



Mylan Laboratories Limited Plot No.H-12 & H-13, MIDC Waluj Industrial Area

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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	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
3)	Water content (By KF)	standard or reference standard. Not more than 1.0% w/w	Lot. No. :G0M335 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.	99.2 % w/w
		Also report on 'as-is' basis.	98.8 % w/w

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

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	Prepared By	Checked By Approved By
Name	Vishal Deove	Molan Mokash 3. Gokpan Shrian
Sign	9-	M 2 3 JUN 2010
Date	21/04/16	21104111 * FAX: 273001 Stry 13
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