National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
	General Operations and Information		
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*		
1.02	Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?		
1.03	Are nonsterile compounded prescriptions picked up at the pharmacy?		
1.04	Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?		
1.05	Are nonsterile compounded prescriptions mailed to patients in their homes or residential facilities?		
1.06	Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?		
1.07	Are nonsterile compounded prescriptions mailed to the practitioner for administration to the patient in the office, clinic, or facility?		
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*		
2.01	Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?		
2.02	Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?		
2.03	Does the pharmacy have a sales force that promotes compounded preparations? *List compounds promoted.*		
2.04	Does the pharmacy distribute non-patient specific compounded preparations for promotional purposes? *List compounds provided.*		
2.05	If yes, does the sales force hand-deliver these compounds? *List compounds provided.*		
2.06	If yes, are any of these controlled substances? *List compounds provided.*		
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?		
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? *Provide List.*		
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Provide List.*		
5.00	Does the pharmacy compound topicals (gels, creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Provide List.*		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
6.00	Does the pharmacy compound vitamin or nutritional supplements? *Provide List.*		
7.00	Does the pharmacy sell any compounds over-the-counter? *Provide list.*		
8.00	Does the pharmacy compound investigational drugs? *Provide List.*		
9.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate volume or percent compounded currently.*		
9.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.		
9.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*		
10.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding.* 1. 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 beyond-use dates (BUD)s. 2. 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, Indomethacin Topical precautions. Gel, and Potassium Bromide Oral Solution (Veterinary).*		
11.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding.* 1. 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. 2. Making a preparation for which stability data for that specific formula is not available. *Examples include Morphine Sulfate Suppositories, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.*		
12.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding.* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. *Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.*		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
13.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of compounding with hazardous drugs.* NIOSH list of hazardous drugs including chemotherapy, hormones, etc.		
13.01	Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?		
14.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*		
15.00	Does the pharmacy compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding.*		
16.00	**APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?		
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *Indicate the source of APIs.*		
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified.*		
16.03	Does the pharmacy use active ingredients that are not from an FDA-registered facility? *If so, indicate sources.*		
16.04	Does the computer track on-hand quantities of APIs used for compounding? *If not, explain.*		
17.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*		
18.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*		
19.00	Does the pharmacy use scales/balances for nonsterile compounding?		
19.01	If so, what type of scale/balanced is used? *List manufacturer and model number*		
19.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency*		
19.03	Describe the pharmacist checks for the measurement of each ingredient		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
20.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? **Note: If the facility indicates "yes", please ask each question below to verify.**		
20.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?		
20.02	Does the pharmacy continuous quality improvement program include personnel testing and verification?		
20.03	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?		
20.04	Does the pharmacy continuous quality improvement program include end product testing (such as: pH, weight, potency, particulates, consistency, etc.)?		
20.05	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding nonsterile compounded products?		
20.06	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?		
20.07	Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?		
20.08	Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?		
	Component Selection and Use		
	Total Non-Compliant (Includes Unknowns)	**0**	
21.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
21.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound.		
21.02	USP- or NF-grade substances used, if available		
21.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.		
21.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels.*		
21.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding		
21.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.		
21.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*		
21.08	All APIs and components received without an expiration date are labeled with the date they were received.		
21.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.		
21.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).		
22.00	Where water is an ingredient, purified or distilled water is used.		
23.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.		
24.00	Pharmacy confirms that there are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
25.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.		
26.00	For **animal compounding:** The compounding meets the same standards as compounding for human patients.		
26.01	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.		
26.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.		
26.03	The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.		
26.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.		
26.05	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)		
	Beyond Use Dating (BUD)		
	Total Non-Compliant (Includes Unknowns)	**0**	
27.00	BUDs are assigned from the day of preparation.		
28.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.		
29.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*		
29.01	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.*		
30.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.		
31.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).		
32.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.		
	Environment		
	Total Non-Compliant (Includes Unknowns)	**0**	
33.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
34.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.		
35.00	Only one preparation compounded at a time.		
36.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.		
37.00	The compounding area is well lit.		
38.00	The pharmacy performs **hazardous** non-sterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*		
38.01	Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.		
38.02	If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.		
39.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available.		
39.01	If hazardous drugs are used, appropriate protective attire is available (gowns, gloves, hair and shoe covers, eye and face protection, etc.).		
40.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.		
41.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is **recommended** - not required)*		
42.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.		
43.00	**Temperature** in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.		
43.01	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.		
43.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.		
43.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
43.04	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.		
43.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.		
44.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.		
44.01	Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.		
44.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.		
44.03	Humidity monitoring is also performed in **drug storage areas** (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.		
44.04	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.		
44.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.		
45.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.		
46.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.		
47.00	All components and packaging containers and closures are properly rotated to use oldest first.		
48.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)		
49.00	Trash is disposed of in a safe, sanitary, and timely manner.		
49.01	Hazardous waste is disposed of in a safe, sanitary, and timely manner.		
	Training *-Verify records of all compounding personnel (up to 10).*		
	Total Non-Compliant (Includes Unknowns)	**0**	
50.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0
Inspection Date: 01/00/1900

		Finding	Notes
51.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.		
52.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.		
53.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.*		
54.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually.		
54.01	If performing hazardous nonsterile compounding, there is documentation available showing employees are evaluated at least annually.		
55.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.		
	Compounding Equipment		
	Total Non-Compliant (Includes Unknowns)	**0**	
56.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*		
57.00	Scales, balances, or other types of equipment used for measurement shall be routinely inspected, calibrated as necessary (per manufacturer instructions), and checked to ensure proper performance. *Describe procedure used.*		
58.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function.		
58.01	Hood filters are checked regularly and replaced when necessary.		
59.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.*		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
60.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.		
	Documentation		
	Total Non-Compliant (Includes Unknowns)	**0**	
61.00	The pharmacy creates a master formulation record the first time before compounding a new preparation		
61.01	Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.		
61.02	The **master formulation record** includes:		
61.03	Official or assigned name, strength, and dosage form		
61.04	All necessary calculations		
61.05	Description of all ingredients and their quantities		
61.06	Compatibility and stability information including references (when available)		
61.07	Equipment used for the preparation		
61.08	Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors)		
61.09	Container used and packaging requirements		
61.10	Assigned BUD information		
61.11	Labeling information including the name of and quantity or concentration of each active ingredient		
61.12	Description of the finished preparation		
61.13	Storage requirements		
61.14	Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).		
62.00	The pharmacy creates a compounding record for each compound prepared		
62.01	The **compounding record** includes:		
62.02	Official or assigned name, strength and dosage of the preparation		
62.03	Master Formulation Record reference		
62.04	Sources, lot numbers, and expiration dates of all components		
62.05	Total quantity or number of dosage units compounded		
62.06	Person compounding the preparation		
62.07	Person performing the quality control procedures		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
62.08	Person who approved the preparation		
62.09	Date of compounding		
62.10	Assigned internal identification number or prescription number		
62.11	Description of the final preparation		
62.12	Assigned BUD		
62.13	Duplicate label		
62.14	Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)?		
62.15	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate		
	Compounding Procedures		
	Total Non-Compliant (Includes Unknowns)	**0**	
63.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.		
64.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.		
65.00	The containers and closures selected meet USP standards (from container supplier).		
66.00	Container selection determined by physical and chemical properties of the preparation.		
67.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.		
68.00	Personnel don appropriate protective garb when performing compounding.		
68.01	If hazardous compounding, personnel don appropriate protective garb when compounding.		
69.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*		
70.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
71.00	There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created.		
72.00	There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.*		
73.00	Personnel are appropriately garbed for protection when cleaning.		
74.00	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment.* ***Compounding MUST be observed****, if compounding is not being performed at the time of survey, mark as "Non-Compliant".*		
74.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "* ***Denial of Authorization****" form. List individual who signs the Denial of Authorization*		
	Finished Preparation Release Checks and Tests		
	Total Non-Compliant (Includes Unknowns)	**0**	
75.00	The finished preparation is observed to appear as expected in the master formulation record and documented.		
76.00	As appropriate, the final completed preparation assessed for quality control and is documented, such as weight, mixing, clarity, odor, color, consistency, pH, and strength.		
77.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.		
78.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.		
78.01	If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient		
78.02	If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.		
79.00	There are appropriate quality control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Review validation of equipment and personnel performance documentation.*		
80.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
80.01	Labeling contains generic name and quantity or concentration of each active ingredient.		
80.02	Labeling contains assigned BUD.		
80.03	Labeling contains storage and handling information.		
80.04	If hazardous, labeling contains storage and handling information.		
80.05	Labeling contains prescription or control number, whichever is applicable.		
81.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).		
82.00	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.		
83.00	Preparations are stored and secured properly prior to dispensing based upon conditions upon which BUD was assigned.		
84.00	Preparations are examined immediately after preparation **AND** again immediately prior to dispensing for any signs of instability.		
	Patient Counseling and Communication		
	Total Non-Compliant (Includes Unknowns)	**0**	
85.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of products such as fentanyl, hormones and chemotherapy medications?		
86.00	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?		
87.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?		
88.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.		

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.