



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

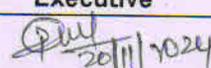
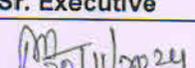
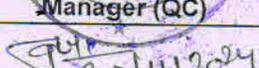
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name : Hydralazine Hydrochloride injection USP	
Batch No. : GA24J-60A	Mfg. Date : 10/2024
Batch Size : 30770 Vials	Exp. Date : 09/2026
Sample Qty. : 75 Ampoules	Analytical Report No.: AFP20240685
Date of Receiving : 06/11/2024	Date of Completion : 20/11/2024
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless liquid solution filled in amber coloured glass ampoule.	A clear colourless liquid solution filled in amber coloured glass ampoule.		
2.	Identification BY IR	The IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelength as those of USP Hydralazine hydrochloride RS similarly treated and prepared.	Complies		
3.	Uniformity of filled volume	Not less than nominal volume	Min: 1.0ml Max: 1.1 ml		
4.	Average fill volume	Not less than 1 ml	1.02 ml		
5.	pH	Between (3.40 to 4.4)	4.38		
6.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/container	Less than 6000 particles/ container		
	≥ 25µm	NMT 600 particles/ container	Less than 600 particles/ container		
7.	Sterility	Should be Sterile	Sterile		
8.	Bacterial Endotoxins	NMT 1.45 USP Eu/mg	Less than 1.45 USP Eu/mg		
9.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Hydralazine hydrochloride USP		20.0 mg	19.808 mg	99.04 %	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 U.S.P. and IHS with respect to the above test only.

Name	Prepared By Punam Kumari	Checked By Anuj Kumar	Approved By Vikas Gupta
Designation	Executive	Sr. Executive	Manager (QC)
Sign/ Date	 20/11/2024	 20/11/2024	 20/11/2024

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