

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title**Certificate of Analysis Finished Product**

Product Name	KETROCAN Injection	A.R. No.	ARN/FP/25/035
Generic Name	Ketorolac Tromethamine Injection IP 1ml	Sampled qty.	60 Ampoules
Batch No.	ARN2545A	Sampled by	Anuj Verma
Batch Size	1,53,000 Ampoules	Sampled on	14/10/2025
Mfg. Date	10/2025	Date of Testing	14/10/2025
Exp. Date	09/2027	Date of Release	29/10/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber glass ampoule.	A clear colourless solution filled in amber glass ampoule.
2.	Identification (By HPLC)	Prepare a mixture of equal volumes of the test solution and reference solution (b) and chromatograph the mixture as directed in the Assay. The chromatogram thus obtained exhibits two main, peaks corresponding to ketorolac and naproxen.	Complies
3.	Nominal fill volume	NLT 1ml	1.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml
5.	pH	6.9 to 7.9	7.62
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Ampoule NMT 600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	32/Ampoule 2/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT 5.8 EU/mg of Ketorolac Tromethamine.	Less than 5.8 EU/mg of Ketorolac Tromethamine.
9.	Assay: (By HPLC) Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Ketorolac Tromethamine IP	30 mg	29.986 mg	99.95%	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not complies as per IP/BP/USP/HS.

Analysis by

Checked by

