



Pacebiotech Pharma (India) Pvt. Ltd.

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

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	ADR - Injection (Adrenaline Bitartrate Injection IP 1mg/ml)		
Batch No.	25AF092A	A.R. No.	PV250577
Batch Size	70200 Ampoules	Sample Quantity	60 Nos
Mfg. Date	06/2025	Date of Testing	19/06/2025
Exp. Date	05/2027	Date of Release	05/07/2025
Reference Batch No	25AF092	MFG. Lic. No.	N-MB-2023/263

Sr. No.	Test	Specification	Observation
1.	Description	A clear, colourless or almost colourless solution	A clear, colourless solution
2.	Identification (A) BY HPLC (B) By Chemically (C) By Chemically	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponding to the peak in the chromatogram obtained with reference solution. B. To 1 ml add dropwise a 0.25 per cent w/v solution of ferric chloride until an emerald-green colour is produced. Add sodium bicarbonate solution gradually the solution changes first to blue and then to red. C. To 10 ml add 2 ml of disodium hydrogen phosphate solution and sufficient iodine solution to produce a brown colour. Add 0.1M sodium thiosulphate dropwise until excess iodine is removed a red colour is produced.	Complies
3.	pH	Between 2.8 to 3.6	3.53
4.	Extractable Volume	NLT 1.0 ml	1 ml
5.	Appearance of solution	It is not pinkish and does not contain a precipitate. If any yellow colour is observed it is not more intense than a reference solution prepared by diluting 0.4 ml of 0.7 M iodine to 100 ml with water, when viewed similarly.	Complies
6.	Noradrenaline	NMT 1.0 %	Complies



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7.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
8.	Bacterial Endotoxins	NMT 357 EU/mg	Less than 357 EU/mg
9.	Sterility	Should be complies	Under Sterility
10.	Assay: Each ml contains Adrenaline Bitartrate IP eq to Adrenaline 1mg/ml	(0.90 to 1.15 mg) 90.0 to 115.0 %	(0.998mg) 99.85%

Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 05/07/2025	 05/07/2025	 05/07/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC