



AMERICAN REMEDIES HEALTHCARE PVT. LTD.
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

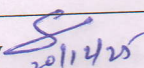
Title :

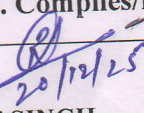
Certificate of Analysis Finished Product


Product Name	GLYCOLYTE Injection	A.R. No.	ARN/FP/25/067
Generic Name	Glycopyrrolate Injection IP 1ml	Sampled qty.	60 Ampoules
Batch No.	ARN2566A	Sampled by	Aakash
Batch Size	1,00,000 Ampoules	Sampled on	05/12/2025
Mfg. Date	11/2025	Date of Testing	05/12/2025
Exp. Date	10/2027	Date of Release	20/12/2025

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.		
2.	Identification by TLC	A. The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution. B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution (a).	Complies Complies		
3.	Nominal fill volume	NLT-1ml	1.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume	1.1 ml		
5.	pH	2.0 to 3.0	2.61		
	Particulate Matter				
	a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT-6000/Ampoule NMT-600/ Ampoule	11/Ampoule 1/Ampoule		
	(b.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies		
6.	Sterility	No microbial growth should be observed.	Complies		
7.	Bacterial Endotoxins	NMT 555.5 EU/mg of glycopyrrolate.	Less than 555.5 EU/mg of glycopyrrolate.		
8.	Assay: Each ml contains:				
Ingredients		Labeled claim	Found	% of labeled amount	Limits % of labeled amount
Glycopyrrolate IP		0.2 mg	0.19969mg	99.85%	93.0 to 107.0%

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 
NAME: SUFIYAN ANSARI

Checked by 
NAME: RAMANJEET SINGH

Approved by 
NAME: MRS. SWATI