

**Title : Certificate of Analysis Finished Product**

|                     |                                                           |                        |                      |
|---------------------|-----------------------------------------------------------|------------------------|----------------------|
| <b>Product Name</b> | <b>AONE-SB Injection</b>                                  | <b>A.R. No.</b>        | <b>ARB/FP/26/007</b> |
| <b>Generic Name</b> | <b>Ceftriaxone &amp; Sulbactam for Injection IP 1.5gm</b> | <b>Sampled qty.</b>    | <b>45 Vials</b>      |
| <b>Batch No.</b>    | <b>ARB2603A</b>                                           | <b>Sampled by</b>      | <b>Aakash</b>        |
| <b>Batch Size</b>   | <b>10,000 Vials</b>                                       | <b>Sampled on</b>      | <b>27/04/2026</b>    |
| <b>Mfg. Date</b>    | <b>04/2026</b>                                            | <b>Date of Testing</b> | <b>28/04/2026</b>    |
| <b>Exp. Date</b>    | <b>03/2028</b>                                            | <b>Date of Release</b> | <b>12/05/2026</b>    |

| 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 $\pm 10\%$                                                                                                                                                                                      | -0.92% & +1.14%                                |                     |                            |
| 4.                                                                                                                                                                           | Average weight                                                             | Informative $\pm 2\%$ .                                                                                                                                                                                        | 1739.6 mg                                      |                     |                            |
| 5.                                                                                                                                                                           | pH                                                                         | 4.5 to 8.0                                                                                                                                                                                                     | 6.66                                           |                     |                            |
| 6.                                                                                                                                                                           | Related Substance                                                          |                                                                                                                                                                                                                |                                                |                     |                            |
|                                                                                                                                                                              | Any secondary peak                                                         | NMT 1.0%                                                                                                                                                                                                       | 0.401%                                         |                     |                            |
|                                                                                                                                                                              | Sum of all secondary peaks                                                 | NMT 5.0%                                                                                                                                                                                                       | 0.932%                                         |                     |                            |
| 7.                                                                                                                                                                           | Particulate Matter                                                         | 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. | 31/vial<br>0/vial<br><br>Complies              |                     |                            |
|                                                                                                                                                                              | (a.) Sub-Visible particle count                                            |                                                                                                                                                                                                                |                                                |                     |                            |
|                                                                                                                                                                              | (1.) Particles $\geq 10\mu\text{m}$<br>(2.) Particles $\geq 25\mu\text{m}$ |                                                                                                                                                                                                                |                                                |                     |                            |
|                                                                                                                                                                              | (b.) Visual                                                                |                                                                                                                                                                                                                |                                                |                     |                            |
| 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                                                                                                                                                                                                        | 1014.0895 mg                                   | 101.41%             | 90.0 to 110%               |
| Sterile Sulbactam Sodium IP<br>Eq. to Sulbactam                                                                                                                              |                                                                            | 500 mg                                                                                                                                                                                                         | 511.0923 mg                                    | 102.22%             | 90.0 to 110%               |
| Remarks: In the opinion of the undersigned, the above test results are in compliance with the requirements of the Indian Pharmacopoeia (IP) for the above mentioned product. |                                                                            |                                                                                                                                                                                                                |                                                |                     |                            |

**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/THS.

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