T.C SAĞLIK BAKANLIĞI

TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU

RUHSATNAME

15.02.2022 tarih ve 2022/39 sayılı bu Ruhsatname **CALCİCARD 12,5 MG/5 ML I.V. İNFUZYONLUK ÇÖZELTİ HAZIRLAMAK İÇİN KONSANTRE** isimli beşeri tıbbi ürün için **VEM İLAÇ SAN. VE TİC. ANONİM ŞİRKETİ** firması adına tahsis edilmiştir.

Eki : Sertifika
Ruhsatname ID: 3156395
İş bu Ruhsatname eki sertifika ile geçerlidir.

Doç. Dr.Tolga KARAKAN
Kurum Başkanı

T.C.
SAĞLIK BAKANLIĞI
Türkiye İlaç ve Tıbbi Cihaz Kurumu

Ruhsatname ID : 3156395

Bu sertifika **15.02.2022** tarih ve **2022/39** sayılı Ruhsatname **CALCİCARD 12,5 MG/5 ML I.V. İNFÜZYONLUK ÇÖZELTİ HAZIRLAMAK İÇİN KONSANTRE** isimli **İlaç** için düzenlenmiştir.

REÇETELİ / REÇETESİZ	:	REÇETELİ
REÇETE TÜRÜ	:	BEYAZ REÇETE
RUHSAT SAHİBİ	:	VEM İLAÇ SAN. VE TİC. ANONİM ŞİRKETİ
ETKİN MADDE ADI	:	LEVOSİMENDAN
ÜRETİM YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş., KAPAKLI / TEKİRDAĞ
PRİMER AMBALAJLAMA YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş., KAPAKLI / TEKİRDAĞ
SEKONDER AMBALAJLAMA YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş., KAPAKLI / TEKİRDAĞ
SERİ KONTROL ANALİZ YERİ İÇEREN SERİ SERBEST BIRAKMA YERİ	:	VEM İLAÇ SAN. VE TİC. A.Ş., KAPAKLI / TEKİRDAĞ
RAF ÖMRÜ(AY)	:	24 AY
SAKLAMA SICAKLIĞI (^{0}C)	:	2-8 C ARASINDA BUZDOLABINDA
AMBALAJ TANIMI	:	KUTUDA; GRİ BROMOBUTİL TIPALI, PEMBE FLİP-OFF KAPAKLI 5 ML'LİK TİP I RENKSİZ, CAM FLAKON
AMBALAJ BOYUTU	:	1 ADET
RUHSAT HARCI	:	02.02.2022/60
ANALİZ HARCI	:	09.03.2020/31907400920 11.11.2020/39953801358

Dr. Asım HOCAOĞLU
Kurum Başkan Yardımcısı

T.C. MINISTRY OF HEALTH

TURKISH DRUG AND MEDICAL DEVICE INSTITUTION

LICENSE

This registration certificate dated **15.02.2022** and numbered **2022/39** is allocated for the human medicinal product called **"CALCICARD 12.5 mg/5 ml IV Concentrate for Solution for Infusion**" on behalf of VEM ILAC SAN. VE TIC. ANONIM SIRKETI.

Appendix: Certificate
Authorization ID: 3156395
This license is valid with its appendix certificate.

Assoc.Dr. Hakki GURSOZ
Head of Institution

T.C. MINISTRY OF HEALTH
Turkish Drug and Medical Device Institution

Authorization ID: 3156395

This certificate is prepared as an appendix to license dated **15.02.2022** and numbered **2022/39** for the **drug** called **"CALCICARD 12.5 mg/5 ml IV Concentrate for Solution for Infusion".**

PRESCRIPTION/NON-PRESCRIPTION:	PRESCRIPTION
TYPE OF PRESCRIPTION:	WHITE
MARKETING AUTHORIZATION: HOLDER	VEM ILAC SAN. VE TIC. ANONIM SIRKETI
NAME OF ACTIVE SUBSTANCE:	LEVOSIMENDAN
LICENSOR / ORIGIN COMPANY:	VEM ILAC SAN. VE TIC. A.S. KAPAKLI/TEKIRDAG
MANUFACTURING SITE:	VEM ILAC SAN. VE TIC. A.S. KAPAKLI/TEKIRDAG
PRIMARY PACKAGING SITE:	VEM ILAC SAN. VE TIC. A.S. KAPAKLI/TEKIRDAG
SECONDARY PACKAGING SITE:	VEM ILAC SAN. VE TIC. A.S. KAPAKLI/TEKIRDAG
BATCH CONTROL ANALYSIS SITE:	VEM ILAC SAN. VE TIC. A.S.
BATCH RELEASE SITE	KAPAKLI/TEKIRDAG
SHELF LIFE (MONTH):	24 MOUNTHS
STORAGE TEMPERATURE (°C):	2-8°C IN REFRIGERATOR
DEFINITION OF PACKAGING:	IN BOX, WITH GREY BROMOBUTYL RUBBER STOPPER, PINK FLIP-OFF CAP, TYPE I COLORLESS GLASS VIAL(5 ML)
SIZE OF PACKAGING:	1 VIAL
LICENSE CHARGE RECEIPT:	02.02.2022/60
ANALYSIS CHARGE RECEIPT:	09.03.2020/ 31907400920 11.11.2020/ 39953801358

Dr. Asım HOCAOĞLU
Vice-Chairman of Agency

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

EVRAK ÜZERİNDE SOĞUK MÜHÜR VARDIR

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. 2/134 Sarıyer/İSTANBUL
Site Address	Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi 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 DIŞ TİCARET LTD.ŞTİ. YEMİNLİ TERCÜMANLIK Sakarya Cad. No:11/5 ANKARA Tel:(0312)434 22 28 (0312)433 73 28 Çankaya V.D. 322 002 7886

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

№ 10082

Ferhat GÜNGÖR
Vice President of Inspectorate
(Signature)

29 KASIM 2023
T.C. ANKARA 4.NOTERLİĞİ
Asiye Özlem ASAN
Yeminli Başkatip
Derya TOMBAKOĞLU

DÜNYA DİLLERİ TERCÜME İÇ ve DIŞ TİCARET LTD. ŞTİ.

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA
Tel: (0312) 218 30 00Fax: (0312) 218 34 60

No 10082

	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
	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

29 KASIM 2023

26/10/2023

TR/GMP/2023/209

Ferhat GÜNGÖR
Vice President of Inspectorate
(Signature)

DÜNYA DİLLERİ TERCÜME
İÇ ve DIŞ TİCARET LTD.ŞTİ.

T.C. ANKARA 2. NOTERLİĞİ
Asiye Özlem ASAN
Yeminli Başkâtip
Derya TOMBAKOĞLU

	- 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

No 10082

26/10/2023 TR/GMP/2023/209

Ferhat GÜNGÖR
Vice President of Inspectorate
(Signature)

T.C. 29 KASIM 2023
ANKARA 4.NOTERİ
Asiye Özlem ASLAN T.C.
Yeminli Başkatip
Derya TOMBAKOĞLU

BÜNYA DİLLERİ TERCÜME
İÇ ve DIŞ TİCARET LTD.ŞTİ.
YEMİNLİ TERCÜMANLIK
Sakarya Cad. No:31 Yüksel / ANKARA
Tel:(0312)434 22 28 Fax:(0312)438 73 28
Çankaya V.D. 322 002 7388

№ 10082

29 KASIM 2023

- 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

26/10/2023

TR/GMP/2023/209

Ferhat GÜNGÖR
Vice President of Inspectorate
(Signature)

T.C. ANKARA 4 NOTERİ Asiye Özlem ASAN Yeminli Başkatip Derya TOMBAKOĞLU

DÜNYA DİLLERİ TERCÜME İÇ ve DIŞ TİCARET LTD. ŞTİ. YEMİNLİ TERCÜMANLIK Sakarya Cad. No:11/1 ÇANKAYA/ANKARA Tel:(0312)434 22 22 Fax:(0312)438 73 28 Çankaya V.D. 322 002 7886

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

26/10/2023 № 10082 TR/GMP/2023/209

Ferhat GÜNGÖR
Vice President of Inspectorate
(Signature)

DÜNYA DİLLERİ TERCÜME İÇ ve DIŞ TİCARET LTD. ŞTİ. YEMİNLİ TERCÜMANLIK Sakarya Cad. No:1/19 Kızılay/ANKARA Tel:(0312) 434 22 28 Fax:(0312) 438 73 28 Çankaya V.D. 322 002 7686

T.C. 29 KASIM 2023 ANKARA 4.NOTERİ Asiye Özlem ASAN T.C. Yeminli Başkatip Derya TOMBAKOĞLU

No 10082
29 KASIM 2023

- 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

TR/GMP/2023/209

Ferhat GÜNGÖR
Vice President of Inspectorate
(Signature)

DÜNYA DİLLERİ TERCÜME BÜROSU
İşbu Çeviri [illegible] İNGİLİZCE [illegible] TÜRKÇE [illegible] aslına sadık kalınarak çevrilmiştir.

ŞBU ÇEVİRİNİN DAİREMİZDE KİMLİĞİ SAKL
YEMİNLİ TERCÜMANIMIZ Fatih [illegible] DAN
TARAFINDAN TÜRKÇE [illegible] DAN
İNGİLİZCE [illegible] YA ÇEVRİLDİĞİ
NU ONAYLARIM
ANKARA NOTERİ
Asiye Özlem ASLAN
Yeminli Baskatip

DÜNYA DİLLERİ TERCÜME
İÇ ve DIŞ TİCARET LTD.ŞTİ.
YEMİNLİ TERCÜMANLIK
Çankaya V.D. 322 002 7686

APOSTILLE

(Convention de La Haye du 5 Octobre 1961)

1. ...s/Staat TÜRKİYE - LA TURQUIE

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

2. Derya TOMBAKOĞLU tarafından imzalanmıştır./Has been signed by/a été signé par/durch ... unterschrieben

3. İmzalayanın sıfatı Başkatip'dır./Acting in the capacity of/Agissant en qualité de/Titel des Unterzeichneten

4. ANKARA 4. NOTERLİĞİ 'nin mühür/damgasını taşımaktadır-bears the seal/stamp of-/est revétu du sceau/timbre de-trägt Siegel/Stempel von

TASDİK / CERTIFIED / ATTESTE / BEGLAUBIGUNG:

5. Çankaya Kaymakamlığı' da/at/à/in

6. 27.02.2024 günü/the/le/Am

7. Şef Ferah Diba ARSLAN tarafından/by/par/durch den/die

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

9. Mühür - Damga/Seal-stamp/Sceau-timbre/Siegel-Stempel

10. İmza/Signature/Signature/Unterschrift:

.....

.....