

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/265/24-25 Report Date: 03-09-2024

Name of the product

:KETROCAN 30 Injection 1ml

Generic Name

:Ketorolac Tromethamine Injection I.P

Batch No.

: KT413

Batch Size

:100000

Mfg. Date. Exp. Date.

: AUG-2024

Quantity of Sample

: JULY-2027 :100 Nos

Date of Sampling

:19-08-2024

Date of Commencement of analysis

:19-08-2024

Date of Completion of analysis

: 02-09-2024

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
рН	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	27.0mg to 33.0 mg	30.88mg
Each ml contains: Ketroloac Tromethamine I.P 30mg	(90% to 110%)	(102.93%)

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: Date: 03 09 2024

Date

Personan Charge of Testing