

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title**:****Certificate of Analysis Finished Product**

Product Name	MILRICAN Injection	A.R. No.	ARN/FP/26/030
Generic Name	Milrinone Lactate Injection 10ml	Sampled qty.	45 Ampoules
Batch No.	ARN2632A	Sampled by	Rakesh
Batch Size	10,020 Ampoules	Sampled on	04/07/2026
Mfg. Date	06/2026	Date of Testing	06/07/2026
Exp. Date	05/2028	Date of Release	20/07/2026

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless to yellowish solution filled in amber glass ampoule.	A clear colourless solution filled in amber glass ampoule.		
2.	Identification (By HPLC)	In the assay, the principal peak of Milrinone in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.	Complies		
3.	Nominal fill volume	NLT 10ml	10.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	10.1 ml		
5.	pH	3.0 to 4.5	3.81		
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particles	NMT 6000/Ampoule NMT 600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	44/Ampoule 0/Ampoule Complies		
7.	Sterility	No microbial growth should be observed.	Complies		
8.	Bacterial Endotoxins	NMT 25 EU/mg of Milrinone.	Less than 25 EU/mg of Milrinone.		
9.	Assay: (By HPLC) Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Milrinone Lactate Eq. to Milrinone		1.00 mg	0.991 mg	99.13%	-90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is ~~not~~ of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ ~~not~~ complies as per IP/BP/USP/IHS.

Analysis by

NAME: SHAHRUKH KHAN

Checked by

NAME: SURJEET KAUR

Approved by

NAME: MRS. SWATI DHAWAN