



# NEST HEALTHCARE PRIVATE LIMITED

PLOT NO. 300,G.I.D.C,ODHAV,AHMEDABAD-382415  
 REG.OFF.: PLOT NO. 300,G.I.D.C,ODHAV,AHMEDABAD-382415  
 C.I.No. : U24232GJ2014PTC079983  
 Email : mkt@nest-india.com Website : www.nest-india.com

## QUALITY CONTROL DEPARTMENT

Page 1 of 1

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

### FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : NOVALIP-5	<b>A.R. No.</b> : FPD/210610A
<b>Packing</b> : 10x10 TAB	<b>Rel. Dt.</b> : 06-10-2021
<b>Generic Name</b> : ATORVASTATIN TABLETS IP 5 MG	<b>T.R. Slip No.</b> : FPTR210836
<b>Product Code</b> : NOVA01	<b>T.R. Slip Dt.</b> : 28-09-2021
<b>Batch No.</b> : NHD21464A	<b>Analysis Date</b> : 06-10-2021
<b>Actual Batch Size</b> : 55000 TAB (550 BOX)	
<b>Packing Batch Size</b> : 55000 TAB	
<b>Sample Size</b> : 50.000 TAB	
<b>Released Qty</b> : 55000.000 TAB (550 BOX)	
<b>Mfg. Dt.</b> : 09/2021	
<b>Exp. Dt.</b> : 08/2023	
<b>Test Packing</b> : 10X10	
<b>Mfg. Lic No.</b> : G/25/2184	
<b>Test As Per</b> : 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 )	104.7 mg	102.0 mg ± 5.0 %
3	UNIFORMITY OF WEIGHT	-4.51 % to +1.98 %	± 7.5 % of Average weight
4	THICKNESS	3.02 mm	3.10 ± 0.2 mm
5	DIAMETER	6.34 mm	6.30 ± 0.2 mm
6	HARDNESS	8.5 kg/cm <sup>2</sup>	NLT 2.5 kg/cm <sup>2</sup>
7	DISINTEGRATION TIME	10 min 47 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: 88.57 % Max: 94.88 %	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: 86.94 % Max: 94.15 %	85.0 % to 115.0 %
12	ASSAY	4.841 mg 96.83 %	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"

<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
 06/10/21	 06/10/21	 06/10/21