

Certificate of Analysis

Raw Material — Active Pharmaceutical Ingredient (API)



MATERIAL NAME β -Nicotinamide Adenine Dinucleotide (NAD+)	CAS NUMBER 53-84-9
MATERIAL GRADE Research / Compounding Grade Raw Material	MOLECULAR FORMULA C ₂₁ H ₂₇ N ₇ O ₁₄ P ₂
INTENDED USE Pharmaceutical Compounding — For Research Use Only	MOLECULAR WEIGHT 663.43 g/mol
PHYSICAL FORM White to Yellowish Powder	

VELARA BATCH NO. NAD-LYO-2603	MANUFACTURE DATE October 2025	RETEST / EXPIRY DATE October 2027	COA ISSUE DATE March 3, 2026
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ANALYTICAL RESULTS

TEST	SPECIFICATION	RESULT	STATUS	METHOD
IDENTIFICATION & APPEARANCE				
Appearance	White to yellowish powder	Conforms	PASS	Visual Inspection
Visible Particulates (1g/25mL)	No visible particulates	Conforms	PASS	Visual Inspection
ASSAY & PURITY				
Assay — HPLC (Purity)	≥ 95.0%	99.0%	PASS	HPLC
Assay — UV (Dry Basis)	≥ 90.0%	99.1%	PASS	UV Spectrophotometry
PHYSICOCHEMICAL PROPERTIES				
Water Content	≤ 5.0%	1.46%	PASS	Karl Fischer Titration
pH (100 mg/mL aqueous solution)	2.0 – 4.0	2.34	PASS	Potentiometric (pH Meter)
Sodium Content	≤ 1.0%	0.11%	PASS	Ion Chromatography (IC)
ELEMENTAL IMPURITIES				
Lead (Pb)	≤ 0.1 ppm	<i>Not Detected</i>	PASS	ICP-MS per USP <232>
Arsenic (As)	≤ 0.1 ppm	<i>Not Detected</i>	PASS	ICP-MS per USP <232>
Mercury (Hg)	≤ 0.1 ppm	<i>Not Detected</i>	PASS	ICP-MS per USP <232>
Cadmium (Cd)	≤ 0.1 ppm	<i>Not Detected</i>	PASS	ICP-MS per USP <232>
ENDOTOXIN				
Bacterial Endotoxin	< 0.20 EU/mg	< 0.20 EU/mg	PASS	LAL per USP <85>

IMPURITY PROFILE

PARAMETER	SPECIFICATION	RESULT	STATUS
Total Related Impurities	≤ 2.0%	≤ 1.0%	PASS
Largest Single Impurity	≤ 0.5%	Conforms	PASS

Derived from HPLC purity result of 99.0%. Individual impurity profiling available upon request.

✓ All analytical results conform to specification — Raw Material released for pharmaceutical compounding use

RESIDUAL SOLVENTS

TEST	SPECIFICATION	RESULT	STATUS
Methanol	≤ 0.05%	<i>Not Detected</i>	PASS
Ethanol	≤ 1.0%	0.031%	PASS

Complies with ICH Q3C Class 3 solvent limits. Method: Gas Chromatography (GC).

MICROBIOLOGICAL QUALITY

TEST	SPECIFICATION	RESULT	STATUS
Total Aerobic Microbial Count (TAMC)	≤ 750 CFU/g	< 10 CFU/g	PASS
Total Yeast & Mold Count (TYMC)	≤ 50 CFU/g	< 10 CFU/g	PASS
Coliform Bacteria	< 3 MPN/g	< 3 MPN/g	PASS

Methods referenced: USP <61> / USP <62> equivalent. Testing performed per analytical protocol on file.

STORAGE CONDITIONS & STABILITY

<p>RECOMMENDED STORAGE</p> <p>2–8°C (short-term) –25°C to –15°C (long-term)</p>	<p>SPECIAL PRECAUTIONS</p> <p>Protect from light Keep container tightly sealed Store in dry environment</p>	<p>SHELF LIFE & RETEST</p> <p>24 months from manufacture date Retest Date: October 2027 Based on stability data on file</p>
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API SOURCE & MANUFACTURING QUALITY

QUALIFIED MANUFACTURER PROFILE

MANUFACTURING TECHNOLOGY

Proprietary whole-enzyme catalytic biosynthesis — a green synthesis platform eliminating harmful chemical solvents and fermentation byproducts. No solvent residues beyond ICH Q3C Class 3 limits.

PURIFICATION PROCESS

Proprietary seven-step purification system applied post-synthesis, achieving consistent HPLC purity ≥ 99.0% and ensuring stability across documented shelf life.

INTELLECTUAL PROPERTY

Manufacturer holds more than 200 invention patents covering coenzyme biosynthesis processes, purification technologies, and formulation methods — recognized as a global industry leader in this API category.

ACADEMIC & RESEARCH VALIDATION

Manufacturing process and API quality have been utilized in peer-reviewed research published by internationally recognized academic institutions, supporting the scientific credibility of this raw material.

Manufacturer identity is confidential. Full manufacturer COA, batch records, and supply chain documentation are retained on file by Velara Medical Group Quality Unit and are available upon verified request. Contact: [\[email protected\]](#)

QUALITY STATEMENT

COMPLIANCE & EVALUATION FRAMEWORK

This material has been evaluated according to internal quality specifications aligned with internationally recognized guidelines:

ICH Q7 — GMP for APIs
ICH Q3C — Residual Solvents
ICH Q3D — Elemental Impurities
USP <232>/<233>
USP <85> — Bacterial Endotoxin
USP <61>/<62> — Microbial

Analytical results meet established acceptance criteria for research and pharmaceutical compounding applications. This material is approved for use in Velara Medical Group lyophilization production under batch **NAD-LYO-2603**.

DOCUMENT CONTROL

DOCUMENT ID	VERSION	ISSUE DATE	PREPARED BY	APPROVED BY
VEL-COA-NAD-032601	2.0	March 3, 2026	Quality Unit — Velara Medical Group	Quality Assurance

Electronically generated — valid without wet signature.

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