Swiss Garnier
LIFE SCIENCES
22-23, Industrial Area, Mehatpur,
Dist. UNA, (H.P.) - 174 315

**CERTIFICATE OF ANALYSIS**
QUALITY CONTROL

# FINISHED PRODUCT

**A.R. NUMBER : SGB/2425/QCP/QFG/01268**

| | | | |
|---|---|---|---|
| PRODUCT NAME | : ANGEDIL 5 TABS * 1 X 30 | | |
| BATCH NUMBER | : 355TAF001 | BATCH SIZE | : 200000 NOS |
| MFG DATE | : 11/2024 | EXP DATE | : 10/2026 |
| SAMPLE QTY. | : 4.000 JAR | A. R. DATE | : 13/11/2024 |
| SPECIFICATION NO. | A00137-01-00 | | |

| Srl. | TEST NAME | OBSERVATION | SPECIFICATION |
|---|---|---|---|
| 1 | Appearance | White coloured, round shaped, biconvex, uncoated tablets plain on both sides. | White to off-white coloured, round shaped, biconvex, uncoated tablets plain on both sides. |
| 2 | Identification (By HPLC) | Complies | In the test of assay the retention time of principal peak of sample preparation must correspond to the Nicorandil working standard solution. |
| 3 | Average Weight | 175.37 mg | 176 mg ± 5.0 % (167 mg to 185 mg) |
| 4 | Uniformity Of Weight | - 1.52 % to + 1.27 % | Individual weight of tablet does not deviate by more than ± 7.5 % from the average weight. |
| 5 | Dimension | 3.46 mm | Thickness: 3.40 mm to 3.80 mm |
| 6 | Hardness | 5.24 Kp | 3 Kp - 12 Kp |
| 7 | Friability | 0.27 % | NMT 1.0 % |
| 8 | Disintegration Time | 03 minutes 27 seconds | NMT 15 min in water at 37°C ± 2°C. |
| 9 | Dissolution | 98.93 % to 102.15 % | Q. NLT 75 % of the labeled amount of Nicorandil. |
| 10 | Uniformity of Dosage Units (By HPLC) | L1 = 1.47 | L1 = NMT 15.0 |
| 11 | Microbial Limits | | |
| | 1.Total Aerobic viable count: | . | . |
| | a.Total Bacterial count | 20 CFU/g | NMT 1000 CFU/g |
| | b.Total Yeast & Mould count | < 10 CFU/g | NMT 100 CFU/g |
| | 2.Escherichia coli | Absent | Should be absent/g |

Assay Details :
Each uncoated tablet contains:

| SRL. | ACTIVE INGREDIENT | RESULT | LIMITS |
|---|---|---|---|
| 1 | Nicorandil IP | 5.0382 mg (100.8 %) | Between 4.5 and 5.5 mg |

**REMARKS : THE SAMPLE COMPLIES AS PER IP. SPECIFICATION**

Prepared by

Checked by 13/11/24

Approved by 13/11/24