



# ALVENTA PHARMA LIMITED

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

Quality Control Department

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

|              |                                   |                    |              |
|--------------|-----------------------------------|--------------------|--------------|
| Product Name | Citistroke-2                      | A.R. No.           | FG/G/24A0040 |
| Generic Name | Citicoline Injection IP 250 mg/ml | Sample Quantity    | 65 Ampoules  |
| Batch No.:   | AA40507                           | Sample Received on | 25/05/2024   |
| Batch Size:  | 5300 Ampoules                     | Analysis Date      | 25/05/2024   |
| Mfg. Date.   | 05/2024                           | Release Date       | 08/06/2024   |
| Exp. Date    | 04/2027                           | Page No.:          | Page 1 of 1  |

| Sr. No. | Test Parameter                         | Acceptance Criteria  | Result  |             |         |
|---------|--|--|---|-------------|---------|
| 1.      | Description                            | A clear colourless liquid filled in 2 ml clear glass ampoule.  | A clear colourless liquid filled in 2 ml clear glass ampoule.                               |             |         |
| 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.      | pH                                     | Between 6.3 to 8.0   | 6.54  |             |         |
| 4.      | Extractable volume                     | Not less than 2.0 ml   | 2.17 ml   |             |         |
| 5.      | Particulate Matter                     | The Solution should be clear, colourless and free from any visible particle.   | The Solution is clear, colourless and free from any visible particle.                       |             |         |
| 6.      | Sterility                              | Should be sterile  | Sterile   |             |         |
| 7.      | Bacterial Endotoxins Tests             | NMT 0.175 EU/mg of Citicoline  | Less than 0.175 EU/mg   |             |         |
| 8.      | Assay:                                 |  |   |             |         |
|         | Each ml contains:                      | Claim  | Limit   | mg          | %       |
|         | Citicoline Sodium IP Eq. to Citicoline | 250 mg   | Between 90.0 % to 110.0 % of stated amount of Citicoline.<br>(Between 225.0 mg to 275.0 mg) | 243.1060 mg | 97.24 % |

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        | 08/06/2024    | 08/06/2024    | 08/06/2024   |