

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

**Title : Certificate of Analysis Finished Product**

|                     |   |                        |               |
|---------------------|---|------------------------|---------------|
| <b>Product Name</b> | AONE-SB Injection                                 | <b>A.R. No.</b>        | ARB/FP/26/008 |
| <b>Generic Name</b> | Ceftriaxone & Sulbactam for Injection IP<br>1.5gm | <b>Sampled qty.</b>    | 45 Vials      |
| <b>Batch No.</b>    | ARB2602A  | <b>Sampled by</b>      | Aakash        |
| <b>Batch Size</b>   | 20,000 Vials                                      | <b>Sampled on</b>      | 27/04/2026    |
| <b>Mfg. Date</b>    | 04/2026   | <b>Date of Testing</b> | 28/04/2026    |
| <b>Exp. Date</b>    | 03/2028   | <b>Date of Release</b> | 12/05/2026    |

| S. No.  | Tests  | Specifications   | Observations                                   |                     |                            |
|---|--|--|--|---------------------|----------------------------|
| 1.  | Description  | A white to off white powder filled in clear glass vial.  | A white dry powder filled in clear glass vial. |                     |                            |
| 2.  | Identification   | In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peak in the chromatogram obtained with reference solution (c).   | Complies                                       |                     |                            |
| 3.  | Uniformity of Weight   | Average weight $\pm 10\%$  | -0.76% & +0.65%                                |                     |                            |
| 4.  | Average weight   | Informative $\pm 2\%$ .  | 1753.9 mg                                      |                     |                            |
| 5.  | pH   | 4.5 to 8.0   | 6.66   |                     |                            |
| 6.  | Related Substance  |  |  |                     |                            |
|   | Any secondary peak   | NMT 1.0%   | 0.437%   |                     |                            |
|   | Sum of all secondary peaks   | NMT 5.0%   | 1.056%   |                     |                            |
| 7.  | Particulate Matter   |  |  |                     |                            |
|   | (a.) Sub-Visible particle count<br>(1.) Particles $\geq 10\mu\text{m}$<br>(2.) Particles $\geq 25\mu\text{m}$<br>(b.) Visual | 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. | 50/vial<br>0/vial<br>Complies                  |                     |                            |
| 8.  | Sterility  | No microbial growth should be observed.  | Complies                                       |                     |                            |
| 9.  | Bacterial Endotoxins   | NMT 0.2 EU/mg of Ceftriaxone.  | Less than 0.2 EU/mg Ceftriaxone.               |                     |                            |
| 10.   | Assay: (By HPLC)<br>Each vial Contains:  |  |  |                     |                            |
| Ingredients   |  | Labeled Claim  | Found  | % of labeled amount | Limits % of labeled amount |
| Sterile Ceftriaxone Sodium IP<br>Eq. to anhydrous Ceftriaxone |  | 1000 mg  | 1025.2793 mg                                   | 102.53%             | 90.0 to 110%               |
| Sterile Sulbactam Sodium IP<br>Eq. to Sulbactam               |  | 500 mg   | 507.4444 mg                                    | 101.49%             | 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/BP/USP/IHS.

|   |   |  |
|---|---|--|
| <b>Analysis by</b><br>NAME: NIKHIL SHARMA | <b>Checked by</b><br>NAME: SUFIYAN ANSARI | <b>Approved by</b><br>NAME: MRS. SWATADHAWAN |
|---|---|--|