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

Certificate No: TR/GMP/2026/22

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	: 15 Temmuz Mahallesi Cami Yolu Caddesi No:50 Güneşli Bağcılar/ İSTANBUL
Manufacturing Authorization Date	: 28.01.2026
Manufacturing Authorization Number	: TR/ÜY/2019/12-8

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 03-05.06.2024, 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.*

Prof. Dr. Ahmet AYAR
President of the Agency

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) 1.1.1.4 Small volume liquids Eye drops, solution Ear/eye drops, solution Ear/eye/nasal drops, solution Eye drops, suspension Ear/eye drops, suspension
	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 Modified-release capsule, hard Gastro-resistant capsule, hard Capsule, hard Prolonged-release capsule, hard Vaginal capsule, hard 1.2.1.2 Capsules, soft shell Vaginal capsule, soft Capsule, soft 1.2.1.5 Liquids for external use Pressurised inhalation, solution Oromucosal solution Oromucosal spray, solution Oromucosal/laryngopharyngeal solution Oromucosal/laryngopharyngeal solution/spray, solution Nasal drops, solution Nasal spray, solution Nasal spray, solution/oromucosal solution Nasal/oromucosal spray, solution Nasal/oromucosal solution Cutaneous solution Cutaneous spray, solution Gargle Gargle/mouthwash Gargle/nasal wash Ear drops, solution Ear spray, solution Transdermal solution Transdermal spray, solution Shampoo Ear drops, suspension Ear spray, suspension Nasal drops, suspension Nasal spray, suspension Ear/nasal drops, suspension Pressurised inhalation, suspension 1.2.1.6 Liquids for internal use Oral solution Oral drops, solution Oral drops, emulsion Oral emulsion Oral drops, liquid

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	Oral liquid Oral drops, suspension Oral suspension Syrup 1.2.1.8 Other solid dosage forms Modified-release granules Modified-release granules for oral suspension Effervescent granules Gastro-resistant granules Granules Granules for oral solution Granules for oral suspension Gastro-resistant granules for oral suspension Prolonged-release granules Prolonged-release granules for oral suspension Lozenge/Pastille Compressed lozenge Effervescent powder Inhalation powder Powder for oral suspension Oral powder Inhalation powder, hard capsule Pellet Mikropellet 1.2.1.11 Semi-solids Nasal cream Cream Ear cream Rectal cream Vaginal cream Gel Ear gel Oral gel Transdermal gel Vaginal gel Nasal ointment Cutaneous spray, ointment Cutaneous/nasal ointment Ear ointment Ointment Transdermal ointment Vaginal ointment 1.2.1.12 Suppositories Pessary Suppository 1.2.1.13 Tablets Orodispersible tablet Chewable tablet Chewable/dispersible tablet Soluble tablet Modified-release tablet Gastro-resistant tablet Film-coated tablet Coated tablet Tablet Prolonged-release tablet Vaginal tablet 1.2.1.15 Other non-sterile medicinal products *(....free text)* Granules for oral solution in sachet Granules and solvent for oral suspension Granules for oral suspension in sachet Suspension and solution for spray Oral solution in sachet Powder for oral solution in sachet Granules in sachet Coated granules in sachet
	1.2.2 Batch certification
1.5	**Packaging**

Adres: Söğütözü Mahallesi 2176. Sok. No:3 06520 Çankaya/ANKARA
Tel: (0312) 218 30 00 Fax: (0312) 218 34 60

	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft 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 1.5.1.15 Other non-sterile medicinal products (….free text)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	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:
1.2.1.15: Also valid for "metered dose inhaler".
1.2.1.6: Also valid for "Oral spray"
1.2.1.8: The "Micropellet" permit is valid for "Micropellet capsule".

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

1 MANUFACTURING OPERATIONS - HUMAN INVESTIGATIONAL 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) 1.1.1.4 Small volume liquids Eye drops, solution Ear/eye/nasal drops, solution Eye drops, suspension Ear/eye drops, suspension
	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 Modified-release capsule, hard Gastro-resistant capsule, hard Capsule, hard Prolonged-release capsule, hard Vaginal capsule, hard 1.2.1.2 Capsules, soft shell Vaginal capsule, soft Capsule, soft 1.2.1.5 Liquids for external use Pressurised inhalation, solution Oromucosal solution Oromucosal spray, solution Oromucosal/laryngopharyngeal solution Oromucosal/laryngopharyngeal solution/spray, solution Nasal drops, solution Nasal spray, solution Nasal spray, solution/oromucosal solution Nasal/oromucosal spray, solution Nasal/oromucosal solution Cutaneous solution

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Cutaneous spray, solution
Gargle
Gargle/mouthwash
Gargle/nasal wash
Ear drops, solution
Ear spray, solution
Transdermal solution
Transdermal spray, solution
Shampoo
Ear drops, suspension
Ear spray, suspension
Nasal drops, suspension
Nasal spray, suspension
Ear/nasal drops, suspension
Pressurised inhalation, suspension

1.2.1.6 Liquids for internal use

Oral solution
Oral drops, solution
Oral drops, emulsion
Oral emulsion
Oral drops, liquid
Oral liquid
Oral drops, suspension
Oral suspension
Syrup

1.2.1.8 Other solid dosage forms

Modified-release granules
Modified-release granules for oral suspension
Effervescent granules
Gastro-resistant granules
Granules
Granules for oral solution
Granules for oral suspension
Gastro-resistant granules for oral suspension
Prolonged-release granules
Prolonged-release granules for oral suspension
Lozenge/Pastille
Compressed lozenge
Effervescent powder
Inhalation powder
Powder for oral suspension
Oral powder
Inhalation powder, hard capsule
Pellet
Mikropellet

1.2.1.11 Semi-solids

Nasal cream
Cream
Ear cream
Rectal cream
Vaginal cream
Gel
Ear gel
Oral gel
Transdermal gel
Vaginal gel
Nasal ointment
Cutaneous spray, ointment
Cutaneous/nasal ointment
Ear ointment
Ointment
Transdermal ointment
Vaginal ointment

1.2.1.12 Suppositories

Pessary
Suppository

1.2.1.13 Tablets

Orodispersible tablet
Chewable tablet

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	Chewable/dispersible tablet Soluble tablet Modified-release tablet Gastro-resistant tablet Film-coated tablet Coated tablet Tablet Prolonged-release tablet Vaginal tablet 1.2.1.15 Other non-sterile medicinal products *(....free text)* Granules for oral solution in sachet Granules and solvent for oral suspension Granules for oral suspension in sachet Suspension and solution for spray Oral solution in sachet Powder for oral solution in sachet Granules in sachet Coated granules in sachet
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft 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 1.5.1.15 Other non-sterile medicinal products (....free text)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	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:
1.2.1.15: Also valid for "metered dose inhaler".
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