



# ALVENTA PHARMA LIMITED

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

## Quality Control Department

### CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

|              |                                        |                    |              |
|--------------|----------------------------------------|--------------------|--------------|
| Product Name | Omforce-D                              | A.R. No.           | FG/G/24A0009 |
| Generic Name | Omeprazole and Domperidone Capsules IP | Sample Quantity    | 60 Capsules  |
| Batch No.:   | AGC40103                               | Sample Received on | 19/01/2024   |
| Batch Size:  | 7.50 Lac                               | Analysis Date      | 19/01/2024   |
| Mfg. Date.   | 01/2024                                | Release Date       | 25/01/2024   |
| Exp. Date    | 12/2025                                | Page No.:          | Page 1 of 2  |

| Sr. No. | Test Parameter                             | Acceptance Criteria                                                                                                                                                     | Result                                                                                                                   |          |         |
|---------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|----------|---------|
| 1.      | Description                                | Blue colored caps & transparent colored body filled with white and orange colour pellets, size “2” hard gelatin capsule.                                                | Blue colored caps & transparent colored body filled with white and orange colour pellets, size “2” hard gelatin capsule. |          |         |
| 2.      | Identification                             | In the assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the reference solution. | Complies                                                                                                                 |          |         |
| 3.      | Average filled weight                      | 275.0 mg ± 5.0%.                                                                                                                                                        | 281.80 mg                                                                                                                |          |         |
| 4.      | Uniformity of filled weight                | ± 10 % of average filled weight.                                                                                                                                        | Min: 268.94 mg ; Max: 293.43 mg<br>- 4.57% ; + 4.13%                                                                     |          |         |
| 5.      | Disintegration                             | Not more than 30 minutes.                                                                                                                                               | 07 minutes 36 seconds.                                                                                                   |          |         |
| 6.      | Dissolution:                               |                                                                                                                                                                         |                                                                                                                          |          |         |
|         | For Omeprazole:                            |                                                                                                                                                                         |                                                                                                                          |          |         |
|         | Acid Medium                                | Not more than 10.0%                                                                                                                                                     | Min. = 4.86% ; Max. = 7.58%<br>Avg. = 6.48%                                                                              |          |         |
|         | Buffer Medium                              | Not less than 70.0% (Q)                                                                                                                                                 | Min. = 76.30% ; Max. = 102.70%<br>Avg. = 84.46%                                                                          |          |         |
|         | For Domperidone                            | Not less than 75.0% (Q)                                                                                                                                                 | Min. = 99.40% ; Max. = 106.40%<br>Avg. = 103.07%                                                                         |          |         |
| 7.      | Uniformity of content (For Domperidone)    | The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)                                                            | 5.36                                                                                                                     |          |         |
| 8.      | Assay:                                     |                                                                                                                                                                         |                                                                                                                          |          |         |
|         | Each hard gelatin capsule contains:        | Claim                                                                                                                                                                   | Limit                                                                                                                    | mg       | %       |
|         | Omeprazole IP (As enteric coated granules) | 20 mg                                                                                                                                                                   | Between 90.0% to 110.0% stated amount of Omeprazole (Between 18.0 mg to 22.0 mg)                                         | 19.98 mg | 99.90%  |
|         | Domperidone IP (As granules)               | 10 mg                                                                                                                                                                   | Between 90.0% to 110.0% of the Stated amount Domperidone (Between 9.0 mg to 11.0 mg)                                     | 10.14 mg | 101.40% |

| Particulars | Prepared By   | Checked By    | Approved By  |
|-------------|---------------|---------------|--------------|
| Name        | Harveen Kumar | BURGESH KUMAR | Gautam Singh |
| Designation | Executive     | QC Head       | Head-QA      |
| Signature   |               |               |              |
| Date        | 25/01/2024    | 25/01/2024    | 25/01/2024   |



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| Sr. No. | Test Parameter                | Acceptance Criteria | Result             |
|---------|-------------------------------|---------------------|--------------------|
| 9.      | Microbial Limit Tests:        |                     |                    |
| i.      | Total aerobic microbial count | NMT 1000 cfu/g      | 20 cfu/g           |
| ii.     | Total yeast & mould count     | NMT 100 cfu/g       | Less than 10 cfu/g |
| iii.    | Pathogen: E. 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        | 25/01/2024    | 25/01/2024    | 25/01/2024   |