REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND
MEDICAL DEVICES AGENCY

TURKISH MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

Certificate No: TR/GMP/2021/276

CERTIFICATE OF GMP COMPLIANCE OF MANUFACTURER
Part 1

Issued following an inspection in accordance with current Good Manufacturing Practice Guidelines, and the Regulation on Manufacturing Plants of Medicinal Products for Human Use* and the Law No 1262 on Pharmaceutical and Medicinal Preparations. These regulations are in line with the requirements of Pharmaceutical Inspection Co-operation Scheme (PIC/s) and the Directives of the European Commission.

Turkish Medicines and Medical Devices Agency confirms the following:

Manufacturer's Name	:ONKO İLAÇ SANAYİ VE TİCARET ANONİM ŞİRKETİ
Head Office / Correspondence Address	: Koşuyolu Caddesi No:34 Kadıköy/İSTANBUL
Site Address	: GOSB 1700. Sokak No:1703 Çayırova/KOCAELİ
Manufacturing Authorization Date	: 12/01/2021
Manufacturing Authorization Number	:TR/ÜY/2020/36-1

Has been inspected in accordance with current Good Manufacturing Practice Guidelines, the Regulation on Manufacturing Plants of Medicinal Products for Human Use, the Law No 1262 on Pharmaceutical and Medicinal Products.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12-13, 16-17/04/2018 it is considered that it complies with the requirements of Good Manufacturing Practice (GMP).

This certificate reflects the status of the manufacturing site at the time of the inspection, and Turkish Medicines and Medical Devices Agency should be consulted to verify compliance of the manufacturing site with GMP requirements if more than 3 years have elapsed since the date of 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 by Turkish Medicines and Medical Devices Agency upon request.

**This regulation is aligned with European Union Directive Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use, and Directive 2001/83/EC on the Community code relating to medicinal products for human use.*

Digitally signed by Chitic Vlad
Date: 2022.06.23 14:08:04 EEST
Reason: MoldSign Signature
Location: Moldova

14/12/2021

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Vice President of the Agency

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Part 2

■ Human Medicinal Products *

1. MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS*

If the company is engaged in manufacture of products with special requirements, e.g. radiopharmaceuticals or products containing penicillin, sulphanomides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients, this should be stated under the relevant product type and dosage form.

1.1	**Sterile Products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids -Solution for Solution for Infusion Special Requirement-Oncological, Cytotoxic -Concentrate for solution for infusion Special Requirement-Oncological, Cytotoxic 1.1.1.2 Lyophilisates Special Requirement-Oncological, Cytotoxic 1.1.1.3 Small volume liquids -Injection solution Special Requirement-Oncological, Cytotoxic, High potent - Solution for infusion Special Requirement-Oncological, Cytotoxic, High potent - Concentrate for solution for infusion Special Requirement-Oncological, Cytotoxic, High potent 1.1.1.6 Other aseptically prepared products *(....free text)* - Solution for injection in pre-filled syringe Special Requirement-Oncological, Cytotoxic
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.1-Large volume liquids - Solution for infusion Special Requirement-Oncological, Cytotoxic, -Concentrate for solution for infusion Special requirement-Oncological, Cytotoxic 1.1.2.3 Small volume liquids -Injection solution Special requirement-Oncological, Cytotoxic - Solution for infusion Special Requirement-Oncological, Cytotoxic, - Concentrate for solution for infusion Special Requirement-Oncological, Cytotoxic 1.1.2.5 Other terminally sterilised prepared products *(....free text)* -Solution for injection in pre-filled syringe Special Requirement-Oncological, Cytotoxic
	1.1.3 Batch certification
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 -Hard capsule Special Requirement-Oncological, Cytotoxic, 1.2.1.13 Tablets - Film-coated tablet Special Requirement-Immunsupresan -Tablet Special Requirement-Immunsupresan 1.2.2 Batch certification

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1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products 1.3.1.2 Immunological products 1.3.1.5 Biotechnology products 1.3.2 Batch certification 1.3.2.2 Immunological products
1.5	**Packaging**
	1.5.1 Primary Packaging 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
	1.6.4 Biological testing

Any restrictions or clarifying remarks related to the scope of this certificate *:

-"In this facility, non-cytotoxic sterile products are produced on the A block side and highly active cytotoxic products on the B block side. "
-1.1.1.1:Applies to "vial production".
-1.1.1.2: Applies to "Production of lyophilisate vials for solution for injection".
-1.1.1.4: Applies to "vial production".
-1.1.1.6: Also applies to "Production of lyophilisate solution for injection in oncological pre-filled syringe".
-1.1.2.1: Applies to "vial production".
- 1.1.2.3: Applies to "vial production".
-1.2.1.1.: "Hard capsule; applies to "capsule pilot production".
-1.2.1.13: It is also valid for "pilot production of film-coated tablets".
-1.2.1.13: Also applies to "tablet pilot production".
-1.3.1.2: Applies to primary packaging, secondary packaging, quality control testing and bach releases of inactivated coronavac vaccine named "Coronavac 600SU/0.5ml IM suspension for injection vial" and "Coronavac 600SU/0.5ml IM suspension for injection containing pre-filled syringe" in Facility A where non-cytotoxic products are produced.
-1.3.1.5: Applicable to "Only filling products with insulin glargine active substance".
-1.3.2.2: Applies to inactivated coronavac vaccine named "Coronavac 600SU/0.5ml IM suspension for injection vial" and "Coronavac 600SU/0.5ml IM suspension for injection containing pre-filled syringe" in Facility A where non-cytotoxic products are produced.

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2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile Products 2.2.1.1 Aseptically prepared Special Requirement-Oncological, Cytotoxic 2.2.1.2 Terminally sterilised Special Requirement-Oncological, Cytotoxic
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Any restrictions or clarifying remarks related to the scope of this certificate *:

The validity period of the certificate has been extended in line with the approval of the authority dated 03/12/2021 and numbered E-24931227-020-6568, and this certificate is valid until 31/12/2022.

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