



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/23A0802
Generic Name	Nebivolol HCL Tablets IP 5 mg	Sample Quantity	60 Tablets
Batch No.	AGT30969	Sample Received on	25/09/2023
Batch Size	1.50 Lac	Analysis Date	25/09/2023
Mfg. Date	09/2023	Release Date	03/10/2023
Exp. Date	08/2025	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 (By HPLC)	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 \pm 3%	290.93 mg		
4.	Uniformity of weight	\pm 5.0 % of its average weight.	Min: 280.80 mg ; Max: 297.60 mg - 3.48% ; + 2.29%		
5.	Hardness	NLT 4.0 Kg/cm ²	4.75 Kg/cm ²		
6.	Disintegration	Not more than 15 minutes.	01 minutes 08 seconds.		
7.	Friability	NMT 1.0 %w/w	0.14 %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)	5.39		
9.	Dissolution	Not more than 70.0% (Q)	Minimum = 95.63% Maximum = 97.44% Average = 96.56%		
10.	Assay (By HPLC): 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)	4.884 mg	97.68%
11.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g	25 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 Alam	Gaurang Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	03/10/2023	03/10/2023	03/10/2023