



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis

Product Name: Risperidone

### Product Information

Item	Details
Product Number	RIS-20260225
Batch Number	RIS-SH2026022501
Brand	SIGALD
CAS Number	106266-06-2
MDL Number	MFCD00869456
Formula	C <sub>23</sub> H <sub>27</sub> FN <sub>4</sub> O <sub>2</sub>
Formula Weight	410.49 g/mol
Quality Release Date	25 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)	≥ 99.0%	99.6%	%	HPLC (Ph. Eur. 10.0)
Melting Point	169-173°C	171.5°C	°C	Capillary Melting Point Method
Loss on Drying	≤ 0.5%	0.21%	%	105°C, 2 hours
Residue on Ignition	≤ 0.1%	0.04%	%	800±25°C
Heavy Metals (Pb)	≤ 10 ppm	1.8 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Related Substances (Individual)	≤ 0.1%	0.03%	%	HPLC
Related Substances (Total)	≤ 0.5%	0.11%	%	HPLC
Optical Rotation	[α] <sub>20</sub> <sup>D</sup> : -118° to -128°	-123.2°	°	1% in CHCl <sub>3</sub> , 100mm tube
Solubility in Chloroform	Freely soluble	Complies	-	Ph. Eur. Solubility Test

### Certification

This batch of Risperidone has been tested in accordance with the relevant industrial and pharmaceutical raw material standards, and all test results meet the specified requirements. The product is qualified for use.

Issue Date: 25 FEB 2026