

TURKISH MINISTRY OF HEALTH  
Turkish Medicines and Medical Devices Agency

10082

29 KASIM 2023

Certificate No: TR/GMP/2023/209

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:                  | VEM İLAÇ SAN. VE TİC. A. Ş.                                                                  |
| Head Office / Correspondence Address: | Maslak Mah. AOS 55.Sok. 42 Maslak A Blok Sit. No.<br>2/134 Sarıyer/İSTANBUL                  |
| Site Address                          | Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi<br>Fatih Bulvarı No:38 Kapaklı/TEKİRDAĞ |
| Manufacturing Authorization Date:     | 12/08/2023                                                                                   |
| Manufacturing Authorization Number:   | TR/ÜY/2019/5-9                                                                               |

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 01-04, 07.11.2022, 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 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.*

26/10/2023

Ferhat GÜNGÖR  
Vice President of Inspectorate  
(Signature)

DÜNYA DİLLERİ TERCÜME  
İÇ ve DİŞ TİCARET LTD.ŞTİ.  
YEMİNLİ TERCÜME ANLİTİ  
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Çankaya V.D. 322 002 7886

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA  
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ANKARA ANOTERİ  
Yemini Tercüme  
Derya TOMBAKOĞLU

TURKISH MINISTRY OF HEALTH  
Turkish Medicines and Medical Devices 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 products (processing operations for the following dosage forms)

1.1.1.1 Large Volume Liquids

- Solution for infusion
- Irrigation solution
- Concentrate for solution for infusion
- Emulsion for infusion

1.1.1.2 Lyophilisates Products

Special requirement – Hormone, Oncological

1.1.1.4 Small Volume Liquids

- Solution for injection
- Special requirement – Hormone
- Eye drops, solution
- Solution for infusion
- Special requirement - Hormone
- Eye drops, solvent for reconstitution
- Solvent for parenteral use
- Eye drops, prolonged-release
- Concentrate for solution for injection
- Special requirement – Hormone
- Concentrate for solution for infusion
- Special requirement – Hormone
- Emulsion for injection
- Special requirement - Hormone
- Eye Drop, Emulsion
- Emulsion for infusion
- Special requirement - Hormone
- Suspension for injection
- Special requirement - Hormone
- Eye Drop, Suspension

1.1.1.5 Solids and implants

- Powder for solution for injection
- Special requirement - Beta lactam antibiotics - Penem, Beta lactam antibiotics – Penicillin
- Powder for suspension for injection
- Powder for solution for infusion
- Special requirement - Beta lactam antibiotics - Penem, Beta lactam antibiotics – Penicillin

1.1.1.6 Other Aseptically Prepared Products (...explain)

- Eye drops, solution in single dose pot
- Eye drops, emulsion in single dose pot
- Eye drops, suspension in single dose pot
- Solution for injection in cartridge
- Solution for injection in ready to use injector
- Solution for injection in ready to use syringe

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T.C.  
ANKARA 4. NOBEL  
Asiye Özlem ASAN  
Yeminli Eczacı  
Derya TOMBAKOĞLU

29 KASIM 2023

BÜNYA DİLLERİ TERÇÜME  
İÇ VE DİŞ TİCARİ LTD. STİ.  
YEMİNLİ Eczacı  
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1.1.2 Products, sterilized in its final container (processing operations for the following dosage forms)

- 1.1.2.1. Large Volume Liquids
- Solution for Infusion
  - Irrigational solution
  - Solvent for Solution for Infusion
  - Emulsion for Infusion
- 1.1.2.3. Small Volume Liquids
- Solution for Injection / infusion
  - Solution for injection
  - Solution for infusion
  - Solvent for solution for infusion
  - Solvent for parenteral usage
  - Emulsion for Injection / infusion
  - Emulsion for injection

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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  
Special requirement – Hormone
  - Gastro-resistant capsule, hard  
Special requirement – Hormone
  - Capsule, hard  
Special requirement – Hormone
  - Prolonged-release capsule, hard  
Special requirement - Hormone
- 1.2.1.2 Capsules, soft shell
- Chewable capsule, soft  
Special requirement – Hormone
  - Modified-release capsule, soft  
Special requirement – Hormone
  - Gastro-resistant capsule, soft  
Special requirement – Hormone
  - Prolonged-release capsule, soft  
Special requirement – Hormone
  - Capsule, soft  
Special requirement – Hormone
  - Rectal solution  
Special requirement – Hormone
  - Vaginal solution  
Special requirement – Hormone
  - Rectal emulsion  
Special requirement – Hormone
  - Vaginal emulsion  
Special requirement – Hormone
- 1.2.1.5 Liquids for external use
- Inhalation vapour, solution
  - Oromucosal spray, solution
  - Nasal drop, solution
  - Nasal spray, solution
  - Cutaneous solution  
Special requirement – Hormone
  - Cutaneous spray, solution

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- Gargle
- Concentrate for cutaneous solution
- Special requirement – Hormone
- Nasal drops, emulsion
- Nasal spray, emulsion
- Cutaneous emulsion
- Special requirement – Hormone
- Cutaneous liquid
- Cutaneous spray, suspension
- Cutaneous suspension
- Special requirement – Hormone
- Nasal drops, suspension
- Nasal spray, suspension
- Shampoo
- Rectal suspension
- Special requirement – Hormone
- Vaginal suspension
- Special requirement – Hormone
- 1.2.1.6 Liquids for internal use
- Oral solution
- Special requirement - Hormone
- Oral drops, solution
- Oral drops, emulsion
- Oral emulsion
- Special requirement - Hormone
- Oral liquid
- Special requirement – Hormone
- Oral drops, suspension
- Oral suspension
- Special requirement – Hormone
- Syrup
- Special requirement - Hormone
- 1.2.1.8 Other solid dosage forms
- Modified-release granules
- Special requirement - Hormone
- Effervescent granules
- Special requirement - Hormone
- Gastro-resistant granules
- Special requirement - Hormone
- Granules
- Special requirement - Hormone
- Granules for syrup
- Special requirement - Hormone
- Prolonged-release granules
- Special requirement - Hormone
- Oral lyophilisate
- Special requirement - Hormone
- Pastille
- Effervescent powder
- Special requirement - Hormone
- Powder for inhalation
- Powder for oral solution
- Powder for oral suspension
- Special requirement – Hormone

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T.C. 29 KASIM 2023  
ANKARA 4. NOTERİ  
Asiye Özleni ASKIN  
Yeminli Başkayıp  
Derya TOMBAK OĞLU



**SÜNYA DİLLERİ TERCÜME**  
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- Powder for rectal suspension
- Special requirement - Hormone
- Powder for syrup
- Special requirement - Hormone
- 1.2.1.11 Semi-solids
- Cream
- Special requirement - Hormone
- Rectal cream
- Special requirement - Hormone
- Vaginal cream
- Special requirement - Hormone
- Gel
- Special requirement - Hormone
- Oral gel
- Special requirement - Hormone
- Rectal gel
- Special requirement - Hormone
- Vaginal gel
- Special requirement - Hormone
- Ointment
- Special requirement - Hormone
- Rectal ointment
- Special requirement - Hormone
- Vaginal ointment
- Special requirement - Hormone
- Oral paste
- Special requirement - Hormone
- Pessary
- Special requirement - Hormone
- 1.2.1.13 Tablets
- Orodispersible tablet
- Special requirement - Hormone
- Chewable tablet
- Special requirement - Hormone
- Chewable/dispersible tablet
- Special requirement - Hormone
- Soluble tablet
- Special requirement - Hormone
- Modified-release tablet
- Special requirement - Hormone
- Gastro-resistant tablet
- Special requirement - Hormone
- Film-coated tablet
- Special requirement - Hormone
- Coated tablet
- Special requirement - Hormone
- Tablet for Suspension
- Special requirement - Hormone
- Tablet
- Special requirement - Hormone
- Prolonged-release tablet
- Special requirement - Hormone
- 1.2.1.15 Other non-sterile medicinal products (enter text)
- Powder and solvent for oral solution

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|            |                                                                                                                                                                                                                                                                                             |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            | Special requirement – Hormone<br>- Powder and solvent for oral suspension<br>Special requirement – Hormone<br>- Granules in sachets<br>Special requirement – Hormone                                                                                                                        |
|            | 1.2.2 Batch certification                                                                                                                                                                                                                                                                   |
| <b>1.3</b> | <b>Biological medicinal products</b>                                                                                                                                                                                                                                                        |
|            | 1.3.1 Biological medicinal products<br>1.3.1.5 Biotechnology products                                                                                                                                                                                                                       |
|            | 1.3.2 Batch certification<br>1.3.2.5 Biotechnology products                                                                                                                                                                                                                                 |
| <b>1.5</b> | <b>Packaging</b>                                                                                                                                                                                                                                                                            |
|            | 1.5.1 Primary Packaging<br>1.5.1.1 Hard Capsules<br>1.5.1.2 Soft Capsules<br>1.5.1.5 Liquids for External Usage<br>1.5.1.6 Liquids for Internal Usage<br>1.5.1.8 Other Solid Dosage Formats<br>1.5.1.11 Semi-Solids<br>1.5.1.13 Tablets<br>1.5.1.15 Other Non-Sterile Products (enter text) |
|            | 1.5.2. Secondary Packaging                                                                                                                                                                                                                                                                  |
| <b>1.6</b> | <b>Quality Control Tests</b>                                                                                                                                                                                                                                                                |
|            | 1.6.1. Microbiological (sterility)<br>1.6.2. Microbiological (non-sterility)<br>1.6.3. Chemical/Physical<br>1.6.4. Biological                                                                                                                                                               |

Restrictions or clarifying remarks related to the scope of these manufacturing activities\*:

- 1.1.1.4: It is also valid for "Nebuliser solvent" pharmaceutical form in order to be manufactured in the Vial 2 line.
- 1.1.1.4: It is also valid for vial manufacturing activities as small volume parenteral with oncological special requirements in new oncology building.
- 1.1.1.1: It is also valid for "Solution for Infusion / Injection" manufacturing.
- 1.1.1.2: It is valid for "Lyophilisate for solution for injection", "Lyophilisate for solution for infusion", "Lyophilisate for suspension for injection" and "lyophilizate vial manufacturing".
- 1.1.1.4: It is also valid for nebuliser solution/emulsion/suspension in the BFS line.
- 1.1.1.4: "Solution for injection" is valid for production of the vials, ampoules and carpules.
- 1.1.1.4: Eye drops solution/suspension/emulsion are manufactured in the BFS line.
- 1.1.1.4: Eye drops solution/suspension are also manufactured in vial primary packaging.
- 1.1.1.5: "Powder for solution for injection" and "Powder for suspension for injection" are valid for vial primer packaging.
- 1.1.1.5: "Powder for solution for infusion" is only valid for vial and penem and penicillin lines.
- 1.2.1.13: "Chewable/Dispersible tablet", "Soluble tablet", "Tablet for Solution", "Modified-release tablet", "Tablet for Suspension" are valid only for hormone.

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Vice President of Inspectorate  
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- 1.2.1.15: It is also valid for "MDI (Metered dose inhaler)". Also, "Powder and solvent for oral solution" and "Powder and solvent for oral suspension" are valid only for hormone.
- 1.2.1.5: "Inhalation vapour, solution", is valid for "Solution for Inhalation, vial" in the BFS manufacturing line in the additional inhaler facility.
- 1.2.1.8: "Powder for inhalation" is valid for "MDI (Metered dose inhaler)" and "DPI (Dry powder inhaler)" forms in the additional inhaler facility.
- 1.2.1.8: It is also valid for "Lyophilized powder for suspension", "Oral lyophilized powder for suspension (hormone)", "Powder (hormone)".
- 1.3.1.5: It is also valid for the primary packaging of biotechnological products in the pre-filled syringe line.
- 1.3.1.5: In the additional biotechnology facility, it is valid for the manufacturing of the biotech active substance called "erythropoietin".
- 1.5.1.15: It is also valid for "MDI (Metered dose inhaler)". Also "Powder and solvent for oral solution" and "Powder and solvent for Oral suspension" are valid only for hormone.

///OFFICIAL SEAL///

26/10/2023

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Ferhat GÜNGÖR  
Vice President of Inspectorate  
(Signature)

DÜNYA DİLLERİ TERCÜME BÜROCU  
İşbu Çeviriye İngilizce ve Türkçe olarak  
sadık kalınarak çevrilmiştir.

ŞBU ÇEVİRİNİN DAİREMİZDE KİMLİĞİ SAKL  
YEMİNLİ TERCÜMECİNİZ FATİH  
TARAFINDAN TÜRKÇE  
İNCELEME VE YAZIYLA ONAYLANDIĞI  
NU ONAYLARIM

ANKARA ANOTERİ  
Asiye Özlem ASAN  
Yeminli Baskı

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APOSTILLE

( Convention de La Haye du 5 Octobre 1961 )

/Staat TÜRKİYE - LA TURQUIE

İşbu resmi belge/This public document/Le présent acte public/Dieses zeugnis wurde

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3. İmzalayanın sıfatı Başkatip'dir./Acting in the capacity of/Agissant en qualité de/Titel des  
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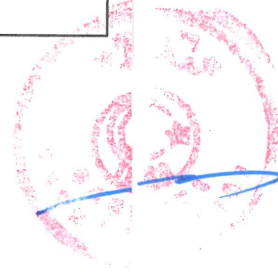
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7. Şef Ferah Diba ARSLAN tarafından/by/par/durch den/die

8. No : 216652 ile tasdik edilmiştir./No:/sous No:/unter Nr.

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