

## 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/725/23-24 Report Date: 01-04-2024

Name of the product

:Phenvil injection 2ml

Generic Name

:Pheniramine Maleate injection I.P

Batch No. **Batch Size**  : PM407

: 104000

Mfg. Date.

: Mar-2024

Exp. Date.

:Feb-2027

Quantity of Sample

:100 Nos

Date of Sampling

Pate of Commencement of analysis

:17-03-2024 :17-03-2024

Cate of Completion of analysis

: 31-03-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless solution.
Identification: (By T.L.C)	The principal Spot in the chromatogram obtained with the test solution corresponds to that in thechromatogram obtained with the reference solution.	Complies to IP specification
рН	4.5 to 5.5	5.31
Extractable Volume	NLT-2.0ml	2.1 ml
Particulate matter	No visible particles	No visible particles
Related substances	Any secondary spot in thechromatogram obtained with the test solution is not more intense than the spot in thechromatogram obtained with the reference solution.	Complies to IP specification
Sterility	To comply as per IP	Comply as per IP
Assay	90.0% to 110.0%	100.26%
Each ml contains: Pheniramine maleate I.P 22.75 mg	(20.47mg to 25.02 mg)	22.81mg

In the opinion of the undersigned the sample referred to above is of Standard Quality/Not Standard Quality as OBSERVATION:

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

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