



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.	: A24A-08D	Mfg. Date	: 01/2024
Batch Size	: 98400 Ampoules	Exp. Date	: 12/2025
Sample Qty.	: 65 Ampoules	Analytical Report No.:	MFP20240002
Date of Receiving	: 09/02/2024	Date of Completion	: 22/02/2024
Mfg. License No.	: N-MB/18/201		

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	2.1 ml	
5.	pH	3.0 to 4.60	3.50	
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	Under analysis	
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	2.04 mg	102.0 %	90.0% to 115%

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:-	Signature:- Date:-	Signature:- Date:-

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

