



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

:

## Certificate of Analysis Finished Product

|              |                             |                 |               |
|--------------|-----------------------------|-----------------|---------------|
| Product Name | CITISTROKE Injection IP 2ml | A.R. No.        | ARN/FP/25/051 |
| Generic Name | Citicoline Injection IP     | Sampled qty.    | 45 Ampoules   |
| Batch No.    | ARN2562A                    | Sampled by      | Rakesh        |
| Batch Size   | 24,975 Ampoule              | Sampled on      | 21/11/2025    |
| Mfg. Date    | 11/2025                     | Date of Testing | 21/11/2025    |
| Exp. Date    | 10/2027                     | Date of Release | 07/12/2025    |

| S. No.                                     | Tests  | Specifications   | Observations   |                            |
|--|--|--|--|----------------------------|
| 1.   | Description  | A clear colourless solution filled in clear glass ampoule.   | A clear colourless solution filled in clear glass ampoule. |                            |
| 2.   | Identification   | In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the working standard solution.                          | Complies   |                            |
| 3.   | Nominal fill volume  | NLT 2 ml   | 2.0 ml   |                            |
| 4.   | Extractable Volume   | NLT Nominal volume or NMT 110% of Nominal volume.  | 2.1 ml   |                            |
| 5.   | Related Substances   |  |  |                            |
|  | 5-cytidylic acid   | NMT- 1.5%  | Not Detected   |                            |
|  | Any other secondary peak   | NMT- 0.5%  | Not Detected   |                            |
|  | Sum of all secondary peak other than 5'cytidylic acid  | NMT- 2.0%  | Not Detected   |                            |
| 6.   | pH   | 6.3 to 8.0   | 7.15   |                            |
| 7.   | Particulate Matter<br>(A.) Light Obscuration.<br>Particle Count Test<br>(1.) Particles $\geq 10\mu\text{m}$<br>(2.) Particles $\geq 25\mu\text{m}$<br>(B.) Visual Particle | NMT-6000/Ampoule<br>NMT-600/Ampoule<br>The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection. | 23/Ampoule<br>0/Ampoule<br>Complies                        |                            |
| 8.   | Sterility  | No microbial growth should be observed.  | Complies   |                            |
| 9.   | Bacterial Endotoxins   | NMT 0.175 EU/mg of Citicoline.   | Less than 0.175 EU/mg of Citicoline.                       |                            |
| 10.  | Assay:<br>Each ml contains:  |  |  |                            |
| Ingredients                                | Labeled Claim  | Found  | % of labeled amount  | Limits % of labeled amount |
| Citicoline Sodium I.P<br>Eq. to Citicoline | 250 mg   | 256.51mg   | 102.60%  | 90.0% to 110.0%            |

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not complies as per IP/BP/USP/HHS.

|  |  |                                       |
|--|--|---------------------------------------|
| Analysis by<br><br>NAME: SHAHRUKH KHAN | Checked by<br><br>NAME: SUFIYAN ANSARI | Approved by<br><br>NAME: SWATI DHAWAN |
|--|--|---------------------------------------|