Regierungspraesidium Tuebingen Leitstelle Arzneimittelueberwachung Baden-Wuerttemberg

CERTIFICATE NUMBER: ***DE_BW_01_GMP_2023_0087***

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: ***Merckle GmbH***
Site address: ***Ludwig-Merckle-Strasse 3, Weiler, Blaubeuren, Baden-Wuerttemberg, 89143***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012960*** / ***LOC-100018421***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_BW_01_MIA_2023_0057*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-07-21***, 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]

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.*

Digitally signed by Chitic Vlad
Date: 2023.10.17 22:33:18 EEST
Reason: MoldSign Signature
Location: Moldova

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	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 1.2.1.13 Tablets
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products 1.3.2.8 Other: Hylak(en)
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets
	1.5.2 Secondary packaging

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	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
	2.3.4 Other: active pharmaceutical ingredients, biotechnologically manufactured(en)

Clarifying remarks (for public users)

ad 1.1.2.3: The parametric release of Midazolam, Cimetidin, Tramadol, Clonidin und Metoclopramid ampoules according to Annex 17 of the EU GMP Guideline is included. ad 1.1.3: Batch certification covers all sterile dosage forms and the parametric release of Midazolam, Cimetidin, Tramadol, Clonidin, Metoclopramid und Cotrimoxazol ampoules according to Annex 17 of the EU GMP Guideline. ad 1.2.1.8 / 1.5.1.8: Powder and granules ad 1.2.2: Batch certification covers all non-sterile dosage forms.

2023-06-13

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

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Confidential
Regierungspräsidium Tübingen
Tel:***Confidential***
Fax:***Confidential***