

Pace

Add Pace To Health

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/25/045
Generic Name	Acetylcysteine Solution USP 200mg/ml	Sampled qty.	45 Ampoules
Batch No.	A25024F	Sampled by	Rakesh
Batch Size	20,000 Ampoules	Sampled on	07/05/2025
Mfg. Date	04/2025	Date of Testing	07/05/2025
Exp. Date	03/2027	Date of Release	22/05/2025

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)	A. Compare the spectrum obtained with the test solution residue corresponds to the spectrum obtained with the working standard.	Complies
	(By HPLC)	B. In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with working standard solution.	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	7.32
6.	Particulate Matter	NMT 6000/Ampoule NMT 600/Ampoule . The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	27/Ampoule 3/Ampoule Complies
	(A.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visible particulate matter		
7.	Sterility	No microbial growth should be observed.	Complies
8.	Assay: Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Acetylcysteine USP	200 mg	204.57 mg	102.29%	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/ IHS.

Analysis by NAME: SANDHYA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: SWATI DHAWAN
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