



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

:

Certificate of Analysis Finished Product

Product Name	MUCANIX 2ml Injection	A.R. No.	ARN/FP/25/084
Generic Name	Acetylcysteine Solution USP	Sampled qty.	45 Ampoules
Batch No.	ARN25107A	Sampled by	Rakesh
Batch Size	50,400 vials	Sampled on	05/01/2026
Mfg. Date	01/2026	Date of Testing	06/01/2026
Exp. Date	12/2027	Date of Release	20/01/2026

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	7.00	
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 can be seen with naked eye.	56/Ampoule 6/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	206.47359 mg	103.24%	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/HS.

Analysis by *[Signature]*

NAME: FIROJ KHAN

Checked by *[Signature]*

NAME: RAMANJEET SINGH

Approved by *[Signature]*

NAME: MRS. SWATI DHAWAN

