

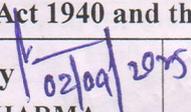
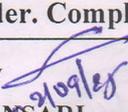
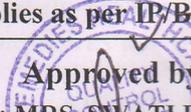
**Title : Certificate of Analysis Finished Product**

|                     |  |                        |               |
|---------------------|--|------------------------|---------------|
| <b>Product Name</b> | AONE SB 1.5g Injection                         | <b>A.R. No.</b>        | ARB/FP/25/005 |
| <b>Generic Name</b> | Ceftriaxone & Sulbactam for Injection IP 1.5gm | <b>Sampled qty.</b>    | 45 Vials      |
| <b>Batch No.</b>    | ARB2505A                                       | <b>Sampled by</b>      | Rakesh        |
| <b>Batch Size</b>   | 20,020 Vials                                   | <b>Sampled on</b>      | 17/08/2025    |
| <b>Mfg. Date</b>    | 08/2025  | <b>Date of Testing</b> | 18/08/2025    |
| <b>Exp. Date</b>    | 07/2027  | <b>Date of Release</b> | 02/09/2025    |

| 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 $\pm 10\%$  | -1.15% & +0.72%                                |
| 4.     | Average weight                          | Informative $\pm 2\%$ .  | 1746.9 mg                                      |
| 5.     | pH                                      | 4.5 to 8.0   | 6.89   |
| 6.     | Related Substance                       |  |  |
|        | Any secondary peak                      | NMT 1.0%   | Not detected                                   |
|        | Sum of all secondary peaks              | NMT 5.0%   | Not detected                                   |
| 7.     | Particulate Matter                      |  |  |
|        | (a.) Sub-Visible particle count         |  |  |
|        | (1.) Particles $\geq 10\mu\text{m}$     | NMT 6000/vial  | 909/vial                                       |
|        | (2.) Particles $\geq 25\mu\text{m}$     | NMT 600/vial   | 245/vial                                       |
|        | (b.) Visual                             | The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that cannot be seen with naked eye. | 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 Eq. to anhydrous Ceftriaxone | 1000 mg       | 1031.71 mg | 103.17%             | 90.0 to 110%               |
| Sterile Sulbactam Sodium IP Eq. to Sulbactam               | 500 mg        | 507.49 mg  | 101.50%             | 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/HHS:**

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