

Inspection Report

Facility Information

Name: *OPTIMAL BALANCE PHARMACY LLC*

License Number: 34829

Class of License: AS

Inspection Information

Type: *Compliance*

Purpose: *New Pharmacy*

Date: *06/24/2025*

Arrival Time: *10:00 AM*

Departure Time: *2:45 PM*

Action Taken: *Inspection*

General Comments: *No C2 medications ordered or stored in pharmacy.
Pharmacy is licensed for 10 states.*

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary *Satisfactory*

01. Required licenses posted *Satisfactory*

09. Active licenses/certifications *Satisfactory*

62. No aiding and abetting *Satisfactory*

65. Proper registration procedures *Satisfactory*

79. Identification badges *Satisfactory*

Inventory Records

15. Change of PIC inventory *Not Applicable*

17. Meets inventory requirements *Satisfactory*

59. Proper drug destruction *Satisfactory*

68. Change of ownership controlled substance inventory *Not Applicable*

69. Annual controlled substance inventory *Satisfactory*

Comment

Annual controlled substance inventory completed on: 5/1/25 closing of business

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?) *Satisfactory*

34. Notifications	Satisfactory
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76. PIC (Does the pharmacy have a pharmacist-in-charge?)	Satisfactory
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Environment/Equipment/Security

03. Orderly/Clean	Satisfactory
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04. Balance inspection	Satisfactory
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Comment

Number of balances: 4

05. Equipment Inspection	Satisfactory
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07. Security	Satisfactory
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08. Environment	Satisfactory
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48. Drugs (procurement, temperature, security, out-of-date, samples)	Satisfactory
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90. TSBP complaint notification	Satisfactory
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Controlled Substances

10. Prescriptions separated	Satisfactory
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24. Theft/Loss	Satisfactory
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Comment

No theft or loss has occurred.

26. Controlled substance prescription compliance	Satisfactory
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30. Controlled substance invoices dated/initialed by pharmacist	Satisfactory
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35. Controlled substance invoices separated	Satisfactory
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46. Drug distribution	Satisfactory
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53. Possession of controlled substances	Satisfactory
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Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	Satisfactory
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Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	Satisfactory
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45. Proper dispensing/labeling	Satisfactory
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54. Proper prepackaging procedures	Not Applicable
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Library

06. Required Library	Satisfactory
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Training

60. Documentation of required training	Satisfactory
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61. Supervision of supportive personnel	Satisfactory
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Patient/Computer/Dispensing Records

18. Records available	Satisfactory
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22. Data processing system compliance	Satisfactory
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25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	Satisfactory
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37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	Satisfactory
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56. Prescription transfers	Satisfactory
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67. Written drug information provided	Satisfactory
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80. Patient counseling	Satisfactory
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82. Patient Medication Records	Satisfactory
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84. Drug regimen review	Satisfactory
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86. Absence of pharmacist records	Satisfactory
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Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	Satisfactory
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92. Automated dispensing policy & procedures/SOPs	Not Applicable
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Non-Sterile Compounding

03. Orderly/Clean/Hand Hygiene	Satisfactory
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04. Balance inspection (for non-sterile compounding)	Satisfactory
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Comment

Number of balances: 2

05. Equipment Inspection	Satisfactory
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06. Non-sterile Library	Satisfactory
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32. Non-sterile compound label (Is label complete?)	Satisfactory
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38. Area/Environment for non-sterile compounding	Satisfactory
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43. Records for non-sterile compounding	Satisfactory
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60. Documentation of non-sterile required training	Satisfactory
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70. Required policies & procedures/SOPs	<i>Satisfactory</i>
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87. Quality Control/Assurance	<i>Satisfactory</i>
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Compounded Dosage Forms

Allergen extracts	<i>No</i>
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Parenteral solutions	<i>No</i>
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Parenteral suspensions	<i>No</i>
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Preservative-free parenterals	<i>No</i>
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Ophthalmic preparations	<i>No</i>
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Oral or nasal inhalation preparations (not topical spray)	<i>Yes</i>
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Bath or soaks for live organs/tissues	<i>No</i>
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Irrigations for wounds or body cavities	<i>No</i>
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Any other sterile preparations (implants, pellets, etc) [list]	<i>No</i>
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Investigational drugs	<i>No</i>
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Blood products or other biological materials (wound care, autologous, eye drops, etc)	<i>No</i>
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Any compounds using federally controlled substances Schedule I-V (list and percentage)	<i>Yes</i>
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Does the pharmacy use lyophilizer?	<i>No</i>
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Environment (Sterile)

S109. Is the cleanroom clean and free of objects that shed particles?	<i>Satisfactory</i>
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S110. Is the cleanroom used only for sterile preparations?	<i>Satisfactory</i>
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S119. Does the cleanroom contain only appropriate supplies?	<i>Satisfactory</i>
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S101. Does the ante-area provide at least ISO Class 8 air quality under dynamic conditions?	<i>Satisfactory</i>
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S115. Does the ante-area contain a hands-free sink with hot and cold running water?	<i>Satisfactory</i>
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S102. Does the buffer area provide at least ISO Class 7 air quality under dynamic conditions?	<i>Satisfactory</i>
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S106. Is the buffer area free from sources of water (e.g., sink, floor drains)?	<i>Satisfactory</i>
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S108. Is there hands-free access to the buffer area?	<i>Satisfactory</i>
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S113. Are floors, walls, ceilings & fixtures smooth, impervious and free from cracks & crevices?	<i>Satisfactory</i>
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S112. Does the floor covering enable regular disinfection?	<i>Satisfactory</i>
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S118. Are supplies stored above the floor to permit adequate floor cleaning?	<i>Satisfactory</i>
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S127. Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area and ante-area and between the ante-area and the general environment? Is the pressure differential at least 0.02" wc? *Satisfactory*

S116. Are temperature and humidity monitored, documented and within the required range? *Satisfactory*

S167. Is there a thermometer available for the cleanroom and refrigerator(s)? *Satisfactory*

Primary Engineering Control (PECs) Device

S126. Is the laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02" wc? *Satisfactory*

S121. Is the PEC able to maintain at least ISO Class 5 conditions while compounding sterile preparations? *Satisfactory*

S246. Are hazardous drugs prepared in a Class II/III vertical flow BSC or CACI located in an ISO Class 7 area physically separated from other areas? *Satisfactory*

S247. Does the area where the BSC or CACI is located have not less than 0.01" wc negative pressure adjacent to the positive pressure ISO Class 7 area? *Satisfactory*

S105. Does the CAI or CACI provide unidirectional airflow? *Not Applicable*

S104. If the CAI or CACI is used for high-risk sterile compounding, is it placed in an ISO Class 8 area? *Not Applicable*

S122. If the CAI is not required to be placed in an ISO Class 7 area, does the pharmacy maintain documentation from the manufacturer? *Not Applicable*

S124. Is the PEC certified by an independent contractor every 6 months and when relocated? *Satisfactory*

S125. Are prefilters inspected periodically and replaced as needed? *Satisfactory*

S128. Are differential pressures monitored and documented at least every work shift (at a minimum daily) or by a continuous recording device? *Satisfactory*

Equipment and Supplies

S174. Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? *Satisfactory*

S177. Does the pharmacy have lint-free towels or wipes? *Satisfactory*

S180. Does the pharmacy have masks, caps, gowns with tight cuffs, shoes covers, and beard covers (if applicable)? *Satisfactory*

S176. Does the pharmacy have handwashing agents with bactericidal action? *Satisfactory*

S175. Does the pharmacy have disinfectant cleaning solutions and dedicated cleaning supplies? *Satisfactory*

S179. Does the pharmacy have hazardous spill kits, if applicable? *Satisfactory*

S171. Does the pharmacy have appropriate containers for needles and syringes? *Satisfactory*

S170. Does the pharmacy have sterile isopropyl alcohol, sterile gloves, and waterless alcohol-based surgical hand scrub? *Satisfactory*

S178. Does the pharmacy have appropriate filters and filtration equipment?	<i>Satisfactory</i>
S181. If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy, and document at least daily?	<i>Not Applicable</i>
S172. Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?	<i>Satisfactory</i>

High Risk CSPs

S103. If high-risk CSPs are compounded, does the buffer area provide physical separation from other compounding areas?	<i>Satisfactory</i>
S231. Is sterility testing performed if CSPs are prepared in groups > 25, or	<i>Satisfactory</i>
S232. If MDVs are prepared for multiple patients or when exposed > 12 hours at 2-8 degrees C before sterilized, or	<i>Satisfactory</i>
S233. If exposed > 6 hours at warmer than 8 degrees C before sterilized?	<i>Satisfactory</i>
S237. Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk sterile compounding?	<i>Satisfactory</i>
S238. Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2-micron filter to remove particulate matter? Is sterilization by filtration performed with a sterile 0.2 – 0.22 micrometer pore size filter within an ISO Class 5 environment or better?	<i>Satisfactory</i>
S165. Are filter integrity tests being performed and documented (e.g., bubble point test)?	<i>Satisfactory</i>
S239. Are pre-sterilization procedures (weighing and mixing) completed in an ISO Class 8 environment or better?	<i>Satisfactory</i>

Sterile Library

S154. Does the pharmacy have a reference on injectable drugs?	<i>Satisfactory</i>
S155. Does the pharmacy have a specialty reference?	<i>Satisfactory</i>
S156. Does the pharmacy have all of the required (USP chapters 71, 85, 795, 797, 1163) and applicable USP chapters?	<i>Satisfactory</i>

Hazardous CSPs

S242. Do personnel wear protective apparel at all times when hazardous drugs are handled?	<i>Satisfactory</i>
S243. Do personnel use appropriate safety and containment techniques when preparing hazardous CSPs?	<i>Satisfactory</i>
S244. Do personnel dispose of hazardous waste in compliance with local, state, and federal regulations?	<i>Satisfactory</i>
S245. Do personnel affix a proper label, including proper precautions inside and outside of the packaging?	<i>Satisfactory</i>

S248. Does the pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?	<i>Satisfactory</i>
S249. Does the pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment (e.g., closed-system vial transfer device within a BSC)?	<i>Satisfactory</i>
S250. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	<i>Satisfactory</i>
Does the pharmacy have a plan to comply with USP <800> by the implementation date?	<i>Yes</i>
Are hazardous drugs stored separately in compliance with USP <800> (negative pressure at least -0.01" wc to adjacent areas and with at least 12 ACPH)?	<i>Yes</i>
Is hazardous drug waste quarantined in a designated area?	<i>Yes</i>
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)?	<i>Yes</i>

Personnel Cleansing, Garbing, Hand Hygiene

S202. Does hand sanitizing and gowning occur in the ante-area (outside of the buffer area)?	<i>Satisfactory</i>
S180. Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclose at the neck? Is the order of garbing appropriate (dirtiest to cleanest)?	<i>Satisfactory</i>
S194. Before entering the buffer area, do compounding personnel remove cosmetics?	<i>Satisfactory</i>
S195. Before entering the buffer area, do compounding personnel remove all hand, wrist, and other body jewelry/piercings?	<i>Satisfactory</i>
S196. Are natural nails kept neat and trim and no wearing of artificial nails or extenders?	<i>Satisfactory</i>
S200. Do compounding personnel remove debris from underneath fingernails using a nail cleaner under running warm water?	<i>Satisfactory</i>
S192. Are personnel with an apparent illness or open lesions compounding sterile preparations?	<i>Satisfactory</i>
S241. When compounding personnel temporarily exit the ISO Class 7 environment, are re-donning procedures properly followed?	<i>Satisfactory</i>
S201. Do compounding personnel engage in proper hand hygiene?	<i>Satisfactory</i>
S203. Do compounding personnel completely dry hands and forearms using lint-free disposable towels or hand dryer?	<i>Satisfactory</i>
S204. Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside the buffer area and prior to donning sterile gloves?	<i>Satisfactory</i>
S206. Is sterile isopropyl alcohol applied to gloves throughout the day and when non-sterile surfaces are touched?	<i>Satisfactory</i>

Cleaning/Disinfection Procedures

S182. Does the pharmacy have written procedures on the cleaning and disinfecting of the direct and contiguous compounding areas (e.g., beginning of shift, every 30 minutes, before each batch, spills)?	<i>Satisfactory</i>
S230. Is cleaning performed by trained personnel using approved agents (described in written SOPs)?	<i>Satisfactory</i>
S228. Are supplies & equipment that are removed from shipping cartons wiped with a disinfecting agent (e.g., sterile IPA)?	<i>Satisfactory</i>
S226. Are work surfaces and floors in the ante-area and buffer area cleaned and disinfected daily with dedicated supplies?	<i>Satisfactory</i>
S227. Are walls, ceilings and shelving in the ante-area and buffer area cleaned and disinfected at least monthly?	<i>Satisfactory</i>
S229. Does the pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, name of individual who performed the cleaning)?	<i>Satisfactory</i>

Environmental Sampling

S270. Is surface sampling conducted in all ISO classified areas on a periodic basis?	<i>Satisfactory</i>
S272. Is viable air sampling performed?	<i>Satisfactory</i>
S273. Is viable air sampling documented by properly trained individuals for all risk levels every 6 months?	<i>Satisfactory</i>
S271. Are environmental sampling results evaluated and addressed (i.e., action levels followed)?	<i>Satisfactory</i>

Records of CSPs

S252. Does the pharmacy maintain records relating to CSPs for a minimum of 2 years?	<i>Satisfactory</i>
S253. Do compounding records include the date and time of preparation of a CSP?	<i>Satisfactory</i>
S254. Do compounding records include the complete formula of a CSP?	<i>Satisfactory</i>
S257. Do compounding records include the quantities of materials used in a CSP?	<i>Satisfactory</i>
S255. Do compounding records include the signature or initials of who prepared a CSP?	<i>Satisfactory</i>
S256. Do compounding records include the signature or initials of who conducted the final check of a CSP?	<i>Satisfactory</i>
S258. Do compounding records include the container used and the number of units prepared for a CSP?	<i>Satisfactory</i>
S259. Do compounding records include the criteria used to determine the beyond-use date of a CSP?	<i>Satisfactory</i>
S260. Do compounding records include the documentation of performance of quality control procedures?	<i>Satisfactory</i>
S261. Are master worksheets and preparation worksheets for batch compounding complete?	<i>Satisfactory</i>
S262. Are master worksheets developed and approved by a pharmacist?	<i>Satisfactory</i>

General Operational Requirements

S166. Is a pharmacist available at all times (24/7)?	<i>Satisfactory</i>
S187. Are written SOPs developed and implemented for all significant procedures in the compounding area to include at a minimum: the facility, equipment, personnel, preparation evaluation, quality assurance, preparation recall, packaging, and storage of CSPs?	<i>Satisfactory</i>
S188. Does the pharmacy have all required written policies (e.g., pharmaceutical care services, sampling plan, recalls)?	<i>Satisfactory</i>
S158. If the pharmacy compounds commercially available products, does the pharmacy document the need by verifying and monitoring a drug shortage list (including if the preparation is quarantined/not available once removed from the shortage list)? Or,	<i>Satisfactory</i>
S158. Does the pharmacy document the need for compounding commercially available products by individual patient needs determined by the prescribing practitioner (i.e, hypersensitivity to inactive ingredients or alternate dosage form)?	<i>Satisfactory</i>
S275. If the pharmacy dispenses prescriptions to patients in other states, does the pharmacy have proper licensure in those states?	<i>Satisfactory</i>

Office Use Compounding & Distribution of CSPs

S163. Does the pharmacy have a written agreement with the prescriber that meets all requirements to distribute compounded sterile preparations to practitioners for office use?	<i>Not Applicable</i>
S162. If the pharmacy is distributing CSPs to another pharmacy, does the pharmacy meet the requirements for such distribution?	<i>Not Applicable</i>
Is the pharmacy registered with the FDA as an Outsourcing Facility (503B)?	<i>No</i>

Quality Control & Verification of Compounding Accuracy

S207. Does a pharmacist review all compounding records for accuracy and perform the final check of a CSP?	<i>Satisfactory</i>
S185. Are periodic in-process checks for CSPs defined in written procedures and conducted as defined?	<i>Satisfactory</i>
S191. Are all drug components USP/NF grade substances manufactured in an FDA-registered facility? If USP/NF grade substances are not available, are the drug components of chemical grade in CP, AR, ACS, or Food Chemical Codex categories?	<i>Satisfactory</i>
S191. Is a Certificate of Analysis available for all components of the preparation if materials are not purchased through an FDA-registered facility?	<i>Satisfactory</i>
S191. Are any CSPs prepared by the pharmacy listed on the federal FDA list of drug products that are withdrawn or removed from the market for safety reasons?	<i>Satisfactory</i>

Veterinary Compounding

Are APIs or other components labeled for veterinary use segregated or marked to prevent use for human compounding?	<i>Not Applicable</i>
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Does the pharmacy meet the same standards for animal compounding as human compounding?	<i>Not Applicable</i>
Is the pharmacist knowledgeable or does the pharmacy have up-to-date references regarding species limits that can result in toxicity when compounding with particular drugs/excipients?	<i>Not Applicable</i>
Does the pharmacy document if the animal is a pet or used for food?	<i>Not Applicable</i>
Is the pharmacist familiar with, or does the pharmacy have the most up-to date references regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals?	<i>Not Applicable</i>
Does the pharmacy have a list of drugs and components that have been designated by state or federal authorities as prohibited ingredients in CSPs for food-producing animals?	<i>Not Applicable</i>
Is the pharmacist familiar with, or does the pharmacy have the most up-to-date reference regarding regulations for drug use in performance animals?	<i>Not Applicable</i>

Label

S209. Is the CSP properly labeled to include the generic name(s), and	<i>Satisfactory</i>
S210. For outpatient prescriptions, does the label include a statement that the CSP has been compounded by the pharmacy?	<i>Satisfactory</i>
S211. Does the label include a beyond-use date?	<i>Satisfactory</i>
S213. If the CSP is compounded as a batch, does the label contain a unique lot number assigned to the batch, and	<i>Satisfactory</i>
S214. Quantity, and	<i>Satisfactory</i>
S215. Appropriate ancillary instructions, such as storage or cautionary statements, and	<i>Satisfactory</i>
S216. Any device-specific instructions, if appropriate?	<i>Not Applicable</i>
S220. Are CSPs assigned a beyond-use date based on the specified labeling for the drug, appropriate literature sources, or direct testing?	<i>Satisfactory</i>

Training & Competency Testing

S129. Has each pharmacist completed the required education and training prior to engaging in sterile compounding?	<i>Satisfactory</i>
S130. Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?	<i>Satisfactory</i>
S142. Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation/testing (e.g., media-fill testing, gloved fingertip/thumb testing)? Does the pharmacy have an on-the-job training program?	<i>Satisfactory</i>
S144. Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel (e.g., observation of aseptic technique, media-fill testing, gloved fingertip/thumb testing, continuing education)?	<i>Satisfactory</i>

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



AMIRZADEH, REZA



Larry Eatough