EudraGMDP

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GMP Certificates Non-Compliance Report Print Preview

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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

nddress: 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

• 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.

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.

Human Medicinal Products

1 MANUFACTURING OPERATIONS

Human Investigational Medicinal Products

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

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

Bezirksregierung Düsseldorf

Tel : Confidential

Fax : Confidential

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Due to the restrictions caused by COVID-19, the period of validity of MIA's, WDA's, GMP and GDP certificates is automatically extended until the end of 2022, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are conducted where and when possible. Competent authorities reserve the right to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP/GDP certificates, as appropriate

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Documents issued by UK authorities up to and including 31 December 2020 remain available for consultation in EudraGMDP. However, they are no longer included or updated from 1 January 2021, with the exception of the documents pertaining to sites located in Northern Ireland.

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