

Lääkealan turvallisuus- ja kehittämiskeskus

CERTIFICATE NUMBER: **003953/06.08.02.00/2017IMP**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1, 2}

Part 1

Issued following an inspection in accordance with :

Art. 15 of Directive 2001/20/EC

The competent authority of Finland confirms the following:

The manufacturer: **Orion Oyj / Orion Corporation / Orion Pharma**

Site address: **Orionintie 1, Espoo, 02200, Finland**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **006356/06.08.00.04/2018** in accordance with Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-09-13** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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.

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

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| Human Investigational Medicinal Products | |
| 1 MANUFACTURING OPERATIONS | |
| 1.1 | Sterile products |
| | <i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids |
| | <i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids |
| | <i>1.1.3 Batch certification</i> |
| 1.2 | Non-sterile products |
| | <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: inhalation powders(en) 1.2.1.13 Tablets |
| | <i>1.2.2 Batch certification</i> |
| 1.5 | Packaging |
| | <i>1.5.1 Primary Packing</i> 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: inhalation powders(en) 1.5.1.13 Tablets |
| | <i>1.5.2 Secondary packing</i> |
| 1.6 | Quality control testing |
| | <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> |

| 2 IMPORTATION OF MEDICINAL PRODUCTS | |
|--|---|
| 2.1 | Quality control testing of imported medicinal products |
| | 2.1.1 <i>Microbiological: sterility</i> 2.1.2 <i>Microbiological: non-sterility</i> 2.1.3 <i>Chemical/Physical</i> 2.1.4 <i>Biological</i> |
| 2.2 | Batch certification of imported medicinal products |
| | 2.2.1 <i>Sterile products</i> 2.2.1.1 <i>Aseptically prepared</i> 2.2.1.2 <i>Terminally sterilised</i> |
| | 2.2.2 <i>Non-sterile products</i> |
| 2.3 | Other importation activities |
| | 2.3.1 <i>Site of physical importation</i> |
| | 2.3.2 <i>Importation of intermediate which undergoes further processing</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. The authorization covers also the batch certification of comparator products.

2018-10-30

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

Confidential
Finnish Medicines Agency
 Tel: **Confidential**
 Fax: **Confidential**