



DERREN HEALTHCARE PVT. LTD.

Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India
Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chachrawadi,
Ahmedabad-382 213, Gujarat (India)

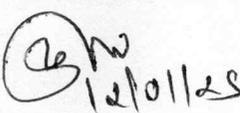
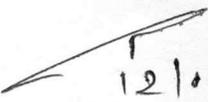
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Name of Product	Nitroglycerine Injection IP 5mg/ml (NITROCAN 25)		
Batch No.	BU24005	A.R. No.	FP/24/0157
Mfg. Date	12/24	Exp. Date	11/26
Sampled Qty.	41 Nos.	Date of Analysis	29/11/24
Batch Size	125 Ltr.	Date of Release	12/01/25
Container Type	Amber Coloured glass Ampoules	Fill volume	5.0 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
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	5.1 ml	NLT 5.0 ml
3	Identification		
3.1	Identification A by HPLC	The retention time of the Sample solution is corresponds to that of the Standard solution, as obtained in the Assay.	The retention time of the Sample solution Should be corresponds to that of the Standard solution, as obtained in the Assay.
4	pH	6.18	3.0 to 6.5
5	Bacterial endotoxin	Less than 0.1 Eu/ml	NMT 0.1 Eu/ml
6	Particulate matter		
6.1	By Visual Inspection	The solution is free from particles that is observed by inspection with the unaided eye.	The solution should be free from particles that can be observed by inspection with the unaided eye.
6.2	By Light Obscuration Method	≥ 10 microns= 112.67 /Container ≥ 25 Microns= 5.67 /Container	Sub visible particle by LPC ≥ 10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
7	Sterility test	Sterile	Should be sterile
8	Assay		
8.1	Each ml contains Nitroglycerine IP 5.0 mg	102.6 %	90.0% to 110.0% of the stated amount of Nitroglycerine

Conclusion: The above sample complies as per IP specification.

In the opinion of the undersigned the sample referred to above is **of standard** / ~~not of standard~~ quality as defined in the act and the rules made there under for the reasons given above.

Prepared By	Checked By	Approved By
 12/01/25 QC Executive	 12/01/25 QC Sr,Executive	  QA MANAGER