



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name : NOR- ADR Sterile Noradrenaline Concentrate IP.	
Batch No. : A24J-02	Mfg. Date : 10/2024
Batch Size : 142480 Ampoules	Exp. Date : 09/2026
Sample Qty. : 65 Ampoules	Analytical Report No.: MFP20240090
Date of Receiving : 16/10/2024	Date of Completion : 30/10/2024
Spec No. : FP/NOR/SPC/001	STP No. : FP/NOR/STP/001

S. No.	Tests	Specifications	Observations	
1.	Description	A clear colourless or almost colorless solution filled in 2 ml amber colour glass ampoule.	A clear colourless or almost colorless solution filled in 2 ml amber colour glass ampoule.	
2.	Identification			
	By Chemically	A strong reddish violet colour should be produced.	A strong reddish colour produced.	
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	2.04 ml	
5.	pH	3.0 to 4.60	4.15	
6.	Particulate Matter			
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/Ampoule	
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/Ampoule	
7.	Sterility	Should be Sterile	Sterile	
8.	Bacterial Endotoxins	NMT 83.4 Eu/mg of noradrenaline.	Less than 83.4 Eu/mg	
9.	Assay : Each ml contains:-			
Composition:	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Noradrenaline Bitartrate IP	2.0 mg	2.01 mg	100.50 %	90.0% to 115%

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:- <i>A</i> 30/10/2024	Signature:- Date:- <i>A</i> 30/10/2024	Signature:- Date:- <i>J</i> 30/10/2024

Format No.: VH/SOP/QC-062/FT-01-00