

CERTIFICATE OF ANALYSIS

Physical & Chemical Characteristics

Analysis Item	Specification	Result
Appearance	Yellow or Orange-yellow, Crystalline powder	Complies
Identification (Ph.Eur. Meth.A–C; USP; JP)	Must conform	Complies
Specific optical rotation (Ph.Eur.)	-115 to -135°	-128
Specific optical rotation (USP)	-115 to -135°	-120
Specific optical rotation (FCC)	+56.5 to +59.5°	Complies
Absorbance (Ph.Eur.)	223,267,373,444 nm	Complies
Maxima A 373/267 nm	0.31 to 0.33	0.32
Maxima A 444/267 nm	0.36 to 0.39	0.38
Impurity A	≤0.025 g/100g	0.008
Impurity B	≤0.2 g/100g	0.04
Impurity C	≤0.2 g/100g	0.0
Impurity D	≤0.2 g/100g	0.1
Unspecified impurities	≤0.10 g/100g each	0.00
Total Impurities	≤0.5 g/100g	0.1
Lumiflavin (USP)	≤0.025	0.005
Lumiflavin (JECFA)	≤0.025 g/100g	0.008
Sulfated ash (Ph.Eur.)	≤0.1%	0.03%
Residue on ignition (USP)	≤0.3%	0.03%
Loss on drying (Ph.Eur.)	≤1.5%	0.9%
Assay (Ph.Eur.)	97.0–103.0 g/100g	99.9%
Assay (USP)	98.0–102.0 g/100g	99.3%
Assay (JECFA)	98.0–101.0 g/100g	99.9%
Particle size <50µm (SOP-0855)	≥99 g/100g	Complies

Heavy Metals

Analysis Item	Specification	Result
Heavy Metals (USP)	≤10 mg/kg	Complies
Lead (KP ICP)	≤1 mg/kg	Complies
Cadmium (KP ICP)	≤1 mg/kg	Complies
Mercury (KP ICP)	≤0.1 mg/kg	Complies
Arsenic (KP ICP)	≤1 mg/kg	Complies

Microbiological Tests

Analysis Item	Specification	Result
Total microbial aerobic count (USP)	≤1000 CFU/g	Complies
Total combined yeast and mold (USP)	≤100 CFU/g	Complies
Enterobacteria and other gram-negative (USP)	≤100 CFU/g	Complies
Escherichia coli (Ph.Eur.)	Negative	Negative
Salmonella (Ph.Eur.)	Negative	Negative
Staphylococcus aureus (Ph.Eur.)	Negative	Negative
Pseudomonas aeruginosa (Ph.Eur.)	Negative	Negative

Conclusion: The product meets the requirements of the current USP/EP/FCC/JP/E101/JECFA monograph