Medicines Authority

CERTIFICATE NUMBER: ***MT/014HM/2021***

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 Malta confirms the following:
The manufacturer: ***Farma-Tek Ilac Sanayi Ve Ticaret A.S.***
Site address: ***Kizilcikdere Koyu Mevkii, Kirklareli Organize Sanayi Bolgesi Mah. 1, Cadde No:12, Kirklareli, 39100, Turkey***
DUNS Number: ***64-439-1997***

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 ***2021-02-07***, 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. 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	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.8 Other solid dosage forms: micropellet, non-sterile powder filling(en) 1.2.1.11 Semi-solids 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.8 Other solid dosage forms: micropellet, non-sterile powder filling(en) 1.5.1.11 Semi-solids 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

This certificate is limited in scope to products intended for the EU/EEA markets

2021-06-04

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

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Confidential
Medicines Authority
Tel:***Confidential***
Fax:***Confidential***

The EudraGMDP database is maintained and operated by the EMA. Access to the general public is granted in order to enhance availability of information related to the EMA mandate. The content of the database is provided by the National Competent Authorities (NCA) of the EEA. For this reason, the EMA accepts no responsibility or liability whatsoever (including but not limited to any direct or consequential loss or damage it might occur to you and/or any other third party) arising out of or in connection with the information on this database. Any questions about the content should be addressed to the relevant NCA. Please click here to get list of NCA's.

Due to the restrictions caused by COVID-19, the period of validity of GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2024, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are now being conducted and scheduling of these inspections may be independent of the extended validity period stated above. Competent authorities will continue to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP and GDP certificates, as appropriate.

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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
16984	8699788731134	VI-PLEX E 300 MG/2 ML ENJEKSİYONLUK ÇÖZELTİ, 100 ADET	d-alfatokoferol asetat	A11HA03	OSEL İLAÇ SAN. VE TİC. A.Ş.	05.05.1999	191/27			13.11.2020	0	
16985	8699788751659	Vİ-PLEX E 300 MG/2 ML ENJEKSİYONLUK ÇÖZELTİ, 5 ADET	d-alfatokoferol asetat	A11HA03	OSEL İLAÇ SAN. VE TİC. A.Ş.	05.05.1999	191/27			13.11.2020	0	
16986	8699188751147	Vİ-PLEX E 300 MG/2 ML ENJEKSİYONLUK ÇÖZELTİ, 50 ADET	d-alfatokoferol asetat	A11HA03	OSEL İLAÇ SAN. VE TİC. A.Ş.	05.05.1999	191/27			13.11.2020	0	
16987	8699788751161	VI-PLEX K 10 MG 3 AMPUL	menadione	B02BA02	OSEL İLAÇ SAN. VE TİC. A.Ş.	05.05.1999	191/22				0	
16988	8699788751185	VI-PLEX K 10 MG/2 ML AMPUL, 100 ADET	menadion sodyum bisülfit	B02BA02	OSEL İLAÇ SAN. VE TİC. A.Ş.	05.05.1999	191/22				0	
16989	8699788751611	VI-PLEX K 10 MG/2 ML AMPUL, 5 ADET	menadion sodyum bisülfit	B02BA02	OSEL İLAÇ SAN. VE TİC. A.Ş.	05.05.1999	191/22				0	
16990	8699788751178	VI-PLEX K 10 MG/2 ML AMPUL, 50 ADET	menadion sodyum bisülfit	B02BA02	OSEL İLAÇ SAN. VE TİC. A.Ş.	05.05.1999	191/22			02.03.2018	0	
16991	8699788751215	VI-PLEX K 20 MG 2MLX100 AMPUL	menadione	B02BA02	OSEL İLAÇ SAN. VE TİC. A.Ş.	05.05.1999	191/21				0	
16992	8699788751628	VI-PLEX K 20 MG 2MLXAMPUL, 5 ADET	menadione	B02BA02	OSEL İLAÇ SAN. VE TİC. A.Ş.	05.05.1999	191/21				0	
16993	8699566355864	VIRALEX % 5 KREM, 5 G	asiklovir	D06BB03	SANTA FARMA İLAÇ SAN. A.Ş.	09.01.1998	185/80				0	
16994	8699693010056	VIRAMUNE 200 MG TABLET, 60 ADET	nevirapine	J05AG01	BOEHRİNGER INGELHEİM İLAÇ TİC. A.Ş.	15.09.1999	106/58				0	
16995	8699543090764	VİRANİS 200 MG FİLM TABLET, 168 ADET	ribavirin	J05AB04	ALİ RAİF İLAÇ SAN. A.Ş.	14.05.2010	224/71			29.10.2021	0	
16996	8699543090740	VİRANİS 200 MG FİLM TABLET, 70 ADET	ribavirin	J05AB04	ALİ RAİF İLAÇ SAN. A.Ş.	14.05.2010	224/71			29.10.2021	0	
16997	8699543090757	VIRANIS 200 MG FILM TABLET, 84 ADET	ribavirin	J05AB04	ALİ RAİF İLAÇ SAN. A.Ş.	14.05.2010	224/71				0	
16998	8699738090357	VIRATIT 0.5 MG FILM TABLET, 30 ADET	entekavir monohidrat	J05AF10	FARMA-TEK İLAÇ SAN. VE TİC. A.Ş.	21.02.2017	2017/75				0	
16999	8699738090364	VIRATIT 1 MG FILM TABLET, 30 ADET	entekavir monohidrat	J05AF10	FARMA-TEK İLAÇ SAN. VE TİC. A.Ş.	21.02.2017	2017/76				0	
17000	8698760090014	VIREAD 245 MG FILM KAPLI TABLET, 30 ADET	tenofovir disoproksil	J05AF07	GİLEAD SCİENCES İLAÇ TİC. LTD. STİ.	22.05.2007	122/55				0	
17001	8699540090811	VİRENTE 0,5 MG FİLM TABLET, 30 ADET	entekavir monohidrat	J05AF10	NOBEL İLAÇ SAN. VE TİC. A.Ş.	23.01.2015	2015/31			17.09.2021	0	
17002	8699540090828	VİRENTE 1MG FİLM TABLET, 30 ADET	entekavir monohidrat	J05AF10	NOBEL İLAÇ SAN. VE TİC. A.Ş.	23.01.2015	2015/30			17.09.2021	0	
17003	8680177220092	VIRGAN 1,5MG/G OFTALMIK JEL	gansiklovir	S01AD09	THEA PHARMA İLAÇ TİC LTD. STİ	15.02.2013	135/55				0	
17004	8680881090950	VIRMOL 125 MG FILM KAPLI TABLET, 14 ADET	famciclovir	J05AB09	NEUTEC İLAÇ SAN. TİC. A.Ş.	09.05.2011	231/91			18.05.2018	0	
17005	8680881090967	VIRMOL 250 MG FILM KAPLI TABLET, 21 ADET	famciclovir	J05AB09	NEUTEC İLAÇ SAN. TİC. A.Ş.	14.07.2011	233/44			18.05.2018	0	
17006	8680881090974	VIRMOL 500 MG FILM KAPLI TABLET, 14 ADET	famciclovir	J05AB09	NEUTEC İLAÇ SAN. TİC. A.Ş.	10.05.2011	231/93			18.05.2018	0	
17007	8680881090981	VIRMOL 500 MG FILM KAPLI TABLET, 21 ADET	famciclovir	J05AB09	NEUTEC İLAÇ SAN. TİC. A.Ş.	10.05.2011	231/93			18.05.2018	0	
17008	8680881091001	VIRMOL 750 MG FILM KAPLI TABLET, 14 ADET	famciclovir	J05AB09	NEUTEC İLAÇ SAN. TİC. A.Ş.	10.05.2011	231/92			18.05.2018	0	
17009	8680881090998	VIRMOL 750 MG FILM KAPLI TABLET, 7 ADET	famciclovir	J05AB09	NEUTEC İLAÇ SAN. TİC. A.Ş.	10.05.2011	231/92			18.05.2018	0	
17010	8680008010601	VIROFO 10 MG TABLET,30 ADET	adefovir dipivoksil	J05AF08	HELBA İLAÇ İÇ VE DIŞ SAN. TİC. A.Ş.	23.03.2016	2016/311			12.02.2021	1	