

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/224/24-25 Report Date: 09-08-2024

Name of the product

:PHENVIL Injection 2ml

Generic Name

:Pheniramine Maleate Injection I.P

Batch No.

: PM412

Batch Size

: 100000

Mfg. Date.

: JULY-2024

Exp. Date.

:JUNE-2027

Quantity of Sample

:100Nos

Date of Sampling

:25-07-2024

Date of Commencement of analysis

:25-07-2024

ate of Completion of analysis

: 08-08-2024

| SPECIFICATION | OBSERVATION |
|--|--|
| A clear, colourless solution. | A clear, colourless solution. |
| 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 |
| 4.5 to 5.5 | 4.88 |
| NLT-2.0ml | 2.1ml |
| No visible particles | No visible particles |
| 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 |
| To comply as per IP | Comply as per IP |
| 90.0% to 110.0% | 99.43% |
| (20.47mg to 25.02 mg) | 22.62mg |
| | A clear, colourless solution. The principal Spot in the chromatogram obtained with the test solution corresponds to that in thechromatogram obtained with the reference solution. 4.5 to 5.5 NLT-2.0ml No visible particles Any secondary spot in thechromatogram obtained with thetest solution is not more intense than the spot in thechromatogram obtained with the reference solution. To comply as per IP 90.0% to 110.0% |

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 CARRIEDOUT.

Analysed By:

Checked B