Regierungspraesidium Tuebingen

CERTIFICATE NUMBER: ***DE_BW_01_GMP_2025_0198***

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. 111(5) of Directive 2001/83/EC as amended

The competent authority of Germany confirms the following:
The manufacturer: ***TECHPharm GmbH***
Site address: ***Draisstrasse 14, Bruchsal, Baden-Wuerttemberg, 76646, Germany***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012775*** / ***LOC-100020903***

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 ***2025-07-03*** , 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. 15 of Directive 2001/20/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

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

1.6 refers also to quality control testing of sterile and non-sterile raw and starting materials, active pharmaceutical ingredients, packaging materials, semi-finished and finished dosage forms of human medicinal products/human investigational medicinal products. 1.6.2: refers to: - Ph. Eur. 2.6.12: Microbial enumeration test - Ph. Eur. 2.6.13: Microbiological test for specified micro-organisms - Ph. Eur. 2.6.14: Bacterial endotoxins - Ph. Eur. 2.6.31: Microbiological examination of herbal medicinal products for oral use - Ph. Eur. 2.6.32: Test for bacterial endotoxins using recombinant factor C 1.6.3 refers to: - Ph. Eur. 2.2: Physical and physico-chemical methods - Ph. Eur. 2.3: Identification - Ph. Eur. 2.4: Limit tests - Ph. Eur. 2.5: Assays - Ph. Eur. 2.9: Pharmaceutical technical procedures

2025-09-05

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

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