

**EMPREE MEDICAMENTS (I) PVT. LTD****Finished Product Certificate of Analysis**

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|----------------------------|--|------------------------|-----------------------|
| Name of the Product | AMERICAN O₂Z Tablets | | |
| Generic Name: | Ofloxacin & Ornidazole Tablets IP | | |
| Batch No. | T2604133 | AR No. | AR/26/FGR/0186 |
| Mfg. Date | 04/2026 | Batch Size | 1,50,000 Tab's |
| Exp. Date | 03/2029 | Date of Release | 22/04/2026 |
| Specification No.: | FPS/TOIP637/00 | Sample Quantity | 60 Tablets. |
| License No. | KTK/25/293/91 | | |

| Sr. No. | TEST | RESULT | SPECIFICATION LIMIT |
|----------------|---|--|--|
| 1 | Description | Orange coloured, elongated shaped, film coated tablets having break line on one side and plain on other side of each tablet. | Orange coloured, elongated shaped, film coated tablets having break line on one side and plain on other side of each tablet. |
| 2 | Identification | | |
| | By HPLC | The principle peak in the chromatogram obtained with sample solution correspond to the principle peak obtained with standard solution. | The principle peak in the chromatogram obtained with sample solution correspond to the principle peak obtained with standard solution. |
| 3 | Average Weight | 619.8 mg | 620 mg \pm 5.0% (Limis:589 mg to 651 mg) |
| 4 | Uniformity of Weight | Max. + 1.34 % Min. - 1.17 % | Individual weight shall not deviates \pm 5 % of the weight |
| 5 | Disintegration test | 03 minutes 45 Second | Not more than 30 minutes |
| 6 | Dissolution | | |
| | Ofloxacin | Max. = 99.88% Min. = 96.50 % Avg. = 98.17% | NLT 80.0 % |
| | Ornidazole | Max = 99.93% Min = 97.85% Avg = 99.04% | |
| 7 | Assay: Each film coated tablet contains : Ofloxacin IP100 mg Ornidazole IP.....250 mg | 99.09 mg/tablet. (99.09%) 249.70 mg/tablet(99.88%) | 90.0% to 110.0 % |

REMARK: The product complies as per the above specification.

| | Prepared By | Checked By | Approved By |
|-----------|--------------------|-------------------|--------------------|
| Signature | | | |
| Date | 22/04/2026 | 22/04/2026 | 22/04/2026 |