LAURUS Labs
Chemistry for Better Living

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002195

CERTIFICATE OF ANALYSIS

Product Name	Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets 50mg/200mg/25mg	A.R. No.	AR/FCD/2658/1224
Batch No.	24180413	Date of Release	29/10/2024
Manufacturing Date	Oct-2024	Batch size	1088523 Tablets
Shelf Life / Expiry Date	Sep-2027	Specification No.	PS/ADET1/01 Ver.No.:1
Pack Style	HDPE Bottle 30's	Market	PEPFAR

S.No	Test Parameter	Specification	Result
1	Description	White to off-white,oval shaped film-coated tablets debossed with 'L17' on one side and plain on other side	white,oval shaped film-coated tablets debossed with 'L17' on one side and plain on other side
2	Identification		
	A. By HPLC	The retention time of the main peaks of Dolutegravir, Emtricitabine & Tenofovir Alafenamide in the sample chromatogram should match with the retention times of standard chromatogram as obtained in Assay by HPLC	The retention time of the main peaks of Dolutegravir, Emtricitabine & Tenofovir Alafenamide in the sample chromatogram matches with the retention times of standard chromatogram as obtained in Assay by HPLC
	B. By TLC	The Retention factors (Rf) of Dolutegravir, Emtricitabine and Tenofovir Alafenamide in sample solution should match with that of the respective standard.	The Retention factors (Rf) of Dolutegravir, Emtricitabine and Tenofovir Alafenamide in sample solution matches with that of the respective standard.
	C. For Titanium Dioxide	A yellow red to an orange color should develop.	A yellow red to an orange color developed.
3	Water content by KF (% w/w)	Not more than 5.0	1.7
4	Uniformity of Dosage Units by HPLC (by Content Uniformity)		
	For Dolutegravir	The acceptance value should be not more than 15.0	3.3
	For Emtricitabine	The acceptance value should be not more than 15.0	2.4
	For Tenofovir Alafenamide	The acceptance value should be not more than 15.0	2.7
5	Dissolution by HPLC [Apparatus-2 (Paddle), 900mL of pH 6.8 Phosphate buffer with 0.1% SLS, 60 rpm]		
	For Dolutegravir	Not less than 80% (Q) of the labeled amount is dissolved in 45 minutes	1)93 2)92 3)91 4)90 5)90 6)88 Mean:90 Min:88 Max:93

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S.No	Test Parameter	Specification	Result		
	For Emtricitabine	Not less than 80 % (Q) of the labeled amount is dissolved in 30 minutes.	1)96 4)99 Mean:97	2)97 5)96 Min:96	3)100 6)96 Max:100
	For Tenofovir Alafenamide	Not less than 80 % (Q) of the labeled amount is dissolved in 30 minutes.	1)96 4)95 Mean:95	2)95 5)96 Min:93	3)97 6)93 Max:97
6	Assay by HPLC (% Label claim)				
	For Dolutegravir	Not less than 90.0 and not more than 110.0 of the labeled amount.	100.3		
	For Emtricitabine	Not less than 90.0 and not more than 110.0 of the labeled amount.	100.1		
	For Tenofovir Alafenamide	Not less than 90.0 and not more than 110.0 of the labeled amount	99.7		
7	Related Substances by HPLC (% w/w)				
	Method A (Tenofovir Alafenamide related)				
	Tenofovir impurity	Not more than 3.0	0.05		
	PMPA Anhydrate	Not more than 2.5	0.10		
	Phenol Impurity	Not more than 2.0	Below Disregard Limit		
	Phenyl PMPA	Not more than 0.75	Below Disregard Limit		
	PMPA isopropyl alaninate	Not more than 1.0	0.10		
	Method A (Emtricitabine related)				
	5-Fluorocytosine	Not more than 0.2	Below Disregard Limit		
	Sulfoxide isomer-1	Not more than 0.2	Below Disregard Limit		
	Sulfoxide isomer-2	Not more than 0.2	Below Disregard Limit		
	5-Fluorouracil analogue	Not more than 0.2	Below Disregard Limit		
	Any unspecified impurity	Not more than 0.2	0.05		
	Method B				
	Emtricitabine-cis-cyclic impurity	Not more than 1.0	Below Quantitation Limit		
	Emtricitabine-trans-cyclic impurity	Not more than 2.0	Below Quantitation Limit		
	Method C (Dolutegravir related)				
	Impurity B	Not more than 0.2	Below Disregard Limit		
	Any unspecified impurity	Not more than 0.2	Below Disregard Limit		

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S.No	Test Parameter	Specification	Result
	Total Impurities(Method A+Method B+Method C)	Not more than 7.0	0.30
8	Microbial Enumeration tests & tests for specified micro-organisms#		
	Total aerobic microbial count (CFU/g)	Not more than 10^3	Not Applicable
	Total Yeast and Molds Count (CFU/g)	Not more than 10^2	Not Applicable
	Escherichia coli (in 1g)	Must be absent	Not Applicable
9	Residual solvents	Meets requirements for residual solvents USP <467> as per Option 2 limits	Meets requirements for residual solvents USP <467> as per Option 2 limits
10	Elemental impurities	Meets the requirement for elemental impurities as per ICH Q3D, Option 3	Meets the requirement for elemental impurities as per ICH Q3D, Option 3

Remarks: The product complies / does not complies as per above specification.
Note: #This test is performed one batch annually.

	Prepared by	Reviewed by	Approved by
Name	P. Rajesh	T. Rama Krishnaiah	Venkatramireddy C.
Signature			
Date	26/12/2024	26/12/2024	26/12/2024
Department	QC	Q.C	

QUALITY ASSURANCE
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