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. : A24G-06A		**Mfg. Date**	: 07/2024
Batch Size : 100920 Ampoules		**Exp. Date**	: 06/2026
Sample Qty. : 60 Ampoules		**Analytical Report No.:** MFP20240055	
Date of Receiving : 08/07/2024		**Date of Completion** : 22/07/2024	
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	2.04 ml
5.	pH	3.0 to 4.60	3.84
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	1.985 mg	99.25 %	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