Digitally signed by Marginã Veaceslav
Date: 2019.01.31 16:24:15 EET
Reason: MoldSign Signature
Location: Moldova

Government of Upper Bavaria - Central Authority for Supervision of Medicinal Products in Bavaria (GMP/GCP)

CERTIFICATE NUMBER: ***DE_BY_04_GMP_2018_0085***

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

The competent authority of Germany confirms the following:
The manufacturer: ***Wasserburger Arzneimittelwerk GmbH***
Site address: ***Herderstrasse 1,2 und Molkerei-Bauer-Strasse 18, Wasserburg, Bayern, 83512, Germany***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_BY_04_MIA_2018_0092*** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-09-08*** , 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.

---

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/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 Medicinal Products Human Investigational 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 1.1.1.2 Lyophilisates 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
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.1 Filtration
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.2 Terminally sterilised
2.3	**Other importation activities**
	2.3.4 Other: Active ingredients of animal origin Active substances of microbial origin(en)

Clarifying remarks (for public users)

The activities listed in Appendix 2 (manufacturers authorisation) relating to investigational medicinal products incl. Placebos, but do not include the packaging of investigational medicinal products. External storage: Lager BABAG. Am Leitenfeld 1, 83547 Babensham/Neudeck storage of packaging materials and documentation Eberl International Spedition GmbH & Co. KG, Gewerbestr. 1, 83365 Aiging storage of packaging materials

2018-07-30

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

---

Confidential
Government of Upper Bavaria - Central Authority for Supervision of Medicinal Products in Bavaria (GMP/GCP)
Tel: ***Confidential***
Fax: ***Confidential***