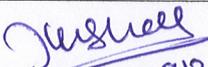


Format No.: KBPL/QC/030/F03-01			
Product Name	MUCANIX		
Generic Name	Acetylcysteine Injection BP 200 mg/ml		
Batch No.	K20324005	A.R. No.	FP/09/24/00019
Mfg. Date	Aug – 2024	Sampling Quantity	50 Ampoules
Exp. Date	Jul – 2026	Sampling Date	12/09/2024
Batch Size	200 Litre X 2 Lot	Date of Analysis	12/09/2024
Pack Quantity	NA	Date of Release	27/09/2024
Ref. Spec. No.	FP/SPC/0017-01	Page No.	Page 1 of 1
Pack Size/Type	5 X 5 ml Ampoules		

Sr. No.	Test	Specification	
1.	Description	A Clear colourless solution.	A Clear colourless solution.
2.	Identification		
	By IR	The sample spectrum is concordant with the reference spectrum of Acetylcysteine	Complies
3.	Acidity or alkalinity (pH)	Between 6.5 to 7.5	6.9
4.	Related Substance (By HPLC)		
	N,N'-diacetylcysteine	NMT 1 %.	0.58 %
	Cysteine or cystine	NMT 0.5 %.	0.17 %
	Total	NMT 1 %.	0.91 %
5.	Hydrogen sulfide	The absorbance of the solution Obtained from the injection is not greater than the absorbance of the solution obtained from the standard 100 ppm with reference to the content of acetylcysteine.	Complies
6.	Extractable Volume	NLT as per label claim.	5.1 ml
7.	Assay	NLT 95.0 to NMT 105.0 %	100.9 %
8.	Particulate matter		
	≥ 10 µm	NMT 6000 no. of particles per container	16 particles per container
	≥ 25 µm	NMT 600 no. of particles per container	0 particles per container
9.	Sterility	Should be sterile.	Sterile
10.	BET	Not more than 0.3 IU/ml	Less than 0.3 IU/ml

CONCLUSION: The Finish Product Sample Complies / ~~Does not complies~~ as per ~~H/WP/BP/USP~~ Specification.

Function	Prepared By	Reviewed By	Approved By
Name	Maya Sirsat	Kushal Deshmukh	Avnish Kumar
Designation-Department	Executive-QC	Asst. Manager-QC	Manager-QC
Sign & Date	 27/09/2024	 27/09/2024	 27/09/2024

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