DERREN HEALTHCARE PRIVATE LIMITED

PLOT NO 33,35/P & 36/P, XCELON INDUSTRIAL PARK,
SARKHEJ-BAVLA HIGHWAY, VILL. VASNA - CHACHARWADI,
TA : SANAND. DIST.AHMEDABAD - 382213, GUJARAT,INDIA

FINISHED PRODUCT ANALYTICAL TEST REPORT

Product Name	**MUCANIX 1 GRAM INJECTION 5 ML AMPOULE**		
Generic Name	ACETYLCYSTEINE INJECTION IP	**Batch No. /Lot No.**	BT26004
		Mfg. Dt.	09/2026
		Exp. Dt.	08/2028
		Receipt Dt.	21/09/2026
		Release Dt.	07/10/2026
		Sample Size	35.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0354
		Manufactured By	DERREN
Analysis	KRUNAL HARMATSINH CHAVDA	**Theoretical Yield/Batch Size**	52,615.000 Ampoule

Sr.	Test	Limit	Result
1	Description	Clear, colourless solution free from visible particles and fibers	Clear, colourless solution free from visible particles and fibers
2	Extractable volume	NLT 5.0 ml	5.1 ml
3	Identification By IR	The IR spectrum obtained from the dried residue Should be complies with the spectrum of Acetylcysteine IPRS or the reference spectrum of Acetylcysteine	The IR spectrum obtained from the dried residue is complies with the spectrum of Acetylcysteine IPRS or the reference spectrum of Acetylcysteine
4	pH	6.5 to 7.5	6.85
5	BACTERIAL ENDOTOXIN	NMT 0.2 EU/ml of Acetyl cysteine	Less than 0.2 EU/ml of Acetyl cysteine
6	Hydrogen Sulphide	NMT 100 ppm	Less than 100 ppm
7	Uniformity of dosage units	Value of 10 Dosage units is less than or equal 15.	4.06 For L1
8	Related Substances	.	.
	Acetylcysteine Impurity A	NMT 0.5%	Not Detected
	Acetylcysteine Impurity B	NMT 1.0%	Not Detected
	Acetylcysteine Impurity C	NMT 1.0 %	Not Detected
	Any other individual impurity	NMT 1.0 %	Not Detected
9	Particulate matter	.	.

Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per IP specification.

Prepared By	Checked By	Approved By
07/10/26	07/10/26	07/10/26

DERREN HEALTHCARE PRIVATE LIMITED

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		A.R. No.	FP/26/0354
		Manufactured By	DERREN
Analysis	KRUNAL HARMATSINH CHAVDA	**Theoretical Yield/Batch Size**	52,615.000 Ampoule

Sr.	Test	Limit	Result
	By Visual inspection	The solution should be free from particles that can be observed by inspection with the unaided eye.	The solution is free from particles that can be observed by inspection with the unaided eye.
	By light obscuration method	Sub visible particle by LPC >10 microns=NMT 6000/Container > 25 Microns=NMT 600/Container	Sub visible particle by LPC >10 microns= 177.33/Container > 25 Microns=4.00/Container
10	Sterility test	Should be sterile	Sterile
11	Assay by HPLC Each ml Contains:Acetyl cysteine 200 mg/ml	95.0% to 105.0% of the stated amount of Acetyl cysteine	103.57% of the stated amount of Acetyl cysteine

Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per IP specification.

Prepared By	Checked By	Approved By
07/10/26	07/10/26	07/10/26

DERREN HEALTHCARE PVT. LTD. QUALITY ASSURANCE DEPT. AHMEDABAD