Austrian Federal Office For Safety In Health Care

CERTIFICATE NUMBER: ***480050-101991887***

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 as amended
Art. 94(1) of Regulation (EU) 2019/6 as amended
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Austria confirms the following:
The manufacturer: ***Takeda Austria GmbH***
Site address: ***Sankt-Peter-Straße 25, Linz, Oberösterreich, 4020, Austria***
OMS Organisation Id. / OMS Location Id.: ***ORG-100001145*** / ***LOC-100004155***

Other
API-A123(6)-R2019/6/EU,API-A111(1)-D2001/83/EC,NIP-A40-D2001/83/EC
(Veterinary) NIP-A88-R2019/6/EU
(Investigational product) NIP-A61-R2014/536/EU

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-08-24*** , 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]
- 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. 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. 15 of Directive 2001/20/EC, Art. 80(5) of Directive 2001/82/EC and Art. 111(5) of Directive 2001/83/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
Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids 1.1.2.4 Solids and implants
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.6 Human or animal extracted products
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products 1.3.2.8 Other: Actovegin Granulat / Actovegin granules, Actovegin Granulat / Actovegin granules(en)
1.4	**Other products or manufacturing activity**
	1.4.3 Other: Verblindung / Blinding(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use
	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	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing
	2.3.4 Other: Biological active substances(en)

Manufacture of active substance. Names of substances subject to inspection:
ACTOVEGIN CONCENTRATE(en)
Lornoxicam(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:ACTOVEGIN CONCENTRATE

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.2 Extraction of substance from animal source 3.2.6 Purification of extracted substance
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.3 Microbiological testing including sterility testing 3.6.4 Biological Testing

Active Substance:Lornoxicam	
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.3 Microbiological testing including sterility testing

Clarifying remarks (for public users)

Takeda Austria GmbH; Die vollständige Liste der importierten / in Verkehr gebrachten Wirkstoffe ist dem Bundesamt für Sicherheit im Gesundheitswesen bekannt. / The complete list of imported / distributed Active Substances is available at the Austrian Federal Office for Safety in Health Care.; ad 1.4.3. nur für klinische Prüfpräparate / only Investigational Medicinal Products; Probebetrieb betreffend Verfahren INS-480050-101906786 bis / valid until: 06/2025

2023-12-20

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

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Confidential
AGES PharmMed
Tel:***Confidential***
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Digitally signed by Guțan Ghenadie
Date: 2024.08.01 09:20:07 EEST
Reason: MoldSign Signature
Location: Moldova