LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Medical Products Agency

CERTIFICATE NUMBER : ***6.2.1-2020-079580***

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. 80(5) of Directive 2001/82/EC as amended
Art. 15 of Directive 2001/20/EC

The competent authority of Sweden confirms the following:
The manufacturer :***Oriola Sweden AB***
Site address :***Fibervägen, Solsten, Mölnlycke, 435 33, Sweden***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***6.2.1-2020-079580*** in accordance with Art. 40 of Directive 2001/83/EC , Art. 44 of Directive 2001/82/EC and Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-08-27*** , 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.

[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.*

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Part 2

Human Medicinal Products
Veterinary Medicinal Products
Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.5	**Packaging**
	1.5.2 Secondary packaging

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Clarifying remarks (for public users)

1.5.2 Re-packaging and re-labelling of medicinal products. Packaging and labelling of investigational medicinal products, including blinded randomised investigations. (1.5.2 Ompackning, ommärkning och tilläggsmärkning av läkemedel. Packning och märkning av kliniska prövningsläkemedel, inklusive blindade randomiserade prövningar.) 2.3.1 Sampling of finished product, storage and distribution of medicinal products after importation from third country. (2.3.1 Provuttag av slutprodukt, lagerhållning och distribution av läkemedel efter import från tredje land.) The authorisation does not include batch release after importation from third country. (Tillståndet omfattar inte frisläppning efter import från tredje land.)

2021-11-26

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

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

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