纳维盈医化科技
NEWAY SINOPHC TECH

NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Name: Diclofenac Diethylamine
Product Information

Product Number	DDE-20260205
Batch Number	DDE-SH2026020501
Brand	SIGALD
CAS Number	78213-16-8
MDL Number	MFCD00072105
Formula	$C_{18}H_{22}ClNO_2$
Formula Weight	319.83 Da
Quality Release Date	05 FEB 2026

Test Results

Test	Specification (Industry 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)	≥ 99.0%	99.5%	%	High Performance Liquid Chromatography (HPLC)
Melting Point	145-150℃	147.2℃	℃	Melting Point Apparatus
Loss on Drying	≤ 0.5%	0.2%	%	Gravimetry (105℃, 2h)
Residue on Ignition	≤ 0.1%	0.03%	%	600℃ Ignition Method
pH Value (1% aq. solution,25℃)	6.0-7.5	6.8	-	Digital pH Meter
Heavy Metals (Pb)	≤ 10 ppm	1.5 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.3 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Chloride (Cl^-)	≤ 0.01%	0.003%	%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.01%	0.002%	%	Turbidimetric Method
Related Substances	≤ 0.5%	0.12%	%	HPLC
Total Aerobic Microorganisms	≤ 100 CFU/g	18 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Particle Size (Pass through)	≥95% 100 mesh	98%	-	Sieve Analysis
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with pharmaceutical and chemical raw material industrial standards and meets all specified requirements. It is qualified for use in pharmaceutical preparations, topical medicinal cosmetics and medical device additives.
Issue Date:05 FEB 2026