



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

Title

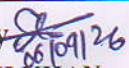
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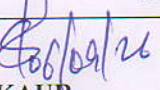
Certificate of Analysis Finished Product

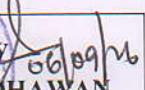
Product Name	GLYCOLYTE Injection	A.R. No.	ARN/FP/26/055
Generic Name	Glycopyrrolate Injection IP 1ml	Sampled qty.	60 Ampoules
Batch No.	ARN2646A	Sampled by	Rakesh
Batch Size	99,500 Ampoules	Sampled on	22/08/2026
Mfg. Date	08/2026	Date of Testing	23/08/2026
Exp. Date	07/2028	Date of Release	06/09/2026

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	2.81		
	Particulate Matter	NMT-6000/Ampoule NMT-600/ Ampoule The solution is free from particles of foreign matter particles that can be observed on visual inspection.	25/Ampoule 0/Ampoule Complies		
	a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$				
	(b.) Visual				
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	0.20335mg	101.68%	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: SHAHRUKH KHAN

Checked by 
NAME: SURJEET KAUR

Approved by 
NAME: MRS. SWATI DHAWAN