

Empree



EMPREE MEDICAMENTS (I) PVT. LTD

Finished Product Certificate of Analysis

Name of the Product	AMERICAN O ₂ Z Tablets		
Generic Name:	Ofloxacin & Ornidazole Tablets IP		
Batch No.	T2606230	AR No.	AR/26/FGR/0342
Mfg. Date	06/2026	Batch Size	2,00,000 Tab's
Exp. Date	05/2029	Date of Release	27/06/2026
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	621.2 mg	620 mg $\pm$ 5.0% (Limis:589 mg to 651 mg)
4	Uniformity of Weight	Max. + 1.16 % Min. - 1.56 %	Individual weight shall not deviates $\pm$ 5 % of the weight
5	Disintegration test	03 minutes 50 Second	Not more than 30 minutes
6	Dissolution		
	Ofloxacin	Max. = 100.84 % Min. = 98.02 % Avg. = 99.32 %	NLT 80.0 %
	Ornidazole	Max = 98.62 % Min = 97.31 % Avg = 98.11 %	
7	Assay: Each film coated tablet contains : Ofloxacin IP100 mg Ornidazole IP.....250 mg	99.37 mg/tablet. (99.37 %) 247.98 mg/tablet (99.19 %)	90.0% to 110.0 %

REMARK: The product complies as per the above specification.

	Prepared By	Checked By	Approved By
Signature			
Date	27/06/2026	27/06/2026	27/06/2026