



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

## Title : Certificate of Analysis Finished Product

|              |   |                 |               |
|--------------|---|-----------------|---------------|
| Product Name | AZIDIME AVB Injection   | A.R. No.        | ARB/FP/25/007 |
| Generic Name | Ceftazidime & Avibactam Powder for Concentrate for Solution for Infusion 2.5g | Sampled qty.    | 45 Vials      |
| Batch No.    | ARB2507A  | Sampled by      | Anuj Verma    |
| Batch Size   | 5000 Vials  | Sampled on      | 31/08/2025    |
| Mfg. Date    | 08/2025   | Date of Testing | 31/08/2025    |
| Exp. Date    | 07/2027   | Date of Release | 13/09/2025    |

| S. No. | Tests   | Specifications  | Observations                                    |
|--------|---|---|---|
| 1.     | Description   | A white dry powder filled in clear glass vial.  | A white dry powder filled in clear glass vial.  |
| 2.     | Identification (By HPLC).   | In the Assay, the principal peak of Ceftazidime & Avibactam Sodium in the chromatogram obtained with the test solution corresponds to the peak of Ceftazidime & Avibactam Sodium in the chromatogram obtained with the working standard solution. | Complies  |
| 3.     | Uniformity of Weight  | Average weight $\pm 10\%$   | -1.40% & +1.22%                                 |
| 4.     | Average weight  | Informative $\pm 2\%$ .   | 3158.2 mg                                       |
| 5.     | 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/vial<br>NMT 600/vial<br>The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.                                    | 2454.00/vial<br>166.00/vial<br>Complies         |
| 6.     | Sterility   | No microbial growth should be observed.   | Complies  |
| 7.     | Bacterial Endotoxins  | NMT 0.1 EU/mg of Ceftazidime & Avibactam.   | Less than 0.1 EU/mg of Ceftazidime & Avibactam. |
| 8.     | Assay: (By HPLC)<br>Each glass vial contains:   |   |   |

| Ingredients  | Labeled Claim | Found      | % of labeled amount | Limits % of labeled amount |
|--|---------------|------------|---------------------|----------------------------|
| Ceftazidime Pentahydrate (Sterile)IP<br>Eq. to Anhydrous Ceftazidime<br>(A sterile mixture of Ceftazidime & Sodium Carbonate | 2000 mg       | 2052.71 mg | 102.64%             | 90.0% to 110%              |
| Avibactam Sodium (Sterile)<br>Eq. to Avibactam   | 500 mg        | 490.24 mg  | 98.05%              | 90.0% to 110%              |

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/RP/USP/IHS.

|                                    |                                    |  |
|------------------------------------|------------------------------------|--|
| Analysis by<br>NAME: NIKHIL SHARMA | Checked by<br>NAME: SUFIYAN ANSARI | Approved by<br>NAME: MRS. SWATI DHAWAN |
|------------------------------------|------------------------------------|--|