



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Diarahel Plus	A.R. No.	FG/G/24A0291
Generic Name	Ofloxacin, Ornidazole & Racecadotril Oral Suspension	Sample Quantity	14 Bottles
Batch No.:	AGL40731	Sample Received on	15/07/2024
Batch Size:	15,000 Bottles	Analysis Date	15/07/2024
Mfg. Date.	07/2024	Release Date	26/07/2024
Exp. Date	06/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Orange colour Suspension filled in 30 ml amber colour PET bottle sealed with ROPP aluminium cap.	Orange colour Suspension filled in 30 ml amber colour PET bottle sealed with ROPP aluminium cap.		
2.	Identification	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.	Complies		
3.	Weight per ml	Between 0.800 gm/ml to 1.200 gm/ml	1.1131 gm/ml		
4.	pH	Between 4.0 to 6.0	5.54		
5.	Average fill Volume	Not less than 30.0 ml	30.4 ml		
6.	Uniformity of filled Volume	Not less than 28.5 ml	Min:- 30.0 ml Max:- 31.0 ml		
7.	Assay:				
	Each 5 ml contains:	Claim	Limit	mg	%
	Ofloxacin IP	50 mg	Between 90.0 % to 110.0 % of stated amount (Between 45.0 mg to 55.0 mg)	48.25 mg	96.51%
	Ornidazole IP	125 mg	Between 90.0 % to 110.0 % of stated amount (Between 112.5 mg to 137.5 mg)	128.80 mg	103.04%
	Racecadotril IP	15 mg	Between 90.0 % to 110.0 % of stated amount (Between 13.5 mg to 16.5 mg)	15.0662 mg	100.44%
8.	Microbial Limit Tests:				
a.	Total aerobic microbial count	NMT 100 cfu/ml		35 cfu/ml	
b.	Total yeast and mould count	NMT 10 cfu/ml		Less than 10 cfu/ml	
c.	Pathogens:				
i.	Escherichia coli	Should be absent/ml		Absent/ml	
ii.	Salmonella	Should be absent/ml		Absent/ml	

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	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	26/07/2024	26/07/2024	26/07/2024