



NEST HEALTHCARE PRIVATE LIMITED

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QUALITY CONTROL DEPARTMENT

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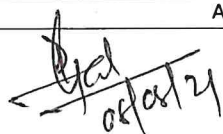
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : NOVALIP-10 Packing : 10x10 TAB Generic Name : ATORVASTATIN TABLETS IP 10 MG	A.R. No. : FPD/210423B Rel. Dt. : 08-08-2021 T.R. Slip No. : FPTR210630 T.R. Slip Dt. : 27-07-2021 Analysis Date : 08-08-2021
Product Code : NOVA02 Batch No. : NHD21337B Actual Batch Size : 50000 TAB (500 BOX) Packing Batch Size : 50000 TAB Sample Size : 50.000 TAB Released Qty : 50000.000 TAB (500 BOX)	Mfg. Dt. : 06/2021 Exp. Dt. : 05/2023 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 brick red colored, round biconvex shaped, film coated tablets with both side plain.	A brick red colored, round biconvex shaped, film coated tablets with both side plain.
2	AVERAGE WEIGHT (TABLETS)	104.7 %	103.0 mg \pm 5.0 %
3	UNIFORMITY OF WEIGHT	-2.12 % to +1.80 %	\pm 7.5 % of Average weight
4	THICKNESS	3.00 mm	3.10 \pm 0.2 mm
5	DIAMETER	6.19 mm	6.30 \pm 0.2 mm
6	HARDNESS	5.5 kg/cm ²	NLT 3.0 kg/cm ²
7	DISINTEGRATION TIME	09 min 21 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	79.05 % to 97.62 %	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	97.55 % to 103.31 %	85.0 % to 115.0 %
12	ASSAY	9.95 mg 99.58 %	Atorvastatin calcium IP Eq. to Atorvastatin 10 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  08/08/21	Checked By  08/10/21	Approved By  08/08/21
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