



# 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  
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## 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-20	<b>A.R. No.</b> : FPD/210433B
<b>Packing</b> : 10x10 TAB	<b>Rel. Dt.</b> : 26-07-2021
<b>Generic Name</b> : ATORVASTATIN TABLETS IP 20 MG	<b>T.R. Slip No.</b> : FPTR210619
<b>Product Code</b> : NOVA03	<b>T.R. Slip Dt.</b> : 23-07-2021
<b>Batch No.</b> : NHD21338B	<b>Analysis Date</b> : 26-07-2021
<b>Actual Batch Size</b> : 50000 TAB (500 BOX)	<b>Mfg. Dt.</b> : 06/2021
<b>Packing Batch Size</b> : 50000 TAB	<b>Exp. Dt.</b> : 05/2023
<b>Sample Size</b> : 50.000 TAB	<b>Test Packing</b> : 10X10
<b>Released Qty</b> : 50000.000 TAB (500 BOX)	<b>Mfg. Lic No.</b> : G/25/2184
<b>Remarks</b> :	<b>Test As Per</b> : IH
	<b>Location</b> : ODHAV
	<b>Make</b> : 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 )	202.1 mg	202 mg $\pm$ 5.0 %
3	UNIFORMITY OF WEIGHT	-1.66 % to +3.24 %	$\pm$ 7.5 % of Average weight
4	THICKNESS	4.01 mm	4.10 $\pm$ 0.2 mm
5	DIAMETER	8.02 mm	8.10 $\pm$ 0.2 mm
6	HARDNESS	5.2 kg/cm <sup>2</sup>	NLT 3.5 kg/cm <sup>2</sup>
7	DISINTEGRATION TIME	04 min 13 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	83.51 % to 95.41 %	NLT 70 (D) + 5 % of the stated amount of C33H35FN2O5.
10	RELATED SUBSTANCE	Any Unknown Impurity: Not detected Total Impurity: Not detected	Any Unknown Impurity: NMT 1.0 % Total Impurity: NMT 4.0 %
11	ASSAY	20.00 mg 100.0 %	Atorvastatin Calcium IP Eq. to Atorvastatin 20 mg [Limit : 18.0 mg to 22.0 mg, 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>  26/07/21	<b>Checked By</b>  26/07/21	<b>Approved By</b>  26/07/21
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