

CERTIFICATE OF ANALYSIS

NIACINAMIDE PC

Product Code: 14345

Batch No. : 11554

Re-Test Date : 02/2029

Test	Result	Limits / Specifications	Dimension / Units
Appearance visual	crystalline powder	crystalline powder	
Colour visual	white	white	
Assay HPLC	99.9	99.0 to 101.0	% w/w
Related Substances:			
3-cyanopyridine HPLC	< 0.05	max. 0.10	% w/w
Any unknown impurity HPLC	0.06	max. 0.10	% w/w
Total of impurities HPLC	0.1	max. 0.2	% w/w
Nicotinic acid HPLC	62 ppm	max. 100	ppm
pH of solution Ph.Eur. of Nicotinamide	6.6	6.0 to 7.5	
Clarity of solution Ph.Eur. of Nicotinamide	0.16	max. 3.00	NTU
Colour values (CIELAB) L* Colour Instrument Measurement	99.9	90.0 to 101.0	
Colour values (CIELAB) a* Colour Instrument Measurement	0.2	-10.0 to 10.0	
Colour values (CIELAB) b* Colour Instrument Measurement	-0.3	-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	128.8	128 to 131	°C
melting range end. point Ph. Eur. of Nicotinamide	129.7	128 to 131	°C
Particle Size Fraction			
min. 50 µm sieve analysis	100	min. 90	% w/w
min. 250 µm sieve analysis	3	max. 8	% w/w
Sulphated Ash Ph.Eur. of Nicotinamide	< 0.05	max. 0.10	% w/w
Heavy Metals USP (method II) of Niacinamide	0.9	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	0.65	0.63 to 0.67	
Identification IR, EP/USP of Niacinamide	corresponds	corresponds	
Loss on drying Ph.Eur. of Nicotinamide	corresponds	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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Quality Control Department