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BASG - Bundesamt für Sicherheit im Gesundheitswesen

CERTIFICATE NUMBER : 481703-0012

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 Austria confirms the following:

The manufacturer : **SANDOZ Private Limited**

Site address : **MIDC, Plot No. 8-A/2, 8-B; T.T.C. Ind. Area, Kalwe Block, Navi Mumbai, 400708, India**

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC , transposed in the following national legislation:
§ 63 Medicines Act (Arzneimittelgesetz) and Ordinance 2009 (Arzneimittelbetriebsordnung 2009) . .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2017-01-14** , 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 fulfill the GMP recommendations of WHO.

Part 2

Human Medicinal Products

Human Investigational 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

1.2.1.13 Tablets

1.5 Packaging

1.5.1 Primary Packing

1.5.1.1 Capsules, hard shell

1.5.1.13 Tablets

1.6 Quality control testing

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/Physical

2017-09-25

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

Confidential

Austrian Medicines and Medical Devices Agency

Tel : **Confidential**

Fax : **Confidential**