

Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

Certificate of Analysis Finished Product

Product Name	GLYCOLYTE Injection	A.R. No.	NL/FP/25/292
Generic Name	Glycopyrrolate Injection-IP 1ml	Sampled qty.	60 Ampoules
Batch No.	A25327D	Sampled by	Rakesh
Batch Size	5,000 Ampoules	Sampled on	01/01/2026
Mfg. Date	12/2025	Date of Testing	01/01/2026
Exp. Date	11/2027	Date of Release	19/01/2026

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	2.86		
	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	3/Ampoule 0/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	0.20156mg	100.78%	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 per Mrs. Suniti Dharma
The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not complies as per IP/ BP/ USP/ IHS.
Registration: 00117

Analysis by S. 19/01/26

Checked by 19/01/26

Approved by 19/01/26

Qualification: M.Sc. Clinical Microbiology

Registration: 00117