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

Certificate No: TR/GMP/2026/49

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 Bağcılar/İstanbul/TÜRKİYE
Site Address	: ÇOSB G.O. Paşa Mah. 6. Cad. No.30 Çerkezköy/Tekirdağ/Türkiye
Manufacturing Authorization Date	: 31.12.2025
Manufacturing Authorization Number	: TR/ÜY/2020/29-13

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 03-05.03.2025, 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) 1.1.1.1 Large volume liquids - Solution for solution for infusion - Solution for infusion - Concentrate for concentrate for solution for infusion - Concentrate for solution for infusion 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids - Solution for injection/infusion - Solution for injection - Solution for solution for injection - Eye drops, solution - Solution for solution for infusion - Ear/eye drops, solution - Ear/eye/nasal drops, solution - Solution for infusion - Solvent for solution for infusion - Solvent for parenteral use - Concentrate for concentrate for solution for infusion - Concentrate for solution for injection - Concentrate for solution for infusion - Concentrate for solution for injection/infusion - Eye drops, suspension - Ear/eye drops, suspension 1.1.1.6 Other aseptically prepared products *(....free text)* - Eye drops, solution in single-dose container - Eye drops, suspension in single-dose container
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids - Solution for solution for infusion - Solution for infusion - Concentrate for concentrate for solution for infusion - Concentrate for solution for infusion 1.1.2.3 Small volume liquids - Solution for injection - Solution for solution for infusion - Solution for infusion - Solvent for solution for infusion - Concentrate for concentrate for solution for infusion - Concentrate for solution for injection - Concentrate for solution for infusion - Concentrate for solution 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) 1.2.1.1 Capsules, hard shell - Modified-release capsule, hard - Gastro-resistant capsule, hard - Capsule, hard - Prolonged-release capsule, hard

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1.2.1.5 Liquids for external use
- 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 wash
- Nasal/oromucosal spray, solution
- Nasal/oromucosal solution
- Cutaneous solution
- Cutaneous solution/concentrate for oromucosal solution
- Cutaneous spray, solution
- Ear drops, solution
- Ear 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 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 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
- Powder for oral solution
- Powder for oral suspension
- Oral powder

1.2.1.9 Pressurized preparations

1.2.1.11 Semi-solids
- Nasal cream
- Ear cream
- Rectal cream
- Vaginal cream
- Ear gel
- Oral gel
- Transdermal gel
- Vaginal gel
- Nasal ointment
- Cutaneous spray, ointment
- Cutaneous/nasal ointment
- Ear ointment
- Transdermal ointment

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	- 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 - Effervescent tablet - Gastro-resistant tablet - Film-coated tablet - Tablet - Prolonged-release tablet 1.2.1.15 Other non-sterile medicinal products *(....free text)* - Granules for oral solution in sachet - Granules for oral suspension in sachet - Oral solution in sachet - Powder for oral solution in sachet - Oral emulsion in sachet - Oral suspension in sachet - Granules in sachet - Gel in sachet - Coated granules in sachet - Syrup in sachet
	1.2.2 Batch certification
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 1.5.1.15 Other non-sterile medicinal products *(....free text)*
	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:
1.1.1.1: This applies to the production of vial products in large volume solution form.
1.1.1.2: This applies to the production of vials in lyophilized powder form.
1.1.1.4: This applies to the production of small-volume liquid solutions in vials, small-volume solutions and suspensions in ampoules, single-dose eye drops, and multi-dose eye and ear drops.
1.1.1.6: This also applies to "Nebulization Solution", "Nebulization Suspension" and "Nebulization Emulsion" activities.
1.1.2.1: This applies to the production of vial products in large volume solution form.
1.1.2.3: This applies to the production of small volume solution in ampoules, suspension in ampoules, and small volume liquid solution in vials.
1.2.1.15: This also applies to "Cream in Sachets" and "Pellet in Sachets" products.1.2.1.9: "Bag on Valve (BOV), Basınçlı Kapta Çözelti, Basınçlı Kapta Köpük" faaliyetleri için geçerlidir.

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1.4.3: The facility is permitted to carry out storage and shipping operations for products and raw materials.
1.5.1.15: This applies to bottle filling, tube filling, sachet filling, and packaging processes.

■ 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) 1.1.1.1 Large volume liquids - Solution for solution for infusion - Solution for infusion - Concentrate for concentrate for solution for infusion - Concentrate for solution for infusion 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids - Solution for injection/infusion - Solution for injection - Solution for solution for injection - Eye drops, solution - Solution for solution for infusion - Ear/eye drops, solution - Ear/eye/nasal drops, solution - Solution for infusion - Solvent for solution for infusion - Solvent for parenteral use - Concentrate for concentrate for solution for infusion - Concentrate for solution for injection - Concentrate for solution for infusion - Concentrate for solution for injection/infusion - Eye drops, suspension - Ear/eye drops, suspension 1.1.1.6 Other aseptically prepared products *(....free text)* - Eye drops, solution in single-dose container - Eye drops, suspension in single-dose container
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids - Solution for solution for infusion - Solution for infusion - Solvent for solution for infusion - Concentrate for concentrate for solution for infusion - Concentrate for solution for infusion 1.1.2.3 Small volume liquids - Solution for injection - Solution for solution for infusion - Solution for infusion - Solvent for solution for infusion - Concentrate for concentrate for solution for infusion - Concentrate for solution for injection - Concentrate for solution for infusion - Concentrate for solution for injection/infusion
	1.1.3 Batch certification

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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 1.2.1.5 Liquids for external use - 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 wash - Nasal/oromucosal spray, solution - Nasal/oromucosal solution - Cutaneous solution - Cutaneous solution/concentrate for oromucosal solution - Cutaneous spray, solution - Ear drops, solution - Ear 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 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 - 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 - Powder for oral solution - Powder for oral suspension - Oral powder 1.2.1.9 Pressurized preparations 1.2.1.11 Semi-solids - Nasal cream - Ear cream - Rectal cream - Vaginal cream - Ear gel - Oral gel - Transdermal gel

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	- Vaginal gel - Nasal ointment - Cutaneous spray, ointment - Cutaneous/nasal ointment - Ear 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 - Effervescent tablet - Gastro-resistant tablet - Film-coated tablet - Tablet - Prolonged-release tablet 1.2.1.15 Other non-sterile medicinal products *(....free text)* - Granules for oral solution in sachet - Granules for oral suspension in sachet - Oral solution in sachet - Powder for oral solution in sachet - Oral emulsion in sachet - Oral suspension in sachet - Granules in sachet - Gel in sachet - Coated granules in sachet - Syrup in sachet
	1.2.2 Batch certification
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 1.5.1.15 Other non-sterile medicinal products *(....free text)*
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological (sterility)
	1.6.2 Microbiological (non-sterility)
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1.1.1.6: This also applies to "Nebulization Solution", "Nebulization Suspension" and "Nebulization Emulsion" activities.

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1.1.2.1: This applies to the production of vial products in large volume solution form.
1.1.2.3: This applies to the production of small volume solution in ampoules, suspension in ampoules, and small volume liquid solution in vials.
1.2.1.15: This also applies to "Cream in Sachets" and "Pellet in Sachets" products.1.2.1.9: "Bag on Valve (BOV), Basınçlı Kapta Çözelti, Basınçlı Kapta Köpük" faaliyetleri için geçerlidir.
1.4.3: The facility is permitted to carry out storage and shipping operations for products and raw materials.
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