EudraGMDP

Thu 18 Feb 2021 19:26:51 BST

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

Chief Pharmaceutical Inspectorate

CERTIFICATE NUMBER :***IWZJ.405.11.2017.MG.2***

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

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of Poland confirms the following:

The manufacturer :***Teva Operations Poland Sp. z o.o.***

Site address : ***ul. Mogilska 80, Kraków, 31-546, Poland***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***138/0018/15*** in accordance with Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-09-08*** , 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 Investigational Medicinal Products

1 MANUFACTURING OPERATIONS

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)
1.2.1.13 Tablets
1.2.2 Batch certification

1.5 Packaging

1.5.1 Primary Packaging
1.5.1.13 Tablets
1.5.2 Secondary packaging

Digitally signed by Margină Veaceslav
Date: 2021.02.18 20:34:16 EET
Reason: MoldSign Signature
Location: Moldova

Clarifying remarks (for public users) :

Points 1.2.1.13 and 1.5.1.13 concerns also manufacturing of medicinal products containing highly potent hormones.

2017-11-23

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

Confidential

Chief Pharmaceutical Inspectorate

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 2021. On-site inspections will resume as soon as there is a consensus that the period of the public health crisis has passed. The clarifying remark section of individual MIA's, WDA's, GMP and GDP certificates will indicate any exceptions. Competent authorities reserve the right to inspect a manufacturing site should the need arise.

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

[EMA © 2014. EudraGMDP 6.4.9.4 build 2021/01/28 15:49]