

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


Report No: TT/FG/736/23-24
 Report Date: 07-04-2024

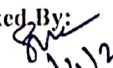
Name of the product	: Glycolyte injection 1ml
Generic Name	: Glycopyrrolate injection I.P
Batch No.	: GP401
Batch Size	: 52000
Mfg. Date.	: Mar-2024
Exp. Date.	: Feb-2027
Quantity of Sample	: 100 Nos
Date of Sampling	: 23-03-2024
Date of Commencement of analysis	: 23-03-2024
Date of Completion of analysis	: 06-04-2024

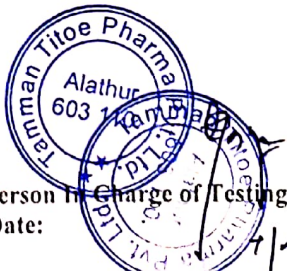
TEST NAME	SPECIFICATION	OBSERVATION
Description	A clear, colourless solution.	A clear, colourless Solution
Identification BY TLC	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	Complies to IP specification
pH	2.0 to 3.0	2.85
Extractable Volume	NLT- 1.0ml	1.1 ml
Particulate matter	No visible particles	No visible particles
Bacterial endotoxins	NMT 555.5Eu/mg of Glycopyrrolate	Complies to IP specification
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%	0.198mg (99.00%)

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: 07/04/24

Checked By: 
 Date: 7/4/24


 Person in Charge of Testing
 Date: 7/4/24