



K alchem International, Inc
Compounding Chemicals You Can Trust



WESTERN DRUGS LIMITED

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CERTIFICATE OF ANALYSIS

HSN CODE: 29362920

Purchase Order No.	Date	Our Reference No.	C. O. A. Date	Lab Register Page No.
2014609	24.01.2020	EXP. No. - 5538	10.02.2020	19-20/03/181
Name of Product	Lot No.	Date of Manufacturing:	Date of Expiry:	Date of Analysis
NIACINAMIDE USP (POWDER)	19-20/NMD[P]/U/165	FEB. - 2020	JAN. - 2025	07.02.2020

Tests	USP 42	Results
Appearance	White crystalline powder has a bitter taste. Its solution is neutral to litmus.	Complies
Identification: -		
A. IR Test	IR spectrum to match with Reference standard No. 1	Matches
B. UV Test - Ratio A ₂₄₅ to A ₂₆₂ nm	0.63 to 0.67	0.646
Melting point	128° to 131° C	130° C
Loss on Drying	< 0.5% w/w	0.19 % w/w
Sulphated Ash / Residue on Ignition	< 0.1% w/w	0.04 % w/w
Readily Carbonizable Sub.	No more colour than matching Fluid A	Complies
Assay (On Dried Basis)		
A. Non Aqueous Titration	N.A.	N.A.
B. HPLC Method	98.5 to 101.5 % w/w	99.63 % w/w


Special Requirement

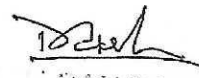
S. No.	Tests	Specifications	Results
1.	Particle Size (ASTM)	Min. 85 % to pass through 100 mesh sieve	98.78 % Passes
2.	Microbiological Limit Tests: -		
	a) Total Plate Count	Not more than 1000 cfu/g	< 50 cfu/g
	b) Yeasts & Molds Count	Not more than 100 cfu/g	< 10 cfu/g
	c) Escherichia Coli	Should be Absent/g.	Absent/g.
	d) Salmonella Species	Should be Absent/g.	Absent/g.
	e) Enterobacterial Count	Should be Absent/g.	Absent/g.
	f) Staphylococcus aureus	Should be Absent/g.	Absent/g.
3.	Heavy Metals: - Lead	< 0.5 PPM	ND (Detection limit min. 0.15 PPM)
	Arsenic	< 1.5 PPM	ND (Detection limit min. 0.01 PPM)
	Cadmium	< 0.5 PPM	ND (Detection limit min. 0.1 PPM)
	Mercury	< 0.1 PPM	ND (Detection limit min. 0.01 PPM)

Note: ND - Not Detected

REPORT: Certified that the material referred above confirms to the following specifications:

1. Manufacturing specifications of WDL.
2. USP 42 for Niacinamide (Nicotinamide)


N. SINGH
(Approved Chemist)


N. SINGH
MANAGER
LABORATORY

BIN NO.: AAACW2424PFT001

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