


Title

:

Certificate of Analysis Finished Product

| | | | |
|--------------|---------------------------------|-----------------|--------------|
| Product Name | FOXATIM 1G Injection | A.R. No. | BD/FP/24/247 |
| Generic Name | Cefotaxime for Injection IP 1gm | Sampled qty. | 45 Vials |
| Batch No. | B24210A | Sampled by | Vineet |
| Batch Size | 36,236 Vials | Sampled on | 14/08/2024 |
| Mfg. Date | 07/2024 | Date of Testing | 14/08/2024 |
| Exp. Date | 06/2026 | Date of Release | 28/08/2024 |

| S. No. | Tests | Specifications | Observations |
|--------|---|---|---|
| 1. | Description | An Off-white to pale yellow, crystalline powder filled in clear glass vial. | An Off-white to pale yellow, crystalline powder filled in clear glass vial. |
| 2. | Identification (By IR) | A. The absorption spectrum of the test preparation should exhibit maxima at same wavelength with that obtained with similar preparation of Cefotaxime working standard. | Complies |
| | (By HPLC) | B. In assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the working reference solution. | Complies |
| | (By Chemical) | C. Gives the reactions of sodium salts. | Complies |
| 3. | Uniformity of weight | Average weight $\pm 10\%$ | -1.46% & +1.77% |
| 4. | Average weight | Informative. | 1102.28 mg |
| 5. | pH | 4.5 to 6.5 | 5.92 |
| 6. | Water | NMT-3.0% | 1.70% |
| 7. | Related Substances | | |
| | Single impurities | NMT-1.0% | 0.25% |
| | Total impurities | NMT-4.0% | 0.71% |
| 8. | Particulate Matter (IHS) | | |
| | (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ | NMT-6000/vial NMT-600/vial | 173/vial 19/vial |
| | (b.) Visual | The solution is free from particles of foreign matter particles that can be observed on visual inspection. | Complies |
| 9. | Sterility | No microbial growth should be observed. | Complies |

Analysis by 

Checked by 



Pace

Add Pace To Health

Pace Biotech



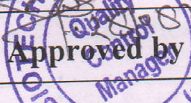
Surajpur, Paonta Sahib, Distt. Sirmour (H.P)

Certificate of Analysis Finished Product

| | | | |
|---------------------|---------------------------------|------------------------|--------------|
| Title | : | | |
| Product Name | FOXATIM 1G Injection | A.R. No. | BD/FP/24/247 |
| Generic Name | Cefotaxime for Injection IP 1gm | Sampled qty. | 45 Vials |
| Batch No. | B24210A | Sampled by | Vineet |
| Batch Size | 36,236 Vials | Sampled on | 14/08/2024 |
| Mfg. Date | 07/2024 | Date of Testing | 14/08/2024 |
| Exp. Date | 06/2026 | Date of Release | 28/08/2024 |

| | | | | | |
|---|--------------------------------------|--------------------------------|--------------|--------------------------------------|-----------------------------------|
| 10. | Bacterial Endotoxins | NMT- 0.20 EU/mg of Cefotaxime. | | Less than- 0.20 EU/mg of Cefotaxime. | |
| 11. | Assay: Each glass vial Contains : | | | | |
| Ingredients | | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
| Cefotaxime Sodium (Sterile) IP Eq. to Anhydrous Cefotaxime | | 1000 mg | 976.25 mg | 97.63% | 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/HS.

| | | |
|---|--|---|
| Analysis by  | Checked by  | Approved by  |
|---|--|---|

