



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Offdryl	A.R. No.	FG/G/24A0405
Generic Name	Diphenhydramine Hydrochloride, Ammonium Chloride, Sodium Citrate and Menthol Syrup	Sample Quantity	14 Bottles
Batch No.:	AGL40929	Sample Received on	29/09/2024
Batch Size:	20,000 Bottles	Analysis Date	29/09/2024
Mfg. Date.	09/2024	Release Date	19/10/2024
Exp. Date	08/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brown colour liquid filled, in 100 ml amber colour PET bottle sealed with ROPP aluminium cap.	Brown colour liquid 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	1.094 gm/ml		
4.	pH	Between 4.0 to 6.0	5.45		
5.	Average filled Volume	Not less than 100.0 ml	101.6 ml		
6.	Uniformity of filled Volume	Not less than 95.0 ml	Min:- 100.0 ml Max:- 104.0 ml		
7.	Assay:				
	Each 5 ml contains:	Claim	Limit	mg	%
	Diphenhydramine Hydrochloride IP	14.08 mg	Between 90.00 % to 110.00 % of stated amount (Between 12.67 mg to 15.49 mg)	14.040 mg	99.72%
	Ammonium Chloride IP	138 mg	Between 90.00 % to 110.00 % of stated amount (Between 124.20 mg to 151.80 mg)	136.99 mg	99.27%
	Sodium Citrate IP	57.03 mg	Between 90.00 % to 110.00 % of stated amount (Between 51.33 mg to 62.73 mg);	57.21 mg	100.32%
	Menthol IP	1.14 mg	Between 90.00 % to 110.00 % of stated amount (Between 1.03 mg to 1.25 mg)	1.1783 mg	103.36%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Aniket Kumar Rai	Balchish Singh
Designation	Executive	Executive	Plant Head
Signature			
Date	19/10/2024	19/10/2024	19/10/2024



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Sr. No.	Test Parameter	Acceptance Criteria	Result
8.	Microbial Limit Tests:		
a.	Total aerobic microbial count	NMT 100 cfu/ml	25 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	Harveen Kumar	Ankit Kumar	Bakul Singh
Designation	Executive	Executive	Plant Head
Signature			
Date	19/10/2024	19/10/2024	19/10/2024