

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/258/24-25 Report Date: 28-08-2024

Name of the product

:ADR Injection 1ml

Generic Name

:Adrenaline Bitartrate Injection I.P

Batch No. Batch Size : AD411

Mfg. Date.

: 150000 : AUG-2024

Exp. Date.

: JULY-2026

Quantity of Sample

:100 Nos

Date of Sampling

: 14-08-2024

Date of Commencement of analysis

: 14-08-2024

te of Completion of analysis

: 28-08-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless solution.
Identification: A.In The Assay	The principal Peakt in the chromatogram obtained with the test solution corresponds to that in thechromatogram obtained with the reference solution(a).	Complies to IP specification
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	3.81
Appearance of solution:	If any yellow colour is observed it is not more than reference solution prepared by diluting 0.4ml of0.1M lodine to 100ml with water when viewed similarly.	Complies to IP specification
ractable Volume :	NLT- 1.0 ml / Ampoule	1.1 ml
Particulate matter:	No visible particles	Complies
Sterility Test:	To comply as per IP	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/Net Standard Quality as

in the act and the rules made there under for the reason given below.

REMARKS

COMPLIES AS PER IP WITH RESPECT TO THE ABOVE TESTS ONLY CARRIEDOUT.

Checked By Date:

Person In Date: