



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

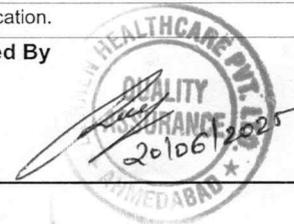
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Product Name	N-ACETYLE INJECTION 5ML AMP	Specification No.	DHPL/FP/SPEC/ACETA/02/00
Generic Name	ACETYLCYSTEINE INJECTION	Batch No. /Lot No.	BT25003
		Mfg. Dt.	06/2025
		Exp. Dt.	05/2027
		Receipt Dt.	06/06/2025
		Release Dt.	20/06/2025
		Sample Size	41.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0114
		Manufactured By	DERREN
Analysis	DHIREN MUKESHBHAI PATEL	Theoretical Yield/Batch Size	55,769.000 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 2.0 ml	2.0 ml
3	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 should be concordant with the reference spectrum of the Acetyl cysteine acid RS/WS.
4	pH	6.5 to 7.5	7.4
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=58.67/Container > 25 Microns=0.67/Container
7	Sterility test	Should be sterile	sterile
8	Assay Each ml Contains:Acetyl cysteine 200 mg	95.0% to 105.0% of the stated amount of Acetyl cysteine.	99.4% of the stated amount of Acetyl cysteine.

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

Prepared By 20/06/25	Checked By 20/06/25	Approved By 20/06/25
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