



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

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Product Name	MUCANIX 5ML	Specification No.	DHPL/FP/SPEC/ACETA/02/01
Generic Name	ACETYLCYSTEINE INJECTION	Batch No. /Lot No.	BT26001
		Mfg. Dt.	03/2026
		Exp. Dt.	02/2028
		Receipt Dt.	28/03/2026
		Release Dt.	11/04/2026
		Sample Size	35.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0150
		Manufactured By	DERREN
		Theoretical Yield/Batch Size	54,807.000 Ampoule

Analysis: DHAVAL GHANSHYAMBHAI PATEL

Sr.	Test	Limit	Result
1	Description	Clear, colorless solution free from visible particles and fibers.	Clear, colorless solution free from visible particles and fibers.
2	Extractable volume	NLT 2.0 ml	2.0 ml
3	Identification Identification By IR	The infrared absorption spectrum of the test preparation should be concordant with the reference spectrum of the Acetyl cysteine acid RS/WS	The infrared absorption spectrum of the test preparation is concordant with the reference spectrum of the Acetyl cysteine acid RS/WS
4	pH	6.5 to 7.5	6.8
5	Bacterial Endotoxin test	NMT 0.3 EU/ml of Acetyl cysteine	NLT 0.3 EU/ml of Acetyl cysteine
6	Particulate matter By Visual inspection By light obscuration method	The solution should be free from particles that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns=NMT 6000/Container > 25 Microns=NMT 600/Container	The solution is free from particles that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns= 156.00/Container > 25 Microns= 4.00/Container
7	Sterility test	Should be sterile	sterile
8	Assay	95.0 % to 105.0% of the stated amount of Acetylcysteine.	99.49% of the stated amount of Acetylcysteine.

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

Prepared By

D

DHAVAL
QC OFFICER

11/04/26

Checked By

for

R

NUTAN PRAJAPATI
QC HEAD

11/04/26

Approved By

KRUNAL GAJERA
QA HEAD



DHAVALP 11/04/2026 03:27 PM

FgAnlCert02