

Quality Control Laboratories

Certificate of Analysis

Name of Product: Nicotinamide EP		Date of Mfg.: Apr. 2018	
Batch No. : 18-0187		Date of Exp.: Mar. 2023	
Batch Size: 1000 kg		Date of Sampling: 10/04/2018	
Qty. Dispatched: 1000 kg		Date of Analysis: 29/04/2018	
A. R. No.: FPNA/0187/2018		Sample Qty.: 100 gm	
CAS No.: 98-92-0		Mfg. Lic. No. : 28 - (823)	
Sr.No.	Tests	Specifications	Observation
1.	Description	A white or almost white crystalline powder or colorless crystals.	White crystalline powder.
2.	Solubility	Freely soluble in water and in ethanol, Slightly soluble in methylene chloride.	Complies
3.	Identification	A. By Melting point 128°C to 131°C B. By infrared absorption spectrophotometry C. Thin-layer chromatography The principal spot in the chromatogram obtained with the test solution is similar in position and size to the spot in the chromatogram obtained with the reference solution(0.25%)	129°C to 130°C Complies Complies
4.	Appearance of solution	Solution S is clear and not more intensely colored than reference solution BY ₇	Complies
5.	pH	6.0 to 7.5 determined on solution S	7.3
6.	Related substances (By HPLC)	A) Unspecified impurity : Max 0.10% B) Specified impurity : 1) Pyridine-3-carboxylic acid (Nicotinic acid) : NMT 0.10% 2) Pyridine-3-Carbonitrile : NMT 0.10% 3) Pyridine-2-carboxamid (Picolinamide) : NMT 0.10% 4) Pyridine-4-carboxamide (isonicotinamide) : NMT 0.10% 5) Pyridine-3-carboxamide-1-oxid : NMT 0.10% (Nicotinamide -N-oxide) C) Total impurities = A + B : NMT.0.2%	0.05% Not Detected Not Detected Not Detected Not Detected Not Detected 0.05%

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Factory: C-18, MIDC Taloja, 410 208 New Mumbai, Dist.- Raigad

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Sr.No.	Tests	Specifications	Observation
7.	Loss on drying	NMT 0.5%	0.2%
8.	Sulphated ash	NMT 0.10%	0.05%
9.	Assay by titration	NLT 99.0% and NMT 101.0% (on dried basis)	99.8%
10.	Additional tests: 1. Residual solvents a. Benzene b. Methanol	NMT 2 ppm NMT 3000 ppm	Not Detected Not Detected
OPINION: The product complies as per the test mentioned in EP 9.0 and additional test.			
Prepared by <u>Amol Kad</u> <u>09/05/2018</u>		Checked by <u>Pradnya Bansode</u> <u>09/05/2018</u>	
		Approved by <u>Dr.C.V. Shabadi</u> <u>09/05/2018</u>	

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