VELLINTON HEALTHCARE

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	**: Phenylcan 10** Phenylephrine Injection I.P.		
Batch No.	: GA26I-72F	**Mfg. Date**	: 09/2026
Batch Size	: 10030 Ampoules	**Exp. Date**	: 08/2028
Sample Qty.	: 65 Ampoules	**Analytical Report No.:**	AFP20260572
Date of Receiving	: 26/09/2026	**Date of Completion**	: 10/10/2026
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	Clear colourless liquid solution filled in 1 ml amber colour 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	5.20
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 I.P.	10 mg	10.1106mg	101.11 %	95.0% to 105 %

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

	Prepared By	Checked By	Approved By
Name	**Manisha**	**Punam Kumari**	**Vinit Kumar**
Designation	**Sr. Officer (QC)**	**Executive (QC)**	**Asst. Manager (QC)**
Sign/ Date	10/10/2026	10/10/2026	

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