



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 6 mg/2ml	
Batch No. : GA24E-08B	Mfg. Date : 05/2024
Batch Size : 14730 Ampoules	Exp. Date : 04/2026
Sample Qty. : 65 Ampoules	Analytical Report No.: AFP20240256
Date of Receiving : 22/05/2024	Date of Completion : 05/06/2024
Neutral Code No. : N-MB/18-201	

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless liquid solution filled in 2 ml transparent glass ampoules.	A clear colourless liquid solution filled in 2 ml transparent 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: 2.0ml Max: 2.1 ml
4.	Average fill volume	Not less than 2 ml	2.05 ml
5.	pH	Between (4.50 to 7.5)	5.90
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	3.01 mg	100.33 %	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.

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager In Charge
Signature:- <i>[Signature]</i>	Signature:- <i>[Signature]</i>	Signature:- <i>[Signature]</i>
Date:- 05/06/2024	Date:- 05/06/2024	Date:- 05/06/2024

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