

TAMMAN TITOE

PREVENTION AND CURE

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/705/23-24
Report Date: 23-03-2024

Name of the product : Metocan injection 2ml
Generic Name : Metoclopramide Hcl injection I.P
Batch No. : ME405
Batch Size : 104000
Mfg. Date. : Mar-2024
Exp. Date. : Feb-2027
Quantity of Sample : 100 Nos
Date of Sampling : 08-03-2024
Date of Commencement of analysis : 08-03-2024
Date of Completion of analysis : 22-03-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless Solution
Identification:		
A. By UV absorbance (230nm 360 nm)	Maxima at about 273 and 309nm	Complies to IP specification
B. Colour Reaction	A yellow –orange colour is produced.	Complies to IP specification
C. Reaction(A) of chloride	Reprecipitated by the addition of dilute nitric acid.	Complies to IP specification
pH	3.5 to 5.5	4.40
Extractable Volume	NLT- 2ml/Ampoule	2.1ml
Related substance	In the chromatogram obtained with the test solution, the area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.5 per cent).	Complies to IP specification
Particulate matter	No visible particles	No visible particles
Bacterial endotoxins	NMT 2.5 EU/mg of Metoclopramide.	LT 2.5 EU/mg
Sterility Test	To comply as per IP	Complies
Assay		
Each 2ml contains:	9.0mg to 11.0mg	9.77mg
Metoclopramide Hydrochloride	(90.0 % - 110%)	97.7%
I.P equivalent to Anhydrous Metoclopramide Hcl 10mg		

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.

Analysed By: V. B. J.
Date: 23/3/24

Checked By: [Signature]
Date: 23/3/24

Person In Charge of Testing
Date: 23/3/24

