



# 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-80                 | A.R. No.           | FG/G/24A1281 |
| Generic Name | Telmisartan Tablets IP 80 mg | Sample Quantity    | 75 Tablets   |
| Batch No.:   | AGT40889                     | Sample Received on | 13/09/2024   |
| Batch Size:  | 1.50 Lac                     | Analysis Date      | 13/09/2024   |
| Mfg. Date.   | 08/2024                      | Release Date       | 20/09/2024   |
| Exp. Date    | 07/2026                      | Page No.:          | Page 1 of 1  |

| Sr. No. | Test Parameter                 | Acceptance Criteria                                                                                                                                                    | Result                                                                             |           |                    |  |
|---------|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-----------|--------------------|--|
| 1.      | Description                    | Brick red colour, round shaped, biconvex, having both side plain, uncoated tablet.                                                                                     | Brick red colour, round shaped, biconvex, having both side plain, uncoated 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%                                                                                                                                                         | 303.553 mg                                                                         |           |                    |  |
| 4.      | Uniformity of weight           | ± 5.0% of its average weight.                                                                                                                                          | Min: 296.11 mg ; Max: 307.23 mg<br>-2.45% ; +1.21%                                 |           |                    |  |
| 5.      | Disintegration                 | Not more than 15 minutes.                                                                                                                                              | 09 minutes 35 seconds.                                                             |           |                    |  |
| 6.      | Hardness                       | Not less than 4.0 Kg/cm <sup>2</sup>                                                                                                                                   | 6.75 Kg/cm <sup>2</sup>                                                            |           |                    |  |
| 7.      | Friability                     | Not more than 1.0%w/w                                                                                                                                                  | 0.28 %w/w                                                                          |           |                    |  |
| 8.      | Dissolution                    | Not less than 75.0% (Q) of the labeled amount is dissolved in 30 minutes.                                                                                              | Minimum = 88.48%<br>Maximum = 91.54%<br>Average = 89.72%                           |           |                    |  |
| 9.      | Assay:                         |                                                                                                                                                                        |                                                                                    |           |                    |  |
|         | Each uncoated tablet contains: | Claim                                                                                                                                                                  | Limit                                                                              | mg        | %                  |  |
|         | Telmisartan IP                 | 80 mg                                                                                                                                                                  | Between 90.0 % to 110.0 % of labeled amount.<br>(Between 72.0 mg to 88.0 mg)       | 82.016 mg | 102.52 %           |  |
| 10.     | Microbial Limit Tests:         |                                                                                                                                                                        |                                                                                    |           |                    |  |
| i.      | Total aerobic microbial count  | NMT 1000 cfu/g                                                                                                                                                         |                                                                                    |           | 40 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 | Tanvej        | Shashi Kumar |
| Designation | Executive     | Sr. Executive | Manager - QA |
| Signature   |               |               |              |
| Date        | 20/09/2024    | 20/09/2024    | 20/09/2024   |