AMERICAN REMEDIES
Care & Cure with Research

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/26/092
Generic Name	Ketorolac Tromethamine Injection IP 1ml	**Sampled qty.**	60 Ampoules
Batch No.	ARN2696A	**Sampled by**	Shivanand
Batch Size	99,000 Ampoules	**Sampled on**	14/10/2026
Mfg. Date	09/2026	**Date of Testing**	15/10/2026
Exp. Date	08/2028	**Date of Release**	29/10/2026

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	7.28
6.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test (1.) Particles ≥10µm (2.) Particles ≥25µm (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.	46/Ampoule 0/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	30.00006mg	100.00%	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/IHS~~.

Analysis by	Checked by	Approved by
29/10/26	29/10/26	29/10/26
NAME: FIROJ KHAN	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
Designation : QC Head
Qualification : M.Sc. Clinical Microbiology