State Agency Of Medicines

CERTIFICATE NUMBER: ***ZVA/LV/2025/020H***

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. 63 of Regulation (EU) 536/2014 as amended

The competent authority of Latvia confirms the following:
The manufacturer: ***Oribalt Rīga SIA***
Site address: ***Dzirnieku Iela 26, Marupe, 2167, Latvia***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012153*** / ***LOC-100067038***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***R00035*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC, transposed in the following national legislation:Cabinet Regulation No. 304 (Adopted 18 April 2006) § 5 "Regulations Regarding the Procedures for the Manufacture and Control of Medicinal Products, Requirements for the Qualification and Professional Experience of a Qualified Person and the Procedures for the Issuance of the certificate of Good Manufacturing Practice to a Medicinal Products Manufacturing Undertaking" and Cabinet Regulation No. 304 (Adopted 18 April 2006) §§ 5-7 "Regulations Regarding the Procedures for the Manufacture and Control of Medicinal Products, Requirements for the Qualification and Professional Experience of a Qualified Person and the Procedures for the Issuance of the certificate of Good Manufacturing Practice to a Medicinal Products Manufacturing Undertaking".

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-09-03***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2. [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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 111(5) of Directive 2001/83/EC and Art. 15 of Directive 2001/20/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human 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

Any restrictions related to the scope of this certificate:

Clarifying remarks (for registered users)

1.5.2. Including batch certification after secondary packaging for human medicinal products; 2.3.1. Importation, storage and distribution of medicinal products only manufactured by "Novartis Pharma" Importation, secondary packaging, storage and distribution of investigational medicinal products without batch certification (batch certification should be performed by manufacturer's Qualified Persons

Clarifying remarks (for public users)

1.5.2. Including batch certification after secondary packaging for human medicinal products; 2.3.1. Importation, storage and distribution of medicinal products only manufactured by "Novartis Pharma" Importation, secondary packaging, storage and distribution of investigational medicinal products without batch certification (batch certification should be performed by manufacturer's Qualified Persons

2025-10-31

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

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Sergejs Akulics
State Agency Of Medicines
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