



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Ibubrook Plus	A.R. No.	FG/G/24A0287
Generic Name	Ibuprofen & Paracetamol Oral Suspension	Sample Quantity	14 Bottles
Batch No.:	AGL40720	Sample Received on	12/07/2024
Batch Size:	15,000 Bottles	Analysis Date	12/07/2024
Mfg. Date.	07/2024	Release Date	19/07/2024
Exp. Date	06/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Pink colour Suspension filled in 100 ml amber colour PET bottle sealed with ROPP aluminium cap.	Pink colour Suspension filled in 100 ml amber colour PET bottle sealed with ROPP aluminium cap.		
2.	Identification	In the assay, 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.	Weight per ml	Between 0.800 gm/ml to 1.200 gm/ml	1.0736 gm/ml		
4.	pH	Between 4.0 to 6.0	5.16		
5.	Average filled Volume	Not less than 100.0 ml	102.32 ml		
6.	Uniformity of filled Volume	Not less than 95.0 ml	Min:- 100.5 ml Max:- 105.1 ml		
7.	Assay:				
	Each 5 ml contains:	Claim	Limit	mg	%
	Ibuprofen IP	100 mg	Between 90.0 % to 110.0 % of stated amount (Between 90.0 mg to 110.0 mg)	98.82 mg	98.82%
	Paracetamol IP	162.5 mg	Between 90.0 % to 110.0 % of stated amount (Between 146.25 mg to 178.75 mg)	163.779 mg	100.79%
8.	Microbial Limit Tests:				
a.	Total aerobic microbial count		NMT 100 cfu/ml	30 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	19/07/2024	19/07/2024	19/07/2024