

**A/C OF HEALING PHARMA INDIA PVT LTD**  
**QUALITY CONTROL DEPARTMENT**  
**THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER**

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# FINISHED PRODUCT CERTIFICATE OF ANALYSIS

|                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                      |
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| <b>Product Name</b> : VARENISMART 1<br><b>Packing</b> : 10 TAB<br><b>Generic Name</b> : VARENICLINE TARTRATE TABLETS 1 MG<br><br><b>Product Code</b> : TV-132HEAL<br><b>Batch No.</b> : TV-1320004<br><b>Actual Batch Size</b> : 303000 TAB<br><br><b>Sample Size</b> : 50.000 TAB<br><b>Released Qty</b> : 303000.000 TAB (30300 CAR)<br><b>Remarks</b> : PASS | <b>A.R. No.</b> : F/0623/2425<br><br><b>Rel. Dt.</b> : 17-06-2024<br><b>T.R. Slip No.</b> : CHPAP24071<br><b>T.R. Slip Dt.</b> : 15-06-2024<br><b>Analysis Date</b> : 15-06-2024<br><b>Specification No.</b> : CRFS/TV-132HEAL/24<br><br><b>Specification Dt</b> : 20-01-2024<br><b>STP No.</b> : STP/TV-132HEAL/AS PER IH<br><br><b>Location</b> : GORWA01<br><b>Make</b> : HEALING |
| <b>Mfg. Dt.</b> : MAY-2024<br><b>Exp. Dt.</b> : APR-2027<br><b>Test Packing</b> : 10 TABS<br><br><b>Mfg. Lic No.</b> : G/25A/5141-A                                                                                                                                                                                                                             | <b>Test As Per</b> : IH                                                                                                                                                                                                                                                                                                                                                              |

| Sr. | Test                      | Result                                                                            | Specification                                                                                        |
|-----|---------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| 1   | DESCRIPTION               | A White colored, Round shaped, Biconvex, Film coated tablets, plain on both side. | A White colored, Round shaped, Biconvex, Film coated tablets, plain on both side.                    |
| 2   | AVERAGE WEIGHT OF TABLETS | 202.6 mg                                                                          | 206.00mg $\pm$ 7.5% of avg. weight                                                                   |
| 3   | UNIFORMITY OF WEIGHT      | H.L : +2.17 %<br>L.L : -1.78%                                                     | Complies Within $\pm$ 7.5% of avg. weight                                                            |
| 4   | THICKNESS                 | 3.22 mm                                                                           | 3.40 mm $\pm$ 0.3 mm                                                                                 |
| 5   | DIAMETER                  | 8.06 mm                                                                           | 8.10 mm $\pm$ 0.2 mm                                                                                 |
| 6   | DISINTEGRATION TIME       | 00 Minutes 50 Seconds in Water Medium at 37°C                                     | NMT 30 min.                                                                                          |
| 7   | UNIFORMITY OF CONTENT     | MAX = 101.88%<br>MIN = 97.58%<br>AVG = 99.55%                                     | Limit :85.0 % to 115.0 %                                                                             |
| 8   | ASSAY                     | 99.63 %                                                                           | Each film coated tablets contains :<br>1) Varenicline Tartrate.....1 mg<br>[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                                                                                                              | Checked By                                                                                                  | Approved By                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| <br>MANSI MARADIYA<br>TRAINEE OFFICER | <br>MANISHA<br>EXECUTIVE | <br>ASMITA<br>QUALITY HEAD |