



# 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

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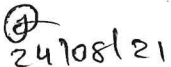
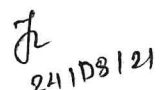
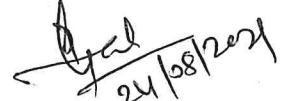
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

### FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : METORYL M PLUS	<b>A.R. No.</b> : FPD/210509A
<b>Packing</b> : 10x10 TAB	<b>Rel. Dt.</b> : 24-08-2021
<b>Generic Name</b> : GLIMEPIRIDE 1 & METFORMIN 1000 SR TAB	<b>T.R. Slip No.</b> : FPTR210681
<b>Product Code</b> : METO25	<b>T.R. Slip Dt.</b> : 16-08-2021
<b>Batch No.</b> : NHD21402A	<b>Analysis Date</b> : 24-08-2021
<b>Actual Batch Size</b> : 60000 TAB (600 BOX)	
<b>Packing Batch Size</b> : 60000 TAB	
<b>Sample Size</b> : 50.000 TAB	
<b>Released Qty</b> : 60000.000 TAB (600 BOX)	
<b>Mfg. Dt.</b> : 08/2021	
<b>Exp. Dt.</b> : 07/2023	
<b>Test Packing</b> : 10X10	
<b>Mfg. Lic No.</b> : G/25/2184	
<b>Test As Per</b> : IP	
<b>Remarks</b> :	
<b>Location</b> : ODHAV	
<b>Make</b> : NHPL	

Sr.	Test	Result	Specification
1	DESCRIPTION	A white-brick red coloured, oblong, biconvex shaped, uncoated bilayered tablets with both side plain.	A white-brick red coloured, oblong, biconvex shaped, uncoated bilayered tablets with both side plain.
2	AVERAGE WEIGHT ( TABLETS )	1288.4 mg	1302 mg ± 5.0 %
3	UNIFORMITY OF WEIGHT	-1.15 % to +1.25 %	± 5.0 % of Average weight
4	THICKNESS	7.22 mm	7.20 ± 0.2 mm
5	WIDTH	10.02 mm	10.00 ± 0.2 mm
6	LENGTH	20.05 mm	20.00 ± 0.2 mm
7	HARDNESS	12.3 kg/cm <sup>2</sup>	NLT 10.0 kg/cm <sup>2</sup>
8	FRIABILITY	0.08 %	NMT 1.0 % w/w
9	IDENTIFICATION	Complies	In the Assay, principle peaks in the chromatogram obtained with the test solution corresponds to the principle peaks in the chromatogram obtained with the reference solution.
10	DISSOLUTION		
	1 Metformine HCl (After 1 Hour)	Min: 33.11 % Max: 37.56 %	25.0 % to 50.0 %
	2 Metformine HCl (After 3 Hour)	Min: 67.41 % Max: 69.81 %	50.0 % to 75.0 %
	3 Metformine HCl (After 10 Hour)	Min: 85.13 % Max: 93.54 %	NLT 80.0 %
	4 Glimepiride	Min: 86.23 % Max: 93.34 %	NLT 70.0 (D) + 5 % of the stated amounts of C24H34N4O5S.
11	UNIFORMITY OF CONTENTS	Min: 87.21 %	L.C. = Label Claim (1 mg)

Conclusion : The above sample complies as per IP  
 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>
 24/08/21	 24/08/21	 24/08/2021



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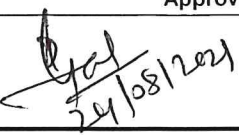
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<b>Remarks</b> :	<b>Location</b> : ODHAV <b>Make</b> : NHPL

Sr.	Test	Result	Specification
		Max: 101.05 %	Standard/Limit: 85.0 % to 115.0 %
12	ASSAY		
1	ASSAY	996.8 mg 99.68 %	1) Metformine Hydrochloride IP 1000 mg (in Prolonged release form) [Limit : 900 mg to 1100 mg, 90.0 % to 110.0 %]
2	ASSAY	0.959 mg 95.96 %	2) Glimepiride IP 1 mg [Limit : 0.9 mg to 1.1 mg, 90.0 % to 110.0 %]

Conclusion : The above sample complies as per IP

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>  24/08/21	<b>Checked By</b>  24/08/21	<b>Approved By</b>  24/08/21
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