# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

**Title : Certificate of Analysis Finished Product**

| | | | |
|---|---|---|---|
| **Product Name** | **AMPIGYL-SB** Injection | **A.R. No.** | ARB/FP/25/016 |
| **Generic Name** | Ampicillin & Sulbactam for Injection 1.5gm | **Sampled qty.** | 45 Vials |
| **Batch No.** | ARB2612A | **Sampled by** | Rakesh |
| **Batch Size** | 10,000 Vials | **Sampled on** | 24/06/2026 |
| **Mfg. Date** | 06/2026 | **Date of Testing** | 25/06/2026 |
| **Exp. Date** | 05/2028 | **Date of Release** | 10/07/2026 |

| S. No. | Tests | Specifications | Observations |
|---|---|---|---|
| 1. | Description | A white or almost white powder filled in clear glass vial. | Almost white powder filled in clear glass vial. |
| 2. | Identification | In the Assay, the principal peaks of Ampicillin & sulbactam in the chromatogram obtained with the test solution corresponds to the peak of Ampicillin & sulbactam in the chromatogram obtained with the working standard solution. | Complies |
| 3. | Uniformity of Weight | Average weight ±10% | -1.40% & +1.31% |
| 4. | Average weight | Informative ±2%. | 1649.2 mg |
| 5. | Particulate Matter | | |
| | (A.) Light Obscuration Particle Count Test | | |
| | (1.) Particles ≥10µm | NMT 6000/vial | 843/vial |
| | (2.) Particles ≥25µm | NMT 600/vial | 3/vial |
| | (B.) Visual Particle | Constitute the injection as directed on the label; The solution is essentially free from particles of foreign matter that can be seen on visual inspection. | Complies |
| 6. | Sterility | Powder for Injection comply with the test for sterility. | Complies |
| 7. | Bacterial Endotoxins | NMT 0.17 EU/mg of Ampicillin & Sulbactam. | Less than 0.17 EU/mg of Ampicillin & Sulbactam. |
| 8. | Assay: (By HPLC) Each vial contains: | | |

| Ingredients | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
|---|---|---|---|---|
| Ampicillin Sodium (Sterile) IP Eq. to anhydrous Ampicillin | 1000 mg | 954.1864 mg | 95.42% | 90.0 to 110.0% |
| Sulbactam Sodium (Sterile) IP Eq. to anhydrous Sulbactam | 500 mg | 489.9228 mg | 97.98% | 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.**

| Analysis by | Checked by | Approved by |
|---|---|---|
| NAME: NIKHIL SHARMA 10/07/26 | NAME: SURJEET KAUR 10/07/26 | NAME: MRS. SWATI DHAWAN 10/07/26 |