# ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

**Quality Control Department**

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

| | | | |
|---|---|---|---|
| **Product Name** | Telmaheal 40-AMH | **A.R. No.** | FG/G/24A1090 |
| **Generic Name** | Telmisartan, Amlodipine and Hydrochlorothiazide Tablets | **Sample Quantity** | 90 Tablets |
| **Batch No.:** | AGT40776 | **Sample Received on** | 31/07/2024 |
| **Batch Size:** | 1.50 Lac | **Analysis Date** | 31/07/2024 |
| **Mfg. Date.** | 07/2024 | **Release Date** | 08/08/2024 |
| **Exp. Date** | 06/2026 | **Page No.:** | Page 1 of 2 |

| Sr. No. | Test Parameter | Acceptance Criteria | Result |
|---|---|---|---|
| 1. | **Description** | White and blue coloured, round shaped, biconvex, both side plain, uncoated bilayered tablet. | White and blue coloured, round shaped, biconvex, both side plain, uncoated bilayered tablet. |
| 2. | **Identification** | In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution. | Complies |
| 3. | **Average weight** | 300.00 mg ± 3% | 298.87 mg |
| 4. | **Uniformity of weight** | ± 5% of its average weight. | Min: 284.26 mg ; Max: 307.16 mg<br>-4.89% ; +2.77% |
| 5. | **Disintegration** | Not more than 15 minutes. | 10 minutes 30 seconds. |
| 6. | **Hardness** | Not less than 4.0 $Kg/cm^2$ | 4.58 $Kg/cm^2$ |
| 7. | **Friability** | Not more than 1.0% w/w | 0.06 % w/w |
| 8. | **Uniformity of content:** | | |
| | **For Amlodipine** | The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25) | 2.39 |
| | **For Hydrochlorothiazide** | The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25) | 3.73 |

**9. Assay :**

| Each uncoated bilayered tablet contains: | Claim | Limit | mg | % |
|---|---|---|---|---|
| **Telmisartan IP** | **40 mg** | Between 90.0% to 110.0% (Between 36.0 mg to 44.0 mg) | 39.6177 mg | 99.04% |
| **Amlodipine Besylate IP Eq. to Amlodipine** | **5 mg** | Between 90.0% to 110.0% (Between 4.5 mg to 5.5 mg) | 4.9234 mg | 98.47% |
| **Hydrochlorothiazide IP** | **12.5 mg** | Between 90.0% to 110.0% (Between 11.25 mg to 13.75 mg) | 12.1373 mg | 97.10% |

| Particulars | Prepared By | Checked By | Approved By |
|---|---|---|---|
| **Name** | Praveen Kumar | DORGESH KUMAR | Gautam Singh |
| **Designation** | Executive | QC Head | Head-QA |
| **Signature** | | | |
| **Date** | 08/08/2024 | 08/08/2024 | 08/08/2024 |

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| | | | |
|---|---|---|---|
| **10.** | **Microbial Limit Tests:** | | |
| **i.** | **Total aerobic microbial count** | NMT 1000 cfu/g | 50 cfu/g |
| **ii.** | **Total yeast and mould count** | NMT 100 cfu/g | Less than 10 cfu/g |
| **iii.** | **Pathogens: Escherichia coli** | Should be absent/g | Absent/g |

**Remarks:** The above test parameters are complies/ ~~not complies~~ as per ~~IP/BP/USP~~ & In-House Specification.

| **Particulars** | **Prepared By** | **Checked By** | **Approved By** |
|---|---|---|---|
| **Name** | Praveen Kumar | DURGESH KUMAR | Gautam singh |
| **Designation** | Executive | QC Head | Head-QA |
| **Signature** | | | |
| **Date** | 08/08/2024 | 08/08/2024 | 08/08/2024 |