Nevada State Board of Pharmacy
431 W. Plumb Lane Reno, Nevada 89509
(775) 850-1440 (800)-364-2081 Fax (775) 850-1444
Non-Sterile Compounding NAC 639-66611-639.67079

Non-Sterile Compounding

- ***For each standard,***
- ***Mark "Yes" in the compliance box if your facility is 100% compliant with that standard.***
- ***If facility never compounds under a specific requirement mark "NA" in the N/A box or NA by the section header.***
- ***If you are compliant with an item, but not in the exact manner stated due to an exception described below, please note "Exception" in the compliant box.***
- ***If non-compliant, provide an explanation and action plan for correction.***
- ***If an exception, provide documentation of equivalence or superiority.***
- ***USP <797> states, "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein."***
- ***Indicate your policy and procedures reference number in the yes/no boxes in the sterile compounding section of the form.***
- ***Note: The included references to NAC are a guide. Additional regulations and/or statutes may apply. It is your responsibility to understand and comply with all administrative codes and statutes related to the compounding you intend to do.***

Have all environmental, training, competencies, exceptions, action plans, and all other related documents available for review.

Attach a list certifying the personnel on the list are competent and proficient to correctly perform all the tasks related to non-sterile compounding. Please sign, print your name and date the list. (Please refer to the remarks page for instructions on the certification list.)

(the cover letter must be attached to your inspection form. Circle yes for compliant and no for non compliant. You may make comments as needed)

Standard Operating Procedures

The licensed pharmacy has a detailed written Standard Operating Procedures Manual (or Policy and Procedure Manual) with detailed instructions that describe how, when (frequency), and by whom all requirements in LCB file R035-06 are to be met.	Yes	No
All compounded prescriptions are only prepared to fill: (a) a patient specific prescription, (b) a chart order for immediate use by the patient, or (c) to prepare for the filling of future patient specific prescriptions or chart orders based upon the previous use of the history of a practitioner and patient who regularly uses the pharmacy.	Yes	No
The compounded drug is only sold to the patient, the agent of the patient, or a practitioner who will be administering the drug(s) to the patient. The compounded product must be dispensed or sent directly to the patient.	Yes	No
Compounded products are always dispensed pursuant to a prescription or chart order and are never dispensed pursuant to an invoice or other request for sale from a practitioner.	Yes	No
The patient is properly counseled about the compounded preparation at the time of dispensing, If applicable.	Yes	No
• Proper Use	Yes	No
• Storage	Yes	No
• Evidence of instability	Yes	No

• NAC 639.707 Counseling requirements and NAC 639.708 Recordkeeping	Yes	No
Date of receipt of bulk product is noted on the container (USP 795)	Yes	No
Packages of ingredients that lack a supplier expiration date are assigned a conservative expiration date not to exceed 3 years based on the nature of the component and it's degradation mechanism, the container in which it is packaged and the storage conditions. Appropriate inspection and testing should be done to ensue the ingredient has retained purity and quality. Have documentation available. (USP 795)	Yes	No
If a product is transferred from the original manufacturer's container, the container is identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container	Yes	No
Adoption of Standards NAC 639.670		
1. Federal Standard 209E "airborne particulate cleanliness classes in clean rooms and clean zones."		
2. International Standard 49 "Class II (Laminar Flow) Bio-safety Cabinetry NSF/ANSI 49-2007		
3. USP – NF 2008		
4. The Food Chemicals Codex 6th edition		
5. Reagent Chemicals: Specifications and Procedures 10th edition		
6. Appendix A publication No. 2004-165 Preventing Occupational Exposures to Anti-neoplastic and other hazardous drugs in healthcare setting (National Institute for Occupational Safety and Health NIOSH)		
If a standard changes, if after 120 days the Board has not disapproved a standard, the change is deemed approved by the Board.		
Compounded product's active ingredients must meet one of the following three standards: (USP 795)		
1. Non sterile ingredients, substances and excipients are official USP or NF grade (All Certificates of Analysis (COA) are on file.	Yes	No
2. If non USP or NF food, cosmetics or other substances are used, the active ingredients are from an approved FDA manufacturer or distributor and are accompanied by a Certificates of Analysis. All Certificates are on file.	Yes	No
3. If neither 1 nor 2 are met, the active ingredients have been certified by the compounding pharmacy through independent analysis by a laboratory to the satisfaction of the Board.	Yes	No

Circle sources of non USP or NF substances: • Analytical Reagent (ARA): • Certified American Chemical Society (ACS): • Food Chemicals Codex grade (FCC):	Other (list):

Equipment NAC 639.6701 NAC 639.67033		
Records are available for review for all equipment used in compounding. The records include, but are not limited to, equipment setup, calibration, filter changes, any periodic testing required and cleaning of the equipment.	Yes	No
• Cleaning/Calibration/Maintenance daily log	Yes	No
• Required certifications on file for all equipment requiring certification (attach)	Yes	No
• Check weight certification and recertification (against absolute standard testing weight) (Dept of Agriculture Nevada does certification of weights 775-688-2533 ext 233 2150 Frazer Ave Sparks, NV 89431)	Yes	No
Balances/Scales (at least one of which must be sensitive to 1/2 grain, with weights, including, without limitation, apothecary and avoirdupois, from 1/2 grain to 4 ounces and from 0.02 gm to 100 gm.)	Yes	No
Laminar Flow or other Primary Engineering Controls	Yes	No
Autoclaves/Dry ovens/Incubators (attach certifications/testing)	Yes	NA
Is a biological indicator or other testing required, according to the manufacturer's literature, to validate the efficiency of any equipment and is it being done and documented?	Yes	No
Other (attach list)	Yes	No
All training and environmental records must be readily available for review for the last 2 years	Yes	No
Records of all equipment calibrations, maintenance, testing kept for the life of the equipment	Yes	No
Compounding Personnel Documentation NAC 639.67013		
Documentation is on file for EACH person who compounds non- sterile products that they are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities (not limited to):		
• Perform proper hand cleansing before and after compounding	Yes	No
• Perform disinfection of compounding surfaces	Yes	No
• Select and appropriately don protective garb	Yes	No
• Identify, weigh and measure ingredients	Yes	No
• Label and quality inspect non-sterile products	Yes	No
• Treatment of employees of the pharmacy with regard to contact and inhalation exposure.	Yes	No
• Procedures for containment, cleaning and disposal with regard to breaks and spills	Yes	No
Hazardous Drugs training including:		
• Protection of personnel and compounding environment from contamination by hazardous drugs	Yes	No
Master Compounding (formulation) Record		
Records are maintained for 2 years	Yes	No
A Master Formulation record is kept. The record is followed each time that each specific formulation is compounded. The record contains but is not limited to:		
1. Official or assigned name, strength, and dosage form of the preparation	Yes	No
2. All necessary calculations including calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients.	Yes	No
3. Description of all ingredients and quantities	Yes	No
4. Compatibility and stability information, including references (when available)	Yes	No

5. Equipment needed to prepare the preparation, when appropriate	Yes	No
6. Mixing instructions that should include:	Yes	No
• Order of mixing	Yes	No
• Mixing temperatures or other environmental controls	Yes	No
• Duration of mixing	Yes	No
• Other factors pertinent to the replication of the preparation as compounded	Yes	No
7. Container to use in dispensing and packaging requirements	Yes	No
8. Labeling information including the name of and quantity or concentration of each ingredient	Yes	No
9. Description of final preparation	Yes	No
10. Storage requirements	Yes	No
11. Quality control procedures and expected results	Yes	No
12. A copy of documentation validating any extended beyond use dates should be /is recommended to be attached to the master record	Yes	No
Compounding Record NAC 639.6701 NAC 639.6702 NAC 639.67019		
A detailed compounding record is maintained on the prescription or in the computer for each compounded preparation including but not limited to:		
1. Official or assigned name, strength, and dosage of the preparation	Yes	No
2. Master Formulation record reference for the preparation	Yes	No
3. Sources, lot numbers, and expiration dates of all components in the formulation	Yes	No
4. Total quantity or number of doses units compounded	Yes	No
5. The order of each step in the compounding of each non-sterile product	Yes	No
6. The name and initials of the person(s) who prepared the preparation	Yes	No
7. The name of the person and initials who performed the quality control procedures	Yes	No
8. The name and initials of the compounder who approved the preparation		
9. The date of the compounding	Yes	No
10. The assigned internal identification (lot number) number or prescription number	Yes	No
11. Description of the final preparation	Yes	No
12. The assigned Beyond Use Date	Yes	No
13. A duplicate label as described in the Master Formulation record (either a batch label or a prescriptive label) is attached	Yes	No
14. Results of quality control procedures (e.g., weight range of the filled capsules, PH of aqueous liquids, etc.)	Yes	No
15. Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver	Yes	No
16. Any deviations from the master formulation record are documented	Yes	No
Documentation is available on site to support beyond use dates used on each product	Yes	No
Material Safety Data Sheets (MSDSs) now called SDS sheets are available to compounding personnel for all drugs and chemicals used in compounding	Yes	No

Non-Sterile Compounding Categories (USP 795)		
This facility compounds pharmaceuticals in the following compounding categories:		
○ **Simple**	Yes	No
Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs: or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. ○ Examples include captopril oral solution and indomethacin topical gel		
○ **Moderate**	Yes	No
Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation is not available. ○ Examples include diphenhydramine troches and mixing two or more manufactured cream products when the stability of the mixture is not known		
○ **Complex**	Yes	No
Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. ○ Examples include transdermal dosage forms, modified-release preparations and some inserts and suppositories for systemic effects	Yes	No
Non-Sterile Compounded Drug Labeling NAC 639.6703		
Non-sterile compounded product labels include, without limitation any amount of non-sterile compounded drug product in excess of the amount required by the prescription or chart order and any non-sterile compounded drug that is compounded in bulk. Each label contains at minimum the following:		
• The internal control number assigned to the compounded product	Yes	No
• The beyond use date of the compounded product is calculated from the day of preparation of the non-sterile compound	Yes	No
• As appropriate, the concentration of each active ingredient in the final compounded product	Yes	No
• Common name of final product or the name of each active ingredient	Yes	No
• Storage conditions	Yes	No

Beyond Use dating /labeling 639.6703		
A pharmacy may use a beyond use date later than the dates listed below if the pharmacy can prove by appropriate testing or published data that the non-sterile compounded product is safe and effective using the extended beyond use date. NAC 639.6703 sub 3		
If multiple strengths of a formula are compounded, documentation is available supporting extended use dating for each formula.	Yes	No
• For non-aqueous liquids and solid dosage forms		
• Not later than the expiration date of the active ingredient with the earliest expiration date, or 6 months after the date the product was compounded, whichever is earlier	Yes	No
• For compounds which contain non-sterile water		
• Not later than 14 days after the date on which the non-sterile compounded drug was compounded	Yes	No
• For water containing topical/dermal and mucosal liquid and semisolid formulations	Yes	No
• The beyond use date is not later than 30 days	Yes	No
4. For compounds other than the above items 1 2, and 3, not later than the intended duration of therapy or 30 days after the date the product was compounded, whichever is earlier	Yes	No
Storage of Non-Sterile Compounded Products NAC 639.67015 NAC 639.6702		
Non-Sterile products, including, without limitation any non-sterile compounded product in excess of the amount required by a prescription or chart order, and any compounded product made in bulk quantities is stored to ensure:		
○ The efficacy of the product is maintained	Yes	No
○ The product remains free of contamination	Yes	No
Designated Area for Non-Sterile Compounding NAC 639.67033		
There is a designed area for compounding non-sterile products	Yes	No
Compounding areas are maintained in a clean and sanitary condition	Yes	No
All items of equipment inspected, maintained, cleaned and validated at appropriate intervals	Yes	No
Hot and cold potable water is available in the compounding area	Yes	No
• Soap or detergent is available	Yes	No
• Air driers or single-service towels are installed	Yes	No
Trash is disposed of in a safe, sanitary and timely manner	Yes	No
The designed area is cleaned using an antiseptic cleaning method before and after any compounding occurs	Yes	No
Equipment used to compound non-sterile drug products is cleaned immediately after compounding to prevent cross contamination	Yes	No
If the pharmacy compounds both sterile and non-sterile drug products, none of the equipment used to compound non-sterile products is used to compound sterile products, unless the equipment is cleaned and sanitized prior to using for sterile compounding	Yes	No
Each employee who compounds non-sterile products washes his/her hands with soap and water or an antimicrobial agent before and after compounding the non-sterile product.	Yes	No

Policies and Procedures NAC 639.67015 NAC639.67035 21CFR 211.113(a)	Yes	No
The pharmacy maintains written policies and procedures for compounding non-sterile compounded products.	Yes	No
• The policies and procedures include but not limited to:		
1. Each final product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have	Yes	No
2. The components used to compound each non-sterile compounded drug product are recorded on the prescription or in the computer record.	Yes	No
3. The amount of each component used to compound each non-sterile product	Yes	No
4. The order of each step in the process of compounding each non-sterile product	Yes	No
5. Beyond Use Dating	Yes	No
6. Chemical and physical stability	Yes	No
7. Cleaning and disinfecting	Yes	No
8. Component quality evaluation	Yes	No
9. Compounding methods	Yes	No
10. Dispensing	Yes	No
11. Documentation	Yes	No
12. Environmental quality and maintenance	Yes	No
13. Equipment maintenance, calibration, and operation	Yes	No
14. Formulation development	Yes	No
15. Labeling	Yes	No
16. Material and final compounded preparation handling and storage	Yes	No
17. Measuring and weighing	Yes	No
18. Packaging and repackaging	Yes	No
19. Patient monitoring, complaints and adverse event reporting	Yes	No
20. Patient or caregiver education and training	Yes	No
21. Personnel cleanliness and garb	Yes	No
22. Purchasing	Yes	No
23. Quality Assurance and Continuous Quality Monitoring Safety	Yes	No
24. Shipping	Yes	No
25. Testing	Yes	No
26. Training and retraining	Yes	No
• The information listed as items 1, 2, and 3 above is recorded on the hard copy of the prescription maintained in the written records of the pharmacy or in the computer system. Item 4 is in the record or references the Compounding record.	Yes	No

Control Procedures NAC 639.67035		
Control procedures for monitoring each final non-sterile product and for validating the compounding process are in place. The control procedures must include, without limitation:		
○ Only one preparation is compounded at one time in a specific workspace	Yes	No
○ Any variation of more than plus or minus 10% in the weight of capsules, tablets or any other solid form of a dosage unit	Yes	No
○ The adequacy of mixing to ensure uniformity and homogeneity of each compounded product	Yes	No
○ If applicable, the clarity, completeness and pH of the compounded product	Yes	No
○ If applicable, the even distribution of coloring agents	Yes	No
○ Any variation of more than plus or minus 10% in the actual yield of a compounded product as compared to the theoretical yield of the compounded product	Yes	No
○ Control procedures to ensure:		
○ If the final compounded product is a capsule, that the capsule is properly locked	Yes	No
○ If the final compounded product is a tablet or other solid form of dosage, the final compounded product is of a uniform size and is intact	Yes	No
○ If the final compounded product is a suppository, the suppository is properly sealed	Yes	No
○ If the final compounded product is an oral liquid, to the extent possible, the liquid is palatable to the patient	Yes	No
○ If final compounded product is a suspension, the visible suspended particles are of uniform size and are readily dispersed upon shaking	Yes	No
○ If final compounded product is a topical compounded product, the final product is smooth and not gritty and has a uniform viscosity unless grittiness is required for a particular therapeutic purpose.	Yes	No

Non-Sterile Hazardous Drugs NAC 639.67037		
The components of hazardous drugs are stores separately from all the other inventory and in such a manner and location to minimize the contamination of other drugs in and employees of the pharmacy	Yes	No
Components are handled with caution by using appropriate gloves while distributing, receiving, stocking, inventorying, and preparing for administrating and disposing of components of a hazardous drug or final compounded product	Yes	No
Employees involved with compounding or otherwise handling hazardous drugs wear personal protective equipment, including, without limitation, gowns, face masks, eye protection, double gloves or chemotherapy gloves	Yes	No
All hazardous waste is disposed of in a manner that complies with any applicable state, federal or local law or regulation	Yes	No
All employees who are known to be a special risk with regard to the properties of hazardous drugs are limited from exposure to those drugs	Yes	No
Does the pharmacy perform hazardous non-sterile compounding in a ventilated cabinet such as a BSC, CAI (non-volatile APIs) or CACI? Note: this is a NIOSH requirement that is referenced in USP 795.	Yes	No
Is testing of the BSC, CAI or CACI certified or tested periodically?	Yes	No
Training NAC 639.67013 NAC 639.67037		
Documentation is available that compounding is only done by individuals that are appropriately trained and validated	Yes	No
All pharmacists, pharmacist interns, technicians and technicians in training or any other person who legally may compound dangerous drugs have been trained in:		
○ The compounding of dangerous drugs	Yes	No
All pharmacists, pharmacist interns, technicians and technicians in training or any other person who legally handles or dispense hazardous drugs have been trained in:		
○ The storage of hazardous drugs	Yes	No
○ The handling of hazardous drugs	Yes	No
○ The safety procedures of hazardous drugs	Yes	No
○ The disposal of hazardous drugs	Yes	No
Any pharmacist, pharmacist intern, technician or technician in training that compounds a hazardous drug that will be administered or dispensed to a patient has receive initial training and		
• Is trained at least once a year:	Yes	No
The training at a minimum shall include:		
• Safe manipulation practices that minimize exposure to the hazardous drug and protects the employees from any overt exposure to the hazardous drug	Yes	No
• Procedures for containment, cleaning and disposal with regard to breaks and spills	Yes	No
• Treatment of employees with regard to exposure by contact and inhalation	Yes	No
The pharmacy shall make and keep a record of any training given	Yes	No

Single Dose and Multiple Dose Containers NAC 639.67057		
~~In the course of compounding~~ a drug product a single-dose container, including, without limitation, a bag, bottle, syringe or vial of a sterile drug product seal is breached, the time and date of the breach is marked on the container	Yes	No
• Single-dose sterile containers entered in worse than ISO Class 5 air quality and stored in worse than ISO 7 are used within 1 hour of entry	Yes	No
~~• Single-dose containers entered in ISO Class 5 or cleaner air and are stored in ISO 7 or cleaner are used within 6 hours of entry~~	Yes	No
~~• Single-dose containers entered in ISO 5 or cleaner air quality and remains in ISO 5 air quality are used within 24 hours~~	Yes	No
Opened single-dose ampoules are not stored. If the entire seal has been removed for a multi-use vial the contents are not stored	Yes	No
Closure sealed multiple-dose containers are used within 28 days after initial opening or entry.	Yes	No
Records including, but not limited to: logs/SOPs, relevant documents related to your facility….	Readily Available	No
Please ensure that all records/logs/SOPs (if relevant to your practice) are organized, complete and readily available for review. This includes but is not limited to:	Yes	No
SOPs relevant to your practice and processes	Yes	No
Humidity (35-60% range) and room temperature (68-77 degrees with short excursions allowed 59-86 degrees)	Yes	No
Compounding records including validation of each ingredient and amount by the pharmacist approving the product compounded	Yes	No
Documentation of extended beyond use dates	Yes	No
Training records for non and hazardous compounding (if applicable)	Yes	No
Certification of each individuals proficiency and competency for the highest level of compounding they will do	Yes	No
Cleaning/Calibration/Maintenance and sanitation records for non-sterile environments	Yes	No
Certifications of equipment used including testing of the equipment if applicable, including: Autoclaves, Ovens, Scales, Automatic Compounding devices	Yes	No
Refrigerator and Freezer records for any excursions out of required range NAC639.525-527	Yes	No
Logs as required by CDC if you administer vaccines	Yes	No
Records of tracking, recalling and destroying the drug products compounded by the pharmacy	Yes	No
Certificates of Analysis	Yes	No

Policies and Procedures (Write in the page reference for your policy and procedures if the following apply to your facility or indicate NA:		
LABELING 639.6703 STANDARDS FOR COMPOUNDING AND DISPENSING GENERALLY 639.67015 Establishment of policies and procedures STANDARDS FOR COMPOUNDING AND DISPENSING NONSTERILE PRODUCTS 639.67035 Establishment of policies and procedures		

Provide a list certifying the personnel on the list are competent and proficient to correctly perform all the tasks related to non-sterile compounding. The list must identify all competencies including didactic, observational and manipulative training received. The list should include all elements listed under training for non-hazardous compounding for the risk level (identify the risk level) you are certifying the person to perform and a separate list for hazardous certification (if applicable). Please review the non-sterile compounding addendum for documentation and training elements that should be addressed at a minimum. Additional training should also be noted. (Refer to sections compounding personnel, documentation and training). Sign and date the list. Your signature on this document also certifies that all documents related to this certification are on file and available for review.

It is affirmed that all information provided herein is true and correct to the best of my knowledge and belief and it is recognized that providing information known to be false may result in disciplinary action.

REMARKS:

If you are required to provide any documentation to the inspector via fax or email attach a copy of the document(s) to this inspection form for future review. If you are required to fax or email information, fax to 702-486-7903 for inspections completed by the Las Vegas Board office or 775-850-1444 for inspections completed by the Reno office. Clearly identify the facility on all documents.

If you are required to fill out a sterile, institutional or retail inspection form, refer to the remarks section of those forms for any additional remarks, suggestions, to do's or citations.

PRINT

SIGN

Managing/Consultant Pharmacist Date

Board of Pharmacy Inspector Date