AMERICAN REMEDIES
Care & Cure with Research

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/26/098
Generic Name	Glycopyrrolate Injection IP 1ml	**Sampled qty.**	60 Ampoules
Batch No.	ARN26107A	**Sampled by**	Shivanand
Batch Size	98,900 Ampoules	**Sampled on**	16/10/2026
Mfg. Date	10/2026	**Date of Testing**	17/10/2026
Exp. Date	09/2028	**Date of Release**	31/10/2026

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	2.87
	Particulate Matter a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm (b.) Visual	NMT-6000/Ampoule NMT-600/ Ampoule The solution is free from particles of foreign matter particles that can be observed on visual inspection.	4/Ampoule 0/Ampoule 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	0.20517mg	102.58%	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/IHS.

Analysis by	Checked by	Approved by
31/10/26	31/10/26	31/10/26
NAME: FIROJ KHAN	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
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Lovely Clinical University, Jalandhar