Thu 11 Jul 2024 21:48:29 BST

Chief Pharmaceutical Inspectorate

CERTIFICATE NUMBER:***ISF.405.42.2023.iP.1 WTC/0018_01_01/227***

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 Poland confirms the following:

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

Site address: **Ul. Mogilska 80, Cracow, 31-546, Poland**

OMS Organisation Id. / OMS Location Id.: **ORG-100018824** / **LOC-100050411**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***138/0018/15*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-09-22***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2. *(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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 111(5) of Directive 2001/83/ECis also applicable to importers.
(2) Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.
(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
1.2.1.5 Liquids for external use
1.2.1.6 Liquids for internal use
1.2.1.8 Other solid dosage forms: granules for oral suspension, powder for solution in sachets, granules in sachets(en)
1.2.1.13 Tablets
1.2.2 Batch certification

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: granules for oral suspension, powder for oral solution in sachets, granules in sachets(en)
1.5.1.13 Tablets
1.5.2 Secondary packaging

Clarifying remarks (for public users):
Points 1.2.1.13 and 1.5.1.13 concern also manufacturing of medicinal products containing highly potent hormones. Point 2.3.2 Importation of intermediate which undergoes further processing: tablets in-bulk, capsules, hard shell in-bulk, capsules soft-shell in primary packaging, pellets to be encapsulated

2023-12-05

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

Confidential
Chief Pharmaceutical Inspectorate
Tel:***Confidential***
Fax:***Confidential***

Digitally signed by Chitic Vlad
Date: 2025.09.07 21:58:45 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Due to the restrictions caused by COVID-19, the period of validity of GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2024, 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 now being conducted and scheduling of these inspections may be independent of the extended validity period stated above. Competent authorities will continue 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 and 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.

As of 28 January 2022, the source of organisational data will change. Additional information and instructions are available on EMA's website