




CERTIFICATE OF ANALYSIS

WORKING STANDARD

Name	: Tenofovir Disoproxil Fumarate	A.R. No.	: MLAWSD16000055
Source Batch No.	: BTDFVSP10810216	Batch No	: 50056182
Date of Standardization	: 20/04/2016	Retest Date	: 18/10/2016
Ref.Specification	: RMSTDF515-02	Validity	: 18/04/2017
Storage Condition	: Store in tight, light resistant containers at 2°C to 8°C.	Standardized against:	Tenofovir Disoproxil Fumarate USPRS Lot. No. : G0M335

S.No.	Test	Specification	Results
1)	Description	White to off-white powder.	Off-white powder.
2)	Identification By Infrared Absorption	The absorption maxima in the spectrum obtained with the sample should correspond in position and relative intensity to those in the spectrum obtained with Tenofovir Disoproxil Fumarate working standard or reference standard.	The absorption maxima in the spectrum obtained with the sample corresponds in position and relative intensity to those in the spectrum obtained with Tenofovir Disoproxil Fumarate USPRS Lot. No. :G0M335
3)	Water content (By KF)	Not more than 1.0% w/w	0.38 % w/w
4)	Assay (By HPLC)	Not less than 98.0% w/w and not more than 102.0% w/w, on anhydrous basis. Also report on 'as-is' basis.	99.2 % w/w 98.8 % w/w

Remarks: This working standard complies/~~does not comply~~ with above reference specification.

	Prepared By	Checked By	Approved By
Name	Vishal Deore	Moham Moham	S. Gokulakrishnan
Sign			
Date	21/04/16	21/04/16	28 JUN 2016

MLLAGB-SOP-QC-GEN-0026 A19-02-09-15