MATRIX

Matrix Laboratories Limited
F-4 & F-12, Malegaon MIDC, Sinnar
Nashik - 422 113, Maharashtra, India

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Name of the Product :	Tenofovir Disoproxil Fumarate Tablets 300 mg		**A.R.No.**	:	MLN/CFP/91777
Batch No.	: 1024339		**Market**	:	PEPFAR
Mfg Date	: Nov.2009		**Batch Size**	:	8,00,000 Tablets
Exp Date	: Oct.2011		**Ref. Spec. No.**	:	FPSTDF007R-04
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S. No.	Test	Specification	Results
05	Related Substances (by HPLC)		
	a. Tenofovir	Not more than 0.2%	0.001 %
	b. Adenine impurity	Not more than 0.2%	Not detected
	c. Mono ester impurity	Not more than 3.0%	0.449 %
	d. Tenofovir disoproxil dimer impurity	Not more than 0.75%	0.049 %
	e. Any other individual unknown impurity	Not more than 0.2%	0.022 %
	f. Total impurities	Not more than 4.0%	0.650%
06	Assay	Tenofovir Disoproxil Fumarate tablets contain not less than 270.00 mg and not more than 315.00 mg of Tenofovir Disoproxil Fumarate, $C_{19}H_{30}N_5O_{10}P.C_4H_4O_4$ (90.0% w/w – 105.0% w/w of labeled amount of Tenofovir Disoproxil Fumarate)	298.04mg (99.3% w/w)
07	Water (by KF)	Not more than 3.5% w/w	3.07% w/w

Remarks: The above Product complies/ ~~Does not comply~~ with the specification No. FPSTDF007R-0

	Prepared By	Checked By	Approved By
Name	Mr. Raundal P.S.	D. D. Shelke	R. G. Akolkar
Sign	Raundal		
Date	01.01.2010	01.01.10	01.01.10

COA Issued On: 01-01-2010

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			Page No.	:	Page 1 of 2

S. No.	Test	Specification	Results
01	Description	Light blue colored, round biconvex film coated tablet debossed with "153" on one side and "M" on other side.	Light blue colored, round biconvex film coated tablet debossed with "153" on one side and "M" on other side.
02	Identification		
	A. By UV	The UV spectrum of the test should match with that of the standard.	The UV spectrum of the test matches with that of the standard.
	B. By HPLC	The retention time of the Tenofovir Disoproxil peak 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 Tenofovir Disoproxil peak in the chromatogram of the test preparation corresponds to that in the chromatogram of the standard preparation as obtained in the 'Assay by HPLC'.
03	Dissolution (by UV)	Complies with USP General Chapter <711> Not less than 80% (Q) of the labeled amount of Tenofovir Disoproxil Fumarate $C_{19}H_{30}N_5O_{10}P.C_4H_4O_4$ is dissolved in 30 minutes.	Complies Min: 102% Max:104 % Avg: 103% RSD: 0.7% Individual values 103%, 103%, 102%, 103%, 104%, 102%
04	Uniformity of dosage units (By weight variation)	Complies with USP General Chapter <905> The Acceptance Value (AV) should be not more than 15.0	Complies AV = 3.6

Contd.....

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