

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/127/24-25 Report Date: 08-07-2024

Name of the product

:Dopacan Injection 5ml

Generic Name

: Dopamine Injection I.P.

Batch No.

: DO402

Batch Size

: 52000

Mfg. Date.

: May-2024

Exp. Date.

: April-2027

Quantity of Sample

:50 Nos

Date of Sampling

:22-06-2024

Date of Commencement of analysis

:22-06-2024

ate of Completion of analysis

: 06-07-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless Solution
Identification: A.(By IR )	The infrared absorption spectrum of sample is concordant with infrared absorption spectrum of Dopamine Hydrochloride RS.	Complies to IP specification
B. Colour reaction.	An intense green colour is produced	Complies to IP specification
рН	2.5 to 5.5	4.91
Extractable Volume	NLT- 5.0ml/Ampoule	5.1 ml
Particulate matter	No visible particles	No visible particles
Bacterial endotoxins	NMT 26.67 EU/ml of a0.16% w/v solution of dopamine Hydrochloride in water for injection.	LT 26.67 EU/ml
Sterility Test	To comply as per IP	Complies
Assay		
Each ml contains: Dopamine	38.0 mg to 42.0 mg	39.96mg
Hydrochloride I.P 40mg	(95.0 % - 105%)	(99.90%)

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.

REMARKS

COMPLIES AS PER IP WITH RESPECT TO THE ABOVE TESTS ONLY CARRIED OUT TO

Analysed By: 🗸 🏈 Date:

Checked By

Person In Charge of Testing

Date: