



# ALVENTA PHARMA LIMITED

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

## Quality Control Department

### CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

|              |                          |                    |              |
|--------------|--------------------------|--------------------|--------------|
| Product Name | Cortibrook-6             | A.R. No.           | FG/G/24A0382 |
| Generic Name | Deflazacort Tablets 6 mg | Sample Quantity    | 120 Tablets  |
| Batch No.:   | AGT40523                 | Sample Received on | 11/05/2024   |
| Batch Size:  | 2.0 Lac                  | Analysis Date      | 11/05/2024   |
| Mfg. Date.   | 05/2024                  | Release Date       | 18/05/2024   |
| Exp. Date    | 04/2026                  | Page No.:          | Page 1 of 1  |

Exp. Date: 07/2023

| Sr.No. | Test Parameter                 | Acceptance Criteria                                                                                                                                                              | Result                                                                         |                    |         |
|--------|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------|---------|
| 1.     | Description                    | White colour, round shaped, biconvex, having both side plain, uncoated tablet.                                                                                                   | White 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 should be corresponds to the peak in the chromatogram obtained with the reference solution. | Complies                                                                       |                    |         |
| 3.     | Average weight                 | 170.00 mg $\pm$ 3%                                                                                                                                                               | 170.217 mg                                                                     |                    |         |
| 4.     | Uniformity of weight           | $\pm$ 7.5% of its average weight.                                                                                                                                                | Min: 166.87 mg ; Max: 177.28 mg<br>-1.97% ; + 4.15%                            |                    |         |
| 5.     | Disintegration                 | Not more than 15 minutes.                                                                                                                                                        | 00 minutes 59 seconds.                                                         |                    |         |
| 6.     | Hardness                       | NLT 4.0 Kg/cm <sup>2</sup>                                                                                                                                                       | 5.68 Kg/cm <sup>2</sup>                                                        |                    |         |
| 7.     | Friability                     | NMT 1.0 %w/w                                                                                                                                                                     | 0.29 %w/w                                                                      |                    |         |
| 8.     | Dissolution                    | Not less than 75.0%                                                                                                                                                              | Minimum = 89.39%<br>Maximum = 98.61%<br>Average = 96.93%                       |                    |         |
| 9.     | Uniformity of content          | The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)                                                                     | 2.09                                                                           |                    |         |
| 10.    | Assay:                         |                                                                                                                                                                                  |                                                                                |                    |         |
|        | Each uncoated tablet contains: | Claim                                                                                                                                                                            | Limit                                                                          | mg                 | %       |
|        | Deflazacort                    | 6 mg                                                                                                                                                                             | Between 90.0 % to 110.0 % of stated amount<br>(Between 5.4 mg to 6.6 mg)       | 6.05729 mg         | 100.95% |
| 11.    | Microbial Limit Tests:         |                                                                                                                                                                                  |                                                                                |                    |         |
| i.     | Total aerobic microbial count  | NMT 1000 cfu/g                                                                                                                                                                   |                                                                                | 30 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        | 18/05/2024    | 18/05/2024    | 18/05/2024   |