



This cert

Certificate No : 2024
Exporting Country : TÜRKİYE
Importing Country : MOLDO

1. Name and dosage for
PENEPIN 0.3 mg/0.3
injection (2 ready to
- 1.1. Active ingredient(s);
Each PENEPIN auto i
the active substance.
For complete quality
see attached.⁴
- 1.2. Is this product licen
in the exporting cou
YES
- 1.3. Is this product actu
country? Yes/no/ur
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 AC
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 -----

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

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 Tıbbi 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

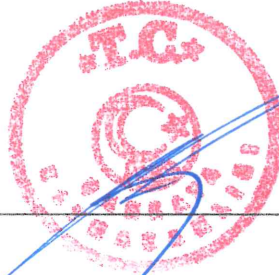
6. 7.05.2024 günü/the/le/Am

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

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

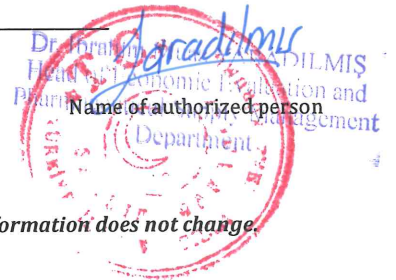
9. Mühür - Damga/Seal-stamp/Sceau-
timbre/Siegel-Stempel

10. İmza/Signature/Signature/Unterschrift:



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

If no, explain : _____





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

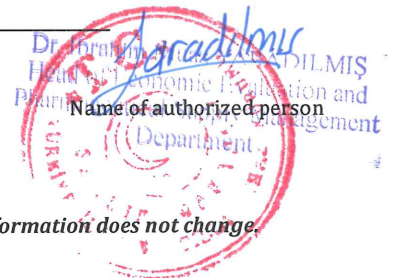
Certificate of a Pharmaceutical Product¹

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)	2B.1 Applicant for certificate (name and address) : -----
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	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 -----
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	2B.3 Why is marketing authorization lacking ? Not required/not requested/under consideration/refused (key in as appropriate) -----
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	2B.4 Remarks : ¹³ -----
2A.1. Number of product licence ⁷ and date of issue : 2014/834- 19 November 2014	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.
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	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
2A.3. Status of product-licence holder : ⁸ a/b/c (key in appropriate category as defined in note 8) A	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
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) -----	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
2A.4. Is Summary Basis of Approval appended ? ¹⁰ yes/no (key in as appropriate): NO	If no, explain : _____
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 -----	

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

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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 42-13 Fax: 0212 272 07 17
V.D. Maslak - VKN 9240498027

RUHSATLI BEŞERİ TIBBİ ÜRÜNLER LİSTESİ

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	DESLODİN 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 İNFÜZYON İÇİN KONSANTRE COZLETİ İÇEREN 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	EMULİD %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 İNFÜZYON ÇÖZELTİSİ İÇEREN FLAKON ,10 FLAKON	levetirasetam	N03AX14	VEM İLAÇ SAN. VE TİC. A.Ş.	08.01.2015	2015/20				0	
5095	8699844750084	EPITOİN 250 MG/5 ML İM/İV 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	EPOSTİN % 0.05 OFTALMIK EMÜLSİYON İÇEREN TEK DOZLUK FLAKON, 30 ADET	siklosporin	S01XA18	VEM İLAÇ SAN. VE TİC. A.Ş.	16.06.2017	2017/422				0	
5162	8699844771492	EPTİCARD 20 MG/10 ML İV 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 İV ENJEKSİYONLUK COZELTI İÇEREN AMPUL, 5 ADET	demir hidroksit sükröz kompleksi	B03AC	VEM İLAÇ SAN. VE TİC. A.Ş.	23.07.2013	252/21				0	
5846	8680184520215	FLIXAIR 0,5 MG/2 ML NEBÜLİZASYON İÇİN TEK DOZLUK İNHALASYON SÜSPANSİYONU İÇEREN 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 NEBÜLİZASYON İÇİN TEK DOZLUK İNHALASYON SÜSPANSİYONU İÇEREN 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 İV İNFÜZYON COZELTİSİ İÇEREN FLAKON, 1 ADET	siprofloksasin laktat	J01MA02	VEM İLAÇ SAN. VE TİC. A.Ş.	19.09.2011	234/90				0	