Mylan Laboratories Limited
F-4 & F-12, Malegaon MIDC, Sinnar,
Nashik-422 113, Maharashtra, India,
Tel : +91 (2551) 230092, 230093, 304777
Fax : +91 (2551) 230924

# CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

| | | | | | |
|---|---|---|---|---|---|
| **Name of the Product :** | | Abacavir and Lamivudine Tablets USP (600mg / 300mg) | **A.R.No.** | : | MLNFP23015498 |
| **Batch No.** | : | 8171916 | **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** | : | 22 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><br>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 : 101 %,<br>Tablet-2 : 105 %,<br>Tablet-3 : 99 %,<br>Tablet-4 : 101 %,<br>Tablet-5 : 101 %,<br>Tablet-6 : 99 %<br>Min: 99 %<br>Max: 105 %<br>Avg: 101 %<br>RSD: 2.1 % |
| | Lamivudine USP 300 mg | Complies with USP General chapter <711><br>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 : 100 %,<br>Tablet-2 : 100 %,<br>Tablet-3 : 101 %,<br>Tablet-4 : 100 %,<br>Tablet-5 : 100 %,<br>Tablet-6 : 100 %<br>Min: 100 %<br>Max: 101 %<br>Avg: 100 %<br>RSD: 0.6 % |

Contd....

Mylan Laboratories Limited
F-4 & F-12, Malegaon MIDC, Sinnar,
Nashik-422 113, Maharashtra, India,
Tel : +91 (2551) 230092, 230093, 304777
Fax : +91 (2551) 230924

# CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

| | | | | | |
|---|---|---|---|---|---|
| **Name of the Product :** | | Abacavir and Lamivudine Tablets USP (600mg / 300mg) | **A.R.No.** | : | MLNFP23015498 |
| **Batch No.** | : | 8171916 | **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** | : | 22 November 2023 | **Page No.** | : | Page 2 of 4 |

| 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 = 7.8 |
| | Lamivudine USP 300 mg | Complies with USP General chapter <905> The Acceptance Value (AV) should be not more than 15.0 | AV = 4.0 |
| 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, $C_{14}H_{18}N_6O$ (90.0% w/w - 110.0% w/w of labeled amount of Abacavir) | 598.81 mg (99.8% w/w) |
| | Lamivudine USP 300 mg | Not less than 270.00 mg and not more than 330.00 mg of Lamivudine, $C_8H_{11}N_3O_3S$ (90.0% w/w – 110.0% w/w of labeled amount of Lamivudine) | 299.71 mg (99.9% 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 |

Contd....

Mylan Laboratories Limited
F-4 & F-12, Malegaon MIDC, Sinnar,
Nashik-422 113, Maharashtra, India,
Tel : +91 (2551) 230092, 230093, 304777
Fax : +91 (2551) 230924

# CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

| | | | | | |
|---|---|---|---|---|---|
| **Name of the Product :** | | Abacavir and Lamivudine Tablets USP (600mg / 300mg) | **A.R.No.** | : | MLNFP23015498 |
| **Batch No.** | : | 8171916 | **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** | : | 22 November 2023 | **Page No.** | : | Page 3 of 4 |

| S. No. | Test | Specification | Results |
|---|---|---|---|
| | B. Lamivudine impurities | | |
| | Cytosine | Not more than 0.2% w/w | Less than 0.05% w/w |
| | 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 developed immediately. |
| 09 | Loss on drying | Not more than 7.0% w/w | 1.87% w/w |

Contd....

Mylan Laboratories Limited
F-4 & F-12, Malegaon MIDC, Sinnar,
Nashik-422 113, Maharashtra, India,
Tel : +91 (2551) 230092, 230093, 304777
Fax : +91 (2551) 230924

# CERTIFICATE OF ANALYSIS

## FINISHED PRODUCT

| | | | | | |
|---|---|---|---|---|---|
| **Name of the Product :** | | Abacavir and Lamivudine Tablets USP (600mg / 300mg) | **A.R.No.** | : | MLNFP23015498 |
| **Batch No.** | : | 8171916 | **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** | : | 22 November 2023 | **Page No.** | : | Page 4 of 4 |

| 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. *Escherichia coli* | 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 Patil | Sanjay Bajpai | Rajendra Adavlekar |
| Designation / Department | Dy. Manager / QC | Manager | Manager / QA |
| Sign | | | |
| Date | 22.11.2023 | 22.11.2023 | 22/11/2023 |