



# - 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

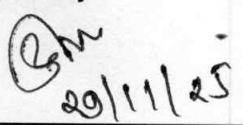
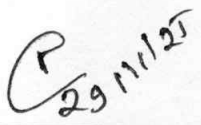

## FINISHED PRODUCT ANALYTICAL TEST REPORT

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<b>Product Name</b>	MUCANIX 5ML	<b>Specification No.</b>	DHPL/FP/SPEC/ACETA/02/00
<b>Generic Name</b>	ACETYLCYSTEINE INJECTION	<b>Batch No. /Lot No.</b>	BT25008
		<b>Mfg. Dt.</b>	11/2025
		<b>Exp. Dt.</b>	10/2027
		<b>Receipt Dt.</b>	15/11/2025
		<b>Release Dt.</b>	29/11/2025
		<b>Sample Size</b>	41.000 Ampoule
		<b>Mfg. Lic. No.</b>	G/28/1862
		<b>A.R. No.</b>	FP/25/0291
<b>Analysis</b>	DHIREN MUKESHBHAI PATEL	<b>Manufactured By</b>	DERREN
		<b>Theoretical Yield/Batch Size</b>	55,769.000 Ampoule

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	2.1 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	6.9
5	Bacterial Endotoxin-test	NMT 0.3 EU/ml of Acetyl cysteine	Less than 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=50.00/Container > 25 Microns=0.00/Container
7	Sterility test	Should be sterile	sterile
8	Assay	95.0 % to 105.0% of the stated amount of Acetylcysteine.	99.3% of the stated amount of Acetylcysteine.

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

<b>Prepared By</b>  29/11/25	<b>Checked By</b>  29/11/25	<b>Approved By</b>  29/11/2025
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