



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name : NALOPID Naloxone Injection IP	
Batch No. : GA24E-63A	Mfg. Date : 05/2024
Batch Size : 19300 Ampoules	Exp. Date : 04/2026
Sample Qty. : 75 Ampoules	Analytical Report No.: AFP20240297
Date of Receiving : 03/06/2024	Date of Completion : 17/06/2024
Mfg. Lic. No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless liquid solution filled in 1 ml amber glass ampoule.	A clear colourless liquid solution filled in 1 ml amber glass ampoule.		
2.	Identification				
	A. By HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
	B. By TLC	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	Complies		
3.	Uniformity of filled volume	Not less than nominal volume	Min: 1.0 ml Max: 1.1 ml		
4.	Average fill volume	Not less than 1 ml	1.1 ml		
5.	pH	Between (3.0 to 4.50)	4.43		
6.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/ Ampoule		
	≥ 25µm	NMT 600 particles/Ampoule	Less than 6000 particles/ Ampoule		
7.	Related substances	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution (0.5%).	Complies		
8.	Bacterial Endotoxins	NMT 70 Eu/ml	Less than 70 Eu/ml		
9.	Sterility	Should be Sterile	Sterile		
10.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Naloxone hydrochloride IP Eq. to anhydrous Naloxone hydrochloride		400 mcg	399.0 mcg	99.75 %	95.0% to 105 %

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 IP 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

