

MYLAN LABORATORIES LIMITED Plot No. 11,12 and 13, Indore SEZ Pharma Zone, Phase –II, sector –III, Pithampur - 454775, Dist: Dhar, Madhya Pradesh, India.

CERTIFICATE OF ANALYSIS (WORKING STANDARD)

Name:: Tenofovir Disoprox	il Fumarate		
Source Batch No.	20157720	W.S. A.R. No.	MLPWSD23000011
Date of Standardisation	Mar 10 2023 1:54PM	Standardized against	Tenofovir Disoproxil
			Fumarate USPRS Batch No.:
			R08290
Storage Condition	Control Room Temprature	Validity	Mar 01, 2024
STP No.	RMPTDF067-06	Ref. Specification	RMSTDF067-06

S. No.	TEST	SPECIFICATION	RESULTS
1	Description	White to off white powder	Off white powder,
2	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 RS / working standard	The absorption maxima in the spectrum obtained with the sample correspond in position and relative intensity to those in the spectrum obtained with Tenofovir Disoproxil Fumarate RS
3	Assay (By HPLC)	On anhydrous basis: Not less than 98.0% w/w and not more than 102.0% w/w On as basis: For information	On as is basis:98.7 % On anhydrous basis:99.1 % w/w
4	Water content (by KF)	Not more than 1.0% w/w	0.42 % w/w

01 1 10	10	- Objective	Assessed Dec		Sharad kumar.Singh	
Checked By	Sande	ep.Shrotriya	Approved By		- J	
Checked On	Mar 10	2023 12:14PM	Approved On		Mar 10 2023 1:54PM	
Printed by: ANIRUDDHA.WAGHMARE		Printed on: Mar 1	Printed on: Mar 10 2023 2:06PM		Copy No.: 2	
-				Page No	o.: 1 of 1	

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