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/2022/173

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 G.O. Paşa Mah. 6. Cad. No.30 Çerkezköy / Tekirdağ
Manufacturing Authorization Date	: 15/05/2022
Manufacturing Authorization Number	: TR/ÜY/2020/29-7

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 10-11/02/2020, 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.*

Ph.D. Pharm. Sevil AZAK SUNGUR
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) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	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 - Capsule, hard - Prolonged-release capsule, hard 1.2.1.5 Liquids for external use - Nasal/oromucosal spray, solution - Cutaneous spray, solution 1.2.1.6 Liquids for internal use - Oral drops, solution - Oral suspension - Syrup 1.2.1.8 Other solid dosage forms - Pastil 1.2.1.11 Semi-solids 1.2.1.12 Suppositories - Suppository 1.2.1.13 Tablets - Chewable tablet - Modified-release tablet - Gastro-resistant tablet - Film-coated tablet - Tablet
1.4	**Other products or manufacturing activity**
	1.4.3 Others *(....free text)*
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms 1.5.1.11 Semi-solids 1.5.1.12 Suppositories 1.5.1.13 Tablets
	1.5.2 Secondary packaging

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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:
- 1.1.1.2: It is applicable for the production of vials in the form of lyophilized powder.
- 1.1.1.4: It is applicable for the production of vials in the form of small-volume liquid solution, ampoules in the form of small-volume solution, ampoules in the form of suspensions and for the production of Multidose Eye and Ear Drops .
- 1.1.2.3: It is applicable to the production of ampoules in the form of small volume solutions, ampoules in the form of suspensions, vials in the form of small volumes of liquid solutions.
- 1.4.3: Storage and dispatch of products and raw materials can be carried out at the facility.

16/05/2022 TR/GMP/2022/173

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