Bezirksregierung Düsseldorf

CERTIFICATE NUMBER :***DE_NW_03_GMP_2020_0046***

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 :***Aesica Pharmaceuticals GmbH***

Site address : ***Alfred-Nobel-Str. 10, Monheim am Rhein, Nordrhein-Westfalen, 40789, Germany***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_NW_03_MIA_2020_0029*** 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 ***2019-09-26*** , 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
1.1.3 Batch certification
1.2 Non-sterile products
1.2.2 Batch certification
1.6 Quality control testing
1.6.3 Chemical/Physical
2 IMPORTATION OF MEDICINAL PRODUCTS
2.3 Other importation activities
2.3.1 Site of physical importation

Clarifying remarks (for public users) :
To 1.1 Sterile Products, 1.1.3 Batch certification: The concession includes only Human Medicinal Products. To 2.3.1: The authorisation refers to the site of physical importation of medicinal products. There are no other manufacturing activities. The importation authorisation for the products is limited. The respective date can be found on the importation authorisation.

2020-08-17

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

Confidential
Bezirksregierung Düsseldorf
Tel :***Confidential***
Fax :***Confidential***

Digitally signed by Chirtoacă Iurie
Date: 2022.01.05 13:37:48 EET
Reason: MoldSign Signature
Location: Moldova