



NEST HEALTHCARE PRIVATE LIMITED

PLOT NO. 300,G.I.D.C,ODHAV,AHMEDABAD-382415
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QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))




FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : NOVALIP-5	A.R. No. : FPD/210444A
Packing : 10x10 TAB	Rel. Dt. : 26-08-2021
Generic Name : ATORVASTATIN TABLETS IP 5 MG	T.R. Slip No. : FPTR210671
Product Code : NOVA01	T.R. Slip Dt. : 12-08-2021
Batch No. : NHD21352A	Analysis Date : 26-08-2021
Actual Batch Size : 55000 TAB (550 BOX)	
Packing Batch Size : 55000 TAB	
Sample Size : 50.000 TAB	
Released Qty : 55000.000 TAB (550 BOX)	
Mfg. Dt. : 07/2021	
Exp. Dt. : 06/2023	
Test Packing : 10X10	
Mfg. Lic No. : G/25/2184	
Test As Per : IH	
Remarks :	Location : ODHAV
	Make : NHPL

Sr.	Test	Result	Specification
1	DESCRIPTION	A white colored, round biconvex shaped, film coated tablets with both side plain.	A white colored, round biconvex shaped, film coated tablets with both side plain.
2	AVERAGE WEIGHT (TABLETS)	100.0 mg	102.0 mg \pm 5.0 %
3	UNIFORMITY OF WEIGHT	-1.90 % to +2.51 %	\pm 7.5 % of Average weight
4	THICKNESS	2.99 mm	3.10 \pm 0.2 mm
5	DIAMETER	6.20 mm	6.30 \pm 0.2 mm
6	HARDNESS	4.9 kg/cm ²	NLT 2.5 kg/cm ²
7	DISINTEGRATION TIME	11 min 36 sec	NMT 30 Minute
8	IDENTIFICATION	Complies	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.
9	DISSOLUTION	Min: 77.08 % Max: 90.58 %	NLT 70 (D) + 5 % of the stated amount of C33H35FN2O5.
10	RELATED SUBSTANCE	Any Individual Impurity: Not Detected Total Impurity: Not Detected	Any Individual Impurity: NMT 1.0 % Total Impurity: NMT 4.0 %
11	UNIFORMITY OF CONTENTS	Min: 97.56 % Max: 99.34 %	85.0 % to 115.0 %
12	ASSAY	4.936 mg 98.73 %	Atorvastatin calcium IP Eq. to Atorvastatin 5 mg [Limit : 90.0 % to 110.0 %]

Conclusion : The above sample complies as per IH

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Prepared By	Checked By	Approved By
 26/08/21	 26/08/21	 26/08/21

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