



Tamman Titoe Pharma Pvt Ltd
56-57, Sidco Pharmaceutical Complex,
Alathur-603 110, Tamilnadu.

QUALITY CONTROL DEPARTMENT
Certificate of Analysis of Finished Product
(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/FG/518/24-25
Report Date:25-01-2025

Name of the product : **GLYCOLYTE Injection 1ml**
Generic Name : Glycopyrrolate Injection I.P
Batch No. : GP501
Batch Size : 104000
Mfg. Date. : JAN-2025
Exp. Date. : DEC-2027
Quantity of Sample : 100 Nos
Date of Sampling : 09-01-2025
Date of Commencement of analysis : 09-01-2025
Date of Completion of analysis : 24-01-2025

TEST NAME	SPECIFICATION	OBSERVATION
Description	A clear, colourless solution.	A clear, colourless Solution
Identification BY TLC	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	Complies to IP specification
pH	2.0 to 3.0	2.80
Extractable Volume	NLT- 1.0ml	1.1 ml
Particulate matter	No visible particles	Complies
Bacterial endotoxins	NMT 555.5EU /mg of Glycopyrrolate	LT 555.5 EU/mg
Sterility Test	To comply as per IP	Complies
Assay Each ml contains : Glycopyrrolate I.P 0.2 mg	0.186mg to 0.214mg 93.0 % to 107%)	0.206mg (103.00%)

OBSERVATION: In the opinion of the undersigned the sample referred to above is of Standard Quality/Not Standard Quality as in the act and the rules made there under for the reason given below.

REMARKS : COMPLIES AS PER IP WITH RESPECT TO THE ABOVE TESTS ONLY CARRIED OUT.

Analysed By:
Date: 25/01/25

Checked By:
Date: 25/01/25

Person In Charge of Testing
Date: 25/01/25

