Plant (Tallinna Farmaatsiatehase AS)***

Site address ***Tondi 33, 11316, Tallinn, ESTONIA***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***381*** in accordance with Art. 40 of Directive 2001/83/EC, Art. 44 of Directive 2001/82/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 ***2015-11-03*** *(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]
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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, after which time the issuing authority should be consulted.
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 EudraGMP http://eudragmp.ema.europa.eu. If it does not appear, please contact the issuing authority.

(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	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use 1.2.1.11 Semi-solids
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.5 Liquids for external use 1.5.1.11 Semi-solids
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2. Microbiological: non-sterility *1.6.3 Chemical/Physical*

2015-11-30

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

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