

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

Report No: TT/ FG/519/24-25
Report Date: 25-01-2025

Name of the product	: KCL Injection 10ml
Generic Name	: Potassium chloride Injection concentrate I.P
Batch No.	: PC503
Batch Size	: 52000
Mfg. Date.	: JAN-2025
Exp. Date.	: DEC-2027
Quantity of Sample	: 50Nos
Date of Sampling	: 09-01-2025
Date of Commencement of analysis	: 09-01-2025
Date of Completion of analysis	: 24-01-2025

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless solution.
Identification:		
Reaction (B) of potassium salts	A white precipitate is produced	Complies to IP specification
Reaction (A) of chlorides	Reprecipitated by the addition of dilute nitric acid	Complies to IP specification
pH	4.0 to 8.0	4.21
Extractable Volume	NLT - 10.0ml	10.2 ml
Particulate matter	No visible particles	No visible particles
Bacterial Endotoxins	NMT-8.8 EU/mEq	LT 8.8 EU/mEq
Sterility	To comply as per IP	Comply as per IP
Assay	95.0% - 105.0%	152.91mg
Each ml contains : Potassium chloride I.P 150 mg	(142.50 mg to 157.50mg)	(101.94%)

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 CARRIEDOUT.**

Analysed By: *[Signature]*
 Date: 25/01/2025

Checked By: *[Signature]*
 Date: 25/01/2025


 Person In Charge of Testing
 Date: *[Signature]*



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/521/24-25

Report Date: 26-01-2025

Name of the product : METOCAN Injection 2ml
Generic Name : Metoclopramide Hcl Injection I.P
Batch No. : ME502
Batch Size : 104000
Mfg. Date. : JAN-2025
Exp. Date. : DEC-2027
Quantity of Sample : 100 Nos
Date of Sampling : 10-01-2025
Date of Commencement of analysis : 10-01-2025
Date of Completion of analysis : 25-01-2025

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless Solution
Identification: A. By UV absorbance (230nm 360 nm) B. Colour Reaction C. Reaction(A) of chloride	Maxima at about 273 and 309nm A yellow –orange colour is produced. Reprecipitated by the addition of dilute nitric acid.	Complies to IP specification Complies to IP specification Complies to IP specification
pH	3.0 to 5.0	4.98
Extractable Volume	NLT- 2 ml/Ampoule	2.1 ml
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: Metoclopramide Hydrochloride I.P equivalent to Anhydrous Metoclopramide Hcl 10mg	4.5mg to 5.5mg (90.0 % - 110%)	10.21mg 102.10%

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 CARRIEDOUT.

Analysed By: V. [Signature]
Date: 26/01/25

Checked By: [Signature]
Date: 26/01/2025

Person-In Charge of Testing
Date: 26/01/25

