

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Name of the Product :	Abacavir and Lamivudine Tablets USP (600mg / 300mg)	A.R.No. :	MLNFP23015528
Batch No. :	3194018	Market :	PERU (TEN)
Mfg. Date :	Oct. 2023	Batch Size :	1,200,000 Tablets
Exp. Date :	Sept. 2025	Ref. Spec. No. :	FPSABL515S-02
Date of Analysis :	23 November 2023	Page No. :	Page 1 of 4

S. No.	Test	Specification	Results
01	Description	Yellow colored, biconvex, film coated tablet, debossed with "M157" on one side and plain on the other side.	Yellow colored, biconvex, film coated tablet, debossed with "M157" on one side and plain on the other side.
02	Identification (By HPLC)	The retention times of the Abacavir and Lamivudine peaks 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 times of the Abacavir and Lamivudine peaks 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 HPLC)		
	Abacavir Sulfate USP equivalent to Abacavir 600 mg	Complies with USP General chapter <711> Not less than 80% (Q) of the labeled amount of Abacavir, $C_{14}H_{18}N_6O$ should be dissolved in 30 minutes.	Tablet-1 : 97 %, Tablet-2 : 102 %, Tablet-3 : 98 %, Tablet-4 : 99 %, Tablet-5 : 99 %, Tablet-6 : 101 % Min: 97 % Max: 102 % Avg: 100 % RSD: 1.8 %
	Lamivudine USP 300 mg	Complies with USP General chapter <711> Not less than 80% (Q) of the labeled amount of Lamivudine, $C_8H_{11}N_3O_3S$ should be dissolved in 30 minutes.	Tablet-1 : 101 %, Tablet-2 : 101 %, Tablet-3 : 99 %, Tablet-4 : 100 %, Tablet-5 : 98 %, Tablet-6 : 99 % Min: 98 % Max: 101 % Avg: 100 % RSD: 1.3 %

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S. No.	Test	Specification	Results
04	Uniformity of Dosage Units (By Content Uniformity)		
	Abacavir Sulfate USP equivalent to Abacavir 600 mg	Complies with USP General chapter <905> The Acceptance Value (AV) should be not more than 15.0	AV = 4.5
	Lamivudine USP 300 mg	Complies with USP General chapter <905> The Acceptance Value (AV) should be not more than 15.0	AV = 3.2
05	Assay (By HPLC)		
	Abacavir Sulfate USP equivalent to Abacavir 600 mg	Not less than 540.00 mg and not more than 660.00 mg of Abacavir, C ₁₄ H ₁₈ N ₆ O (90.0% w/w - 110.0% w/w of labeled amount of Abacavir)	607.91 mg (101.3% w/w)
	Lamivudine USP 300 mg	Not less than 270.00 mg and not more than 330.00 mg of Lamivudine, C ₈ H ₁₁ N ₃ O ₃ S (90.0% w/w - 110.0% w/w of labeled amount of Lamivudine)	303.24 mg (101.1% w/w)
06	Organic Impurities (By HPLC)		
	A. Abacavir impurities		
	Cyclopropyldiaminopurine abacavir	Not more than 0.2% w/w	Less than 0.05% w/w
	Descyclopropyl abacavir	Not more than 0.2% w/w	Less than 0.05% w/w
	Total abacavir related impurities	Not more than 1.0% w/w	Less than 0.05% w/w

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S. No.	Test	Specification	Results
	B. Lamivudine impurities		
	Cytosine	Not more than 0.2% w/w	Not detected
	Lamivudine-S-sulfoxide	Not more than 0.2% w/w	Less than 0.05% w/w
	Lamivudine-R-sulfoxide	Not more than 0.2% w/w	Less than 0.05% w/w
	Lamivudine-uracil derivative	Not more than 0.2% w/w	Less than 0.05% w/w
	Total lamivudine related impurities	Not more than 0.6% w/w	Less than 0.05% w/w
	C. Any individual unspecified impurity	Not more than 0.2% w/w	Less than 0.05% w/w

Additional Tests :

07	Identification (By Thin-layer chromatography)	The R _F value of the principal spots obtained from the test solution should correspond to that obtained from the standard solution.	The R _F value of the principal spots obtained from the test solution corresponds to that obtained from the standard solution.
08	Color identifications		
	A. For Iron oxide	A deep red colour should develop, which does not disappear upon addition of dilute mineral acid.	A deep red colour developed, which does not disappear upon addition of dilute mineral acid.
	B. For Titanium dioxide	A yellow-red to orange-red color should be developed immediately.	An orange-red color is developed immediately.
09	Loss on drying	Not more than 7.0% w/w	2.10% w/w

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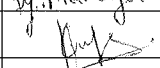
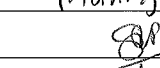
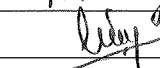
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S. No.	Test	Specification	Results
10	Microbiological Test		
	A. Microbial Enumeration Tests		
	a. Total Aerobic Microbial Count (TAMC)	Not more than 1000 cfu/g	Less than 10 cfu/g
	b. Total Combined Yeasts / Moulds Count (TYMC)	Not more than 100 cfu/g	Less than 10 cfu/g
	B. Test for Specified Micro-organisms		
	a. <i>Escherichia coli</i>	Must be absent / g	Absent / g

Remarks: The above product complies with the specification USP-NF 2021 + IH.

	Prepared By	Checked By	Approved By
Name	Vaibhav Khasu	Sonjay Bajaj	Rajendra Adavkar
Designation / Department	Off. Manager / QA	Manager QA	Manager / QA
Sign			
Date	23/11/23	23/11/23	23/11/2023