



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Name: Ketorolac Product Information

Product Number KET-20260220
Batch Number KET-SH2026022001
Brand SIGALD
CAS Number 74103-06-3
MDL Number MFCD00058777
Formula $C_{19}H_{21}NO_3$
Molecular Weight 311.38 Da
Quality Release Date 20 FEB 2026

Test Results

Test	Specification (USP/EP/BP Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Free-flowing crystalline powder	-	Visual Inspection
Assay (HPLC, dry basis)	≥ 99.0%	99.7%	%	High Performance Liquid Chromatography (HPLC)
Melting Point	159-163°C	161.2°C	°C	Capillary Melting Point Apparatus
Loss on Drying	≤ 0.5%	0.16%	%	Gravimetry (105°C, 2h)
Residue on Ignition	≤ 0.1%	0.02%	%	600°C Ignition Method
pH Value (1% aq. suspension, 25°C)	4.0-6.0	5.2	-	Digital pH Meter
Heavy Metals (Pb)	≤ 10 ppm	0.3 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.1 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Chloride (Cl ⁻)	≤ 0.01%	0.001%	%	Volumetric Method
Sulfate (SO ₄ ²⁻)	≤ 0.01%	0.001%	%	Turbidimetric Method
Related Substances	≤ 0.5%	0.06%	%	HPLC
Total Aerobic Microorganisms	≤ 100 CFU/g	9 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Particle Size (Pass through)	≥95% 100 mesh	99%	-	Sieve Analysis
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with USP/EP/BP pharmaceutical raw material industrial standards and meets all specified requirements. It is qualified for use in pharmaceutical preparations, anti-inflammatory analgesic formulations and scientific research applications.

Issue Date:20 FEB 2026