REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Ravimiamet
Estonian State Agency of Medicines

CERTIFICATE NUMBER: IN-2-14/21/2

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1], [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 (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 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 ***2020-11-17*** (inspection end date), and the directed distant inspection conducted on *2021-03-19*, 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 inspections noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of the general GMP 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 EudraGMP http://eudragmp.ema.europa.eu. If it does not appear, please contact the issuing authority.

(1)The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/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	
1.1	**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 1.1.2 Terminally sterilised 1.1.2.3 Small volume liquids 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 1.4.2.2 Dry heat
1.5	**Packaging**
	1.5.2 Secondary packaging
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
1.1.2 Terminally sterilised with dry heat
1.1.3 Batch certification - in the scope of dosage forms indicated in section 1.1.1 above
1.3.1.2, 1.3.2.2 restriction: Aseptic processing, quality control and release of materials produced by the following methods:
- cultivation of non-pathogenic viruses in cell culture;
- replication of immunomodulating RNA of bacteriophagic origin in cell culture
1.6.4 Biological: endotoxins

2021-03-31

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

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