

Melatonin USP-NF

Product Characteristics

Appearance	White to off-white crystalline powder
Country of Origin	China

Profile	Method	Specification
Solubility	USP	Slightly soluble in water, soluble in acetone, ethyl acetate and methanol
Identification		
IR	USP	Conforms
UV	USP	Conforms
HPLC	USP	Conforms
Chloride and sulfate	USP	≤ 0.02%
Loss on drying	USP	≤ 1.0%
Residue on ignition	USP	≤ 0.1%
Melting range	USP	117 – 120°C
Particle size	USP	≥ 98% through 80 mesh
Bulk density	USP	≥ 0.35 g/ml
Tapped density	USP	≥ 0.45 g/ml
Residual solvents		
Ethanol	USP	≤ 500 ppm
Clarity and degree of opalescence	USP	Clear in 1% solution of ethanol or chloroform
Lead	USP	≤ 1 ppm
Arsenic	USP	≤ 1 ppm
Mercury	USP	≤ 0.1 ppm
Cadmium	USP	≤ 0.5 ppm
Related compounds		
Individual impurity	USP	≤ 0.1%
Total impurity	USP	≤ 1.0%
Assay (on dried basis)	USP	98.5 – 101.5%
Total aerobic plate count	CP	≤ 1,000 CFU/g
Yeast and mold	CP	≤ 100 CFU/g

Salmonella	CP	Absent/10g
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E. coli	CP	Absent/10g
S. aureus	CP	Absent/10g

Storage

Store in tight containers, protected from light, moisture and heat.

Revision: 9/2/22