Bulgarian Drug Agency

CERTIFICATE NUMBER: ***BG/GMP/2022/214***

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 Bulgaria confirms the following:
The manufacturer: ***Ozon OOO***
Site address: ***Ul. Gidrostroiteley 6, Zhigulevsk, 445351, Russian Federation***
OMS Organisation Id. / OMS Location Id.: ***ORG-100034226*** / ***LOC-100054152***

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.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-01-28***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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.

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[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	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
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 Special Requirements 7 Other: solutions, spray, drops(en) 1.2.1.6 Liquids for internal use Special Requirements 7 Other: drops, solutions, syrup, suspension(en) 1.2.1.8 Other solid dosage forms: - powders for oral solution(en) 1.2.1.11 Semi-solids Special Requirements 7 Other: ointment, cream, gel, liniment(en) 1.2.1.13 Tablets Special Requirements 7 Other: tablets, subligual tablets, Special requirements-cytostatics, hormone(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use Special Requirements 7 Other: solutions, spray, drops(en) 1.5.1.6 Liquids for internal use Special Requirements 7 Other: drops, solutions, syrup, suspension(en) 1.5.1.8 Other solid dosage forms: powders for oral solution(en) 1.5.1.11 Semi-solids 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**

	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

It has been a distant assessment. This inspection covers the following activities: Production Section № 1 (multi-product facility dedicated for cytostatic products and hormones) - tablets and hard shell capsules; Production Section № 3 for solid dosage forms: powders for preparation oral solution; Production Section № 5:liquid dosage forms for external use: solution, spray, drops and liquid dosage forms for internal use: drops, solution, syrup, suspension; semi-solid dosage forms: ointment, cream, gel, liniment. Production Section № 6 – solid dosage forms: tablets; Production Section № 8 - solid dosage forms - hard shell capsules (capsules, enteric capsules, sustained release capsules); Production Section № 9 - sterile products: aseptically prepared and terminally sterilized. Site name is: OZON LLC Site address is: 445351 Samara Region, Zhigulevsk, 6 Gidrostroitelei street, Russian Federation

2022-11-11

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

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