

**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)

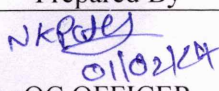
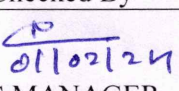
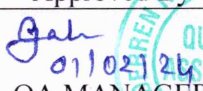
**CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Name of Product	Lignocaine and dextrose Injection IP (NumbOn Heavy Injection)		
Batch No.	BG23004	A.R. No.	FP/24/003
Mfg. Date	12/23	Exp. Date	11/25
Sampled Qty.	71 Nos.	Date of Analysis	11/01/24
Batch Size	150 Ltr.	Date of Release	01/02/24
Container Type	Clear Glass Ampoule	Fill Volume	2.0 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	A clear slightly yellow solution free from visible particles and fibres.	A clear colourless or slightly yellow solution free from visible particles and fibers
2	Extractable volume	2.1 ml	NLT 2.0 ml
3	Identification		
3.1	Identification A by IR	The infrared absorption spectrum of the residue, is concordant with Lignocaine Hydrochloride RS/WS or the reference spectrum of Lignocaine Hydrochloride.	The infrared absorption spectrum of the residue, should be concordant with Lignocaine Hydrochloride RS/WS or the reference spectrum of Lignocaine Hydrochloride.
3.2	Identification B by chemical method	A red precipitate is produced.	A red precipitate Should be produced.
4	pH	6.4	3.0 to 7.0
5	Bacterial endotoxin	Less than 1.1 EU/mg	NMT 1.1 EU/mg
6	Particulate matter		
6.1	By Visual Inspection	The solution is free from particles of the foreign matter that is observed on visual inspection method.	The solution should be free from particles of the foreign matter that can be observed on visual inspection method.
6.2	By Light Obscuration Method	≥ 10 microns= 3111.87/Container ≥ 25 Microns= 66.80/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	Assay Each ml contains: Lignocaine Hydrochloride eq. to 53.3 mg	99.5%	95.0% to 105.0% of the stated amount of Lignocaine Hydrochloride.
8.2	Assay Dextrose eq. to 75.0 mg	99.63%	95.0% to 105.0% of the stated amount of Dextrose.

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  01/02/24 QC OFFICER	Checked By  01/02/24 QC MANAGER	Approved By  01/02/24 QA MANAGER
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