

CERTIFICATE OF ANALYSIS

Product: MELATONIN
Batch number: XPSM251016
Manufacture date: 16/10/2025
CAS: 73-31-4
Country of origin: CHINA

Expiry date: 15/10/2028
Standard: USP-NF 2025

ANALYSIS	SPECIFICATION	RESULTS	ANALYSIS TEST METHOD
Appearance	a white to off-white crystalline powder	conform	visual observation
Solubility	slightly soluble in water, soluble in acetone, ethyl acetate and methanol	conform	USP<1236>
	IR	conform	USP<197K>
Identification	UV	conform	USP<197U>
	HPLC	conform	USP<621>
Chloride and sulfate	0,02 % max	< 0,02 %	USP<221>
Loss on drying	1,0 % max	0,09 %	USP<731>
Residue on ignition	0,1 % max	0,04 %	USP<281>
Melting range	117-120°C	118,4-118,9°C	USP<741>
Particle size	≥ 98 % through 80 mesh	conform	USP<429>
Assay (on the dried basis)	98,5~101,5 %	99,82 %	USP<621>
Clarity and degree of opalescence of liquids	clear in the 1% melatonin solution of ethanol or chloroform	conform	USP<641>
Residual solvent: Ethanol	Meets as per USP	457 ppm	USP<467>
Density:			
Tap density	0,45 g/mL min	0,61 g/mL	USP<616>
Bulk density	0,35 g/mL min	0,40 g/mL	USP<616>
Related compounds:			
Individual impurity	0,1 % max	0,069 %	USP<621>
Total impurity	1,0 % max	0,34 %	USP<621>

CONTAMINANTS

Total heavy metals	10 ppm max	< 10 ppm	USP<231>
Lead	0,5 ppm max	< 0,5 ppm	USP<2232>
Arsenic	1 ppm max	< 1 ppm	USP<2232>
Mercury	0,1 ppm max	< 0,1 ppm	USP<2232>
Cadmium	0,5 ppm max	< 0,5 ppm	USP<2232>

MICROBIOLOGY

Total plate count	1000 cfu/g max	< 1000 cfu/g	USP<2021>
Yeast and mold	100 cfu/g max	< 100 cfu/g	USP<2021>
Escherichia coli	absent / 10g	absent / 10g	USP<2022>
Salmonella	absent / 10g	absent / 10g	USP<2022>
S. aureus	absent / 10g	absent / 10g	USP<2022>

OBSERVATIONS:

Comply with the requirements of USP-NF 2025 and enterprise standard.

Storage: Preserve in tight containers, protected from light.

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