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

TURKISH MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

Certificate No: TR/GMP/2018/333

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	: Mefar İlaç San. A.Ş.
Head Office / Correspondence Address	: Ramazanoğlu Mah. Ensar Cad. No:20 TR-34906 Kurtköy Pendik İstanbul Türkiye
Site Address	: Ramazanoğlu Mah. Ensar Cad. No:20 TR-34906 Kurtköy Pendik İstanbul Türkiye
Manufacturing Authorization Date	: 01/02/2008
Manufacturing Authorization Number	: 2008/01

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 18-21/09/2018, 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.*

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 *(Vial)* 1.1.1.2 Lyophilisates *(Ampoule, vial)* 1.1.1.4 Small volume liquids *(Ampoule, vial, PFS, BFS, BFS strip liquid inhalation-nebulizer)*
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids *(Vial)* 1.1.2.3 Small volume liquids *(Ampoule, vial, PFS)*
	1.1.3 Batch certification
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products 1.3.1.5 Biotechnology products 1.3.1.8 Other biological medicinal products *(Bulk vaccine filled in PFS and Ampoule; 13V conjugate pneumococcus vaccine-Prevenar 13 production; Pentaxim 0,5 PFS filling and packaging; Tetraxim 0,5 IM Injectable Suspension PFS production)*
	1.3.2 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilization of active substances/excipients/finished products 1.4.2.1 Filtration 1.4.2.3 Moist heat
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

27/12/2018 *TR/GMP/2018/333*

Fatih TAN
Vice President of Inspectorate

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

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

بسم الله الرحمن الرحيم

Republic of yemen
Ministry of Health and Population
Supreme Board of Drugs & Medical Appliances
Registration Management

الجمهورية اليمنية
وزارة الصحة العامة والسكان
الهيئة العليا للأدوية والمستلزمات الطبية
إدراة التسجيل

Sr.No: 0021

شهادة تسجيل شركة
Company Registration Certificate

نموذج ف ٢

Type Of Company (نوع الشركة)

- [✓] Pharmaceutical Product Company
- [X] Food Supplement Company
- [X] Medical Appliances Company
- [X] Herbal Medicine Company

اقرت اللجنة الفنية للتسجيل الموافقة على [✓] تسجيل [ ] إعادة تسجيل الشركة طبقا للبيانات التالية:
The Technical Committee Has Approved The [ ] Registration [ ] Re-Registration Of The Company According To The Following Data:.

Local Agent / الوكيل المحلي	Al-Mehdar Bros. Medical Co. / شركة المحضار إخوان	بيانات الجلسة الفنية للتسجيل / Reg.Committee Meeting Data	
Adress of Local Agent / عنوان الوكيل	Sana'a / صنعاء	No. الرقم	24/2014
		Date التاريخ	04/11/2014
Manufacturer Company Name / إسم الشركة المنتجة	MEFAR ILAC SANAYII A.S.		
Country of Origin (بلد المنشأ)	Turkey		
Address (العنوان)	Ramazanoglu Mah. Ensar Cad. NO. 20, 34906, Kurtkoy- Pendik – Istanbul		
Registration No.(رقم التسجيل)	Registration Date(تاريخ التسجيل)	Expire Registration Date(تاريخ إنتهاء التسجيل)	
	04/11/2014	03/11/2019	
Accepted Production Lines / الخطوط المقبولة	General sterile : • ~~Small volume liquid (amp.).~~ • Ear / Eye drops.		
Marketing Authorization Holder Name (إسم الشركة المسوقة)	Galenika A.D.		
Country of Origin (بلد المنشأ)	Republic of Serbia		

الهيئة العليا للأدوية والمستلزمات الطبية
رقم الصادر: ١٤/ش
التاريخ: ٤/١١/٢٠١٤م
المرفقات: ---

رئيس الهيئة العليا للأدوية والمستلزمات الطبية
Chairman of the Supreme board of drugs and medical appliances.

مدير التسجيل
Registration Manager

ملاحظات لجنة التسجيل على الشركة إن وجدت Notes of the Registration Committee on company if available	
1-	
2-	
3-	
4-	
5-	
6-	
7-	
8-	
9-	
10-	

Fees have been paid by:.(تم تسديد الرسوم)

Bank notice No.: إشعار بنكي رقم	Date التاريخ	Provide Notification No: إخطار التوريد رقم	Date التاريخ
1602680	28/01/2016	41833	31/01/2016

According to the following conditions:

1-A scientific office for the pharmaceutical company in Yemen shall be established and managed by a full-time Yemeni pharmacist based on the decisions and regulations regulating it.

2-The Authority shall have the right to cancel the registration of the Company in the following cases:

- ***If the forgery or tampering with its certificates is proven.***
- ***If repeated violations or failure to continue to apply the basics of good manufacturing practice.***
- ***If a decision issued regarding the company's activity or its preparations.***
- ***If the company registration is not renewed every five years from the date of registration***

وذلك وفقاً للشروط التالية :

1- يتم انشاء مكتب علمي للشركة المنتجة للأدوية باليمن ويدار من قبل صيدلاني يمني متفرغ بناءً على القرارات واللوائح المنظمة لذلك.

2- للهيئة الحق في الغاء تسجيل الشركة في الحالات التالية :-

* إذا ثبت التزوير أو التلاعب في شهاداتها.
* إذا ثبت تكرار مخالفاتها أو عدم الاستمرار في تطبيق أسس ممارسة التصنيع الجيد.
* إذا صدر قرار بحضر نشاط الشركة أو مستحضراتها.
* إذا لم يتم تجديد تسجيل الشركة كل خمس سنوات من تاريخ تسجيلها.

رئيس قسم تسجيل الشركات

Head of companies registration

25/3/2018

المختص

Responsible Person

P.O.Box:265 Sana'a - Tel.:+967-1- 619174 - Fax: +967-1- 619173 ص.ب : 265 الجرداء- صنعاء - تلفون :+967 -1-619174 -فاكسميل :+967 -1-619173
E-mail :sbdma@yemen.net.ye www.sbd-ye.org http://www.facebook.com/SBDMAYEMEN1 فيسبوك :

شماره ۶۶۵/۱۳۷۲۹۰
تاریخ ۱۳۹۵/۰۹/۰۷
پیوست ندارد

جمهوری اسلامی ایران
وزارت بهداشت، درمان و آموزش پزشکی
Islamic Republic Of Iran
Ministry Of Health & Medical Education

سازمان غذا و دارو IFDA
FOOD AND DRUG ADMINISTRATION

GMP Certificate

Certificate Code :	FPP-2016-07	FPP-2016-07	**کد گواهی:**
Company Name:	Mefar ilac Sanajll A.S.	مفار ترکیه	**نام شرکت:**
Activity :	Pharmaceutical contract manufacturing	تولیدی قراردادی محصولات دارویی	**فعالیت:**
Authorised Person :	Mrs. Beril Tezcanli	-	**مسوول فنی:**
Date Of Estabillshment License :	1985/05/30	۱۳۶۴	**تاریخ پروانه تاسیس:**
Estabillshment No :	215601	۲۱۵۶۰۱	**شماره پروانه تاسیس:**
Country :	Turkey	ترکیه	**کشور:**
Address :	Ramazanogiu Mah. Ensar code. No: 2034906	-	**نشانی:**
Telephone :	+90 (216) 3784400	۰۹۰ (۲۱۶) ۳۷۸۴۴۰۰	**تلفن:**
Inspected Line/ Product Name :	General inj. Product	فرآورده های تزریقی عمومی	**خط بازدید شده/نام محصول بررسی شده:**
Inspector /s Name :	Dr.H.Sheibani, Dr. M.Karimi	دکتر شیبانی، دکتر کریمی	**نام بازرس/بازرسین:**
Inspection Date :	July 2016	مرداد ماه ۱۳۹۵	**تاریخ بازرسی:**
Issue Date:	Nov 2016	آبان ماه ۱۳۹۵	**تاریخ صدور گواهی:**
Validity Date :	Nov 2018	آبان ماه ۱۳۹۷	**تاریخ انقضای گواهی:**
Authorized Agent in Iran :	Orphan Teb Pars	عرفان طب پارس	**نماینده شرکت در ایران:**

بدینوسیله گواهی می‌شود خط تولید فرآورده های تزریقی عمومی شرکت فوق مورد بازدید کارشناسی روش‌های بهینه تولید (GMP) قرار گرفت و با توجه به شرایط موجود مورد تایید می‌باشد.

This is to certify that above-mentioned production line was duly inspected and approved in accordance with Good Manufacturing Practice principles for pharmaceutical products which are currently in force in the I.R of Iran. Therefore, the production line of General inj. Product Is in compliance with the cGMP standards and relevant principles and regulations.

A.Abdollahiasl Pharm D, PhD
Director General

دکتر اکبر عبداللهی اصل
مدیر کل نظارت و ارزیابی دارو
و مواد مخدر

Add.: FOOD AND DRUG ADMINISTRATION Bldg.,
FAKHR-E-RAZI St., ENGHELAB Ave.,
TEHRAN 1311715311 I.R. IRAN

TEL: +98-21-66467268 / 66467269
FAX: +98-21-66469122
WEBSITE: http://fda.gov.ir
E-Mail: co@fda.ir

جمهورية العراق
وزارة الصحـــة/البيئة
قسم التسجيل
العدد: د.ا.ف./ ٥٧٤٧
التاريخ: ١٢/١٧/ ٢٠١٧ م

كۆماری عیراق
وه زارهتي ته ندروستي
فهرمانگه‌ی کارویاری هونه‌ری

وزارة الصحة العراقية
Iraqi Ministry of Health
Founded 1920

الى /مكتب الرزان العلمي

Mefar Ilac San A.S./Turkey /م
Ramazanoğlu Mah. Ensar Cad. No:20 kurtkoy-Pendik/ Turkey

تحية طيبة . . .

اجتمعت لجنة تسجيل واعادة تسجيل المواقع التصنيعيه المنتجه للادويه والمستلزمات الطبيه بموجب الجلسه المرقمه ٢٤٤ قرار ١٤٢٧ في ٢٠١٧/١١/٢٣و قررت اللجنة :-

الموافقة على تسجيل الموقع التصنيعي كموقع منتج للادوية للخط الانتاجي

- Solution for infusion (vial)

.... مع التقدير

الصيدلانية
شذى صاحب عبد المحمد
مدير قسم التسجيل
١٢/ ١٢/ ٢٠١٧

نسخه منه/الى شعبة تسجيل الشركات

بغداد – باب المعظم – وزارة الصحة/دائرة الامور الفنية / قسم التسجيل/ هاتف ٤١٥٨٤١٥
الموقع على الانترنيت www. Tecmoh.net
registrationmoh@yahoo.com
Bab Al-Moa adham – Baghdad Ministry of Health Tel : 415841

МІНІСТЭРСТВА
АХОВЫ ЗДАРОЎЯ
РЭСПУБЛІКІ БЕЛАРУСЬ

вул. Мяснікова, 39, 220048, г. Мінск
р/р 3604900000010 у ААТ «ААБ Беларусбанк»
Код 795. Тэл. 222-65-47, факс 222-46-27
e-mail: mzrb@belcmt.by,
minzdrav@mailgov.by

МИНИСТЕРСТВО
ЗДРАВООХРАНЕНИЯ
РЕСПУБЛИКИ БЕЛАРУСЬ

ул. Мясникова, 39, 220048, г. Минск
р/с 3604900000010 в ОАО «АСБ Беларусбанк»
Код 795. Тел. 222-65-47, факс 222-46-27
e-mail: mzrb@belcmt.by,
minzdrav@mailgov.by

18.03.2015 № 01-07-19/2693

На № _____

Кому: «Мефар Илач Сан. А.Ш.», Турция
(наименование зарубежного производителя, страны)

ПРИГЛАШЕНИЕ
к участию в конкурсных торгах

Уважаемые господа!

Министерство здравоохранения Республики Беларусь выражает свое почтение и приглашает вас принять участие в конкурсных торгах по закупкам лекарственных средств для государственной системы здравоохранения Республики Беларусь напрямую, без посредников.

Сообщаем, что уведомление о проведении конкурсов публикуется в информационно-аналитическом бюллетене «Конкурсные торги в Беларуси и за рубежом» и размещается на сайте информационного республиканского унитарного предприятия «Национальный центр маркетинга и конъюнктуры цен» www.icetrade.by.

Выдача документов для участия в конкурсах осуществляется РУП «Белфармация» – организацией, подчиненной Министерству здравоохранения Республики Беларусь и уполномоченной на организацию и проведение конкурсов по закупке лекарственных средств.

Для получения дополнительной информации необходимо обращаться в РУП «Белфармация» по адресу:

В.Хоружей, 11, Минск, 220005, Республика Беларусь

тел +375 17 288 21 94, факс: +375 17 288 25 26

e-mail: t_market@pharma.by

Контактные лица:

заместитель генерального директора РУП «Белфармация» Крук Светлана Николаевна, тел +375 17 288 23 15

руководитель группы конкурсных торгов и закупок РУП «Белфармация» Тихончук Татьяна Петровна, тел +375 17 288 16 47

Надеемся на вашу заинтересованность и взаимовыгодное сотрудничество.

С уважением,
Заместитель Министра В.Д.Шило

To: «Mefar Ilac San. A.S.», Turkey
(name of a foreign manufacturer, country)

INVITATION
for participating in competitive bidding

Dear sirs!

The Ministry of Health of the Republic of Belarus expresses its deepest respect and invites you to participate in the competitive bidding on direct medicine procurements for the state health care system of the Republic of Belarus.

We inform you that the notification on the competition is published in information and analysis Competitive Bidding in Belarus and Abroad bulletin and on the Web site of the National Centre for Marketing and Price Study Information: www.icetrade.by.

The documents for participation in competitions are available at «Belfarmatsiya», an organization subordinated to the Ministry of Health of the Republic of Belarus and authorized to organize and hold competitions on medicine procurements.

Further information is available at «Belfarmatsiya» at:

11 V. Khoruzhaya ul., 220005 Minsk, Republic of Belarus

Tel.: +375 17 288 21 94, fax: +375 17 288 25 26

e-mail: t_market@pharma.by

Contact persons:

Svetlana Kruk – Deputy Director General of Belfarmatsiya, tel. +375 17 288 23 15

Tatsiana Tihonchuk – Head of Group of Competitive Bidding and Procurements of Belfarmatsiya, tel. +375 17 288 16 47

We are looking forward to your interest and beneficial cooperation.

Sincerely yours,
Deputy Minister V.D.Shilo

3573

İş bu belgede kayıtlı üretim yerinin adresi Ramazanoğlu Mah.Ensar Cad. No:20 Kurtköy-Pendik/ İSTANBUL" olarak değiştirilmesi uygun bulunmuştur.

25/09/2008
Dr. Halil AKAR
Genel Müdür Yardımcısı

SAYI : 2008/01

T.C.
SAĞLIK BAKANLIĞI
İlaç ve Eczacılık Genel Müdürlüğü

ÜRETİM YERİ İZİN BELGESİ

İşbu belgede kayıtlı tesiste "Bulk aşı üretim ve dolum (kullanıma hazır enjektör, ampul)" faaliyetlerinin gerçekleştirilebileceğine dair şerhtir. 19/10/2016

İstanbul İli, Pendik İlçesi, Sanayi Mahallesi, Sanayi Yolu Caddesi, G-44 Sokak, No:20 Kurtköy adresinde bulunan **Mefar İlaç San. A. Ş.**'ye ait tesiste ampul, flakon, BFS, şırınga formlarında üretim yapılabileceğine dair izin belgesidir.01./02/2008

Dr.Halil AKAR
Genel Müdür Yardımcısı

Dr. Mahmut TOKAÇ
Genel Müdür

"İş bu belgede kayıtlı tesiste 5li BFS strip likit inhaler (nebül) ürün üretimi ve steril liyofilize ampul üretimi yapılabileceğine dair şerhtir." 24/08/2016

İş bu belgede kayıtlı üretim yerinde
"13 V Konjuge Pnömokok Aşısının(Prevenar 13)"
üretiminin yapılması uygundur.

12 Eylül 2012

Ecz. Güven ARTIRAN
Kurum Başkan Yardımcısı

İş bu belgede kayıtlı tesiste "liyofilize flakon"
farmasötik formunda üretim ve "Pentaxim 0.5ml (I.M
Enjektör) Süspansiyon İçin Toz İçeren Kullanıma
Hazır Enjektör" adlı ürünün şırınga dolum ve ambalaj-
lamasının yapılması uygundur.

26 Nisan 2013

Ecz. Güven ARTIRAN
Kurum Başkan Yardımcısı

İş bu belgede kayıtlı tesiste "Tetraxim 0,5ml IM Enjeksiyon İçin Süspansiyon İçeren Kullanıma Hazır Enjektör"
üretiminin yapılması uygundur.

22 Ocak 2014

MINISTERE DE LA SANTE ET DE L'HYGIENE PUBLIQUE

DIRECTION GENERALE DE LA SANTE

DPML
Direction de la Pharmacie, du Médicament et des Laboratoires de Côte d'Ivoire

REPUBLIQUE DE COTE D'IVOIRE
Union – Discipline – Travail

CERTIFICAT DE BONNES PRATIQUES DE FABRICATION

L'inspection effectuée le 22 Aôut 2016 dans l'unité de production de médicaments des laboratoires **MEFAR ILAÇ. San A.Ş** relève que les médicaments pour usage parentéral sous formes solides (lyophilisats), et sous formes liquides (solutions injectables en ampoules et flacons) sont fabriqués dans ladite unité selon les normes de Bonnes Pratiques de Fabrication édictées par l'Organisation Mondiale de la Santé (OMS).

Le **CERTIFICAT DE BONNES PRATIQUES DE FABRICATION DE LA REPUBLIQUE DE COTE D'IVOIRE** est par conséquent délivré à l'unité de fabrication des laboratoires **MEFAR ILAÇ. San A.Ş** sise à **Ramazanoğlu Mah. Ensar Cad. N°20, TR-34906 Kurtköy/Pendik-Istanbul (TURQUIE)** pour la fabrication de médicaments pour usage parentéral sous formes solides (lyophilisats), et sous formes liquides parentérales (solutions injectables en ampoules et flacons).

Ce certificat de Bonnes Pratiques de Fabrication est délivré pour servir et valoir ce que de droit pour une période de cinq (05) ans, à compter de sa date de signature.

Fait à Abidjan, le 09 SEP. 2016

N° 2081 /MSHP/DGS/DPML

Le Directeur

Le Directeur
Docteur DUNCAN A. Rachel

Direction de la Pharmacie du Médicament et des Laboratoires (**DPML**) : 52, Bd de Marseille, BP V 5 Abidjan (Côte d'Ivoire) Tél. (+225) 21 35 73 13 / 13 23 ; Fax : (+225) 21 35 69 58 ; Email : secretariat@dphm.ci

LANDESAMT FÜR SOZIALE DIENSTE SCHLESWIG-HOLSTEIN 59

Landesamt für soziale Dienste Schleswig-Holstein

State Social Services Agency Schleswig-Holstein

Zertifikat-Nr./Certificate no:
DE_SH_01_GMP_2016_0042

BESTÄTIGUNG DER ÜBEREINSTIMMUNG EINES HERSTELLERS MIT GMP

Teil 1

Ausgestellt nach einer Inspektion gemäß

• Art. 111 (5) der Richtlinie 2001/83/EG

Die zuständige deutsche Überwachungsbehörde bestätigt:

Der Hersteller
Mefar Ilac Sanayii A.S.

Anschrift der Betriebsstätte
Mefar Ilac Sanayii A.S.
Ramazanoglu Mah. Ensar Cad. No: 20
34906 Kurtköy/ Pendik/ Istanbul
Türkei

• wurde im Rahmen der in der Zulassung aufgeführten Hersteller mit Sitz außerhalb des Europäischen Wirtschaftsraumes inspiziert gemäß
- Art. 111 (4) der Richtlinie 2001/83/EG
umgesetzt in deutsches Recht durch:
§ 72a Abs. 1 Arzneimittelgesetz

Aufgrund der aus der letzten Inspektion vom 13. Mai 2016 gewonnenen Erkenntnisse wird für die oben genannte Betriebsstätte des Herstellers die Übereinstimmung mit den Anforderungen der Guten Herstellungspraxis festgestellt, die sich aus

• den Grundsätzen und Leitlinien der Guten Herstellungspraxis gemäß
- Richtlinie 2003/94/EG

ergeben.

Dieses Zertifikat bestätigt den Status der Betriebsstätte zum Zeitpunkt der oben genannten Inspektion. Es sollte nicht zur Bestätigung der Übereinstimmung herangezogen werden, wenn seit der genannten

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with

• Art. 111 (5) of Directive 2001/83/EC

The competent authority of GERMANY confirms the following:

The manufacturer
Mefar Ilac Sanayii A.S.

Site address
Mefar Ilac Sanayii A.S.
Ramazanoglu Mah. Ensar Cad. No: 20
34906 Kurtköy/ Pendik/ Istanbul
Turkey

• 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
transposed in the following national legislation:
Sect 72a para 1 Arzneimittelgesetz (German Drug Law)

From the knowledge gained during the inspection of this manufacturer, the latest of which was conducted on 13 May 2016, it is considered that it complies with the Good Manufacturing Practice requirements referred to in

• the principles and guidelines of Good Manufacturing Practice laid down in
- Directive 2003/94/EC

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

Inspektion mehr als drei Jahre vergangen sind. Nach Ablauf dieser Zeit sollte mit der zuständigen Behörde Kontakt aufgenommen werden. Das Zertifikat ist nur bei Vorlage sämtlicher Seiten inklusive der Teile 1 und 2 gültig. Die Echtheit dieses Zertifikates kann ggf. durch die ausstellende Behörde bestätigt werden.

date of that inspection, after which time the issuing authority should be consulted. This certificate is valid only when presented with all pages and both parts 1 and 2. The authenticity of this certificate may be verified with the issuing authority.

Teil 2

• Humanarzneimittel

1 HERSTELLUNGSTÄTIGKEITEN

- Die erlaubten Herstellungstätigkeiten umfassen vollständige und teilweise Herstellung (einschließlich verschiedener Prozesse wie Umfüllen, Abpacken oder Kennzeichnen), Chargenfreigabe und -zertifizierung, Lagerung und Vertrieb der genannten Darreichungsformen sofern nicht anders angegeben;

- Die Qualitätskontrolle und/oder Freigabe und/oder Chargenzertifizierung ohne Herstellungsschritte sollten unter den entsprechenden Punkten spezifiziert werden;

- Unter der relevanten Produktart und Darreichungsform sollte auch angegeben werden, wenn der Hersteller Produkte mit speziellen Anforderungen herstellt, z.B. radioaktive Arzneimittel oder Arzneimittel, die Penicilline, Sulfonamide, Zytostatika, Cephalosporine, Stoffe mit hormoneller Wirkung oder andere potenziell gefährliche Wirkstoffe enthalten (anwendbar für alle Bereiche des Teils 1 mit Ausnahme 1.5.2 und 1.6).

1.1 Sterile Produkte

1.1.1 Aseptisch hergestellt

1.1.1.2 Lyophilisate

1.1.1.4 Kleinvolumige flüssige Darreichungsformen

1.1.1.6 Andere aseptisch hergestellte Produkte
Blow/Fill/Seal (BFS)

1.1.2 Im Endbehältnis sterilisiert

1.1.2.3 Kleinvolumige flüssige Darreichungsformen

1.6 Qualitätskontrolle

1.6.1 Mikrobiologisch: Sterilität

1.6.2 Mikrobiologisch: Prüfung nicht steriler Produkte

1.6.3 Chemisch/Physikalisch

Einschränkungen oder klarstellende Anmerkungen betreffend den Umfang des Zertifikats:

Anmerkungen:
Die Inspektion umfasste folgende sterile Arzneimittel:

- Diclofenac 25mg/ml, 3ml Ampullen (Rotexmedica)
- Vitamin C 100mg/ml, 5ml Ampullen (Rotexmedica)
- Heparin 5000 IU, 5ml Vial (Rotexmedica)
- Variquel, Terlipressinacetat, 1 mg, Vial
- Venofer, Eisensuccinat complex 20 mg/ml

Part 2

• Human Medicinal Products

1 MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1 Sterile Products

1.1.1 Aseptically prepared

1.1.1.2 Lyophilisates

1.1.1.4 Small volume liquids

1.1.1.6 Other aseptically prepared products
Blow/Fill/Seal (BFS)

1.1.2 Terminally sterilised

1.1.2.3 Small volume liquids

1.6 Quality control testing

1.6.1 Microbiological: sterility

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate:

Comments:
The scope of the inspection was on the following sterile medicinal products:

- Diclofenac 25mg/ml, 3ml ampoules (Rotexmedica)
- Vitamin C 100mg/ml, 5ml ampoules (Rotexmedica)
- Heparin 5000 IU, 5ml vial (Rotexmedica)
- Variquel, terlipressin acetate, 1 mg, vials
- Venofer, iron succinate complex 20 mg/mL

- Voriconazole 200 mg Pulver zur Herstellung einer Infusionslösung
- Matever 100mg/ml Konzentrat zur Herstellung einer Infusionslösung
- Olopatadina HCL Abdi 1mg/ml Augentropfen (Lösung)
- Dexamethason 4mg/ml, 1ml Ampulle (Rotexmedica)
- Gentamycin 40mg/ml, 1ml Ampulle (Rotexmedica)
- Gentamycin 40mg/ml, 2ml Ampulle (Rotexmedica)
- Furosemid 10mg/ml, 2ml Ampulle (Rotexmedica)
- Ketamin 50mg/ml, 10ml Vial (Rotexmedica)
- Methylergometrin 0,2 mg/ml, 1ml Ampulle (Rotexmedica)
- Vitamin B complex, 2ml Ampulle (Rotexmedica)

- Voriconazole 200 mg powder for solution for infusion
- Matever 100mg/ml concentrate for infusion
- Olopatadina HCL Abdi 1mg/ml eye-drops (solution)
- Dexamethason 4mg/ml, 1ml ampoule (Rotexmedica)
- Gentamycin 40mg/ml, 1ml ampoule (Rotexmedica)
- Gentamycin 40mg/ml, 2ml ampoule (Rotexmedica)
- Furosemid 10mg/ml, 2ml ampoule (Rotexmedica)
- Ketamin 50mg/ml, 10ml vial (Rotexmedica)
- Methylergometrin 0,2 mg/ml, 1ml ampoule (Rotexmedica)
- Vitamin B complex, 2ml ampoule (Rotexmedica)

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29. September 2016

LANDESAMT FÜR SOZIALE DIENSTE SCHLESWIG-HOLSTEIN 59

Name und Unterschrift des Bearbeiters der zuständigen Behörde

Dr. Beate Reutter
Landesamt für soziale Dienste Schleswig-Holstein
Abteilung 3 - Gesundheits- und Verbraucherschutz
Adolf-Westphal-Straße 4
24143 Kiel
Deutschland

Tel.: +49(0)431 988-5549
Fax: +49(0)431 988-5416

29 September 2016

Name and signature of the authorised person of the Competent Authority

Dr. Beate Reutter
Landesamt für soziale Dienste Schleswig-Holstein
Abteilung 3 - Gesundheits- und Verbraucherschutz
Adolf-Westphal-Straße 4
24143 Kiel
Deutschland

Tel.: +49(0)431 988-5549
Fax: +49(0)431 988-5416

T.C. GIDA TARIM VE HAYVANCILIK BAKANLIĞI
GIDA VE KONTROL GENEL MÜDÜRLÜĞÜ

Ankara
25/05/2018

VETERİNER TIBBİ ÜRÜN ÜRETİCİLERİ İÇİN İYİ ÜRETİM UYGULAMALARI UYGUNLUK SERTİFİKASI

CERTIFICATE OF GOOD MANUFACTURING PRACTICES (GMP) COMPLIANCE OF VETERINARY MEDICINAL PRODUCT MANUFACTURERS

Sertifika No/*Certificate No* : ***GMP/TR/V/Yİ/S0099/2018***

Üretici/*The manufacturer* : **MEFAR İLAÇ SANAYİİ A.Ş.**

Üretim yeri adresi/*Site address* : **Ramazanoğlu Mahallesi Ensar Caddesi No:20 34906 Kurtköy/Pendik/İstanbul**

Bölüm-1

Yukarda bilgileri bulunan üretim yeri Veteriner Tıbbi Ürünler Hakkında Yönetmeliğin 23. Maddesi gereği denetlenmiştir.

Söz konusu üreticiye ait yukarıda belirtilen adresteki üretim yerinde 21-23 Mart 2018 tarihleri arasında gerçekleştirilen denetim sonucunda, yürütülen faaliyetlerin Veteriner Tıbbi Ürünler Hakkında Yönetmelikte belirtilen İyi Üretim Uygulamaları prensipleri ve kılavuzları ile uyumlu olduğu gözlemlenmiştir.[1,2]

Bu sertifika üretim yerinin yukarıda belirtilen tarihte gerçekleştirilen denetim anındaki durumunu yansıtmakta olup 23 Mart 2020 tarihinden sonra uyum durumuna itibar edilmemeli ve sertifikayı düzenleyen yetkili makama danışılmalıdır.

Bu Sertifikanın aslına uygunluğu Gıda, Tarım ve Hayvancılık Bakanlığından doğrulanabilir.

Bu Sertifika ancak Bölüm-1 ve Bölüm-2'den oluşan tüm sayfalarının eksiksiz olarak birlikte sunulması halinde geçerlidir.

Gıda Tarım ve Hayvancılık Bakanlığı veteriner tıbbi ürünler konusunda yetkili otorite olarak yukarıdaki bilgileri onaylamaktadır.

Part 1

The above manufacuring site has been inspected under the national inspection program in accordance with Art. 23 of Regulation On Veterinary Medicinal Products.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 21-23 March 2018, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Regulation on Veterinary Medicinal Products.[1,2]

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 after 23 March 2020. Should this date elapsed, the issuing authority must be consulted regarding the certificate validity.

The authenticity of this certificate may be verified with the issuing authority.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

As the competent authority, The Ministry of Food Agriculture and Livestock of Turkey confirms the above information..

Gıda, Tarım ve Hayvancılık Bakanlığı adına/
On behalf of The Ministry of Food Agriculture and Livestock of Turkey

Muharrem SELÇUK
Genel Müdür
Director General

Adres: Eskişehir Yolu 9. km Lodumlu, Ankara, 06060
Tel: (0312)287 33 60 (10 hat) Fax: (0312) 287 72 66
E-posta: vsu@tarim.gov.tr

[1] Bu Yönetmelik Avrupa Birliği'nin 2001/82/EC ve 91/412/EEC Direktifleri ile uyumludur./ This Regulation complies with the EU Directives 2001//82/EC and 91/412/EEC.
[2] Bu gereklilikler Dünya Sağlık Örgütü'nün GMP tavsiyelerini karşılamaktadır./*This requirements fulfil the GMP recommendations of WHO.*

T.C. GIDA TARIM VE HAYVANCILIK BAKANLIĞI
GIDA VE KONTROL GENEL MÜDÜRLÜĞÜ

Sertifika No/*Certificate No*: GMP/TR/V/Yİ/S0099/2018

Bölüm-2 | ***Part 2***

☒ Veteriner Tıbbi Ürünler

☒ *Veterinary Medicinal Products*

1. ÜRETİM İŞLEM (LER)İ

- İzinli üretim faaliyetleri aksi belirtilmediği sürece toplam ve kısmi üretim (en çeşitli bölme, ambalajlama veya sunum süreçlerini dahil), seri serbest bırakma ve onaylama, depolama ve özel dozaj formlarının dağıtımı süreçlerinin hepsini kapsar.
- Herhangi bir üretim faaliyeti olmaksızın yapılan kalite kontrol testleri ve/veya seri serbest bırakma ve onaylama faaliyetleri ilgili bölümler altında belirtilmelidir;
- Firma özel gerekliliklere sahip ürünlerin üretimini yapıyorsa (ör: radyofarmasötikler; penisilin, sülfonamidler, sitotoksikler ve sefalosporin içeren ürünler; hormonnal etkili ilaçlar veya diğer potansiyel olarak tehlikeli etkin maddeler) bu durum ilgili ürün tipi ve dozaj formu altında belirtilmelidir (Kısım 1.5.2 ve 1.6 haricindeki tüm kısımlara uygulanabilir)

1. MANUFACTURING OPERATION(S)

- Authorized manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary.

- Quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- If the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1. STERİL ÜRÜNLER

1.1.1. Aseptik hazırlananlar *(Aşağıdaki dozaj formları için gerçekleştirilen işlemler)*

1.1.1.1 Büyük hacimli sıvılar

1.1.1.4 Küçük hacimli sıvılar

1.1.2. Son kabında sterilize edilenler *(Aşağıdaki dozaj formları için gerçekleştirilen işlemler)*

1.1.2.1 Büyük hacimli sıvılar

1.1.2.3 Küçük hacimli sıvılar

1.1. STERILE PRODUCTS

1.1.1. Aseptically prepared (Processing operations for the following dosage forms)

1.1.1.1 Large volume liquids

1.1.1.4 Small volume liquids

1.1.2 Terminally sterilised (processing operations for the following dosage forms)

1.1.2.1 Large volume liquids

1.1.2.3 Small volume liquids

Bu sertifikanın kapsamı ile ilgili kısıtlamalar veya açıklayıcı bilgiler:

Any restrictions or clarifying remarks related to the scope of this certificate:

Muharrem SELÇUK
Genel Müdür
Director General

Adres: Eskişehir Yolu 9. km Lodumlu, Ankara, 06060
Tel: (0312)287 33 60 (10 hat) Fax: (0312) 287 72 66
E-posta: vsu@tarim.gov.tr

MINISTRY OF INDUSTRY AND TRADE OF THE RUSSIAN FEDERATION

STATEMENT
of compliance of manufacturer (foreign manufacturer)
of medicinal products for human use
with the requirements of Good Manufacturing Practice rules

No. GMP-00903/18/TR

Part 1

The Ministry of Industry and Trade of the Russian Federation confirms that

Mefar İlaç Sanayi A.Ş.
(full and abbreviated name (if available) of the manufacturer (foreign manufacturer) of medicinal products for human use)

located at

Ramazanoğlu Mah. Ensar Cad. No: 20. Kurtköy/Pendik, Istanbul, Turkey

and carrying out manufacture of medicinal products for human use at

Ramazanoğlu Mah. Ensar Cad. No: 20. Kurtköy/Pendik, Istanbul, Turkey

was inspected in terms of licensing supervision for compliance with licensing requirements during implementation of manufacturing activities of medicinal products in accordance with the license No. ____ of __ _____ ____ (year) according to the legislation of the Russian Federation *or* was inspected in terms of marketing authorization(s) indicating manufacturers located outside the Russian Federation in accordance with the requirements of **Good Manufacturing Practice** rules approved by order No. 916 of June 14, 2013 of the Ministry of Industry and Trade of the Russian Federation.

Based on the information obtained during inspections of this manufacturer, the last of which was carried out from May 21, 2018 to May 24, 2018, it can be stated that manufacturer meets the requirements of Good Manufacturing Practice rules approved by order No. 916 of June 14, 2013 of the Ministry of Industry and Trade of the Russian Federation.

This statement reflects the compliance status of production site of manufacturer (foreign manufacturer) of medicinal products for human use at the time of the above inspection and should not be considered as a document indicating the status of compliance in case of expiration of more than 3 (three) years from the date of this inspection.

The statement is valid in the presence of all its pages (both part 1 and part 2).

Authenticity of this statement is verified in the register of statements of compliance of manufacturers of medicinal products for human use with the requirements of Good Manufacturing Practice rules posted on the official website http://www.minpromtorg.gov.ru, http://www.минпромторг.рф. In case of absence of this statement in the register of statements of compliance of manufacturers of medicinal products for human use with the requirements of Good Manufacturing Practice rules, please inform the Ministry of Industry and Trade of the Russian Federation.

This statement is valid during 3 years from the date of completion of the inspection.

First Deputy Minister (signature) **S.A. Cyb**

/ Blue seal of the Ministry of Industry and Trade of the Russian Federation /

September 12, 2018

(Statement Issue Date)

MINISTRY OF INDUSTRY AND TRADE OF THE RUSSIAN FEDERATION

GMP-00903/18/TR

Part 2

Manufacture and Quality Control
I. MANUFACTURING OPERATIONS – PHARMACEUTICAL PRODUCTS
1. Sterile medicinal products
■ 1. Aseptically manufactured medicinal products (processing operations for the following dosage forms):
□ Large volume liquids
■ Small volume liquids
□ Dispersions
■ Lyophilisates
□ Solid dosage forms and implants
□ Soft dosage forms
□ Other medicinal products
■ 2. Terminally sterilized medicinal products (processing operations for the following dosage forms):
■ Large volume liquids
■ Small volume liquids
□ Solid dosage forms and implants
□ Soft dosage forms
□ Other medicinal products and dosage forms
■ 3. Release quality control (processing operations for the following dosage forms):
2. Non-sterile medicinal products
□ 1. Non-sterile medicinal products (processing operations for the following dosage forms):
□ Hard-shelled capsules
□ Soft-shelled capsules
□ Chewable dosage forms
□ Impregnated dosage forms
□ Liquids for external use
□ Liquids for internal use
□ Medicinal gases
□ Other solid dosage forms
□ Pressurized medicinal products
□ Radionuclide generators
□ Soft dosage forms
□ Suppositories

□ Tablets
□ Transdermal patches
□ Intraruminal devices
□ Other medicinal products and dosage forms
□ 2. Release quality control
3. Biological medicinal products
■ 1. Biological medicinal products:
□ Blood derived medicinal products
□ Immunological medicinal products
□ Somatic cell therapy medicinal products
□ Gene therapy medicinal products
□ Tissue engineered medicinal products
□ Biotech medicinal products
■ Medicinal products extracted from animal sources or human organs (tissues)
□ Other medicinal products
4. Other medicinal products or manufacturing activities
□ Manufacture of:
□ Herbal medicinal products
□ Homeopathic medicinal products
□ Other medicinal products

First Deputy Minister (signature) **S.A. Cyb**

/ Blue seal of the Ministry of Industry and Trade of the Russian Federation /

September 12, 2018

(Statement Issue Date)

■ **2. Sterilization of active substances, excipients and finished medicinal products:**
■ **Filtration**
□ Dry-heat sterilization
■ **Steam sterilization**
□ Chemical sterilization
□ Gamma sterilization
□ Electron beam sterilization
□ 3. Other
□ 4. Primary (inner) packaging:
□ Hard-shelled capsules
□ Soft-shelled capsules
□ Chewable dosage forms
□ Impregnated dosage forms
□ Liquids for external use
□ Liquids for internal use
□ Medicinal gases
□ Other solid dosage forms
□ Pressurized medicinal products
□ Radionuclide generators
□ Soft dosage forms
□ Suppositories
□ Tablets
□ Transdermal patches
□ Intraruminal devices
□ Other medicinal products and dosage forms
■ **5. Secondary (consumer) packaging**
■ **6. Release quality control**
■ **7. Microbiological testing: sterility**
□ 8. Microbiological testing: non-sterility
■ **9. Chemical (physical) testing**
■ **10. Biological testing**
II. QUALITY CONTROL IN TERMS OF IMPORT OF MEDICINAL PRODUCTS
□ 1. Quality control of imported medicinal products:
□ Microbiological testing: sterility
□ Microbiological testing: non-sterility
□ Chemical (physical) testing

□ Biological testing
□ 2. Release quality control (batch certification) of imported medicinal products
□ Sterile medicinal products:
□ Aseptically manufactured medicinal products
□ Terminally sterilized medicinal products
□ Non-sterile medicinal products
□ Biological medicinal products:
□ Blood derived medicinal products
□ Immunological medicinal products
□ Somatic cell therapy medicinal products
□ Gene therapy medicinal products
□ Tissue engineered medicinal products
□ Biotech medicinal products
□ Medicinal products extracted from animal sources or human organs (tissues)
□ Other medicinal products
□ 3. Other import activities:
□ Physical import site
□ Import of intermediate product undergoing further processing
□ Other

First Deputy Minister (signature) **S.A. Cyb**

/ Blue seal of the Ministry of Industry and Trade of the Russian Federation /

September 12, 2018

(Statement Issue Date)

MINISTRY OF INDUSTRY AND TRADE OF THE RUSSIAN FEDERATION

GMP-00903/18/TR

Restrictions or clarifying remarks relating to scope of certificate:
List of medicinal products in respect of which the inspection was carried out:

Trade Name	International Non-proprietary Name or Generic (Chemical) Name of Medicinal Product / Pharmaceutical Substance	Dosage form, strength (if applicable)
Manufacture of finished dosage forms, secondary packaging, quality control		
Ademta	Ademetionine	Lyophilisate for solution for injection, 400 mg, complete with solvent
Tenartessa	Tenoxicam	Lyophilisate for solution for intravenous and intramuscular injection, 20 mg
Asibrox	Acetylcysteine	Solution for injection, 300 mg / 3 ml
Benevron B	Thiamine Hydrochloride, Riboflavin, Pyridoxine Hydrochloride, Cyanocobalamin	Solution for injection

Bumanol	Hydroxocobalamin	Lyophilisate for solution for injection, 97 mg, complete with solvent
Kardovol	Metoprolol Tartrate	Solution for injection, 5 mg / 5 ml
Clodifen	Diclofenac Sodium	Solution for injection, 75 mg / 3 ml
Dianervan	Triphosadenine Disodium Trihydrate, Cocarboxylase, Cyanocobalamin, Nicotinamide	Lyophilisate for solution for intramuscular injection, complete with solvent
Doramycin	Spiramycin	Lyophilisate for solution for injection, 1.5 IU, complete with solvent
Artronovi	Chondroitin Sulfate	Solution for intramuscular injection, 200 mg / 2 ml
Elfunat	Ethylmethylhydroxypyridine Succinate	Solution for injection, 50 mg / ml
Fersinol	Iron (III) Hydroxide	Solution for injection, 100 mg / 2 ml
Glatiramer Acetate	Glatiramer Acetate	Solution for injection, 20 mg / ml, 40 mg / ml

First Deputy Minister (signature) **S.A. Cyb**

/ Blue seal of the Ministry of Industry and Trade of the Russian Federation /

September 12, 2018

(Statement Issue Date)

Insulipon	Thioctic Acid	Solution for injection, 50 mg / vial
Levebrain	Levetiracetam	Concentrate for solution for infusion, 500 mg / 5 ml
Levoximed	Levofloxacin	Solution for infusion, 5 mg / ml
Loxidol	Meloxicam	Solution for intramuscular injection, 15 mg / 1.5 ml
Linozid	Linezolid	Solution for infusion, 5 mg / ml
Medotilin	Choline Alfoscerat	Solution for injection, 1000 mg / 4 ml
Medrolgin	Ketorolac Trometamol	Solution for intramuscular injection, 30 mg / ml
Metacartin	Levocarnitine	Solution for intramuscular injection, 1 mg / 5 ml
Moxicum	Moxifloxacin	Solution for infusion, 400 mg / 250 ml
Nevralon	Thiamine Hydrochloride, Cyanocobalamin, Pyridoxine Hydrochloride, Lidocaine	Solution for injection
Oradro	Clarithromycin	Lyophilisate for solution for injection, 500 mg
Pireticol	Paracetamol	Solution for infusion, 10 mg / ml

Pompezo	Esomeprazole Sodium	Lyophilisate for solution for injection, 40 mg
Ram	Glutathione	Lyophilisate for solution for injection, 600 mg
Ripronat	Meldonium	Solution for injection, 100 mg / ml
Ronocit	Citicoline	Solution for intravenous and intramuscular injection, 500 mg / 4 ml, 1000 mg / 4 ml
Sertofen	Dexketoprofen	Solution for injection, 50 mg / 2 ml
Tamovir	Ganciclovir	Lyophilisate for solution for injection, 500 mg
Teklonin	Teicoplanin	Lyophilisate for solution for injection, 200 mg, 400 mg
Torventa	Torasemide anhydrous	Solution for injection, 10 mg / ml
Toxivenol	Troxerutin, Carbazochrome	Solution for injection

First Deputy Minister (signature) **S.A. Cyb**

/ Blue seal of the Ministry of Industry and Trade of the Russian Federation /

September 12, 2018

(Statement Issue Date)

Ulsepan	Pantoprazole	Lyophilisate for solution for injection, 40 mg
Vanko-WM	Vancomycin	Lyophilisate for solution for injection, 500 mg, 1000 mg
Viroseda	Voriconazole	Lyophilisate for solution for injection, 200 mg
Ziromin	Azithromycin	Lyophilisate for solution for injection, 500 mg
Voranex	Voriconazole	Lyophilisate for solution for intravenous injection, 200 mg
Tigenex	Tigecyclin	Lyophilisate for solution for intravenous injection, 50 mg

First Deputy Minister (signature) **S.A. Cyb**

/ Blue seal of the Ministry of Industry and Trade of the Russian Federation /

September 12, 2018

(Statement Issue Date)

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority
رقم الصـادر : 39427/ع
تاريخ الصـادر : 16 / 05 / 1440 هـ
نـوع المرفـق : لا يوجد
الإحالة : الشركة السعودية للصناعات الدوا
2-1440-1-39427-41-2

بسم الله الرحمن الرحيم

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
(٢٥٥)
قطاع الدواء

المحترم المكرم مدير التشريعات لشركة سبيماكو الدوائية

السلام عليكم ورحمة الله وبركاته ،،،

إشارة إلى طلبكم تسجيل مصنع الشركة التالية:

Mefar Ilac Sanayii A.S.

وبناءً على قرار لجنة تسجيل شركات الأدوية ومنتجاتها رقم ٤٠/sfda/٩٦٨/٥٨ وتاريخ ١٤٤٠/٠٥/٠٨هـ المتضمن الموافقة على تسجيل مصنع الشركة.

وعنوانه:

Ramazanoğlu Mahallesi, Ensar Cd. No:20, Kurtkoy- Pendik/İstanbul - Turkey

وذلك فيما يخص خطوط الإنتاج التالية:

- Sterile Products: General
  - Aseptically Prepared:
    1- Lyophilisates

عليه نأمل تسديد الرسوم المستحقة والبالغة خمسة آلاف ريال حسب ما ورد في المادة الحادية والعشرون من اللائحة التنفيذية لنظام المنشآت والمستحضرات الصيدلانية عن طريق نظام سداد في حساب الهيئة العامة للغذاء والدواء بالإضافة إلى صورة من شهادة قيد الوكالة صادرة من وزارة التجارة والإستثمار ليتسنى لنا إكمال اللازم.

مع أطيب تحياتي،،،

رئيس قسم دعم تسجيل الأدوية البشرية

٥/١٦

حمود بن غازي الحربي

Agency for Medicinal Products and Medical Devices of Croatia

CERTIFICATE NUMBER: ***UP/I-530-10/19-03/19; 381-10-05/241-19-03***

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: ***MEFAR ILAC SANAYII A.S.***
Site address: ***Ramazanoğlu Mah.Ensar Cad. No.20 34906, Kurtkoy - Pendik - Istanbul, Turkey, TR-34906, Turkey***

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 transposed in the following national legislation:
Art. 40 of Medicinal Products Act (official Gazette, No. 76/13, 90/14 and 100/18)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-01-25*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [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. 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 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[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
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packing
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 line1,4, 5 and 6, BFS – 1		

Clarifying remarks (for public users)

1.1.1.4. refer to ampoules, eye drops and nasal drops; 1.1.2.3. refer to ampoules

2019-08-23

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

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Ms. Martina Bencetic Marijanovic
Agency for Medicinal Products and Medical Devices of Croatia
Tel: ***+385 4884141***
Fax: ***+385 14884110***

REPUBLIKA HRVATSKA
AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE

REPUBLIC OF CROATIA
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
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OIB 37926884937

Klasa: UP/I-530-10/19-03/19
Urbroj: 381-10-05/241-19-03

POTVRDA O PROVOĐENJU DOBRE PROIZVOĐAČKE PRAKSE[1,2]

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

DIO 1
Part 1

Nakon provedenog nadzora u skladu sa člankom 111(5) Direktive 2001/83/EZ Europskog parlamenta i Vijeća
Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

Nadležno tijelo Republike Hrvatske potvrđuje sljedeće:
The competent authority of Croatia confirms the following:

Proizvođač: MEFAR ILAC SANAYII A.S.
The manufacturer: MEFAR ILAC SANAYII A.S.

Mjesto proizvodnje: Ramazanoglu Mah. Ensar Cad. No: 20, Kurtkoy-Pendik, TR-34906 Istanbul, Turkey
Site address: Ramazanoglu Mah. Ensar Cad. No: 20, Kurtkoy-Pendik, TR-34906 Istanbul, Turkey

Proveden je nadzor proizvođača izvan Europskog gospodarskog prostora, a koji se navodi u dokumentaciji odobrenja za stavljanje lijeka u promet, u skladu s člankom 111(4) Direktive 2001/83/EZ transponiranim u nacionalnom zakonodavstvu, članak 40. Zakona o lijekovima („Narodne novine“, broj 76/13., 90/14. i 100/18.).
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 transposed in the following national legislation Art. 40 Medicinal Products Act (Official Gazette No. 76/13, 90/14 and 100/18).

Provedenim inspekcijskim nadzorom proizvođača, od kojih je posljednji proveden dana 25. siječnja 2019. utvrđeno je da proizvođač udovoljava principima i smjernicama dobre proizvođačke prakse propisanim Direktivom 2003/94/EZ[3].

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 25th January 2019, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[3].

Ova potvrda odnosi se na stanje mjesta proizvodnje u trenutku provedbe gore navedenog nadzora, i ne treba se smatrati da odražava stvarno stanje usklađenosti ukoliko su prošle više od tri godine od datuma nadzora. Međutim, rok važenja potvrde može se skratiti ili produljiti na temelju principa primijenjenog upravljanja rizicima inspekcije Agencije, na način da se isto unese u polje Ograničenja i pojašnjenja.

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.

Ova potvrda vrijedi isključivo ukoliko sadrži sve stranice, kao i DIO 1 i dijela DIO 2.
This certificate is valid only when presented with all pages and both Parts 1 and 2.

Autentičnost ove potvrde može se provjeriti u EudraGMDP bazi podataka. Ako nije dostupna u EudraGMDP bazi, obratite se tijelu koje je izdalo potvrdu.
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] GMP potvrda iz članka 111(5) Direktive 2001/83/EC primjenjuje se i za uvoznike.
The certificate referred to in paragraph 111(5) of Directive 2001/83/EC is also applicable to importers.

[2] Pojašnjenje ovog obrasca nalazi se u „Help menu" EudraGMDP baze
Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database

[3] Ovi zahtjevi ispunjavaju preporučene zahtjeve WHO za DPP
These requirements fulfil the GMP recommendations of WHO

DIO 2
Part 2

☒ Lijekovi *Human Medicinal Products*

1. PROIZVODNJA ***1. MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS***	
1.1.	**Sterilni lijekovi *Sterile products***
	1.1.1. Aseptički pripravljeni lijekovi *Aseptically prepared (processing operations for the following dosage forms)* 1.1.1.4. Tekućine malih volumena *Small volume liquids*
	1.1.2. Završno sterilizirani lijekovi *Terminally sterilised (processing operations for the following dosage forms)* 1.1.2.3. Tekućine malih volumena *Small volume liquids*
	1.5.2. Vanjsko pakiranje *Secondary packing*
1.6.	**Provjera kakvoće *Quality control testing***
	1.6.1. Mikrobiološko ispitivanje: sterilnost *Microbiological: sterility*
	1.6.2. Mikrobiološko ispitivanje: mikrobiološka čistoća *Microbiological: non-sterility*
	1.6.3. Kemijska/fizička ispitivanja *Chemical/Physical*

Ograničenje ili pojašnjenje vezano za navedeno u ovoj potvrdi:
***Any restrictions or clarifying remarks related to the scope of this certificate*:**

Proizvodna jedinica *Building*	Line / equipment
	Ampoule lines 1, 4, 5 and 6, BFS – 1

1.1.1.4. odnosi se na ampule, kapi za oči i kapi za nos.
1.1.1.4. refer to ampoules, eye drops and nasal drops

1.1.2.3. odnosi se na ampule
1.1.2.3.. refer to ampoules

Datum: 23. kolovoza 2019.
Date: 23th August 2019

Ime, prezime i potpis ovlaštene osobe
nadležnog tijela Republike Hrvatske
Name and signature of the authorised person
of the Competent Authority of Croatia

Inspektor Agencije
Inspector

Martina Bencetić Marijanović,
M. Eng. Bioproc., Univ. Mag Pharm.

Agencija za lijekove i medicinske proizvode
Agency for medicinal products and medical devices

Dragomir Budimir, LLC