



# ALVENTA PHARMA LIMITED

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

## Quality Control Department

### CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

|              |                                         |                    |              |
|--------------|-----------------------------------------|--------------------|--------------|
| Product Name | Tamsuheal 0.4 mg                        | A.R. No.           | FG/G/24A1596 |
| Generic Name | Tamsulosin HCl Modified Release Tablets | Sample Quantity    | 120 Tablets  |
| Batch No.    | AGT41142                                | Sample Received on | 30/11/2024   |
| Batch Size   | 2.0 Lac                                 | Analysis Date      | 30/11/2024   |
| Mfg. Date    | 11/2024                                 | Release Date       | NA           |
| Exp. Date    | 10/2026                                 | Page No.           | Page 1 of 1  |

| Sr. No. | Test Parameter                                            | Acceptance Criteria                                                                                                                                                                          | Result                                                                       |            |         |
|---------|-----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------|---------|
| 1.      | Description                                               | White colour, round shaped, biconvex, both side plain, film coated tablet.                                                                                                                   | White colour, round shaped, biconvex, both side plain, film coated tablet.   |            |         |
| 2.      | Identification                                            | In the assay, the retention time of 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                                            | 173.00 mg ± 3%                                                                                                                                                                               | 174.72 mg                                                                    |            |         |
| 4.      | Uniformity of weight                                      | ± 7.5 % of its average weight.                                                                                                                                                               | Min: 171.46 mg ; Max: 178.17 mg<br>- 1.87% ; + 1.98%                         |            |         |
| 5.      | Hardness                                                  | NLT 4.0 Kg/cm <sup>2</sup>                                                                                                                                                                   | 10.91 Kg/cm <sup>2</sup>                                                     |            |         |
| 6.      | Uniformity of content (Tamsulosin HCl)                    | The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)                                                                                 | 4.65                                                                         |            |         |
| 7.      | Dissolution:                                              |                                                                                                                                                                                              |                                                                              |            |         |
|         | 2 <sup>nd</sup> hour                                      | 15.00% to 40.00%.                                                                                                                                                                            | Min. = 21.86%, Max. = 35.68%,<br>Mean = 29.40%                               |            |         |
|         | 6 <sup>th</sup> hour                                      | 50.00% to 70.00%.                                                                                                                                                                            | Min. = 52.39%, Max. = 73.07%,<br>Mean = 62.35%                               |            |         |
|         | 12 <sup>th</sup> hour                                     | Not less than 80.00% of labeled amount of Tamsulosin                                                                                                                                         | Min. = 81.53%, Max. = 103.97%,<br>Mean = 92.93%                              |            |         |
| 8.      | Assay: Each film coated modified release tablet contains: |                                                                                                                                                                                              |                                                                              |            |         |
|         | Tamsulosin Hydrochloride IP                               | Claim                                                                                                                                                                                        | Limit                                                                        | mg         | %       |
|         |                                                           | 0.4 mg                                                                                                                                                                                       | Between 90.00 % to 110.00 % of stated amount<br>(Between 0.36 mg to 0.44 mg) | 0.40534 mg | 101.33% |
| 9.      | Microbial Limit Tests:                                    |                                                                                                                                                                                              |                                                                              |            |         |
| i.      | Total aerobic microbial count                             | NMT 1000 cfu/g                                                                                                                                                                               |                                                                              | Under test |         |
| ii.     | Total yeast and mould count                               | NMT 100 cfu/g                                                                                                                                                                                |                                                                              | Under test |         |
| iii.    | Pathogens: Escherichia coli                               | Should be absent/g                                                                                                                                                                           |                                                                              | Under test |         |

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 | Kuljeet Kaur | Kavita Nandwani |
| Designation | Executive     | Head QC      | QA Manager      |
| Signature   |               |              |                 |
| Date        | 30/11/2024    | 30/11/2024   | 30/11/2024      |