



DERREN HEALTHCARE PVT. LTD.

Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India
Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi,
Ahmedabad-382 213, Gujarat (India)

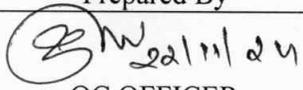
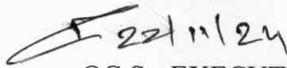
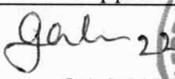
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Name of Product	Acetyl cysteine Injection BP 200mg/ml (MUCANIX)		
Batch No.	BT24003	A.R. No.	FP/24/0125
Mfg. Date	10/24	Exp. Date	09/26
Sampled Qty.	41 Nos.	Date of Analysis	30/10/24
Batch Size	280 Ltr.	Date of Release	22/11/24
Container Type	Amber Glass Ampoule	Fill volume	5.0 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, colourless solution free from visible particles and fibres.	Clear, colorless solution free from visible particles and fibers.
2	Extractable volume	5.2 ml	NLT 5.0 ml
3	Identification		
3.1	Identification By IR	Complies	The infrared absorption spectrum of the test preparation should be concordant with the reference spectrum of the Acetyl cysteine acid RS/WS
4	pH	6.60	6.5 to 7.5
5	Bacterial endotoxin	Less than 0.3 EU/ml	NMT 0.3 EU/ml of Acetyl cysteine
6	Particulate matter		
6.1	By Visual Inspection	The solution is free from particles that is observed by inspection with the unaided eye.	The solution should be free from particles that can be observed by inspection with the unaided eye.
6.2	By Light Obscuration Method	≥ 10 microns=220.00/Container ≥ 25 Microns= 1.67 /Container	Sub visible particle by LPC ≥ 10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
7	Sterility test	Sterile	Should be sterile
8	Assay		
8.1	Each ml Contains: Acetyl cysteine 200 mg	98.5%	90.0% to 110.0% of the stated amount of Acetylcysteine.

Conclusion: The above sample complies as per BP specification.

In the opinion of the undersigned the sample referred to above is **of standard** / ~~not of standard~~ quality as defined in the act and the rules made there under for the reasons given above.

Prepared By  QC OFFICER	Checked By  QC Sr. EXECUTIVE	Approved By  QA MANAGER
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