



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)

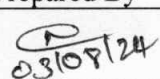
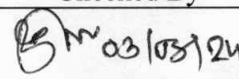
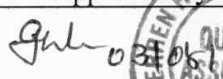
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Name of Product	Milrinone Lactate Injection 1 mg/ml (MILRICAN)		
Batch No.	BM24002	A.R. No.	FP/24/0058
Mfg. Date	07/24	Exp. Date	06/26
Sampled Qty.	34 Nos.	Date of Analysis	20/07/24
Batch Size	60 Ltr.	Date of Release	03/08/24
Container Type	Amber Glass Ampoules	Fill volume	10.0 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, Colourless solution free from visible particles and fibers.	Clear, colourless or almost colourless solution free from visible particles and fibers.
2	Extractable volume	10.5ml	NLT 10.0 ml
3	Identification		
3.1	Identification A by HPLC	The retention time of the milrinone peak of the Sample solution is corresponds to that of the Standard solution, as obtained in the Assay.	The retention time of the milrinone peak of the Sample solution should be corresponds to that of the Standard solution, as obtained in the Assay.
4	pH	3.75	3.2 to 4.0
5	Related Substances		
5.1	Any secondary impurity	Not detected	NMT 0.2%
5.2	Total Impurity	Not detected	NMT 0.5%
6	Bacterial endotoxin	Less than 25.0 EU/mg of Milrinone	NMT 25.0 EU/mg of Milrinone
7	Particulate matter		
7.1	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.
7.2	By Light Obscuration Method	≥ 10 microns= 137.33/Container ≥ 25 Microns= 4.00/Container	Sub visible particle by LPC ≥ 10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
8	Sterility test	Sterile	Should be sterile
9	Assay		
9.1	Each ml contains: Milrinone Lactate eq. to Milrinone 1.0 mg	102.4%	90.0% to 110.0% of the stated amount of Milrinone

Conclusion: The above sample complies as per In-House 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  03/08/24 QC .EXCECUTIVE	Checked By  03/08/24 QC SR .EXCECUTIVE	Approved By  03/08/24 QA MANAGER
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