



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Nebiheal 5 mg	A.R. No.	FG/G/24A1072
Generic Name	Nebivolol Hydrochloride Tablets IP 5 mg	Sample Quantity	90 Tablets
Batch No.	AGT40791	Sample Received on	25/07/2024
Batch Size	1.50 Lac	Analysis Date	25/07/2024
Mfg. Date	07/2024	Release Date	01/08/2024
Exp. Date	06/2026	Page No.	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, round shaped, biconvex, having both side plain, uncoated tablet.	White colour, round shaped, biconvex, having both side plain, uncoated tablet.		
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.	Average weight	290.0 mg ± 3%	294.181 mg		
4.	Uniformity of weight	± 5.0 % of its average weight.	Min: 284.93 mg ; Max: 300.71 mg - 3.14% ; + 2.22%		
5.	Hardness	NLT 4.0 Kg/cm ²	4.75 Kg/cm ²		
6.	Disintegration	Not more than 15 minutes.	01 minutes 10 seconds.		
7.	Friability	NMT 1.0 %w/w	0.15 %w/w		
8.	Uniformity of content	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	4.84		
9.	Dissolution	Not more than 70.0% (Q)	Minimum = 82.44% Maximum = 91.94% Average = 87.65%		
10.	Assay: Each uncoated tablet contains:				
	Nebivolol Hydrochloride IP eq. to Nebivolol	Claim	Limit	mg	%
		5 mg	Between 90.0 % to 110.0 % of stated amount (Between 4.50 mg to 5.50 mg)	5.1224 mg	102.45%
11.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		50 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	Praveen Kumar	Tanvej	Anurag Singh
Designation	Executive	Sr. Executive	Head - QA
Signature			
Date	01/08/2024	01/08/2024	01/08/2024