



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour-173030. HP

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name : Dopacan Dopamine hydrochloride injection IP	
Batch No. : GA24L-13A	Mfg. Date : 12/2024
Batch Size : 25345 Ampoules	Exp. Date : 11/2027
Sample Qty. : 50 Ampoules	Analytical Report No : UFP20240052
Date of Receiving : 28/12/2024	Date of Completion : 11/01/2025
Spec No : FP/DPM/SPC/001	STP No : FP/DPM/STP/001

S. No.	Tests	Specifications	Observations	
1.	Description	A clear colourless solution filled in amber glass ampoule.	A clear colourless solution filled in amber glass ampoule.	
2.	Identification			
	A. By IR	The Infrared absorption spectrum of the residue is concordant with the reference spectrum of Dopamine hydrochloride.	Complies	
	B. By Chemically	An intense green colour should be produced.	Complies	
3.	Uniformity of filled volume	Not less than nominal volume	Min: 5.0 ml Max: 5.1 ml	
4.	Average fill volume	Not less than 5 ml	5.06 ml	
5.	pH	Between (3.0 to 4.5)	3.35	
6.	5-hydroxymethylfurfural	NMT 0.05 %	Complies	
7.	Related substances			
	Area of any secondary peak	NMT 2.5 %	Not detected	
	Area of principal peak	NMT 2.0 %	Not detected	
8.	Particulate Matter			
	≥ 10µm	NMT 6000 particles/container	Less than 6000 particles/container	
	≥ 25µm	NMT 600 particles/container	Less than 600 particles/ container	
9.	Bacterial Endotoxins	NMT 26.67 EU/ml of 0.16%w/v solution of Dopamine HCl.	Less than 26.67 EU/ml of 0.16%w/v solution of Dopamine HCl.	
10.	Sterility	Should be Sterile	Sterile	
11.	Assay : Each ml contains:-			
Composition:	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Dopamine hydrochloride IP	40.0 mg	39.7 mg	99.25 %	95.0% to 105.0 %

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 IP & 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			

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