



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

QUALITY CONTROL DEPARTMENT

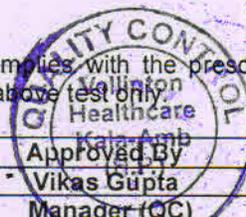
CERTIFICATE OF ANALYSIS

Product Name	: ADENOCAN Adenosine Injection IP		
Batch No.	: GA24K-28D	Mfg. Date	: 11/2024
Batch Size	: 10656 Ampoules	Exp. Date	: 10/2026
Sample Qty.	: 65 Ampoules	Analytical Report No.:	AFP20240712
Date of Receiving	: 16/11/2024	Date of Completion	: 30/11/2024
Neutral Code No.	: N-MB/18-201		

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless liquid solution filled in 2 ml amber glass ampoules.	A clear colourless liquid solution filled in 2 ml amber glass ampoules.		
2.	Identification (By HPLC)	In the assay, the principal peak in the chromatogram obtained with test solution (b) corresponds to that in the chromatogram obtained with reference solution (b).	Complies		
3.	Uniformity of filled volume	Not less than nominal volume	Min: 2.0 ml Max: 2.1 ml		
4.	Average fill volume	Not less than 2 ml	2.02 ml		
5.	pH	Between (4.50 to 7.5)	6.45		
6.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/Ampoule		
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/Ampoule		
7.	Related substances				
	Single impurity	NMT 1.0 %	Complies		
	Total impurities	NMT 1.5 %	Complies		
8.	Sterility	Should be Sterile	Sterile		
9.	Bacterial Endotoxins	NMT 11.62 Eu/mg	Less than 11.62 Eu/mg		
10.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Adenosine IP		3.0 mg	2.998 mg	99.96 %	90.0 to 110%

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 Punam Kumari	Checked By Anuj Kumar	Approved By Vikas Gupta
Designation	Executive	Sr. Executive	Manager (QC)
Sign/ Date	 30/11/2024	 30/11/2024	 30/11/2024



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