Regierungspraesidium Tuebingen

CERTIFICATE NUMBER: ***DE_BW_01_GMP_2025_0224***

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

The competent authority of Germany confirms the following:
The manufacturer: ***Bioassay Labor fuer biologische Analytik GmbH***
Site address: ***Im Neuenheimer Feld 515, Handschuhsheim, Heidelberg, Baden-Wuerttemberg, 69120, Germany***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011526*** / ***LOC-100092934***

Other
(Human) wurde im Rahmen der nationalen Arzneimittelueberwachung inspiziert in Verbindung mit der Taetigkeit als Auftragslabor auf Grundlage des SECT. 14 Abs. 4 Nr. 3 des Arzneimittelgesetzes. (Das Auftragslabor wird in diesem Zertifikat aus systemtechnischen Gruenden als Hersteller bezeichnet.)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-07-13*** , it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [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.

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[1] *The certificate referred to in paragraph 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

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

Clarifying remarks (for public users)

1.6 refers to the following methods of analysis: - In-vivo potency estimation of erythropoesis stimulating agents in the normocythemic mouse assay according to Ph.Eur. Monograph 1316 and validated method for RO0503821 - Bioassays Gonadotropine according to Ph.Eur. Monograph 0958, 2285, 2286, 0498, 0719 and British Ph. Monograph 9002-68-0 as well as United States Ph. 9002-61-3 - Potency estimation of Filgrastim containing solution in the NFS-60 assay according to Ph.Eur. Monograph 2206 - Potency estimation of Human Growth Hormone (hGH) - Potency estimation of Parathyroid hormone (PTH) - Abnormal toxicity according to Russian Ph. GPM.1.2.4.0004.15 - Cell-based potency assay of C-type Natriuretic Peptide CNP) - TNFa - Neutralisation-Assay for Adalimumab - Cell-based Luciferase-Assay for potency determination of C-Type Natriuretic Peptide - Cell-based potency assay of human IgG-1 Antibody - Cell-based binding assay for HDIT 101 - Cell-based cAMP-Hunter GLP (text missing)

2025-11-04

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

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Confidential
Regierungspraesidium Tuebingen
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