

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

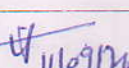
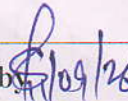
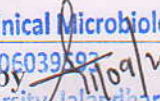
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

**Title : Certificate of Analysis Finished Product**

|              |                             |                 |               |
|--------------|-----------------------------|-----------------|---------------|
| Product Name | TERLISIN Injection          | A.R. No.        | ARN/FP/26/058 |
| Generic Name | Terlipressin Injection 10ml | Sampled qty.    | 45 Ampoules   |
| Batch No.    | ARN2657A                    | Sampled by      | Rakesh        |
| Batch Size   | 10,000 Ampoules             | Sampled on      | 27/08/2026    |
| Mfg. Date    | 08/2026                     | Date of Testing | 27/08/2026    |
| Exp. Date    | 07/2028                     | Date of Release | 11/09/2026    |

| 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 principle peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.                                                   | Complies                                                   |                      |                             |
| 3.                        | Nominal fill volume                                                                                                                                                       | NLT 10ml                                                                                                                                                                                                         | 10.0 ml                                                    |                      |                             |
| 4.                        | Extractable Volume                                                                                                                                                        | NLT Nominal volume or NMT 110% of Nominal volume.                                                                                                                                                                | 10.1 ml                                                    |                      |                             |
| 5.                        | pH (IHS)                                                                                                                                                                  | 3.5 to 5.0                                                                                                                                                                                                       | 4.71                                                       |                      |                             |
| 6.                        | 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. | 378/Ampoule<br>4/Ampoule<br>Complies                       |                      |                             |
| 7.                        | Sterility                                                                                                                                                                 | No microbial growth should be observed.                                                                                                                                                                          | Complies                                                   |                      |                             |
| 8.                        | Bacterial Endotoxins                                                                                                                                                      | NMT 41.66 EU/mg of Terlipressin Acetate.                                                                                                                                                                         | Less than 41.66 EU/mg of Terlipressin Acetate.             |                      |                             |
| 9.                        | Assay: (By HPLC)<br>Each ml contains:                                                                                                                                     |                                                                                                                                                                                                                  |                                                            |                      |                             |
| Ingredients               |                                                                                                                                                                           | Labelled Claim                                                                                                                                                                                                   | Found                                                      | % of labelled amount | Limits % of labelled amount |
| Terlipressin (as Acetate) |                                                                                                                                                                           | 0.10 mg                                                                                                                                                                                                          | 0.10339 mg                                                 | 103.39%              | 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/IHS.

|                                                                                                                     |                                                                                                                       |                                                                                                                              |
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| Analysis by <br>NAME: FIROJ KHAN | Checked by <br>NAME: SURJEET KAUR | Approved by <br>NAME: MRS. SWATI DHAWAN |
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