503PHARMA STABILITY CONSORTIUM

NAD+ 100 mg/mL Preserved

WORKING MASTER FORMULATION RECORD - PHARMACY REVIEW COPY

MFR NUMBER	VERSION	DATE	STATUS
MFR-NADP-100-PRES-01	01	July 2026	Working formulation

This review copy uses beta-NAD disodium salt as the working API candidate. Member sourcing and reproducibility responses will determine which single API form and formulation advance to stability testing. This is not a proposal for parallel free-acid and disodium-salt studies.

1. Product Definition

Attribute	Working specification
Product	NAD+ 100 mg/mL preserved sterile aqueous solution
Working API candidate	Nicotinamide adenine dinucleotide, oxidized form (NAD+), supplied as beta-NAD disodium salt
Strength basis	100 mg/mL expressed as NAD+ free-acid equivalent
Target appearance	Clear, colorless to very pale yellow; essentially free of visible particles
Target pH	6.0 to 6.5; target 6.2
Container-closure	Amber Type I glass multidose vial with compatible coated or bromobutyl stopper and aluminum seal
Storage	2-8 deg C; protect from light; do not freeze, pending stability data

2. Formula

Component	Function	Per 100 mL	Notes
Beta-NAD disodium salt API	Active	Equivalent to 10.000 g NAD+ free acid	Actual weight must be corrected using the supplier COA.
Benzyl alcohol, USP	Preservative	900 mg	0.9% w/v; measure by weight when possible.
Hydrochloric acid and/or sodium hydroxide	pH adjustment	q.s.	Use dilute solution and document the amount used.
Sterile Water for Injection, USP	Vehicle	q.s. to 100 mL	Do not use bacteriostatic water as a substitute.

Required API calculation: for anhydrous disodium salt, nominal API weight = 10.000 g x 1.0678, then correct for assay, purity, water, and salt basis exactly as reported on the COA. Document the calculation used for the batch.

API selection: If your pharmacy stocks NAD+ free acid or another form, report the supplier, product code, and COA. After reviewing member responses, 503Pharma will select one API form and issue the final MFR for that formulation before the study begins.

3. Compounding Procedure

1. Confirm the batch size, intended label basis, API form, supplier COA, and corrected API weight before staging materials.
2. Stage the selected amber Type I glass multidose vials, compatible stoppers and seals, a sterilizing-grade 0.22 micrometer filter, sterile receiving vessel, and transfer set. Record component lot numbers.
3. Protect the API and bulk solution from unnecessary light, heat, vigorous agitation, and prolonged aqueous hold.
4. Charge approximately 70% of the final volume of Sterile Water for Injection into the compounding vessel.
5. Add benzyl alcohol and mix until uniformly dispersed or dissolved.
6. Add the calculated NAD+ API slowly with gentle mixing until dissolved. Do not use heat or a cosolvent to force dissolution.
7. Measure pH and adjust slowly to 6.0-6.5 with dilute HCl and/or NaOH. Record the amount used.
8. Bring to final volume with Sterile Water for Injection and mix gently until homogeneous. Confirm appearance and pH.
9. Sterilize through the selected 0.22 micrometer filter and aseptically fill the selected amber multidose vial configuration.
10. Stopper, crimp, visually inspect, label, and quarantine according to the pharmacy's procedures.

4. Storage and BUD

Store at 2-8 deg C, protected from light. Do not freeze. The beyond-use date and post-puncture period will be established from the completed stability and antimicrobial-effectiveness work. Until those data are available, each pharmacy must follow applicable USP requirements and its own approved procedures.

5. Labeling Considerations

- Contains benzyl alcohol 9 mg/mL.
- Store refrigerated at 2-8 deg C. Protect from light. Do not freeze.
- Do not use if cloudy, materially discolored, or if visible particles are present.
- Final route-specific warnings and in-use dating will be assigned with the finalized formula and supporting data.

6. Pharmacy Review Checklist

Please confirm the following through the pharmacy response form:

- NAD+ API form currently sourced, including supplier, product code, and COA.
- Ability to match the formula, target pH, filtration process, and selected container-closure system.
- Any ingredient, equipment, process, vial, stopper, or seal that would need to be substituted.
- Any practical concern that would prevent routine replication in your pharmacy.

Professional use: This working MFR is intended for qualified compounding professionals. Each pharmacy remains responsible for applicable laws, USP requirements, internal SOPs, staff training, release decisions, and documentation.