



Tamman Titoe Pharma Pvt Ltd
56-57, Sidco Pharmaceutical Complex,
Alathur-603 110, Tamilnadu.

QUALITY CONTROL DEPARTMENT
Certificate of Analysis of Finished Product
(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/FG/302/24-25
Report Date: 25-09-2024

Name of the product :ADR Injection 1ml
Generic Name :Adrenaline Bitartrate Injection I.P
Batch No. : AD413
Batch Size : 205000
Mfg. Date. : SEP-2024
Exp. Date. : AUG-2026
Quantity of Sample :100 Nos
Date of Sampling : 10-09-2024
Date of Commencement of analysis : 10-09-2024
Date of Completion of analysis : 24-09-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless solution.
Identification:	The principal Peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution(a).	Complies to IP specification
A. In The Assay		
B. Colour reaction	The solution changes first to blue and then to red	Complies to IP specification
C. Colour reaction	A red colour is produced	Complies to IP specification
pH	2.8 to 4.0	3.82
Appearance of solution:	If any yellow colour is observed it is not more than reference solution prepared by diluting 0.4ml of 0.1M Iodine to 100ml with water. when viewed similarly.	Complies to IP specification
Extractable Volume :	NLT- 1.0 ml / Ampoule	1.1 ml
Particulate matter:	No visible particles	Complies
Sterility Test:	To comply as per IP	complies
Noradrenaline	The area of the peak corresponding to noradrenaline is not more than the area of the principal peak in the chromatogram with the reference solution (a)	complies
Assay:	0.9 mg to 1.15mg	1.016mg
Each ml contains : Adrenaline Bitartrate I.P Equivalent to Adrenaline 1mg	90.0% - 115.0%	101.60%

OBSERVATION: In the opinion of the undersigned the sample referred to above is of Standard Quality/Not Standard Quality as in the act and the rules made there under for the reason given below.

Analysed By: 
Date: 25/09/2024

Checked By: 
Date: 25/09/2024

Person In Charge of Testing: 
Date: 25/09/2024