Regierungspraesidium Tuebingen

CERTIFICATE NUMBER: ***DE_BW_01_GMP_2025_0045***

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: ***Dumlupinar Mah, Ankara Cad No 2, Kartepe, 41250***
OMS Organisation Id. / OMS Location Id.: ***ORG-100004235*** / ***LOC-100061933***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-11-15***, 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	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 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
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

Inspection and issuance of this GMP certificate were done as competent authority for the importer Devatis GmbH, Spitalstr. 22 in D-79539 Loerrach (Germany) regarding the following medicinal products/active pharmaceutical ingredients: Eye drops in single dose containers (production line SVP-1 and SVP-2, both blow-fill-seal technology) - Azelastine eye drops, Diclofenac eye drops, Ofloxacin eye Drops Eye drops in multi dose containers (PE bottle line) - Bimatoprost eye drops Ampoules (production line ampoules 2) - Diclofenac, solution for injection Vials (vial filling line, including lyophilisators) - Pantoprazole, powder for solution for injection Vials (vial filling line, including terminal sterilization) - Ferric carboxymaltose, dispersion for injection The current validity of this certificate should be verified with EudraGMP.

2025-04-01

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

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Confidential
Regierungspraesidium Tuebingen
Tel:***Confidential***
Fax:***Confidential***

Digitally signed by Guțan Ghenadie
Date: 2025.07.24 08:53:23 EEST
Reason: MoldSign Signature
Location: Moldova
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