Изпълнителна агенция по лекарствата

CERTIFICATE NUMBER: ***BG/GMP/2022/204***

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 confirms the following:
The manufacturer: ***Balkanpharma Dupnitsa AD***
Site address: ***Ul Samokovsko Shose 3, Dupnitsa, 2600, Bulgaria***
OMS Organisation Id. / OMS Location Id.: ***ORG-100009099*** / ***LOC-100016416***

Has been inspected under the national inspection programme 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 ***2022-01-21***, 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 Art. 111(5) of Directive 2001/83/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.*

Digitally signed by Chitic Vlad
Date: 2023.04.20 18:32:13 EEST
Reason: MoldSign Signature
Location: Moldova

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 1.2.1.13 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 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

The site is authorized for production of Human Investigational Medicinal Products. Authorized operations regarding to manufacture of Human Investigational Medicinal Products include manufacturing of 1.2.1 Non-sterile medicinal products: 1.2.1.1 Capsules, hard shell, 1.2.1.13 Tablets, 1.2.2 Batch certification, 1.5 Primary and Secondary Packing and 1.6 Quality control testing (1.6.2 Microbiological: non-sterility and 1.6.3 Chemical/Physical) It has been a distant inspection.

2022-02-24

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

---

Confidential
Bulgarian Drug Agency
Tel:***Confidential***
Fax:***Confidential***