

**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-Chacharvadi,  
Ahmedabad-382 213, Gujarat (India)

**CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)**

Name of Product	Nitroglycerine Injection USP 5mg/ml (NITROCAN 25 INJ)		
Batch No.	BU24001	A.R. No.	FP/24/0025
Mfg. Date	03/24	Exp. Date	02/26
Sampled Qty.	41 Nos.	Date of Analysis	16/03/24
Batch Size	150 Ltr.	Date of Release	30/03/24
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	5.0 ml	NLT 5.0 ml
3	<b>Identification</b>		
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	4.9	3.0 to 6.5
5	Bacterial endotoxin	Less than 0.1 EU/mg	NMT 0.1 EU/mg
6	<b>Particulate matter</b>		
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	$\geq 10$ microns= 3254.00 /Container $\geq 25$ Microns= 81.67 /Container	Sub visible particle by LPC $\geq 10$ microns=NMT 6000/Container $\geq 25$ Microns=NMT 600/Container
7	Sterility test	Sterile	Should be sterile
8	<b>Assay</b>		
8.1	Each ml contains Nitroglycerine USP 5.0 mg	101.2 %	90.0% to 110.0% of the stated amount of Nitroglycerine

**Conclusion:** The above sample complies as per USP 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  30/03/24 QC Executive	Checked By  30/03/24 QC Sr,Executive	Approved By  
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