



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name : Mucanix-400 Acetylcysteine Injection BP.	
Batch No. : GA24B-26A	Mfg. Date : 02/2024
Batch Size : 14800 Ampoules	Exp. Date : 01/2026
Sample Qty. : 65 Ampoules	Analytical Report No.: AFP20240099
Date of Receiving : 06/03/2024	Date of Completion : 20/03/2024
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless liquid solution filled in 2 ml amber glass ampoule.	A clear colourless liquid solution filled in 2 ml amber glass ampoule.		
2.	Identification (By IR)	The IR spectrum of the residues, obtained after drying at 70° at a pressure not exceeding 0.7 kPa for 2hr, should be concordant with the reference spectrum of the Acetylcysteine.	Complies		
3.	Uniformity of filled volume	Not less than nominal volume	Min: 2.0ml Max: 2.1 ml		
4.	Average fill volume	Not less than 5 ml	2.04 ml		
5.	pH	Between (6.50 to 7.50)	7.11		
6.	Related substances				
	N,N-diacetylcysteine	NMT 1.0%	Not detected		
	Any impurity due to cysteine and cysteine.	NMT 0.50%	Not detected		
	Total secondary impurities	NMT 1.0%	Not detected		
7.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/Ampoule		
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/Ampoule		
8.	Sterility	Should be Sterile	Sterile		
9.	Bacterial Endotoxins	NMT 0.3 IU/ml of solution A.	Less than 0.3 lu/ml		
10.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Acetylcysteine BP		200.0 mg	202.66 mg	101.33 %	95.0% to 105%

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 B.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:- 20/03/2024	Signature:- Date:- 20/03/2024	Signature:- Date:- 20/03/2024

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