



I hereby certify that this is a correct and true copy of the original document which I have seen.  
 Espoo, Finland  
 Ex officio  
 16.4.2024  
 Post 20

**fimea**

Lääkkealan turvallisuus- ja kehittämiskeskus  
 Säkerhets- och utvecklingscentret  
 för läkemedelsområdet  
 Finnish Medicines Agency

VISA LIPIAINEN  
 Henkikirjoittaja, julkinen notaari  
 Häradsskrivare, notarius publicus  
 District Registrar, Notary Public

**Finnish Medicines Agency**

CERTIFICATE NUMBER: **FIMEA/2022/002359**



**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**

**Part 1**

Issued following an inspection in accordance with :  
 Art. 94(1) of Regulation (EU) 2019/6 as amended  
 Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Finland confirms the following:  
 The manufacturer: **Orion Corporation**  
 Site address: **Orionintie 1, P. O. Box 65, Espoo, 02200, Finland**  
 OMS Location: **LOC-100006960**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **FIMEA/2019/000732** in accordance with Art. 40 of Directive 2001/83/EC and Art. 88 of Regulation (EU) 2019/6.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2022-06-02**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC<sup>3</sup>
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC<sup>3</sup>

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.

<sup>1</sup>The certificate referred to in paragraph Art. 80(5) of Directive 2001/82/EC and Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.

<sup>2</sup>Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup>These requirements fulfil the GMP recommendations of WHO.

*Peeyo Hanninen*

Part 2

Veterinary Medicinal Products

Human Medicinal Products

**1 MANUFACTURING OPERATIONS**

**1.1 Sterile products**

1.1.1 *Aseptically prepared (processing operations for the following dosage forms)*

1.1.1.4 Small volume liquids  
Special Requirements  
7 Other: Highly potent products(en)

1.1.1.6 Other: oromucosal liquids(en)  
Special Requirements  
7 Other: Highly potent products(en)

1.1.2 *Terminally Sterilised (processing operations for the following dosage forms)*

1.1.2.3 Small volume liquids  
Special Requirements  
7 Other: Highly potent products(en)

1.1.3 *Batch certification*

**1.2 Non-sterile products**

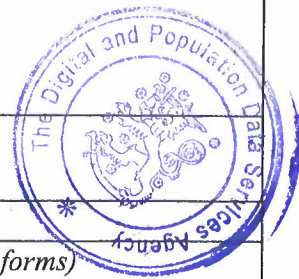
1.2.1 *Non-sterile products (processing operations for the following dosage forms)*

1.2.1.1 Capsules, hard shell  
Special Requirements  
7 Other: Highly potent products(en)

1.2.1.6 Liquids for internal use  
1.2.1.8 Other solid dosage forms  
Special Requirements  
7 Other: Highly potent products(en)

1.2.1.13 Tablets  
Special Requirements  
7 Other: Highly potent products(en)

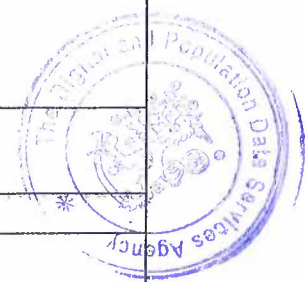
1.2.2 *Batch certification*



*Reijo Hanninen*

<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms Special Requirements 7 Other: Highly potent products(en)
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

<b>2 IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	<i>2.1.1 Microbiological: sterility</i> <i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i> <i>2.1.4 Biological</i>
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	<i>2.2.2 Non-sterile products</i>
<b>2.3</b>	<b>Other importation activities</b>
	<i>2.3.1 Site of physical importation</i>
	<i>2.3.4 Other: herbal(en)</i>



Clarifying remarks (for public users)

**1.1.1.4 Injections, concentrates for injection and infusion. 1.1.2.3 Injections, concentrates for injection and infusion. 1.2.1.6 and 1.5.1.6 Drops. 1.2.1.8 and 1.5.1.8 Inhalation powders.**

*Pirjo Hanninen*

2022-06-30

Name and signature of the authorised person of the  
Competent Authority of Finland



17.2022 *Pirjo Hanninen*

***Pirjo Hanninen***

***Finnish Medicines Agency***

Tel:

Fax:

