CLINICAL PARTNERS

Independent Third-party API Quality Assurance Analytical Chemistry Testing and Certification of Conformance to USP Quality Standards

Building 687 Clifton Street, Nedlands, WA 6009, Australia

T: 08 6488 8181 | qa@clinicalpartners.com.au | ABN: 69 251 247 317

Certification of Analysis and Quality

Certificate ID: NADfaC(PI).2405a MANUFACTURE
API RELEASE

Material/Analyte Identification

Name | Desc. **β-Nicotinamide Adenine Dinucleotide** [free acid] ('NAD') | Parenteral Intermediate Coenzyme (Custom Synthesised)

CAS no.: 53-84-9 Molecular: (i) Formula: C21 H27 N7 O14 P2 (ii) Formula Weight: 663.4251 Da

Additional Identifying Information/References: 1/ https://pubchem.ncbi.nlm.nih.gov/compound/5892

Batch ID: **NADfaC(PI).2405a** Date of Manufacture: 2024\05\17 QA Retest Date: 2026\05\17

Verified Manufacturer Credentials and Manufacturing Quality Standards:

Manufactured by a EMA cGMP Compliant, Audited and Certified CDMO.
Manufactured in the European Union to Conform to USP (if published), else US FDA (if published), else Internal quality standards.

Analytical Chemistry Testing Process Integrity Statement:

(1) Clinical Partners:

(a) was retained by 'GMP Active Ingredients GmbH' (GMP AI) (an API manufacturer) as an independent 3rd party to coordinate and manage quality assurance analytical chemistry testing of the Material/Analyte identified above, and certify the results thereof conform to USP (if published), else FDA (if published), else Internal quality standards.

(b) engaged analytical chemistry testing service provider(s) known to it to be appropriately qualified/credentialed, equipped and proficient in the science of analytical chemistry testing to carry out testing.

(c) commissioned analytical chemistry tests for which a result is stated in the '***Pre Mfg Release***' column of the '**Analytical Testing**' section below to be carried out on sample material isolated from Batch ID 'NADfaC(PI).2405a' by GMP AI immediately post manufacture.

(d) received directly from GMP AI on 2024\06\01 ONE intact unopened tamper-evident hermetically sealed bottle ('Bottle') labelled, 'β-Nicotinamide Adenine Dinucleotide [free acid] ('NAD') ... Batch ID NADfaC(PI).2405a ... '

(2) The Certifier below personally:

(a) isolated sample material from the Bottle in an ISO 7 Cleanroom and labelled it, 'Batch ID NADfaC(PI).2405a'.

(b) commissioned analytical chemistry tests for which a result is stated in the '***Post Mfg Release***' column of the '**Analytical Testing**' section below to be carried out on the sample material isolated from the Bottle.

Analytical Testing

Analysis Property / Analytical Test Method	*Specification*	#	Test Result: *Pre Mfg Release*	Test Result: *Post Mfg Release*
Identification:				
- by Molecular Weight:				
- by ESI-MS	663.4251 +/-1 Da	1	-	-
- by HR-MS	663.4251 +/-1 Da	2	663.38	-
- by Monoisotopic Mass:				
- by LC-MS	663.10912256 +/-0.5 Da	3	-	663.1057
- by Exact Mass:				
- by LC-MS	664.116954 +/-0.5 Da	4	-	-
- by HPLC (214 nm)	Retention time of main peak conforms to that of Reference Standard	5	Conforms	-
- by H-NMR (800 MHz, Solvent: DMSO)	Spectra conforms to that of Reference Standard	6	-	Conforms
Purity:				
- by HPLC (214 nm)	NLT 99%	7	99.36%	-
- Largest Impurity / by HPLC (214 nm)	≤ 0.5%	8	0.29%	-
Content:				
- Assay (enzymatic) NAD	NLT 99% | **Anhydrous, Sodium-free Basis	9	100.11%	-
- Assay (enzymatic) NAD	NLT 97% | **Hydrated, with Sodium Basis	10	**97.76%**	-
- Sodium	NMT 0.1%	11	0.021%	-
- Water Content / by Karl Fischer	NMT 5%	12	2.19%	-
- Residual Organic Solvents:	(USP ⟨467⟩)			
- Ethanol (EtOH)	NMT 5000 PPM (0.5%)	13	0.0016%	-
- Methanol (MeOH)	NMT 3000 PPM (0.3%)	14	Not Detected	-
- Heavy Metals: (by ICP-MS [excl. Hg] & ICP-AES [Hg])				
- Arsenic (As)	< 0.1 PPM (0.00001%)	15	Not Detected	-
- Cadmium (Cd)	< 0.1 PPM (0.00001%)	16	Not Detected	-
- Lead (Pb)	< 0.1 PPM (0.00001%)	17	Not Detected	-
- Mercury (Hg)	< 0.1 PPM (0.00001%)	18	Not Detected	-

CLINICAL PARTNERS

Independent Third-party API Quality Assurance Analytical Chemistry Testing and Certification of Conformance to USP Quality Standards

Building 687 Clifton Street, Nedlands, WA 6009, Australia

T: 08 6488 8181 | qa@clinicalpartners.com.au | ABN: 69 251 247 317

Certification of Analysis and Quality

Certificate ID: NADfaC(PI).2405a MANUFACTURE API RELEASE

Material/Analyte Identification

Name | Desc. **β-Nicotinamide Adenine Dinucleotide** [free acid] ('NAD') | Parenteral Intermediate Coenzyme (Custom Synthesised)

CAS no.: 53-84-9 Molecular: (i) Formula: C21 H27 N7 O14 P2 (ii) Formula Weight: 663.4251 Da

Additional Identifying Information/References: 1/ https://pubchem.ncbi.nlm.nih.gov/compound/5892

Batch ID: **NADfaC(PI).2405a** Date of Manufacture: 2024\05\17 QA Retest Date: 2026\05\17

Analytical Testing

Analysis Property / Analytical Test Method	*Specification*	#	Test Result: *Pre Mfg Release*	Test Result: *Post Mfg Release*
Microbiologicals:				
- Endotoxin / by LAL (Limit)	< 5 EU /mg	19	< 5 EU /mg	-
- Total Microbial Count	< 50 CFU /g	20	19 CFU /g	-
- Total Yeast & Mold Count	< 25 CFU /g	21	4 CFU /g	-
- Coliform	< 3 MPN /g	22	2 MPN /g	-
- Escherichia coli	Not Detected	23	Not Detected	-
- Salmonella	Not Detected	24	Not Detected	-
- Staphylococcus aureus	Not Detected	25	Not Detected	-
Solubility:				
- Dissolution (200 mg /mL Purified Water)	Soluble	26	Soluble	-
- Colour & Clarity of Solution (200 mg /mL Purifie	Colourless & Clear	27	Colourless & Clear	-
Other:				
PH (100 mg /mL Purified Water)	2.2 - 3	28	-	2.52

****SECTION END****

CERTIFICATION:

I hereby certify that all information/data contained herein is true and correct:

Dr Frank Sanfilippo (M: 0401 822 626)
Principal

Certifier Credentials:
BSc BPharm PGradDipPharm PhD MSHPA MPS FANZCAP
Senior Pharmacist, Royal Perth Hospital
Registered and practicing pharmacist since 1986 (AHPRA registration no. PHA0001547246)
Associate Professor (pharmaco, clinical and cardiovascular epidemiology), University of Western Australia
University of Western Australia Staff Member Profile:
https://research-repository.uwa.edu.au/en/persons/frank-sanfilippo
LinkedIn Profile:
https://www.linkedin.com/in/frank-sanfilippo-1151b875/

Conclusion:

The Material/Analyte meets the ***Specification*** of each ***Analysis Property*** tested in the '**Analytical Testing**' section above, and accordingly conforms to USP (if published), else US FDA (if published), else Internal quality standards.

Effective Date: 2024\06\01 Expiry Date: 2026\05\17 (QA Retest Date)