Finnish Medicines Agency

CERTIFICATE NUMBER: ***FIMEA/2022/004584 laboratory***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with :
Art. 63 of Regulation (EU) 536/2014
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: ***Biovian Oy***
Site address: ***Itainen Pitkakatu 4, Turku, 20520, Finland***
OMS Organisation Id. / OMS Location Id.: ***ORG-100015607*** / ***LOC-100053529***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***FIMEA/2021/003430*** in accordance with Art. 40 of Directive 2001/83/EC, Art. 61 of Regulation (EU) No 536/2014 and Art. 88 of Regulation (EU) 2019/6.

Is an active substance manufacturer that has been inspected in accordance with Art. 123(6) of Regulation (EU) 2019/6 and Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-10-14***, 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]
- The principles of GMP for active substances [3] referred to in and Article 47 of Directive 2001/83/EC.

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. 15 of Directive 2001/20/EC, 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

Human Investigational Medicinal Products
Veterinary Medicinal Products
Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical
	1.6.4 Biological

Clarifying remarks (for public users)

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2022-11-23

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

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Finnish Medicines Agency
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