Landesamt für soziale Dienste Schleswig-Holstein

CERTIFICATE NUMBER: ***DE_SH_01_GMP_2022_0025***

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

The competent authority of Germany confirms the following:
The manufacturer: ***Lichtenheldt GmbH Pharmazeutische Fabrik***
Site address: ***Industriestrasse 7 - 11, Wahlstedt, Schleswig-Holstein, 23812, Germany***
OMS Location: ***LOC-100020595***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_SH_01_MIA_2022_0006*** in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-02-17***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [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. 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, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

Manufacturing does NOT cover the release (according to para 16 AMWHV). To 1.5.1.6 and 1.5.1.11 The manufacturing steps blinding and randomization are excluded from the scope of production.

2022-06-30

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

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Confidential
Landesamt für soziale Dienste Schleswig-Holstein
Tel:***Confidential***
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