



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. : GA24K-22C	Mfg. Date : 11/2024
Batch Size : 1590 Ampoules	Exp. Date : 10/2026
Sample Qty. : 65 Ampoules	Analytical Report No.: AFP20240706
Date of Receiving : 16/11/2024	Date of Completion : 30/11/2024
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: 2.0 ml Max: 2.1 ml		
4.	Average fill volume	Not less than 2 ml	2.02 ml		
5.	pH	Between (6.50 to 7.50)	6.66		
6.	Hydrogen sulfide	Should be complies	Complies		
7.	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		
8.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/Ampoule		
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/Ampoule		
9.	Sterility	Should be Sterile	Sterile		
10.	Bacterial Endotoxins	NMT 0.3 IU/ml of solution A.	Less than 0.3 IU/ml		
11.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Acetylcysteine BP		200.0 mg	198.877 mg	99.44 %	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.

Name	Prepared By Punam Kumari	Checked By Anuj Kumar	Approved By Vikas Gupta Manager (QC)
Designation	Executive	Sr. Executive	
Sign/ Date	 30/11/2024	 30/11/2024	 30/11/2024

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