



# 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

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

### FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : ROSUVINN-10	<b>A.R. No.</b> : FPD/210563A
<b>Packing</b> : 10x10 TAB	<b>Rel. Dt.</b> : 21-09-2021
<b>Generic Name</b> : ROSUVASTATIN TABLETS IP 10MG - REX OXIDE OF IRON	<b>T.R. Slip No.</b> : FPTR210767
<b>Product Code</b> : ROBU04	<b>T.R. Slip Dt.</b> : 09-09-2021
<b>Batch No.</b> : NHD21448A	<b>Analysis Date</b> : 21-09-2021
<b>Actual Batch Size</b> : 52000 TAB (520 BOX)	
<b>Mfg. Dt.</b> : 09/2021	
<b>Exp. Dt.</b> : 08/2023	
<b>Test Packing</b> : 10X10	
<b>Packing Batch Size</b> : 52000 TAB	
<b>Mfg. Lic No.</b> : G/25/2184	
<b>Sample Size</b> : 50.000 TAB	
<b>Released Qty</b> : 52000.000 TAB (520 BOX)	<b>Test As Per</b> : IH
<b>Remarks</b> :	<b>Location</b> : ODHAV
	<b>Make</b> : 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	205.5 mg	205 mg $\pm$ 5.0 %
3	UNIFORMITY OF WEIGHT	-2.77 % to +2.88 %	$\pm$ 5.0 % of Average weight
4	THICKNESS	3.98 mm	4.10 $\pm$ 0.2 mm
5	DIAMETER	8.09 mm	8.10 $\pm$ 0.2 mm
6	HARDNESS	5.0 kg/cm <sup>2</sup>	NLT 3.0 kg/cm <sup>2</sup>
7	DISINTEGRATION TIME	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	Min: 95.30 % Max: 102.32 %	NLT 70 (D) + 5 % of the stated amount of C22H28FN3O6S.
10	RELATED SUBSTANCE BY HPLC	Any Unknown Impurity: Not Detected Total Impurity: Not Detected	Any Unknown Impurity: NMT 1.5 % Total Impurity: NMT 3.0 %
11	UNIFORMITY OF CONTENTS	Min: 89.39 % Max: 98.21 %	85.0 % to 115.0 %
12	ASSAY	9.53 mg 95.39 %	Rosuvastatin Calcium IP Eq. Rosuvastatin 10 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>	<b>Checked By</b>	<b>Approved By</b>
 21/09/21	 21/09/21	 21/09/2021

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