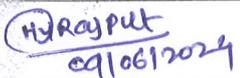
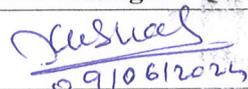
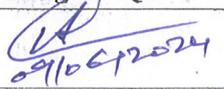


Format No.: KBPL/QC/030/F03-01			
Product Name	MUCANIX		
Generic Name	Acetylcysteine Injection BP 200 mg/ml		
Batch No.	K20324002	A.R. No.	FP/04/24/00016
Mfg. Date	April - 2024	Sampling Quantity	50 Ampoules
Exp. Date	Mar - 2026	Sampling Date	15/04/2024
Batch Size	200 Litre	Date of Analysis	15/04/2024
Pack Quantity	NA	Date of Release	29/04/2024
Ref. Spec. No.	FP/SPC/0017-00	Page No.	Page 1 of 1
Pack Size/Type	5 X 5 ml Ampoules		

Sr. No.	Test	Specification	Result
01	Description	A clear colorless solution.	A clear colorless solution.
02	Identification		
2.1	By Infrared Absorption Spectrophotometry	Spectrum is concordant with the reference spectrum of acetylcysteine.	Complies
03	Acidity or alkalinity	6.5 to 7.5	6.7
04	Extractable volume	NLT 5 ml	5.1 ml
05	Related substances (By HPLC)		
4.1	N, N-Diacetylcysteine	NMT 1.0 %	Not Detected
4.2	Cysteine	NMT 0.5 %	Not Detected
4.3	Total Impurity	NMT 1.0 %	Not Detected
05	Hydrogen Sulfide	The absorbance of the solution obtained from the injection is not greater than the absorbance of the solution from the standard (100 ppm with reference to the content of acetylcysteine)	Complies
06	Particulate Matter		
	≥10µm	NMT 6000 no. of particle per container.	213 particles per container.
	≥ 25µm	NMT 600 no. of particle per container.	12 particles per container.
07	Sterility	Should be Sterile.	Sterile.
08	Bacterial Endotoxin	Not more than 0.3 IU/ml.	Less than 0.3 IU/ml.
09	Assay	NLT 95.0 % and NMT 105.0 %	100.6 %

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

Function	Prepared By	Reviewed By	Approved By
Name	Harshali Rajput	Kushal Deshmukh	Avnish Kumar
Designation-Department	Officer - QC	Asst. Manager - QC	Manager - QC
Sign & Date	 09/06/2024	 09/06/2024	 09/06/2024

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