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

Certificate No: TR/GMP/2024/105

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	: WORLD MEDICINE İLAÇ SAN. VE TİC. A.Ş.
Head Office / Correspondence Address	: 15 Temmuz Mahallesi, Cami Yolu Cad. No:50 Güneşli Bağcılar/İSTANBUL
Site Address	: ÇOSB Gazi Osman Paşa Mahallesi 8. Cadde No:15 Çerkezköy/TEKİRDAĞ
Manufacturing Authorization Date	: 27.08.2024
Manufacturing Authorization Number	: TR/SAY/2024/3-0

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 18.07.2024, 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

Part 2

■ Human Medicinal 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.	
1.4	**Other products or manufacturing activity**
	1.4.3 Others *(....free text)*

Any restrictions or clarifying remarks related to the scope of this certificate *:
1.4.3 It is applicable to the storage of medicinal product packaging materials for human use as well as sampling of primary and secondary packaging materials

19.09.2024 TR/GMP/2024/105

Eray KAPLAN
Vice President of the Agency

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