



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 25 INJ	Specification No.	DHPL/FP/SPEC/NITRO/01/01
Generic Name	NITROGLYCERIN INJECTION	Batch No. /Lot No.	BU26001
composition : Each ml contains Diluted Nitro glycerine IP 5 mg Water For injection.....Q.S.		Mfg. Dt.	03/2026
		Exp. Dt.	02/2028
		Receipt Dt.	30/03/2026
		Release Dt.	13/04/2026
		Sample Size	35.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0153
		Manufactured By	DERREN
Analysis	DHAVAL GHANSHYAMBHAI PATEL	Theoretical Yield/Batch Size	54,807.000 Ampoule

Sr.	Test	Limit	Result
1	Description	Clear, colorless oily liquid free from visible particles and fibers	Clear, colorless liquid free from visible particles and fibers
2	Extractable volume	NLT 5.0 ml	5.0 ml
3	Identification Identification (By HPLC)	The retention time of the sample solution should be correspond to that of the standard solution as obtained in the assay.	The retention time of the sample solution is correspond to that of the standard solution as obtained in the assay.
4	pH	3.0 to 6.5	5.9
5	Bacterial Endotoxin test	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 particle that can be observed by inspection with the unaided eye. >= 10 micron = NMT 6000 / containers >= 25 micron : NMT 600 / containers	The solution is free from particle that can be observed by inspection with the unaided eye. >= 10 micron = 151.33/ containers >= 25 micron = 23.00/ containers
7	Sterility test	Should be sterile	Sterile
8	Assay Assay Each ml Contains:Nitroglycerine 5 mg	90.0 to 110.0 % of the stated amount fo Nitroglycerine	98.3 % of the stated amount fo Nitroglycerine

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

Prepared By DHAVAL QC OFFICER 13/04/2026	Checked By NUTAN PRAJAPATI QC HEAD 13/04/2026	Approved By KRUNAL GAJERA QA HEAD 13/04/2026
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