



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour.

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name : ARRYXIN Digoxin injection IP	
Batch No. : GA24C-38B	Mfg. Date : 03/2024
Batch Size : 20240 Ampoules	Exp. Date : 02/2026
Sample Qty. : 60 Ampoules.	Analytical Report No.: AFP20240144
Date of Receiving : 01/04/2024	Date of Completion : 16/04/2024
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations	
1.	Description	A clear colourless liquid solution filled in clear transparent glass ampoule.	A clear colourless liquid solution filled in clear transparent glass ampoule.	
2.	Identification (By chemically)	A brown ring develops at the interface which gradually becomes blue and finally the upper layer acquires a blue colour.	Complies	
3.	Uniformity of filled volume	Not less than nominal volume	Min: 2.0 ml Max: 2.1 ml	
4.	Average fill volume	Not less than 2 ml	2.05 ml	
5.	pH	Between (6.7 to 7.30)	6.98	
6.	Particulate Matter			
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/Ampoule	
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/Ampoule	
7.	Bacterial Endotoxins	NMT 200.0 Eu/mg of Digoxin.	Less than 200.0 Eu/mg of Digoxin.	
8.	Sterility	Should be Sterile	Sterile	
9.	Assay : Each ml contains:-			
Composition:	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Digoxin IP	250.0 mcg	250.64 mcg	100.26 %	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample submitted complies/~~does not complies~~ with the prescribed standard/~~not standard of quality~~, as according to I.P. and IHS with respect to the above test only.

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager/In-charge
Signature:- Date:- 16/04/2024	Signature:- Date:- 16/04/2024	Signature:- Date:- 16/04/2024

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