Ravimiamet
State Agency of Medicines

Ravimiamet
Estonian State Agency of Medicines

CERTIFICATE NUMBER: IN-2-14/14/7 H I

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 ***Kevelt (Kevelt AS / Aktsiaselts Kevelt)***

Site address ***Teaduspargi 3/1, Tallinn 12618, ESTONIA***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***100*** 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 ***2014-06-05*** (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.

(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.

Ravimiamet
Nooruse 1
50411 Tartu
www.ravimiamet.ee
Tel: 7 374 140
Faks: 7 374 142
info@ravimiamet.ee

State Agency of Medicines
1 Nooruse Street
50411 Tartu, Estonia
www.ravimiamet.ee
Tel: +372 7 374 140
Fax: +372 7 374 142
info@ravimiamet.ee

Human Medicinal Products
Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS

1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.3 Semi-solids 1.1.1.4 Small volume liquids 1.1.1.6 Other: liquid eye preparations *1.1.3 Batch certification*
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products *1.3.2 Batch Certification (list of product types)* 1.3.2.2 Immunological products
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.1 Filtration
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

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

1.1.1.3 Semi-solids: vaginal/endocervical gels.
1.1.1.4. Small volume liquids: parenterals
1.1.1.6 Other: liquid eye preparations
1.3.1.2 restriction: Aseptic processing, quality control and release of materials produced by the following methods:
- cultivation of non-pathogenic viruses in cell culture;
- replication of bacterioph. immunomodulating RNA in cell culture.

1.6.2 Microbiological: production environment
1.6.4 Biological: endotoxins

2014-08-08

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*