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.

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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

Human Medicinal Products

1 MANUFACTURING OPERATIONS

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
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 Batch certification

1.5 Packaging

1.5.1 Primary Packaging
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 Secondary packaging

1.6 Quality control testing

1.6.2 Microbiological: non-sterility
1.6.3 Chemical/Physical

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-Cerificate 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***
