REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
MEDICINES AND MEDICAL
DEVICES AGENCY OF TÜRKİYE

Certificate No: TR/GMP/2024/151

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	: POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
Head Office / Correspondence Address	: Vakıflar OSB Mah. Sanayi Cad. No:22/1 Ergene/TEKİRDAĞ
Site Address	: Vakıflar OSB Mahallesi Sanayi Caddesi No:22/1 Ergene/TEKİRDAĞ
Manufacturing Authorization Date	: TR/ÜY/2019/11-10
Manufacturing Authorization Number	: 01.11.2024

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 19-23.02.2024, 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.*

Eray KAPLAN
Vice President of the Agency

■ 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**
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids - Solution for cardioplegia - Bladder irrigation - Solution for infusion - Solution for peritoneal dialysis - Irrigation solution - Emulsion for infusion 1.1.2.3 Small volume liquids - Emulsion for injection/infusion - Eye drops, emulsion
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use - Inhalation solution
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification 1.3.2.2 Cell therapy products 1.3.2.6 Human or animal extract derived products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use
	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:

1.1.2.1 Applicable to PVC bag, polypropylene bag, glass bottle and polypropylene bottle.

1.1.3 It has been found appropriate to allow parametric release activity for products named "Polifleks %0,9 İzotonik Sodyum Klorür I.V. İnfüzyon için Çözelti", "Polifleks %5 Dekstroz Sudaki I.V. İnfüzyon İçin Çözelti", "Polifleks Laktatlı Ringer I.V. İnfüzyon İçin Çözelti" (PP Torba) and "Polifleks İzolen Dengeli Elektrolit İ.V. İnfüzyon İçin Çözelti" (PP Torba).

1.3.2.2 Valid for batch release activities including batch control analyses for "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products.

1.5.1.5: The inhalation solution is in an aluminum bottle primary packaging.

1.6.4 "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products are valid for serial control analysis.

Eray KAPLAN
Vice President of the Agency

2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.4 Biological
2.2	**Batch certification of imported medicinal products**
	2.2.3 Biological medicinal products 2.2.3.2 Immunological products

Any restrictions or clarifying remarks related to the scope of this certificate:
2.1.4 "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products are valid for serial control analysis.
2.2.3.2 It is valid for batch release activities that include batch control analyzes for "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml iM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products.

■ Human Investigational Medicinal Products (for Phase I, II, III Clinical trials)

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**
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids - Solution for cardioplegia - Bladder irrigation - Solution for infusion - Solution for peritoneal dialysis - Irrigation solution - Emulsion for infusion 1.1.2.3 Small volume liquids - Emulsion for injection/infusion
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use - Inhalation solution
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification 1.3.2.2 Cell therapy products 1.3.2.6 Human or animal extract derived products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use
	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

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Vice President of the Agency

Any restrictions or clarifying remarks related to the scope of this certificate:
1.1.2.1 Applicable to PVC bag, polypropylene bag, glass bottle and polypropylene bottle.
1.1.3 It has been found appropriate to allow parametric release activity for products named "Polifleks %0,9 İzotonik Sodyum Klorür I.V. İnfüzyon için Çözelti", "Polifleks %5 Dekstroz Sudaki I.V. İnfüzyon İçin Çözelti", "Polifleks Laktatlı Ringer I.V. İnfüzyon İçin Çözelti" (PP Torba) and "Polifleks İzolen Dengeli Elektrolit İ.V. İnfüzyon İçin Çözelti" (PP Torba).
1.3.2.2 Valid for batch release activities including batch control analyses for "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products.
1.5.1.5: The inhalation solution is in an aluminum bottle primary packaging.
1.6.4 "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products are valid for serial control analysis.

11.11.2024 TR/GMP/2024/151

Eray KAPLAN
Vice President of the Agency