

	<p>Tamman Titoe Pharma Pvt Ltd 56-57, Sidco Pharmaceutical Complex, Alathur-603 110, Tamilnadu.</p>
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QUALITY CONTROL DEPARTMENT

Certificate of Analysis of Finished Product

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

Report No: TT/FG/475/24-25

Report Date: 27-12-2024

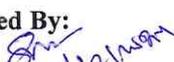
Name of the product	: KETROCAN 30 Injection 1ml
Generic Name	: Ketorolac Tromethamine Injection I.P
Batch No.	: KT415
Batch Size	: 104000
Mfg. Date.	: DEC-2024
Exp. Date.	: NOV-2027
Quantity of Sample	: 100 Nos
Date of Sampling	: 12-12-2024
Date of Commencement of analysis	: 12-12-2024
Date of Completion of analysis	: 26-12-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description	A clear, colourless solution.	A clear, colourless Solution
Identification: In the Assay	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies to IP specification
pH	6.9 to 7.9	7.75
Extractable Volume	NLT- 1.0ml /Ampoule	1.1 ml
Particulate matter	No visible particles	Complies
Bacterial endotoxins	NMT 5.8 EU/mg of Ketorolac Tromethamine.	LT 5.8 EU/mg
Sterility Test	To comply as per IP	Complies
Assay Each ml contains : Ketorolac Tromethamine I.P 30mg	27.0mg to 33.0 mg (90% to 110%)	30.61mg (102.03%)

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: 
Date: 27/12/2024

Checked By: 
Date: 27/12/2024


 Person In Charge of Testing
 Date: 27/12/24