



# 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  
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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> : CARVEDINN-12.5                | <b>A.R. No.</b> : FPD/210501A                 |
| <b>Packing</b> : 10x10 TAB                          | <b>Rel. Dt.</b> : 05-09-2021                  |
| <b>Generic Name</b> : CARVEDILOL TABLETS IP 12.5 MG | <b>T.R. Slip No.</b> : FPTR210678             |
| <b>Product Code</b> : INNO05                        | <b>T.R. Slip Dt.</b> : 13-08-2021             |
| <b>Batch No.</b> : NHD21395A                        | <b>Analysis Date</b> : 05-09-2021             |
| <b>Actual Batch Size</b> : 55000 TAB (550 BOX)      |   |
| <b>Packing Batch Size</b> : 55000 TAB               |   |
| <b>Sample Size</b> : 50.000 TAB                     |   |
| <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 : IP</b>                             |   |
| <b>Remarks :</b>                                    | <b>Location</b> : ODHAV<br><b>Make</b> : NHPL |

| Sr. | Test                       | Result   | Specification  |
|-----|----------------------------|--|--|
| 1   | DESCRIPTION                | A creamy colored, round, biconvex shaped, uncoated tablets with both side plain. | A creamy colored, round, biconvex shaped, uncoated tablets with both side plain.   |
| 2   | AVERAGE WEIGHT ( TABLETS ) | 199.8 mg   | 200 mg ± 5.0 %   |
| 3   | UNIFORMITY OF WEIGHT       | -2.65 % to +3.06 %   | ± 7.5 % of Average weight  |
| 4   | THICKNESS                  | 3.79 mm  | 3.90 ± 0.2 mm  |
| 5   | DIAMETER                   | 7.88 mm  | 8.00 ± 0.2 mm  |
| 6   | HARDNESS                   | 4.9 kg/cm <sup>2</sup>   | NLT 3.0 kg/cm <sup>2</sup>   |
| 7   | DISINTEGRATION TIME        | 02 min 41 sec  | NMT 15 Minute  |
| 8   | FRIABILITY                 | 0.14 %   | 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 the reference solution. |
| 10  | DISSOLUTION                | Min: 82.15 %<br>Max: 107.20 %  | NLT 70 (D) + 5 % of the stated amount of C24H26N2O4.   |
| 11  | RELATED SUBSTANCE          | Any Secondary Impurity: Not Detected<br>Total Impurity: Not Detected             | Any Secondary Impurity: NMT 0.5 %<br>Total Impurity: NMT 2.0 %   |
| 12  | ASSAY                      | 12.67 mg<br>101.44 %   | Carvedilol IP 12.5 mg<br>[Limit : 11.25 mg to 13.75 mg,<br>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"

| Prepared By   | Checked By    | Approved By  |
|---------------|---------------|--------------|
| ②<br>05/09/21 | N<br>05/09/21 | <br>05/09/21 |