Regierungspraesidium Tuebingen Leitstelle Arzneimittelueberwachung Baden-Wuerttemberg

CERTIFICATE NUMBER: ***DE_BW_01_GMP_2023_0140***

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: ***Deva Holding A.S.***
Site address: ***Karaagac Mahallesi, Ataturk Caddesi No 32 Cerkezkoey Organize Sanayi Boelgesi, Kapakli, 59510, Turkey***
OMS Organisation Id. / OMS Location Id.: ***ORG-100004235*** / ***LOC-100052420***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC and Art. 8(2) of Regulation (EC) 726/2004.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-05-31***, 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.*

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.6 Other: sterile powder for solution for injection/infusion Special requirements 1 beta-lactam antibiotics(en)
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 1.2.1.2 Capsules, soft shell 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms 1.2.1.9 Pressurised preparations 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms 1.5.1.9 Pressurised preparations 1.5.1.13 Tablets
	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*

Clarifying remarks (for public users)

ad 1.2.1.8 and 1.5.1.8: Powder for preparation of oral Suspension The current validity of this certificate should be verified with EudraGMDP.

EudraGMDP

Competent Authority of

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

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Digitally signed by Guțan Ghenadie
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