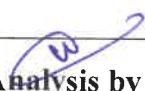




Title : Certificate of Analysis Finished Product

| | | | |
|---------------------|--------------------------------|------------------------|--------------|
| Product Name | AONE Injection | A.R. No. | BD/FP/24/010 |
| Generic Name | Ceftriaxone Injection IP 500mg | Sampled qty. | 45 Vials |
| Batch No. | B23787B | Sampled by | Arvind |
| Batch Size | 5000 Vials | Sampled on | 04/04/2024 |
| Mfg. Date | 03/2024 | Date of Testing | 04/04/2024 |
| Exp. Date | 02/2026 | Date of Release | 19/04/2024 |

| 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 $\pm 10\%$ | -1.15% & +0.80% |
| 4. | Average weight | Informative. | 599.1 mg |
| 5. | Related Substance (By HPLC) | | |
| | Any Impurity | NMT-1.0% | Complies |
| | The sum of all such Impurities | NMT- 4.0% | Complies |
| 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 by S5 or YS5. | Complies |
| 7. | pH | 6.0 to 8.0 | 6.37 |
| 8. | Water | NMT-11% w/w | 10.40% w/w |

 Analysis by
 Checked by
 Approved by

Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

:

Certificate of Analysis Finished Product

| | | | |
|--------------|--------------------------------|-----------------|--------------|
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| Generic Name | Ceftriaxone Injection IP 500mg | Sampled qty. | 45 Vials |
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| | | | | | |
|--|--|---|---|---------------------|----------------------------|
| 9. | Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual | NMT-6000/vial NMT-600/vial The solution is free from particles of foreign matter particles that can be observed on visual inspection. | 82/vial 1/vial Complies | | |
| 10. | Sterility | No microbial growth should be observed. | Complies | | |
| 11. | Bacterial Endotoxins | NMT- 0.2 EU/mg of Ceftriaxone Sodium. | Less than- 0.2 EU/mg of Ceftriaxone Sodium. | | |
| 12. | Assay: Each vial Contains : | | | | |
| Ingredients | | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
| Sterile Ceftriaxone Sodium I.P Eq. to anhydrous Ceftriaxone | | 500 mg | 528.80 mg | 105.76% | 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

Checked by

Approved by