GMP Compliance Menu

Search

GMP Certificates

Non-Compliance Report

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Print Preview | Print Preview (Short version) | Back To Search

Landesverwaltungsamt Sachsen-Anhalt

CERTIFICATE NUMBER :***DE_ST_01_GMP_2022_0011***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER *(1), (2)*

Part 1

Issued following an inspection in accordance with :

The competent authority of Germany confirms the following:

The manufacturer :***mibe GmbH Arzneimittel***

Site address : ***Muenchener Strasse 15, Brehna, Sachsen-Anhalt, 06796, Germany***

OMS Location :

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_ST_01_MIA_2022_0006*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-09-30*** , it is considered that it complies with :

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 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

1 MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)
1.1.1.2 Lyophilisates
1.1.1.3 Semi-solids
1.1.1.4 Small volume liquids
1.1.2 Terminally Sterilised (processing operations for the following dosage forms)
1.1.2.3 Small volume liquids
1.1.3 Batch certification

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)
1.2.1.1 Capsules, hard shell
1.2.1.5 Liquids for external use
1.2.1.6 Liquids for internal use
1.2.1.8 Other solid dosage forms
1.2.1.11 Semi-solids
1.2.1.13 Tablets
Special Requirements:
2 Other highly sensitising materials
1.2.2 Batch certification

1.3 Biological medicinal products (list of product types)

1.3.1 Biological medicinal products (list of product types)
1.3.1.2 Immunological products
1.3.1.8 Other: 1.3.1.8 Medicinal products with active substances of microbial origin(en)
1.3.2 Batch Certification (list of product types)
1.3.2.2 Immunological products
1.3.2.8 Other: 1.3.2.8 Medicinal products with active substances of microbial origin(en)

1.4 Other products or manufacturing activity

1.4.1 Manufacture of
1.4.1.1 Herbal products
1.4.1.3 Other: Batch certification only for the dosage forms Suppositories and Granules(en)

1.5 Packaging

1.5.1 Primary Packaging
1.5.1.1 Capsules, hard shell
1.5.1.2 Capsules, soft shell
1.5.1.5 Liquids for external use
1.5.1.6 Liquids for internal use
1.5.1.8 Other solid dosage forms
1.5.1.11 Semi-solids
1.5.1.13 Tablets
1.5.2 Secondary packaging

1.6 Quality control testing

1.6.1 Microbiological: sterility
1.6.2 Microbiological: non-sterility
1.6.3 Chemical/Physical
1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS
2.1 Quality control testing of imported medicinal products
2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical* *2.1.4 Biological*
2.2 Batch certification of imported medicinal products
2.2.2 Non-sterile products
2.3 Other importation activities
2.3.1 Site of physical importation *2.3.4 Other: 2.3.3 Biological Active Substance - Active Pharmaceutical Ingredients of microbiological origin(en)*

Clarifying remarks (for public users) :

1.5.1.1 Primary and secondary packaging of liquid capsules for internal use 1.2.1.8 and 1.5.1.8 Manufacturing of powder for external use 1.2.1.13 and 1.5.1.13 Manufacturing of tablets with hormons or substances with hormonal effects 1.3.1.2 Inactivated bacterial vaccines and here: other vaccines: production of mRNA-based vaccines

2022-01-20

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

Confidential

Landesverwaltungsamt Sachsen-Anhalt

Tel :***Confidential***

Fax :***Confidential***