



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Name: Diclofenac β -Dimethylaminoethanol Salt
Product Information

Product Number DBDS-20260205
Batch Number DBDS-SH2026020501
Brand SIGALD
CAS Number 68970-85-4
MDL Number MFCD00072107
Formula $C_{18}H_{24}Cl_2N_2O_3$
Molecular Weight 387.30 Da
Quality Release Date 05 FEB 2026

Test Results

Test	Specification (USP/EP Industrial 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)	$\geq 99.0\%$	99.7%	%	High Performance Liquid Chromatography (HPLC)
Melting Point	108-112°C	110.3°C	°C	Capillary Melting Point Apparatus
Loss on Drying	$\leq 0.5\%$	0.18%	%	Gravimetry (105°C, 2h)
Residue on Ignition	$\leq 0.1\%$	0.03%	%	600°C Ignition Method
pH Value (1% aq. solution, 25°C)	6.5-8.0	7.2	-	Digital pH Meter
Heavy Metals (Pb)	≤ 10 ppm	1.1 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Chloride (Cl^-)	$\leq 0.01\%$	0.002%	%	Volumetric Method
Sulfate (SO_4^{2-})	$\leq 0.01\%$	0.001%	%	Turbidimetric Method
Related Substances	$\leq 0.5\%$	0.09%	%	HPLC
Total Aerobic Microorganisms	≤ 100 CFU/g	15 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Particle Size (Pass through)	$\geq 95\%$ 100 mesh	98%	-	Sieve Analysis
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

Certification

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

Issue Date:05 FEB 2026