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Department of Commerce

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STERILE COMPOUNDING

INSPECTION

☐ New Opening ☐ Regular

INFORMATION

Pharmacy Name: _____ Date: _____

Pharmacy License Number: _____ Expiration Date: _____

Controlled Substance License Number: _____ Expiration Date: _____

DEA Registration Number: _____ Expiration Date: _____

Pharmacy FEIN #: _____

Pharmacist-in-Charge (PIC): _____

Pharmacist-in-Charge License Number: _____ Expiration Date: _____

Compounding Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:(a)Shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations [UAC R156-17b-614a (3)]

	Yes	No	GENERAL OPERATIONS AND INFORMATION
			Which categories of compounding does the facility perform?
1.	☐	☐	The pharmacy does perform compounding identified as **low-risk** [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- Low-Risk Level CSPs]* ☐ The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices. ☐ The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/ device to prepare the CSP. ☐ Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing. ☐ For a low-risk level preparation, in the absence of passing a sterility teste (see Sterility Tests <71>) the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see General Notices and Requirements), and for 45 days in solid frozen state between -25°and -10°.
	☐	☐	The pharmacy does perform compounding identified as **medium-risk.** When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exist, such CSPs are at a medium risk of contamination. [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- Medium-Risk Levels CSPs]* ☐ Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered to either multiple patients or to one patient on multiple occasions. ☐ The compounding process includes complex aseptic manipulations other than the single-volume transfer. ☐ The compounding process requires unusually long duration, such as that required to compete dissolution or homogenous mixing. ☐ For a medium-risk preparation, in the absence of passing a sterility test (see Sterility Tests <71>0, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see Generals Notices and Requirements), and for 45 days in solid frozen state between 25°and -10°.