# ZEE LABORATORIES

47, Industrial Area, Gondpur Paonta Sahib Sirmour HP INDIA 173025

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drugs & Cosmetics Act 1940 at the under form 39)

**Work Order No. :** 252612889 **Document No. :** 252615964

| | | | |
|---|---|---|---|
| **Ref. STS No.** | APNT-254/00 | **Product Code** | FG04109 |
| **Product Name** | TAB. AMOLINE 2.5 | | |
| **Generic Name** | Amlodipine Tablets I.P. 2.5MG | | |
| **Batch No.** | 425-1035 | **Date Of Sampling** | 05/07/2025 |
| **Batch Size** | 200000.000 Tab | **Sample Quantity** | 100.000 Tab |
| **Mfg. Date** | 06/2025 **Exp. Date** 11/2027 | **Date Of Analysis** | 05/07/2025 |
| **A. R. No.** | ZL25FG02984 | **Date Of Release** | 07/07/2025 |

| S NO. | Tests | Specification | Results |
|---|---|---|---|
| 1 | Description | White coloured, round, flat, uncoated tablet, plain on both sides | Complies |
| 2 | Identification | Should be positive for Amlodipine Besylate | Complies |
| 3 | Average weight | 120.0 mg ± 7.50% | 118.52 mg |
| 4 | Uniformity of weight | ± 7.5% of the average weight | Complies |
| 5 | Uniformity of contents | ± 7.5% of the average weight | Complies |
| 6 | Disintegration Time | NMT 15 minutes | 3 min |
| 7 | Organic Impurity | Amlodipine related compound A: NMT 1.0% | Complies |
| 8 | Organic Impurity | Amlodipin lactose adduct: NMT 0.5% | Complies |
| 9 | Organic Impurity | Amlodipine glucose/galactose adduct: NMT 0.5% | Complies |
| 10 | Organic Impurity | Any unspecified degradation product: NMT 0.2% | Complies |
| 11 | Dissolution Test Medium: 0.01 M HCl, 500 ml | NLT Q+75% in 30 minutes at 75rpm | 84.85% |
| 12 | Assay: Each uncoated tablet contains: Amlodipine Besylate I.P. Eq. to Amlodipine 2.5 mg | NLT 90.0 and NMT 110.0 of the labelled amount of Amlodipine | 98.36 % |

**Remarks** The above sample complies/~~does not comply~~ with prescribed standards of Quality with respect to above tests as p IP/BP/USP/In house specification.

| Particulars | Prepared / Analysed by | Reviewed By | Approved/Authorized By |
|---|---|---|---|
| Signature: | Ravi | | |
| Name: | Ravi Gautam | Sunil Kohli | Amit Srivastava |
| Designation: | QC Executive | Astt. QCM | QCM |
| Date | 07/07/2025 | 07/07/2025 | 07/07/2025 |

Quality Control Manager