



Kwality Pharmaceuticals Limited
Address: Nag Kalan, Majitha Road, Amritsar - 143601 (India)
Finished Product Certificate of Analysis

Generic Name	Nicorandil for Injection 48mg	Analytical Report No.	KPL1/QC/AR/FP/2026/2172
Product Name	ANGEDIL 48	Reference Pharmacopoeia	IHS
Batch No.	GL290	Batch Size	6000 VIALS
Mfg. Date	May 2026	Exp. Date	April 2028
Sample Received on	20/05/2026	Specification No	KPL1/QC/SLS-11660
Analysis Initiated on	22/05/2026	Date of Release	25/06/2026

Analytical Data

Packing Presentation: CLEAR GLASS VIAL SEALED WITH RED COLORED FLIP OFF HAVING PAPER LABEL.

S.No.	Tests		Specifications			Observations
1	Description					
	A	Before reconstitution	White to off white colored lyophilized cake filled in clear glass vial sealed with red colored flip off having paper label .			Off white colored lyophilized cake filled in clear glass vial sealed with red colored flip off having paper label .
	B	After reconstitution	Clear and colorless solution after reconstitution			Clear and colorless solution after reconstitution
	C	Reconstitution time	Not more than 1 minute			Less than 1 minute
2	pH		Between 5.0 to 8.0			6.70
3	Water		Not more than 3.0 percent			1.66%
4	Bacterial Endotoxins test		Not more than 2.5 EU per mg			Less than 2.5 EU per mg
5	Particulate matter in injections					
	A	$\geq 10\ \mu\text{m}$	Not more than 6000 particles / container			362
	B	$\geq 25\ \mu\text{m}$	Not more than 600 particles / container			12
6	Visible particle test for injection		Shall be free from visible particle			No visible particle observed
7	Sterility test		Should be sterile			It is Sterile
8	Assay		Limit	Claim	Result	%age
	Each vial contains: Nicorandil I.P.		90.0% - 110.0%	48 mg	47.16 mg	98.3%

Conclusion : The above product complies with above specifications and meets the standard quality.

Amrit
25/06/2026

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