

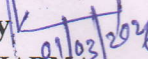
**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

Title : Certificate of Analysis Finished Product

| | | | |
|---------------------|--------------------------------|------------------------|---------------|
| Product Name | AONE Injection | A.R. No. | ARB/FP/25/027 |
| Generic Name | Ceftriaxone Injection IP 500mg | Sampled qty. | 45 Vials |
| Batch No. | ARB2535A | Sampled by | Aakash |
| Batch Size | 10,000Vials | Sampled on | 12/02/2026 |
| Mfg. Date | 02/2026 | Date of Testing | 13/02/2026 |
| Exp. Date | 01/2028 | Date of Release | 01/03/2026 |

| 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 I.R | A. The absorption spectrum of the test preparation should exhibit maxima at same wavelength with that obtained with similar preparation of Ceftriaxone working standard. | Complies |
| | By HPLC | B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution (a). | Complies |
| | By Chemical | C. It gives the reaction A of sodium salts. | Complies |
| 3. | Uniformity of weight | Average weight $\pm 10\%$ | -1.97% & +1.85% |
| 4. | Average weight | Informative $\pm 2\%$. | 604.9mg |
| 5. | Related Substance (By HPLC) | | |
| | Any secondary peak | NMT 1.0% | 0.23% |
| | Sum of all secondary peaks | NMT 5.0% | 0.23% |
| 6. | Appearance of solution | A 1.2 percent w/v solution in carbon dioxide-free water is clear and not more intensely coloured than reference solution BY55 or YS5. | Complies |
| 7. | pH | 6.0 to 8.0 | 6.89 |
| 8. | Water | NMT 11%w/w | 8.62%w/w |

Analysis by 
NAME: NIKHIL SHARMA 01/03/2026Checked by 
NAME: SUFIYAN ANSARI 01/03/26
Approved by 
NAME: MRS. SWATI DHILLON



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| | | | |
|-----|--|--|-------------------------------------|
| 9. | Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle | NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye. | 9/vial 1/vial Complies |
| 10. | Sterility | No microbial growth should be observed. | Complies |
| 11. | Bacterial Endotoxins | NMT 0.2 EU/mg of Ceftriaxone. | Less than 0.2 EU/mg of Ceftriaxone. |
| 12. | Assay: (By HPLC) Each vial contains: | | |

| Ingredients | Labelled Claim | Found | % of labelled amount | Limits % of labelled amount |
|---|----------------|-------------|----------------------|-----------------------------|
| Sterile Ceftriaxone Sodium IP Eq. to anhydrous Ceftriaxone | 500 mg | 517.5504 mg | 103.51% | 90.0 to 115.0% |

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 NAME: NIKHIL SHARMA | Checked by NAME: SUFIYAN ANSARI | Approved by NAME: MRS. SWATI DHAWAN |
|------------------------------------|------------------------------------|--|

