

Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

:

Certificate of Analysis Finished Product

Product Name	ADENOCAN Injection	A.R. No.	NL/FP/26/037
Generic Name	Adenosine Injection IP 2ml	Sampled qty.	45 Ampoules
Batch No.	A26001A	Sampled by	Rakesh
Batch Size	20,000 Ampoules	Sampled on	05/05/2026
Mfg. Date	04/2026	Date of Testing	06/05/2026
Exp. Date	03/2028	Date of Release	21/05/2026

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 (By HPLC)	In the assay, the principle peak in the chromatogram obtained with the test solution (b) corresponds to that in the chromatogram obtained with the reference solution (b).	Complies		
3.	Nominal fill volume	NLT 2ml	2.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml		
5.	pH	4.5 to 7.5	6.28		
6.	Related substances				
	Area of any secondary peak	NMT 1.0%	0.113%		
	Sum of area of all the secondary peaks	NMT 1.5%	0.250%		
6.	Particulate Matter	NMT 6000/Ampoule NMT600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	2/Ampoule 0/Ampoule Complies		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle				
7.	Sterility	No microbial growth should be observed.	Complies		
8.	Bacterial Endotoxins	NMT 11.62 EU/mg of Adenosine.	Less than 11.62 EU/mg of Adenosine.		
9.	Assay: Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Adenosine IP		3 mg	3.20039 mg	106.68%	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/IHS.

Analysis by NAME: FIROJ KHAN	Checked by NAME: SUFIYAN ANSARI	Qualification : M.Sc. Clinical Microbiology Registration No. : 580406039593 NAME: MRS. SWATI DHAWAN Punjab Technical University, Chandigarh
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