Mylan Laboratories Limited
F-4 & F-12, Malegaon MIDC, Sinnar,
Nashik-422 113, Maharashtra, India,
Tel : +91 (2551) 230092, 230093, 304777
Fax : +91 (2551) 230924

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Name of the Product :	Emtricitabine and Tenofovir Disoproxil Fumarate Tablets (200 mg / 300 mg)	**A.R. No. :**	MLNFP23010440
Batch No. :	3186291	**Market :**	PERU (TENDER)
Mfg Date :	July 2023	**Batch Size :**	1,800,000 Tablets
Exp Date :	June 2026	**Ref. Spec. No. :**	FPSETF508R-01
Date of Analysis :	11 August 2023	**Page No. :**	Page 1 of 4

S. No.	Test	Specification	Results
01	Description	Blue coloured, oval shaped, film coated tablets debossed with "M117" on one side and plain on other side.	Blue coloured, oval shaped, film coated tablets debossed with "M117" on one side and plain on other side.
02	Identification (By HPLC)	The retention time of the Emtricitabine and Tenofovir Disoproxil peaks in the chromatogram of the test preparation should correspond to that in the chromatogram of the standard preparation as obtained in the Assay by HPLC.	The retention time of the Emtricitabine and Tenofovir Disoproxil peaks in the chromatogram of the test preparation is corresponds to that in the chromatogram of the standard preparation as obtained in the Assay by HPLC.
03	Dissolution (By HPLC)		
	Emtricitabine 200 mg	Complies with Ph. Eur. General Chapter 2.9.3 At S_1, not less than 85% (Q = 80%) of the labeled amount of Emtricitabine, $C_8H_{10}FN_3O_3S$ should be dissolved in 30 minutes. At S_2, average of 12 units $(S_1 + S_2) \geq Q$ and no unit is $< Q-15\%$.	Tablet-1 : 96 %, Tablet-2 : 95 %, Tablet-3 : 96 %, Tablet-4 : 96 %, Tablet-5 : 94 %, Tablet-6 : 95 % Min: 94 % Max: 96 % Avg: 95 % RSD: 0.8 %
	Tenofovir Disoproxil Fumarate 300 mg	Complies with Ph. Eur. General Chapter 2.9.3 At S_1, not less than 85% (Q = 80%) of the labeled amount of Tenofovir Disoproxil Fumarate, $C_{19}H_{30}N_5O_{10}P$. $C_4H_4O_4$ should be dissolved in 30 minutes. At S_2, average of 12 units $(S_1 + S_2) \geq Q$ and no unit is $< Q-15\%$.	Tablet-1 : 96 %, Tablet-2 : 95 %, Tablet-3 : 95 %, Tablet-4 : 95 %, Tablet-5 : 93 %, Tablet-6 : 94 % Min: 93 % Max: 96 % Avg: 95 % RSD: 1.1 %

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S. No.	Test	Specification	Results
04	Related Substances (By HPLC)		
	A. Emtricitabine impurity		
	S-oxide impurity	Not more than 0.6% w/w	0.085 % w/w
	B. Tenofovir Disoproxil Fumarate impurity		
	a. Mono ester impurity (Tenofovir monosoproxil)	Not more than 2.0% w/w	0.629 % w/w
	b. Tenofovir disoproxil dimer impurity	Not more than 0.2% w/w	0.033 % w/w
	c. Mono POC dimer impurity	Not more than 0.5% w/w	0.007 % w/w
	d. Mix dimer impurity	Not more than 0.75% w/w	Not detected
	C. Any individual unknown impurity	Not more than 0.2% w/w	0.069 % w/w
	D. Total impurities	Not more than 4.0% w/w	1.049 % w/w
05	Assay (By HPLC)		
	Each film coated tablet contains:		
	Emtricitabine 200 mg	Not less than 190.00 mg and not more than 210.00 mg of Emtricitabine, $C_8H_{10}FN_3O_3S$ (95.0% w/w – 105.0% w/w of labeled amount of Emtricitabine)	202.08 mg (101.0 % w/w)
	Tenofovir Disoproxil Fumarate 300 mg	Not less than 285.00 mg and not more than 315.00 mg of Tenofovir Disoproxil Fumarate, $C_{19}H_{30}N_5O_{10}P.C_4H_4O_4$ (95.0% w/w – 105.0% w/w of labeled amount of Tenofovir Disoproxil Fumarate)	305.09 mg (101.7 % w/w)

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S. No.	Test	Specification	Results
06	Water (By KF)	Not more than 4.0% w/w	2.20 % w/w
ADDITIONAL TSETS			
07	Identification (By Thin-layer chromatography)	The principal spots in the chromatogram obtained with the test preparation should be similar in position to that in the chromatograms obtained with standard preparations.	The principal spots in the chromatogram obtained with the test preparation is similar in position to that in the chromatograms obtained with standard preparations.
08	Color identifications		
	A. For FD & C Blue # 2 Aluminum Lake	The test solution should exhibit maximum absorbance at 615 ± 4 nm.	The test solution exhibits maximum absorbance at 614 nm.
	B. For Titanium dioxide	A yellow-red to orange-red color should be developed.	An orange-red color is developed.
09	Uniformity of Dosage Units (By Content Uniformity)		
	Emtricitabine 200 mg	Complies with Ph. Eur General Chapter 2.9.40 The Acceptance Value (AV) should be not more than 15.0.	Tablet-1: 101.1 % Tablet -2: 100.3 % Tablet -3: 100.8 % Tablet -4: 102.4 % Tablet -5: 100.4 % Tablet -6: 98.4 % Tablet -7: 96.9 % Tablet -8: 98.3 % Tablet -9: 98.9 % Tablet -10: 101.4 % Avg.: 99.9 % AV = 4.1

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S. No.	Test	Specification	Results
	Tenofovir Disoproxil Fumarate 300 mg	Complies with Ph. Eur General Chapter 2.9.40 The Acceptance Value (AV) should be not more than 15.0.	Tablet-1: 100.8 % Tablet -2: 100.6 % Tablet -3: 100.9 % Tablet -4: 102.6 % Tablet -5: 100.6 % Tablet -6: 99.0 % Tablet -7: 96.9 % Tablet -8: 98.3 % Tablet -9: 99.0 % Tablet -10: 101.1 % Avg.: 100.0 % AV = 4.0
10	Microbiological Test		
	A. Microbial Enumeration Test		
	a. Total Aerobic Microbial Count (TAMC)	Not more than 1000 cfu/g	10 cfu/g
	b. Total combined Yeasts and Mould Count (TYMC)	Not more than 100 cfu/g	Less than 10 cfu/g
	B. Test for Specified Micro-Organisms		
	a. *Escherichia coli*	Must be absent / 1g	Absent / 1 g
11	Average weight	1040 mg ± 52 mg	1030.8 mg

Remarks: The above product complies with "Ph. Int. Tenth Edition, 2020 + IH" specification.

	Prepared By	Checked By	Approved By
Name	Wajed Khan.	Sanjay Bajpai	Rajendra Adavkar
Designation/Department	Sr. Manager/QC	Manager/QA	Manager/QA
Sign	Wajed Khan		
Date	12.08.2023.	12.08.2023	12/08/2023