



DERREN HEALTHCARE PRIVATE LIMITED

PLOT NO 33,35/P & 36/P, XCELON INDUSTRIAL PARK,
SARKHEJ-BAVLA HIGHWAY, VILL. VASNA - CHACHARWADI,
TA : SANAND. DIST.AHMEDABAD - 382213, GUJARAT,INDIA

FINISHED PRODUCT ANALYTICAL TEST REPORT

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Product Name	NITROCAN 50 INJECTION 10ML AMPOULE	Specification No.	DHPL/FPSPE/NITEOG/10/01
Generic Name	NITROGLYCERIN INJECTION	Batch No. /Lot No.	BU25010
		Mfg. Dt.	11/2025
		Exp. Dt.	10/2027
		Receipt Dt.	17/11/2025
		Release Dt.	01/12/2025
		Sample Size	41.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0297
		Manufactured By	DERREN
Analysis	DHIREN MUKESHBHAI PATEL	Theoretical Yield/Batch Size	40,476.000 Ampoule

Sr.	Test	Limit	Result
1	Description	Clear, colourless oily liquid free from visible particles and fibers.	Clear, colourless oily liquid free from visible particles and fibers.
2	Extractable volume	NLT 10.0 ml	10.0 ml
3	Identification Identification A by HPLC	In the Assay, the principal peak in the chromatogram obtained with test solution should be correspond to the peak in the chromatogram obtained with reference solution.	In the Assay, the principal peak in the chromatogram obtained with test solution is correspond to the peak in the chromatogram obtained with reference solution.
4	pH	3.0 To 6.5	5.7
5	Bacterial endotoxins	NMT 0.1 EU/mg	Less than 0.1 EU/mg
6	Particulate matter By Visual inspection By light obscuration method	The solution should be free from particles that can be observed by inspection with the unaided eye. For =10 µm: Not more than 6000 particles per container For =25 µm: Not more than 600 particles per container	The solution is free from particles that can be observed by inspection with the unaided eye. For =10 µm:223.33 particles per container For =25 µm: 5.33 particles per container
7	Sterility test	Should be sterile	sterile
8	Assay	90.0% to 110.0% of the stated amount of Nitroglycerine	97.9% of the stated amount of Nitroglycerine

Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per IP specification.

Prepared By 01/12/25	Checked By 01/12/25	Approved By 01/12/2025
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DHIRENP 01/12/2025 11:14 AM

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