Agency For Medicinal Products And Medical Devices Of Croatia

CERTIFICATE NUMBER: ***530-10/22-05/07; 381-13-08/310-24-17***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Croatia confirms the following:
The manufacturer: ***Vem Ilac Sanayi Ve Ticaret A.S.***
Site address: ***Cerkezkoy Organize Sanayi Bolgesi Karaagac Mahallesi Fatih Bulvari No. 38, Kapakli, 59510, Türkiye***
OMS Organisation Id. / OMS Location Id.: ***ORG-100034626*** / ***LOC-100054938***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-11-25***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids 1.1.1.6 Other: Powder for solution for injection or infusion(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.5	**Packaging**
	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*

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
		Ampoule-1 Line		***confidential***
		Sterile Powder Line		***confidential***

2024-01-11

Name and signature of the authorised person of the Competent Authority of Croatia

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Confidential
Agency For Medicinal Products And Medical Devices Of Croatia
Tel:***Confidential***
Fax:***Confidential***

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

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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:

.....

.....

Republic Of Turkey Ministry of Health
Turkish Medicines and Medical Devices Agency

This cert

APOSTILLE

(Convention de La Haye du 5 Octobre 1961)

1. Ülke/Country/Pays/Staat TÜRKİYE - LA TURQUIE

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

2. İbrahim Muaz YARADILMIŞ tarafından imzalanmıştır./Has been signed by/a été signé par/durch ... unterschrieben

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

4. Türkiye İlaç ve Tıbbı Cihaz Kurumu '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. 7.05.2024 günü/the/le/Am

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

8. No : 222368 ile tasdik edilmiştir./No:/sous No:/unter Nr.

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

10. İmza/Signature/Signature/Unterschrift:

....

Certificate No : 2024

Exporting Country : TÜRKİY

Importing Country : MOLDO

1. Name and dosage fo PENEPIN 0.3 mg/0.3 injection (2 ready to

1.1. Active ingredient(s) Each PENEPIN auto i the active substance. *For complete qualit see attached.*[4]

1.2. Is this product licen in the exporting cou YES

1.3. Is this product act country ? Yes/no/u If the answer to 1.2 omit section 2B. If the answer to 1.2 with section 2B.[6]

2A.1. Number of product l 2014/834– 19 Nove

2A.2. Product-licence hold VEM İlaç San. ve Tic. Maslak Mahallesi AO 42 Maslak A Blok Sit Sarıyer/İSTANBUL/ Factory address: Çerkezköy Organize Karaağaç Mahallesi I Kapaklı/TEKİRDAĞ/

2A.3. Status of product-lic *category as defined i* A

2A3.1. For categories b a manufacturer producing the dosage form are :[9] (Key in appropriate category as defined in note 8) ----------

2A.4. Is Summary Basis of Approval appended ?[10] yes/no *(key in as appropriate):* NO

2A.5. Is the attached, officially approved product information complete and consonant with the licence?[11] yes/no/not provided *(key in as appropriate):* Not provided.

2A.6. Applicant for certificate, if different from licence holder (name and address) :[12] ----------

the certifying authority on all aspects of the manufacture of the product ?[16] yes/no *(key in as appropriate):* YES

If no, explain : _____

Dr. İbrahim Muaz YARADILMIŞ
Head of Economic Evaluation and Pharmaceutical Management Department

Name of authorized person

This certificate is valid for 2 years from the date of issue unless submitted and approved information does not change.

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA
P. + 90 312 218 30 00

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

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes overleaf)

Certificate No : 2024/1401 **Date:** 30.04.2024

Exporting Country : TÜRKİYE
Importing Country : MOLDOVA

1. Name and dosage form of product :
PENEPIN 0.3 mg/0.3 ml I.M. auto injector with solution for injection (2 ready to use auto-injector/box)

1.1. Active ingredient(s)[2] and amount(s) per unit dose :[3]
Each PENEPIN auto injector contains 0.3 mg epinephrine as the active substance.
For complete qualitative composition including excipients, see attached.[4]

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5] yes/no *(key in as appropriate)* :
YES

1.3. Is this product actually on the market in the exporting country ? Yes/no/unknown *(key in as appropriate):* YES
If the answer to 1.2. is yes, continue with section 2A and omit section 2B.
If the answer to 1.2. is no, omit section 2A and continue with section 2B.[6]

2A.1. Number of product licence[7] and date of issue :
2014/834– 19 November 2014

2A.2. Product-licence holder (name and address) :
VEM İlaç San. ve Tic. A.Ş.
Maslak Mahallesi AOS 55. Sokak
42 Maslak A Blok Sit. No: 2/134
Sarıyer/İSTANBUL/TÜRKİYE
Factory address:
Çerkezköy Organize Sanayi Bölgesi
Karaağaç Mahallesi Fatih Bulvarı No: 38
Kapaklı/TEKİRDAĞ/TÜRKİYE

2A.3. Status of product-licence holder :[8] a/b/c *(key in appropriate category as defined in note 8)*
A

2A3.1. For categories b and c the name and address of the manufacturer producing the dosage form are :[9]
(Key in appropriate category as defined in note 8)

2A.4. Is Summary Basis of Approval appended ?[10] yes/no *(key in as appropriate):* NO

2A.5. Is the attached, officially approved product information complete and consonant with the licence?[11] yes/no/not provided *(key in as appropriate):* Not provided.

2A.6. Applicant for certificate, if different from licence holder (name and address) :[12] ---

2B.1 Applicant for certificate *(name and address)* :

2B.2 Status of applicant : a/b/c *(key in appropriate category as defined in note 8)*

2B.2 For categories b and c the name and address of the manufacturer producing the dosage form are :[9]

2B.3 Why is marketing authorization lacking ?
Not required/not requested/under consideration/refused (key in as appropriate)

2B.4 Remarks :[13]
---

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ? yes/no/not applicable[14] *(key in as appropriate) :* YES
If no or not applicable proceed to question 4.

3.1. Periodicity of routine inspections (years) :
3 YEARS

3.2. Has the manufacture of this type of dosage form been inspected ? yes/no (key in as appropriate) :
YES

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization)[15]
yes/no/not applicable[14] *(key in as appropriate) :* YES

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?[16] yes/no *(key in as appropriate):* YES

If no, explain :_____

Name of authorized person

This certificate is valid for 2 years from the date of issue unless submitted and approved information does not change.

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA
P. + 90 312 218 30 00

General instructions
Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
   (a) manufactures the dosage form;
   (b) packages and/or labels a dosage form manufactured by an independent company; or
   (c) is involved in none of the above.
9. This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
   (a) the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
   (b) the product has been reformulated with a view to improving its stability under tropical conditions;
   (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
   (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
   (e) any other reason, please specify.
14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

UNIT FORMULA

Product Name: PENEPIN 0.3 mg/0.3 ml I.M. Auto-Injector with Solution For Injection

Pharmaceutical form: Auto-Injector with Solution For Injection

Dosage form: Solution for injection containing 0.3 mg /0.3ml epinephrine

Composition (1 Ready to use auto-injector):

Ingredients	Amount	Function	Reference
Active Substances			
Epinephrine	0.33 mg*	Active substance	EP
Excipients			
Sodium chloride	1.8 mg	Isotonizer	EP
Sodium metabisulphite (E 223)	0.51 mg	Antioxidant	EP
Hydrochloric acid**	q.s. for pH = 3.4	pH adjuster	EP
Water for injection	q.s.p. 0.3 ml	Solvent	EP

*Includes 10% excess dose.

** 1% N HCl solution will be used for the pH adjustment.

Packaging: 2 ready to use auto-injector/box

Tufan ŞAHAN
Responsible Manager

VEM İLAÇ SANAYİ VE TİCARET A.Ş.
Maslak Mah. AOS 55. Sok. 42 Maslak A Blok
Sit. No:2/134 Sarıyer/İSTANBUL
Tel:0212 347 75 12-13 Fax:0212 272 07 17
V.D. Maslak - VKN 9240498027

T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU

RUHSATLI BEŞERİ TIBBİ ÜRÜNLER LİSTESİ

İRD-LST-15
/31.12.2019/Rev.01/17.
11.2023

SIRA NO	BARKOD	ÜRÜN ADI	ETKİN MADDE	ATC KODU	RUHSAT SAHİBİ	RUHSAT TARİHİ	RUHSAT NUMARASI	DEĞİŞİKLİK	Bu hafta değişiklik yapılan ürünler ile belirtilmiştir. Yapılan Değişiklikler için DEĞİŞİKLİK kolonuna bakınız.	DEĞİŞİKLİK TARİHİ	RUHSATI ASKIDA OLMAYAN ÜRÜN: 0 MADDE-23 GEREKÇELİ ASKIDA OLAN ÜRÜN: 1 FARMAKOVİJİL/	ASKIYA ALINMA TARİHİ
3964	8699844090548	DESLODIN 5 MG FILM KAPLI TABLET, 20 ADET	desloratadin	R06AX27	VEM İLAÇ SAN. VE TİC. A.Ş.	05.03.2012	241/16			08.03.2024	0	
4331	8699844750183	DOBCARD 250 MG / 20 ML IV INFUZYON ICIN KONSANTRE COZLETI ICEREN AMPUL, 10 ADET	dobutamin hidroklorür	C01CA07	VEM İLAÇ SAN. VE TİC. A.Ş.	17.09.2008	216/93				0	
4446	8699844750053	DOPADREN 200 MG/5 ML IV İNFÜZYON İÇİN KONSANTRE ÇÖZELTİ İÇEREN AMPUL, 5 ADET	dopamin hcl	C01CA04	VEM İLAÇ SAN. VE TİC. A.Ş.	19.12.2006	210/23			12.04.2019	0	
4951	8699844340285	EMULID %1 JEL, 30 G	nimesulid	M02AA26	VEM İLAÇ SAN. VE TİC. A.Ş.	29.06.2011	232/99				0	
4952	8699844341183	EMULİD PLUS % 1 + % 5 JEL	nimesulid/lidokain	M02AA26	VEM İLAÇ SAN. VE TİC. A.Ş.	20.10.2015	2015/814			14.06.2019	0	
5071	8699844761097	EPILEM 500MG/5ML KONSANTRE INFÜZYON ÇÖZELTISI IÇEREN FLAKON ,10 FLAKON	levetirasetam	N03AX14	VEM İLAÇ SAN. VE TİC. A.Ş.	08.01.2015	2015/20				0	
5095	8699844750084	EPITOIN 250 MG/5 ML IM/IV ENJEKSİYONLUK ÇÖZELTİ İÇEREN AMPUL, 5 ADET	fenitoin sodyum	N03AB02	VEM İLAÇ SAN. VE TİC. A.Ş.	11.10.2007	212/83			13.07.2018	0	
5158	8699844611484	EPOSTIN % 0.05 OFTALMIK EMÜLSIYON IÇEREN TEK DOZLUK FLAKON, 30 ADET	siklosporin	S01XA18	VEM İLAÇ SAN. VE TİC. A.Ş.	16.06.2017	2017/422				0	
5162	8699844771492	EPTICARD 20 MG/10 ML IV ENJEKSİYONLUK ÇÖZELTİ İÇEREN FLAKON, 1 ADET	eptifibatid	B01AC16	VEM İLAÇ SAN. VE TİC. A.Ş.	06.07.2017	2017/486				0	
5163	8699844771508	EPTİCARD 75MG/100ML İV İNFÜZYON ÇÖZELTİSİ İÇEREN FLAKON, 1 ADET	eptifibatid	B01AC16	VEM İLAÇ SAN. VE TİC. A.Ş.	06.07.2017	2017/487				0	
5390	8699844340995	ETREXİN % 2 + % 0.05 JEL	isotretinoin+eritromisin	D10AD54	VEM İLAÇ SAN. VE TİC. A.Ş.	07.04.2014	2014/287			23.02.2018	0	
5652	8699844750664	FERICOSE 100 MG/5 ML IV ENJEKSIYONLUK COZELTI ICEREN AMPUL, 5 ADET	demir hidroksit sükroz kompleksi	B03AC	VEM İLAÇ SAN. VE TİC. A.Ş.	23.07.2013	252/21				0	
5846	8680184520215	FLIXAIR 0,5 MG/2 ML NEBÜLIZASYON IÇIN TEK DOZLUK INHALASYON SÜSPANSIYONU IÇEREN FLAKON,10 ADET	flutikazon propiyonat	R03BA05	VEM İLAÇ SAN. VE TİC. A.Ş.	15.12.2016	2016/896			04.05.2018	0	
5847	8680184520208	FLIXAIR 2 MG/2 ML NEBÜLIZASYON IÇIN TEK DOZLUK INHALASYON SÜSPANSIYONU IÇEREN FLAKON,10 ADET	flutikazon propiyonat	R03BA05	VEM İLAÇ SAN. VE TİC. A.Ş.	15.12.2016	2016/895			04.05.2018	0	
5871	8699844690441	FLOTIC 200 MG/100 ML IV INFÜZYON COZELTİSİ İÇEREN FLAKON, 1 ADET	siprofloksasin laktat	J01MA02	VEM İLAÇ SAN. VE TİC. A.Ş.	19.09.2011	234/90				0	