

CERTIFICATE OF ANALYSIS

Product Name:	Melatonin		
CAS No.:	73-31-4	Ref. Standard:	USP 2021
Batch No.:	20220614	Manuf. Date:	Jun. 14, 2022
Net Weight:	500kg	Expiry Date:	Jun. 13, 2024
Storage Condition:	Preserve in tight containers at controlled room temperature, away from sunlight.		

Item	Specification	Result
Assay (on dried basis)	98.5% ~ 101.5%	99.73%
Appearance	A white to off-white crystalline powder	A white to off-white crystalline powder
Solubility	Slightly soluble in water, soluble in acetone, ethyl acetate and methanol	Conforms
Identification	IR	Conforms
	UV	Conforms
	HPLC	Conforms
Tap density	$\geq 0.45\text{g/ml}$	0.56g/ml
Bulk density	$\geq 0.35\text{g/ml}$	0.46g/ml
Particle size	$\geq 98\%$ through 80 mesh	Conforms
Melting range	117-120°C	119.0-119.2°C
Loss on drying	$\leq 1.0\%$	0.09%
Residue on ignition	$\leq 0.1\%$	0.04%
Chloride and Sulfate	$\leq 0.02\%$	Conforms
Clarity and degree of opalescence of liquids	Clear in the 1 % melatonin solution of ethanol or chloroform	Conforms
Heavy Metals	$\leq 10.0\text{ppm}$	Conforms
Lead(Pb)	$\leq 1.0\text{ppm}$	Conforms
Arsenic(As)	$\leq 1.0\text{ppm}$	Conforms
Mercury(Hg)	$\leq 0.1\text{ppm}$	Conforms
Cadmium(Cd)	$\leq 0.5\text{ppm}$	Conforms
Related substance		
Individual impurity	$\leq 0.1\%$	0.047%

Total impurity	$\leq 1.0\%$	0.29%
Microbiological Tests		
Total plate Count	$\leq 1000\text{cfu/g}$	Conforms
Yeast & Mold	$\leq 100\text{cfu/g}$	Conforms
E.Coli.	Negative/10g	Negative
Salmonella	Negative/10g	Negative
Staphylococcus Aureus	Negative/10g	Negative
Conclusion	Conforms to USP 2021 standard.	

Tested by: Tiantian Wang

Checked by: Xiao Wang

Approved by: Yulian Liu

