Swiss Garniers
BIOTECH PVT. LTD.
21- Industrial Area, Mehatpur,
Dist. UNA, (H.P.) - 174 315

CERTIFICATE OF ANALYSIS
QUALITY CONTROL

FINISHED PRODUCT

A.R. NUMBER : SG2/2425/QCP/QFG/01450

PRODUCT NAME	: ANGEDIL 5 TABS * 1 X 30		
BATCH NUMBER	: 148TAF010	**BATCH SIZE**	: 100000 NOS
MFG DATE	: 09/2024	**EXP DATE**	: 08/2026
SAMPLE QTY.	: 4.000 JAR	**SAMPLE DATE**	: 14/09/2024
SPECIFICATION NO.	: A00055-02-02	**A. R. DATE**	: 23/09/2024

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	174.36 mg	176 mg ± 2.0 % (172.5 mg to 179.5 mg)
4	Uniformity of weight	- 0.81 % to + 1.47 %	Individual weight of tablet does not deviate by more than ± 7.5 % from the average weight.
5	Friability	0.12 %	Not More Than 1.0 %
6	Disintegration Time	04 minutes 10 seconds	NMT 15 min in water at 37°C ± 2°C
7	Dissolution (By HPLC)	96.74 % to 101.33 %	Q. NLT 75 % of the labeled amount of Nicorandil.
8	Uniformity of Dasage Units (By HPLC)	L1 = 4.12	L1 = NMT 15.0
9	Microbial Limits (For monitoring only)	.	.
	1. Total Aerobic viable count:	.	.
	a. Total Bacterial Count	30 CFU/g	Not more than 1000 CFU/g
	b. Total Yeast & Mould count	< 10 CFU/g	Not more than 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	4.9880 mg (99.76 %)	Between 4.5 and 5.5 mg

REMARKS : THE SAMPLE COMPLIES AS PER IP. SPECIFICATION

Prepared by
Date : 23/09/24

Checked by
Date : 23/09/24

Approved by
Date : 23/09/24