

# Pace

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# Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

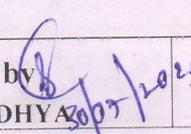
Title

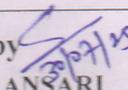
Certificate of Analysis Finished Product

Product Name	MUCANIX 400 Injection	A.R. No.	NL/FP/25/123
Generic Name	Acetylcysteine Solution USP 2ml	Sampled qty.	45 Ampoules
Batch No.	A25103A	Sampled by	Rakesh
Batch Size	10,000 Ampoules	Sampled on	15/07/2025
Mfg. Date	06/2025	Date of Testing	15/07/2025
Exp. Date	05/2027	Date of Release	30/07/2025

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in amber colour glass ampoule.	A clear colourless solution filled in amber colour glass ampoule.		
2.	Identification ( By IR)	The infrared absorption spectrum of the residue, A, is concordant with the working standard spectrum of Acetylcysteine.	Complies		
3.	Nominal fill volume	NLT 2ml	2.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml		
5.	pH	6.0 to 7.5	7.04		
6.	Particulate Matter (A.) Light Obscuration Particle count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visible Particulate matter	NMT 6000/Ampoule NMT 600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that cannot see with naked eye.	65/Ampoule 3/Ampoule Complies		
7.	Sterility	No microbial growth should be observed.	Complies		
8.	Assay: (By HPLC) Each ml contains:				
Ingredients		Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Acetylcysteine	USP	200 mg	197.05 mg	98.53%	90.0 to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/HHS.

Analysis by   
NAME: SANDHYA 30/07/2025

Checked by   
NAME: SUFIYAN ANSARI

Approved by   
NAME: SWATI BHATNAGAR

