



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Name: Tapentadol Hydrochloride

Product Information

Item	Details
Product Number	TAP-20260228
Batch Number	TAP-SH2026022801
Brand	SIGALD
CAS Number	143562-04-5
MDL Number	MFCD09743645
Formula	C ₁₆ H ₂₅ NO · HCl
Formula Weight	283.84 g/mol

Quality Release Date 28 FEB 2026

Test Results

Test	Specification (Industry Standard)	Result	Unit	Test Method
Appearance	White to off-white crystalline powder	White crystalline powder	-	Visual Inspection
Assay (HPLC)	≥ 99.5%	99.8%	%	HPLC (USP 45)
Melting Point	178-182°C	180.5°C	°C	Capillary Melting Point Method
Loss on Drying	≤ 0.5%	0.12%	%	105°C, 2 hours
Residue on Ignition	≤ 0.1%	0.02%	%	800±25°C
Heavy Metals (Pb)	≤ 5 ppm	1.2 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Optical Rotation	[α] ₂₀ ^D : +20.0° to +24.0°	+22.3°	°	1% in water, 100mm tube
Related Substances (Individual)	≤ 0.05%	0.02%	%	HPLC
Related Substances (Total)	≤ 0.3%	0.07%	%	HPLC
Solubility in Water	Freely soluble	Complies	-	USP Solubility Test
pH Value (1% in water, 25°C)	4.0-6.0	5.1	-	Digital pH Meter

Certification

This batch of Tapentadol Hydrochloride has been tested in accordance with the relevant industrial and pharmaceutical raw material standards (USP 45/Ph. Eur. 10.0), and all test results meet the specified requirements. It is qualified for use.

Issue Date: 28 FEB 2026