



QUALITY CONTROL DEPARTMENT

Certificate of Analysis of Finished Product

(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/ FG/413/24-25

Report Date: 26-11-2024

Name of the product : KCL Injection 10ml
Generic Name : Potassium chloride Injection concentrate I.P
Batch No. : PC410
Batch Size : 51000
Mfg. Date. : NOV-2024
Exp. Date. : OCT-2027
Quantity of Sample : 50 Nos
Date of Sampling : 11-11-2024
Date of Commencement of analysis : 11-11-2024
Date of Completion of analysis : 25-11-2024

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	4.60
Extractable Volume	NLT - 10.0ml	10.5 ml
Particulate matter	No visible particles	No visible particles
Bacterial Endotoxins	NMT-8.8EU/mEq	complies
Sterility	To comply as per IP	Comply as per IP
Assay	95.0% - 105.0%	154.41mg
Each ml contains : Potassium chloride I.P 150 mg	(142.50 mg to 157.50mg)	(102.94%)

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: 26/11/2024

Checked By: *[Signature]*
Date: 26/11/2024

Person In Charge of Testing
Date: 26/11/24

