



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Quality Release Date: 26 FEB 2026 Issue Date: 26 FEB 2026

Product Information

Product Name Bupirone Hydrochloride
Product Number BH-20260226
Batch Number BH-SH2026022601
Brand SIGALD
CAS Number 33386-08-2
MDL Number MFCD00058915
Formula $C_{21}H_{31}N_5 O_2 \cdot HCl$
Formula Weight 421.97 g/mol
Molecular Form Anxiolytic pharmaceutical active ingredient (5-HT1A receptor agonist)

Test Results

Test	Specification (Pharmacopoeial Standard USP/EP/CP)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (On Anhydrous Basis)	98.0-102.0%	99.4%	%	High Performance Liquid Chromatography (HPLC)
Water Content	≤ 1.0%	0.4%	%	Karl Fischer Titration
Residue on Ignition	≤ 0.1%	0.02%	%	Ignition at 600°C±50°C
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)
Related Substances (Individual)	≤ 0.5%	0.11%	%	HPLC
Related Substances (Total)	≤ 1.0%	0.32%	%	HPLC
Melting Point	190-195°C	192.5°C	°C	Capillary Melting Point Method
pH Value (1% aqueous, 25°C)	4.0-5.0	4.5	-	Digital pH Meter
Chloride Content	8.0-8.8%	8.4%	%	Volumetric Titration
Microbial Limit	Complies	Complies	-	Pharmacopoeial Microbiological Test
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with USP, EP and CP pharmacopoeial standards for Bupirone Hydrochloride and meets all specified requirements. It is qualified for pharmaceutical API use for research and formulation development.