



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Heal Q-NF	A.R. No.	FG/G/24A0205
Generic Name	Dextromethorphan Hydrobromide, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40351	Sample Received on	18/03/2024
Batch Size:	5.0 Lac	Analysis Date	18/03/2024
Mfg. Date.	03/2024	Release Date	26/03/2024
Exp. Date	02/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	Yellow colour, elongated shaped, biconvex, break line on one side and other side plain, uncoated tablet.	Yellow colour, elongated shaped, biconvex, break line on one side and other side plain, uncoated tablet.
2.	Identification	In the assay, the retention time of 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.	Average weight	340.00 mg $\pm$ 3%	340.644 mg
4.	Uniformity of weight	$\pm$ 5.0% of its average weight.	Min: 336.92 mg ; Max: 343.02 mg - 1.09% ; + 0.70%
5.	Disintegration	Not more than 15 minutes.	04 minutes 46 seconds.
6.	Friability	NMT 1.0%w/w	0.32% w/w
7.	Hardness	NLT 4.0 Kg/cm ²	10.4 Kg/cm ²
8.	Uniformity of content		
	For Dextromethorphan Hydrobromide	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	5.04
	For Phenylephrine Hydrochloride	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	2.52
	For Chlorpheniramine Maleate	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	4.85

Particulars	Prepared By	Checked By	Approved By
Name	Braveen Kumar	Tanvej	Gaurav Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	26/03/2024	26/03/2024	26/03/2024

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9.	Assay:				
	Each uncoated tablet contains:	Claim	Limit	mg	%
	Dextromethorphan Hydrobromide IP	10 mg	Between 90.00 % to 110.00 % of stated amount (Between 9.0 mg to 11.0 mg)	9.69 mg	96.90%
	Phenylephrine Hydrochloride IP	5 mg	Between 90.00 % to 110.00 % of stated amount (Between 4.50 mg to 5.50 mg)	4.8785 mg	97.57%
	Chlorpheniramine Maleate IP	2 mg	Between 90.00 % to 110.00 % of stated amount (Between 1.80 mg to 2.20 mg)	1.976 mg	98.81%
10.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		30 cfu/g	
ii.	Total yeast and mould count	NMT 100 cfu/g		Less than 10 cfu/g	
iii.	Pathogens: <i>Escherichia coli</i>	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	Braveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head QA
Signature			
Date	26/03/2024	26/03/2024	26/03/2024