State Agency Of Medicines

CERTIFICATE NUMBER: ***ZVA/LV/2023/004HV***

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. 15 of Directive 2001/20/EC
Art. 94(1) of Regulation (EU) 2019/6 as amended

The competent authority of Latvia confirms the following:
The manufacturer: ***Olainfarm AS***
Site address: ***Rupnicu Iela 5, Olaine, 2114, Latvia***
OMS Organisation Id. / OMS Location Id.: ***ORG-100002509*** / ***LOC-100000997***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***R00018*** in accordance with Art. 13 of Directive 2001/20/EC, 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 ***2022-11-11***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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 Art. 111(5) of Directive 2001/83/EC, Art. 15 of Directive 2001/20/EC and Art. 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

Human Medicinal Products
Human Investigational Medicinal Products
Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	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 1.2.1.8 Other solid dosage forms: powder/granules for oral/topical solution(en) 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: powder/granules for oral/topical solution(en) 1.5.1.13 Tablets
	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**
	2.2.2 Non-sterile products

Clarifying remarks (for public users)

1) 1.6.2. Biological testing - bacterial endotoxins 2) Veterinary medicinal products - QC testing only 3) Human investigational medicinal products: full scale manufacturing of nonsterile dosage forms, including packaging and labelling (without blinding) and batch certification; 4) 2.2.2. Nasal drops and nasal sprays.

2023-04-06

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

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State Agency Of Medicines
Tel:***Confidential***
Fax:***Confidential***