*Thueringer Landesamt Fuer Verbraucherschutz*

CERTIFICATE NUMBER: ***DE_TH_01H_GMP_2024_0017***

# 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
Art. 15 of Directive 2001/20/EC as amended

The competent authority of Germany confirms the following:
The manufacturer: ***EVER Pharma Jena GmbH***
Site address: ***Otto-Schott-Strasse 15, Sued, Jena, Thuringia, 07745, Germany, GPS: 50.922662, 11.574991***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012405*** / ***LOC-100021350***

Has been inspected under the national inspection programme 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 ***2024-04-25***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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.

---

[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC and Art. 15 of Directive 2001/20/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<br>Human Investigational Medicinal Products |

| 1 MANUFACTURING OPERATIONS | |
|---|---|
| **1.1** | **Sterile products** |
| | *1.1.1 Aseptically prepared (processing operations for the following dosage forms)*<br>1.1.1.4 Small volume liquids<br>1.1.1.6 Other: prefilled syringe(en) |
| | *1.1.2 Terminally Sterilised (processing operations for the following dosage forms)*<br>1.1.2.3 Small volume liquids<br>1.1.2.4 Solids and implants<br>1.1.2.5 Other: prefilled syringe(en) |
| | *1.1.3 Batch certification* |
| **1.5** | **Packaging** |
| | *1.5.2 Secondary packaging* |
| **1.6** | **Quality control testing** |
| | *1.6.1 Microbiological: sterility*<br>*1.6.2 Microbiological: non-sterility*<br>*1.6.3 Chemical/Physical*<br>*1.6.4 Biological* |

| 2 IMPORTATION OF MEDICINAL PRODUCTS | |
|---|---|
| **2.2** | **Batch certification of imported medicinal products** |
| | *2.2.1 Sterile products*<br>2.2.1.1 Aseptically prepared<br>2.2.1.2 Terminally sterilised |

Clarifying remarks (for public users)

***Listed activities under No. 1.1 apply for hormone-containing and non-hormone-containing medicinal products. No. 1.1.1.4 and 1.1.2.3 include manufacturing of cytostatics (vials only). No. 1.1.1.6 includes manufacturing of methotrexate pre-filled syringes. Referring to 1.1.2.4: Sterilisation of terminally sterilised drug products is conducted by contract manufacturer. No. 2.2.1.1 and 2.2.1.2 are only valid for Azacitidine 25 mg/ml powder for suspension for injection 100 mg/150 mg.***

***2024-07-02***

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

---

***Confidential***
***Thueringer Landesamt Fuer Verbraucherschutz***
Tel:***Confidential***
Fax:***Confidential***