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

Certificate No: **TR/GMP/2025/74**

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 Caddesi No:50 Güneşli Bağcılar / İSTANBUL
Site Address	:15 Temmuz Mahallesi Cami Yolu Caddesi No:50 Güneşli Bağcılar / İSTANBUL
Manufacturing Authorization Date	: 08.11.2023
Manufacturing Authorization Number	:TR/ÜY/2019/12-4

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.*

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Vice 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 Capsule, hard Vaginal capsule, hard Prolonged-release capsule, hard Gastro-resistant capsule, hard Modified-release capsule, hard 1.2.1.2 Capsules, soft shell Capsule, soft Vaginal capsule, soft 1.2. 1.5 Liquids for extemal use Nasal spray, solution Ear drops, solution Nasal drops, soluion Cutaneous spray, solution Shampoo Pressurised inhalation, suspension Ear/nasal drops, suspension Nasal spray, suspension Nasal drops, suspension Ear spray, suspension Ear drops, suspension Pressurised inhalation, solution Transdermal spray, solution Transdermal solution Ear spray, solution Gargle/nasal wash Gargle/mouthwash Gargle Cutaneous solution Nasal/oromucosal solution Nasal/oromucosal spray, solution Nasal spray, solution/oromucosal solution Oromucosal/laryngopharyngeal solution/spray, solution Oromucosal/laryngopharyngeal solution Oromucosal spray, solution Oromucosal solution 1 .2.1.6 Liquids for internal use Syrup Oral drops, solution Oral solution Oral suspension Oral drops, suspension Oral liquid

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	Oral drops, liquid Oral emulsion Oral drops, emulsion 1.2.1.8 Other solid dosage forms Inhalation powder Mikropellet Granules Oral powder Lozenge/Pastille Pellet Inhalation powder, hard capsule Powder for oral suspension Effervescent powder Compressed lozenge Gastro-resistant granules for oral suspension Granules for oral suspension Granules for oral solution Gastroresistant granules Effervescent granules Modified-release granules for oral suspension Modified-release granules Prolonged-release granules for oral suspension Prolonged-release granules 1. 2. 1.1 1 Semi-solids Cream Gel Ointment Vaginal ointment Transdermal ointment Ear ointment Cutaneous/nasal ointment Cutaneous spray, ointment Nasal ointment Vaginal gel Transdermal gel Oral gel Ear gel Rectal cream Ear cream Nasal cream Vaginal cream 1.2. 1.12 Suppositories Suppository Pessary 1.2.1.13 Tablets Film-coated tablet Tablet Coated tablet Vaginal tablet Prolonged-release tablet Gastro-resistant tablet Modified-release tablet Soluble tablet Chewable/dispersible tablet Chewable tablet Orodispersible tablet 1.2. l. 15 Other non-sterile medicinal products *(. . free text)* Granules in sachet Coated granules in sachet Powder for oral solution in sachet Oral solution in sachet Suspension and solution for spray Granules for oral suspension in sachet Granules and solvent for oral suspension Granules for oral solution in sachet
	1.2.2 Batch certification
1.5	**Packaging**

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	1.5. 1 Primary Packaging 1.5.l.1 Capsules, hard shell 1.5. l.2 Capsules, soft shell l.5. l.5 Liquids for external use 1.5. l.6 Liquids for internal use l.5. l.8 Other solid dosage forms l.5. l.11 Semi-solids l.5.1.12 Suppositories l.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 ofthis certificate:
1.2. l .6: Also valid for "Oral spray"
1.2.1.8: The "Micropellet" permit is valid for "Micropellet capsule".
1.2. 1.15: Also valid for "metered dose inhaler".

■ 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**
	1.1.1 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 Capsule, hard Vaginal capsule, hard Prolonged-release capsule, hard Gastro-resistant capsule, hard Modified-release capsule, hard 1.2.1.2 Capsules, soft shell Capsule, soft Vaginal capsule, soft 1.2. 1.5 Liquids for extemal use Nasal spray, solution Ear drops, solution Nasal drops, solution Cutaneous spray, solution Shampoo Pressurised inhalation, suspension Ear/nasal drops, suspension Nasal spray, suspension Nasal drops, suspension Ear spray, suspension Ear drops, suspension Pressurised inhalation, solution Transdermal spray, solution

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Transdermal solution
Ear spray, solution
Gargle/nasal wash
Gargle/mouthwash
Gargle
Cutaneous solution
Nasal/oromucosal solution
Nasal/oromucosal spray, solution
Nasal spray, solution/oromucosal solution
Oromucosal/laryngopharyngeal solution/spray, solution
Oromucosal/laryngopharyngeal solution
Oromucosal spray, solution
Oromucosal solution

1 .2.1.6 Liquids for inıernal use

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

1.2.1.8 Other solid dosage forms

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

1. 2. 1.1 1 Semi-solids

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

1.2. 1.12 Suppositories

Suppository
Pessary

1.2.1.13 Tablets

Film-coated tablet
Tablet
Coated tablet
Vaginal tablet

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	Prolonged-release tablet Gastro-resistant tablet Modified-release tablet Soluble tablet Chewable/dispersible tablet Chewable tablet Orodispersible tablet 1.2. l. l5 Other non-sterile medicinal products *(. . free text)* Granules in sachet Coated granules in sachet Powder for oral solution in sachet Oral solution in sachet Suspension and solution for spray Granules for oral suspension in sachet Granules and solvent for oral suspension Granules for oral solution in sachet
	1.2.2 Batch certification
1.5	**Packaging**
	1.5. 1 Primary Packaging 1.5.l.1 Capsules, hard shell 1.5. l.2 Capsules, soft shell l.5. l.5 Liquids for external use 1.5. l.6 Liquids for internal use l.5. l.8 Other solid dosage forms l.5. l.11 Semi-solids 1.5.1.12 Suppositories l.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 ofthis certificate:
1.2. l .6: Also valid for "Oral spray"
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1.2. 1.15: Also valid for "metered dose inhaler".

24.03.2025 TR/GMP/2025/74

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