



CERTIFICATE OF ANALYSIS
QUALITY CONTROL

FINISHED PRODUCT

A.R. NUMBER : SGB/2425/QCP/QFG/01807

PRODUCT NAME	: ANGEDIL 5 TABS * 1 X 30		
BATCH NUMBER	: 355TAF003	BATCH SIZE	: 100000 NOS
MFG DATE	: 12/2024	EXP DATE	: 11/2026
SAMPLE QTY.	: 4.000 JAR	A. R. DATE	: 14/01/2025
SPECIFICATION NO.	A00137-01-01		

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	176.79 mg	176 mg \pm 5.0 % (167 mg to 185 mg)
4	Uniformity Of Weight	- 1.01 % to + 1.08 %	Individual weight of tablet does not deviate by more than \pm 7.5 % from the average weight.
5	Dimension	3.62 mm	Thickness: 3.40 mm to 3.80 mm
6	Hardness	6.11 Kp	3 Kp - 12 Kp
7	Friability	0.31 %	NMT 1.0 %
8	Disintegration Time	01 minute 41 seconds	NMT 15 min in water at 37°C \pm 2°C.
9	Dissolution	98.98 % to 104.81 %	Q. NLT 75 % of the labeled amount of Nicorandil.
10	Uniformity of Dosage Units (By HPLC)	L1 = 8.44	L1 = NMT 15.0
11	Microbial Limits		
	1.Total Aerobic viable count:	.	.
	a.Total Bacterial count	30 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	5.0384 mg (100.8 %)	Between 4.5 and 5.5 mg

REMARKS : THE SAMPLE COMPLIES AS PER IP. SPECIFICATION

Prepared by :
Date : 14/01/25

Checked by :
Date : 14/01/25

Approved by :
Name: Shashi Kumar
Designation: Sr. Manager QC
Qualifications: M.Sc
Enrollment No.: R6-49338
Format No.: F/OC/012/015
B.U. Bhopal