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Regierung von Oberfranken

CERTIFICATE NUMBER : **DE_BY_05_GMP_2019_0016**

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

The competent authority of Germany confirms the following:

The manufacturer : **Alkem Laboratories Limited**

Site address : **167 Mahatma Gandhi, Udyog Nagar, Dabhel, Daman, 396210, India**

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-12-19** , 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

1 MANUFACTURING OPERATIONS
1.2 Non-sterile products
1.2.1 <i>Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell Special Requirements: 1 B-lactam Antibiotics 1.2.1.6 Liquids for internal use 1.2.1.13 Tablets Special Requirements: 1 B-lactam Antibiotics 1.2.1.17 Other: Dry Powder Syrup(en) Special Requirements: 1 B-lactam Antibiotics 1.2.2 <i>Batch certification</i>
1.5 Packaging
1.5.1 <i>Primary Packaging</i> 1.5.1.1 Capsules, hard shell Special Requirements: 1 B-lactam Antibiotics 1.5.1.6 Liquids for internal use 1.5.1.13 Tablets Special Requirements: 1 B-lactam Antibiotics 1.5.1.17 Other non-sterile medicinal products Special Requirements: 1 B-lactam Antibiotics 1.5.2 <i>Secondary packaging</i>
1.6 Quality control testing
1.6.2 <i>Microbiological: non-sterility</i> 1.6.3 <i>Chemical/Physical</i>

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
Das Zertifikat erstreckt sich ueber die Herstellung und Pruefung von Humanarzneimitteln in den Gebaeuden B - Betalactam, C - Cephalosporin, G - General und G1 - General				

Clarifying remarks (for public users) :

The validity of the GMP-Certificate is limited to 18 months since the last day of inspection.

2019-03-18

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

Confidential

Regierung von Oberfranken

Tel : **Confidential**

Fax : **Confidential**

The EudraGMDP database is maintained and operated by the EMA. Access to the general public is granted in order to enhance availability of information related to the EMA mandate. The content of the database is provided by the National Competent Authorities (NCA) of the EEA. For this reason, the EMA accepts no responsibility or liability whatsoever (including but not limited to any direct or consequential loss or damage it might occur to you and/or any other third party) arising out of or in connection with the information on this database. Any questions about the content should be addressed to the relevant NCA. Please [click here](#) to get list of NCA's.

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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