



# 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> : INNORYL -3	<b>A.R. No.</b> : FPD/210464A
<b>Packing</b> : 10x10 TAB	<b>Rel. Dt.</b> : 31-07-2021
<b>Generic Name</b> : GLIMEPIRIDE TABLETS IP 3 MG	<b>T.R. Slip No.</b> : FPTR210640
<b>Product Code</b> : INNO02	<b>T.R. Slip Dt.</b> : 30-07-2021
<b>Batch No.</b> : NHD21371A	<b>Analysis Date</b> : 31-07-2021
<b>Actual Batch Size</b> : 50000 TAB (500 BOX)	<b>Mfg. Dt.</b> : 07/2021
<b>Packing Batch Size</b> : 50000 TAB	<b>Exp. Dt.</b> : 06/2023
<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> : IP
	<b>Location</b> : ODHAV
	<b>Make</b> : NHPL

Sr.	Test	Result	Specification
1	DESCRIPTION	A creamy colored, round shape, biconvex, unscored uncoated tablets.	A creamy colored, round shape, biconvex, unscored uncoated tablets.
2	AVERAGE WEIGHT ( TABLETS )	99.07 mg	100 mg $\pm$ 7.5 %
3	UNIFORMITY OF WEIGHT	-3.70 % to +2.16 %	$\pm$ 7.5 % of Average weight
4	THICKNESS	2.89 mm	3.0 $\pm$ 0.2 mm
5	DIAMETER	6.25 mm	6.4 $\pm$ 0.2 mm
6	HARDNESS	3.5 kg/cm <sup>2</sup>	NLT 1.5 kg/cm <sup>2</sup>
7	DISINTEGRATION TIME	01 min 48 sec	NMT 15 Minute
8	FRIABILITY	0.09 %	NMT 1.0 % w/w
9	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 reference solution (b).
10	DISSOLUTION	92.84 % to 94.15 %	NLT 75.0 (D) + 5.0 % of the stated amount of C24H34N4O5S.
11	RELATED SUBSTANCE	glimepiride impurity B: Not detected Any individual (unknown) Impurity: Not detected Total Impurity (Except glimepiride impurity B ): Not detected Total Impurity: Not detected	glimepiride impurity B: NMT 2.5 % Any individual (unknown) Impurity: NMT 0.5 % Total Impurity (Except glimepiride impurity B ): NMT 1.0 % Total Impurity: NMT 3.5 %
12	UNIFORMITY OF CONTENTS	89.68 % to 91.25 %	85.0 % to 115.0 % of the stated amount of C24H34N4O5S.
13	ASSAY	2.987 mg	Glimepiride IP 3 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>
 31/07/21	 31/07/21	 31/07/21



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<b>Product Name</b> : INNORYL -3 <b>Packing</b> : 10x10 TAB <b>Generic Name</b> : GLIMEPIRIDE TABLETS IP 3 MG	<b>A.R. No.</b> : FPD/210464A <b>Rel. Dt.</b> : 31-07-2021 <b>T.R. Slip No.</b> : FPTR210640 <b>T.R. Slip Dt.</b> : 30-07-2021 <b>Analysis Date</b> : 31-07-2021
<b>Product Code</b> : INNO02 <b>Batch No.</b> : NHD21371A <b>Actual Batch Size</b> : 50000 TAB (500 BOX) <b>Packing Batch Size</b> : 50000 TAB <b>Sample Size</b> : 50.000 TAB <b>Released Qty</b> : 50000.000 TAB (500 BOX)	<b>Mfg. Dt.</b> : 07/2021 <b>Exp. Dt.</b> : 06/2023 <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
		99.58 %	[Limit : 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>  31/07/21	<b>Checked By</b>  31/07/21	<b>Approved By</b>  31/07/21
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