

CERTIFICATE OF ANALYSIS

NIACINAMIDE PC

Product Code: 14345

Batch No. : 10894

Re-Test Date : 12/2027

Test	Result	Limits / Specifications	Dimension / Units
Appearance visual	crystalline powder	crystalline powder	
Colour visual	white	white	
Assay HPLC	99.5	99.0 to 101.0	% w/w
Related Substances: 3-cyanopyridine HPLC	0.01	max. 0.10	% w/w
Any unknown impurity HPLC	0.05	max. 0.10	% w/w
Total of impurities HPLC	0.1	max. 0.2	% w/w
Nicotinic acid HPLC	58	max. 100	ppm
pH of solution Ph.Eur. of Nicotinamide	7.1	6.0 to 7.5	
Clarity of solution Ph.Eur. of Nicotinamide	0.30	max. 3.00	NTU
Colour values (CIELAB) L* Colour Instrument Measurement	98.2	90.0 to 101.0	
Colour values (CIELAB) a* Colour Instrument Measurement	0.0	-10.0 to 10.0	
Colour values (CIELAB) b* Colour Instrument Measurement	0.7	-10.0 to 10.0	
Colour of solution (calc./BY) Ph.Eur. of Nicotinamide	7	min. 7	
melting range start. point Ph. Eur. of Nicotinamide	129	128 to 131	°C
melting range end. point Ph. Eur. of Nicotinamide	131	128 to 131	°C
Particle Size Fraction min. 50 µm sieve analysis	99	min. 90	% w/w
min. 250 µm sieve analysis	1	max. 8	% w/w
Sulphated Ash Ph.Eur. of Nicotinamide	0.04	max. 0.10	% w/w
Heavy Metals USP (method II) of Niacinamide	corresponds	max. 10	ppm

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Test	Result	Limits / Specifications	Dimension / Units
Chloride Limit test JP	<70	max. 70	mg/kg
Sulfate Limit test JP	<190	max. 190	mg/kg
Readily carbonizable substances USP of Niacinamide	passes test	passes test	
Identification UV, USP of Niacinamide	corresponds	0.63 to 0.67	
Identification IR, EP/USP of Niacinamide	corresponds	corresponds	
Loss on drying Ph.Eur. of Nicotinamide	0.1	max. 0.5	% w/w
Lead USP <730>	corresponds*	max. 1	ppm
Microbiology Total Aerobic Microbial Count Ph. Eur. 2.6.12	corresponds*	max. 100	CFU/g
Total Combined Yeast and Moulds Ph. Eur. 2.6.12	corresponds*	max. 100	CFU/g
Escherichia coli Ph. Eur. 2.6.13	corresponds*	negative in 1 g	
Staphylococcus aureus Ph. Eur. 2.6.13	corresponds*	negative in 1 g	
Pseudomonas aeruginosa Ph. Eur. 2.6.13	corresponds*	negative in 1 g	
Candida albicans Ph. Eur. 2.6.13	corresponds*	negative in 1 g	

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