РЕПУБЛИКА БЪЛГАРИЯ
Изпълнителна агенция по лекарствата
REPUBLIC OF BULGARIA
Bulgarian Drug Agency

МАЛ 50150

21. 10. 2021

TO
MS. TUGBA KOC
GENERAL MANAGER
ONKO PHARMACEUTICALS BULGARIA LTD.
KRASNO SELO GRAMADA, BLOCK 18, ENTRANCE B, SUITE 28
1680 SOFIA

SUBJECT: Manufacturing site address correction request on GMP Certificate (BG/GMP/2020/172)

DEAR MS. KOC,

In response to your manufacturing site address correction request with ref. number ИАЛ-44990/21.09.2021 on GMP Certificate (BG/GMP/2020/172), please find attached the updated GMP certificate № BG/GMP/2021/184 of the manufacturing site Onko Ilaç Sanayi ve Ticaret A.S. with address GOSB 1700, Sokak, №:1703 Çayirova/KOCAELI, Republic of Turkey.

Appendix: According to the text.

Sincerely yours,

MScPharm BOGDAN KIRILOV
Executive Director

DRUG AGENCY * BULGARIAN

Digitally signed by Gut
Date: 2021.12.14 16:33
Reason: MoldSign Sign
Location: Moldova

София 1303, ул. Дамян Груев № 8, тел.: (02) 8903 555, факс: (02) 8903434
8, Damyan Gruev Str., 1303, Sofia, Bulgaria, tel: + 359 2 8903555, fax: + 359 2 8903434,
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СЕРТИФИКАТ ЗА ДОБРА ПРОИЗВОДСТВЕНА ПРАКТИКА

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

№ BG/GMP/2021/184

Част 1

Part 1

Издаден в резултат на извършена проверка на производител на лекарствени продукти съгласно чл. 111, ал. 5 от Директива 2001/83/ЕС.

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

Изпълнителна агенция по лекарствата на Република България удостоверява следното:

Bulgarian Drug Agency confirms the following:

Производителят на лекарствени продукти:

The manufacturer:

ONKO İLAÇ SAN. VE TİC. A.Ş.

Адрес на обекта:

Site address:

GOSB 1700. Sokak, №: 1703 Çayirova/KOCAELI, TURKEY

бе проверен във връзка с разрешение за употреба на лекарствени продукти, произведени извън Европейската икономическа зона съгласно чл. 111(4) от Директива 2001/83/ЕС, транспонирани в националното законодателство на Република България с чл. 269, ал.4 от ЗЛПХМ.

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 of Bulgaria Art.269(4) of Medicinal Products for Human Use Act .

При последната проверка на дружеството, проведена на 21/11/2019 бе установено, че условията на производство са в съответствие с принципите и изискванията за добра производствена практика, посочени в Директива 2003/94/ЕС/.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 21/11/2019, it is considered that it complies with principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC/.

Настоящият сертификат отразява условията на местата за производство по време на проверката, посочена по-горе и не трябва да се счита, че отразява действителното състояние на производителя, ако са изминали повече от три години от датата на проверката. Въпреки това, този срок на валидност може да бъде намален или удължен чрез използване оценка на риска, което се посочва в полето „Ограниченията или забележки".

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.

Сертификатът е валиден само, когато е представен с всички страници и двете Части 1 и 2.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

Истинността на този сертификат може да бъде проверена в EudraGMP. Ако не е въведен, Моля свържете се с издаващия орган.

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority

Part 2

	Лекарствени продукти за хуманна употреба/*Human medicinal products*
	ПРОИЗВОДСТВЕНИ ДЕЙНОСТИ/ *MANUFACTURING OPERATIONS**
1	**Стерилни продукти**/*Sterile products*
	1.1.1 Асептично изготвени/*Aseptically prepared*
	1.1.1.1 Течности с голям обем/*Large volume liquids*
	1.1.1.2 Лиофилизати/*Lyophilisates*
	1.1.1.4 Течности с малък обем/*Small volume liquids*
	1.1.2 Стерилизирани в крайна опаковка/*Terminally sterilised*
	1.1.2.1 Течности с голям обем/*Large volume liquids*
	1.1.2.3 Течности с малък обем/*Small volume liquids*
1.2	**Нестерилни продукти**/*Non-sterile products*
	1.2.1 Нестерилни продукти/*Non-sterile products*
	1.2.1.13 Таблетки/*Tablets*
1.5.	**Опаковане**/*Packaging*
	1.5.1. Първично опаковане/*Primary packing*
	1.5.1.13 Таблетки/*Tablets*
	1.5.2 Вторично опаковане/*Secondary packing*
1.6.	**Качествен контрол**/*Quality control testing*
	1.6.1 Микробиологични: стерилни/*Microbiological: sterility*
	1.6.2 Микробиологични: нестерилни/*Microbiological: non-sterility*
	1.6.3 Химични /физични/*Chemical/Physical*

Ограничения или забележки, имащи връзка с обхвата на тези производствени дейности:
Any restrictions or clarifying remarks related to the scope of these manufacturing operations:

Инспекцията включва Facility A и Facility B на производствения обект:
- Стерилни продукти: асептично изготвени, течности с голям и малък обем, и стерилизирани в крайна опаковка, течности с голям и малък обем (Facility A и Facility B);
- Стерилни продукти: асептично изготвени, лиофилизати (Facility B);
- Нестерилни продукти: таблетки и филмирани таблетки (Facility B)

This inspection covers Facility A and Facility B of the manufacturing site:
- *Sterile products: Aseptically prepared, large and small volume liquids and Terminally sterilised, large and small volume liquids (Facility A and Facility B);*
- *Sterile products: Aseptically prepared, Lyophilisates (Facility B);*
- *Non-sterile products: tablets and film-coated tablets (Facility B).*

Въз основа на оценка на риска, валидността на сертификата за ДПП е две години от датата на инспекцията, посочена в сертификата.
Based on the risk assessment, the validity of GMP certificate is restricted to two years of the date of inspection written in this certificate.

05/10/2021

маг.- фарм. Богдан Кирилов
Bogdan Kirilov, MScPharm, MPH
Изпълнителен Директор
Executive Director
Изпълнителна агенция по лекарствата
Bulgarian Drug Agency

София 1303, ул. Дамян Груев № 8, тел.: (02) 8903 555, факс: (02) 8903434
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РЕПУБЛИКА БЪЛГАРИЯ
Изпълнителна агенция по лекарствата
REPUBLIC OF BULGARIA
Bulgarian Drug Agency

Вх. № 35989 / 22-07-2021

TO THE ATTENTION OF
MS. TUĞBA KOÇ
GENERAL MANAGER
ONKO PHARMACEUTICALS BULGARIA LTD.
KRASNO SELO GRAMADA
BLOCK: 18, ENTRANCE: B, SUITE: 28
SOFIA 1680, BULGARIA

SUBJECT: Letter with Ref. № ИАЛ-26951/01.06.2021

DEAR MS. TUĞBA KOÇ,

In response to your letter with ref. № IAL-26951/01.06.2021 about requested inspection of ONKO İLAÇ SAN. VE TİC. A.Ş. with site address Gebze Organized Industrial Zone, 1700 Street No 1703 Çayirova/Kocaeli, Turkey, I inform you the following:

As a result of the national and international restrictions in connection with the current COVID-19 pandemic, including on-site GMP inspections, European Commission jointly with European Medicines Agency and Heads of Medicines Agencies, developed and submitted guidelines on regulatory flexibility in procedures related to manufacturing and marketing to the EU market of medicinal products for human use. The guidelines are intended for manufacturers, marketing authorization holders, distributors and etc., as well as for the national regulatory authorities, and are specified in a document „NOTICE TO STAKEHOLDERS QUESTIONS AND ANSWERS ON REGULATORY EXPECTATIONS FOR MEDICINAL PRODUCTS FOR HUMAN USE DURING THE COVID-19 PANDEMIC“, revised on 26.05.2020 and available at address:
https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf

According to the submitted information the validity of GMP certificates, affected at the time of the WHO-declared pandemic, of sites located in the EEA and sites located outside the EEA is considered automatically extended until the end of 2021, and the obligation of manufacturers and importers to comply with GMP is not waived, with aim of manufacturing of quality, safety and efficacy medicinal products.

Conducting of on-site inspections will resume as soon as COVID-19 restrictions are lifted. The competent authorities reserve the right to inspect a production site if the need arises.

In connection with the above, the current validity of a certificate of Good Manufacturing Practice with № BG/GMP/2020/172, issued to ONKO ILAÇ SAN. VE TİC. A.Ş., Turkey is considered to be automatically extended until the end of 2021, and depending on the development of the epidemic situation in the country related to COVID-19, Bulgarian Drug Agency will notify ONKO ILAÇ SAN. VE TİC. A.Ş., Turkey in a timely manner for the possible dates for conducting a routine on-site inspection or for starting a distant assessment, in order to establish compliance with the requirements of Good Manufacturing Practice of the production site.

Sincerely yours,

MScPHARM BOGDAN KIRILOV
Executive Director

BULGARIAN DRUG AGENCY

София 1303, ул. Дамян Груев № 8, тел.: (02) 8903 555, факс: (02) 8903434
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