



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Healing-O2	A.R. No.	FG/G/24A1038
Generic Name	Ofloxacin and Ornidazole Tablets IP	Sample Quantity	60 Tablets
Batch No.:	AGT40755	Sample Received on	16/07/2024
Batch Size:	5.0 Lac	Analysis Date	16/07/2024
Mfg. Date.	07/2024	Release Date	25/07/2024
Exp. Date	06/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Orange colour, elongated shaped, biconvex, having both side plain, film coated tablet.	Orange colour, elongated shaped, biconvex, having both side plain, film coated tablet.		
2.	Identification	In the assay, the retention time of the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	918.00 mg $\pm$ 3%	915.783 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 905.79 mg ; Max: 932.03 mg -1.09% ; +1.77%		
5.	Disintegration	Not more than 30 minutes.	03 minutes 25 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	18.25 Kg/cm ²		
7.	Dissolution:				
	For Ornidazole	Not less than 75.0% (Q)	Minimum = 91.94% Maximum = 98.24% Average = 94.19%		
	For Ofloxacin	Not less than 75.0% (Q)	Minimum = 98.51% Maximum = 103.47% Average = 100.38%		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Ofloxacin IP	200 mg	Between 90.0 % to 110.0 % of stated amount (Between 180.0 mg to 220.0 mg)	199.90 mg	99.95%
	Ornidazole IP	500 mg	Between 90.0 % to 110.0 % of stated amount (Between 450.0 mg to 550.0 mg)	490.58 mg	98.12%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		45 cfu/g	
ii.	Total yeast and mould count	NMT 100 cfu/g		Less than 10 cfu/g	
iii.	Pathogens: Escherichia coli	Should be absent/g		Absent/g	

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Harveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	25/07/2024	25/07/2024	25/07/2024