



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


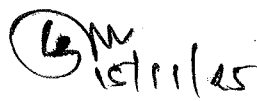
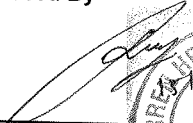
FINISHED PRODUCT ANALYTICAL TEST REPORT

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Product Name	NITROCAN 25 INJ	Specification No.	DHPL/FP/SPEC/NITRO/01/00
Generic Name	NITROGLYCERIN INJECTION	Batch No. /Lot No.	BU25009
composition : Each ml contains Diluted Nitro glycerine IP 5 mg Water For injection.....Q.S.		Mfg. Dt.	10/2025
		Exp. Dt.	09/2027
		Receipt Dt.	01/11/2025
		Release Dt.	15/11/2025
		Sample Size	50.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0265
Analysis	DHIREN MUKESHBHAI PATEL	Manufactured By	DERREN
		Theoretical Yield/Batch Size	55,769.000 Ampoule

Sr.	Test	Limit	Result
1	Description	Clear, colorless oily liquid free from visible particles and fibers	Clear, colorless oily 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	4.6
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 = 280.00/ containers >= 25 micron : 1.67 / 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	97.8 % 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  15/11/25	Checked By  15/11/25	Approved By 
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