



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour.

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name : Phenylcan 10 Phenylephrine Injection IP	
Batch No. : GA25B-07A	Mfg. Date : 02/2025
Batch Size : 10000 Ampoules	Exp. Date : 01/2027
Sample Qty. : 75 Ampoules	Analytical Report No.: AFP20250108
Date of Receiving : 06/02/2025	Date of Completion : 20/02/2025
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless liquid solution filled in 1 ml amber glass ampoules.	A clear colourless liquid solution filled in 1 ml amber glass ampoules.		
2.	Identification Test A (By TLC)	In the test for Related substances, the principal spot in the chromatogram obtained with test solution (b) corresponds to that in the chromatogram obtained with reference solution (b).	Complies		
	Test B By chemically	The ether layer remains colourless.	Complies		
	Test C By chemically	It gives reaction (A) of chlorides.	Complies		
3.	Uniformity of filled volume	Not less than nominal volume	Min: 1.0 ml Max: 1.1 ml		
4.	Average fill volume	Not less than 1 ml	1.05 ml		
5.	pH	4.50 to 6.5	4.93		
6.	Related substances By TLC	Any secondary spot in the chromatogram obtained with test solution (a) is not more intense than the spot in the chromatogram obtained with test solution (b) and not more than two such spots are more intense than the spot in the chromatogram obtained with reference solution (a).	Complies		
7.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/container	Less than 6000 particles/container		
	≥ 25µm	NMT 600 particles/container	Less than 600 particles/container		
8.	Sterility	Should be Sterile	Sterile		
9.	Bacterial Endotoxins	NMT 25.0 EU/mg of Phenylephrine.	Less than 25.0 EU/mg of Phenylephrine.		
10.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Phenylephrine hydrochloride IP		10 mg	10.20 mg	102.0.0%	95.0% to 105 %

Remarks: In the opinion of the undersigned the sample submitted ~~complies/does not comply~~ with the prescribed ~~standard/not standard~~ of quality, as according to I.P. and IHS with respect to the above test only.

Name	Prepared By	Checked By	Approved By
	Punam Kumari	Anuj Kumar	Vikas Gupta
Designation	Executive	Sr. Executive	Manager (QC)
Sign/ Date	<i>[Signature]</i> 20/02/2025	<i>[Signature]</i> 20/02/2025	<i>[Signature]</i> 20/02/2025

Format No.: VH/SOP/QC-062/FT01-01

