



# VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

## QUALITY CONTROL DEPARTMENT

### CERTIFICATE OF ANALYSIS

<b>Product Name</b> : ARRYXIN Digoxin injection IP	
<b>Batch No.</b> : GA24A-17	<b>Mfg. Date</b> : 01/2024
<b>Batch Size</b> : 19910 Ampoules	<b>Exp. Date</b> : 12/2025
<b>Sample Qty.</b> : 65 Ampoules.	<b>Analytical Report No.:</b> AFP20240033
<b>Date of Receiving</b> : 29/01/2024	<b>Date of Completion</b> : 12/02/2024
<b>Mfg. License No.</b> : 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 4 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)	6.81		
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	248.23 mcg	99.29 %	90.0% to 110.0%

**Remarks:** In the opinion of the undersigned the sample submitted ~~complies/does not comply~~ 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:-	Signature:- Date:-	Signature:- Date:-

Format No.: VH/SOP/QC-062/FT01-00

