



CERTIFICATE OF ANALYSIS
QUALITY CONTROL

FINISHED PRODUCT

A.R. NUMBER : SGB/2425/QCP/QFG/01798

PRODUCT NAME	: ANGEDIL 5 TABS * 1 X 30		
BATCH NUMBER	: 355TAF002	BATCH SIZE	: 200000 NOS
MFG DATE	: 12/2024	EXP DATE	: 11/2026
SAMPLE QTY.	: 4.000 JAR	A. R. DATE	: 09/01/2025
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	174.59 mg	176 mg ± 5.0 % (167 mg to 185 mg)
4	Uniformity Of Weight	- 0.94 % to + 1.48 %	Individual weight of tablet does not deviate by more than ± 7.5 % from the average weight.
5	Dimension	3.62 mm	Thickness: 3.40 mm to 3.80 mm
6	Hardness	5.49 Kp	3 Kp - 12 Kp
7	Friability	0.12 %	NMT 1.0 %
8	Disintegration Time	02 minutes 27 seconds	NMT 15 min in water at 37°C ± 2°C.
9	Dissolution	89.74 % to 93.29 %	Q. NLT 75 % of the labeled amount of Nicorandil.
10	Uniformity of Dosage Units (By HPLC)	L1 = 2.84	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	5.0109 mg (100.2 %)	Between 4.5 and 5.5 mg

REMARKS : THE SAMPLE COMPLIES AS PER IP. SPECIFICATION

Prepared by *[Signature]*
Date : 09/01/25

Checked by *[Signature]*
Date : 09/01/25

Approved by *[Signature]*
Date : 09/01/25