Finnish Medicines Agency

CERTIFICATE NUMBER: ***FIMEA/2022/002459***

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 [3]
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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. 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.

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[1] *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.*

[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

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

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1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms Special Requirements 7 Other: Highly potent products(en)
	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*

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

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.

2022-06-30

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

6.7.2022

Pirjo Hanninen
Finnish Medicines Agency
Tel:
Fax: