



MARYLAND

Department of Health

Wes Moore, Governor • Aruna Miller, Lt. Governor • Laura Herrera Scott, M.D., M.P.H., Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue, Baltimore, Maryland 21215-2299

Jennifer L. Hardesty, Board President • Deena Speights-Napata, Executive Director

OPENING INSPECTION FORM FOR STERILE PROCESSING

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business As (d/b/a) or Trade Name _____
Street Address _____
Business Telephone Number _____ Business Fax Number _____
Maryland Pharmacy Permit Number _____
Pharmacy Hours: _____
Name of Inspector: _____

1. PERSONNEL AND FACILITY (COMAR 10.34.14.02 AND 10.34.03.05)

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws

The Pharmacy is located in a residence: Yes No

**2. FACILITY AND EQUIPMENT STANDARDS FOR COMPOUNDING
STERILE PREPARATIONS**

Documentation shows:

YES NO N/A

Certification that each LAFW (Laminar Air Flow Workbench), BSC (Biological Safety Cabinet), and CAI (Compounding Aseptic Isolator) is functioning properly and meets the air quality requirement of ISO Class 5, and is performed by a qualified operator(s) using current, state-of-the-art electronic air sampling. COMAR 10.34.19.03B(5) & (10); COMAR 10.34.19.15D The air quality of the clean room and anteroom area is evaluated by a qualified operator(s) for conformance to ISO Class 7 and ISO Class 8 requirements, as appropriate. COMAR 10.34.19.03B(5); COMAR 10.34.19.15E

Records of clean room testing are maintained and reviewed by the supervising pharmacist. COMAR 10.34.19.

A refrigerator and freezer, if applicable, with sufficient capacity to meet the storage requirements for all material requiring refrigeration/freezing must be available in the facility. Evidence of maintenance of acceptable temperature ranges must be available. COMAR 10.34.19.10A

The facility must contain appropriate waste containers to isolate sharps, hazardous waste, biological, and chemotherapy waste. COMAR 10.34.19.09B(6) & .15F; COMAR 10.34.19.10A(3)

All equipment used in the designated area or clean room must be made of a material that can be easily cleaned and disinfected. COMAR 10.34.19.09B(3)

The Pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01-1A.

YES NO N/A

The Pharmacy has a library of current reference sources consistent with its scope of practice that is accessible to all appropriate personnel. COMAR 10.34.07.03. The Pharmacy has online resources. HO § 12-403(b)(15)

The Pharmacy possesses the current edition of The Maryland Pharmacy Law and Regulation. HO § 12-403(b)(10)(ii)

3. COMPOUNDING AREA COMAR 10.34.19.09

YES NO N/A

Clean room walls, ceilings, counters, lighting fixtures and floors are made of non-porous, nonshedding, cleanable surfaces. COMAR 10.34.19.09B(3)

Supplies are stored in a manner that maintains integrity of an aseptic environment.

The anteroom contains a sink with hot and cold running water. COMAR 10.34.19.09C(2)(a)

4. POLICIES AND PROCEDURES MUST ADDRESS: COMAR 10.34.19.12

Policies and procedures address at least the following:

YES NO N/A

The compounding, filling, and labeling of sterile compounds. COMAR 10.34.19.12C(6)(a), (c) & (d)

Proper labeling of the compounded sterile preparation including the intended route of administration and recommended rate of administration. COMAR 10.34.19.12C(6)(d)

Availability of equipment and supplies. COMAR 10.34.19.12C(3); COMAR 10.34.19.12C(17)(a)

The training of staff in the preparation of compounded sterile preparations. COMAR 10.34.19.12C(10); COMAR 10.34.19.14B

Staff competency evaluations. COMAR 10.34.19.14E

The Quality Assurance Program. COMAR 10.34.19.12C(9); 10.34.19.15

All record keeping requirements. COMAR 10.34.19.12C(7)

A written process, verified by a pharmacist, describing ingredients and the compounding process for each preparation. COMAR 10.34.19.07B(1) and (2)

Documentation demonstrating that all personnel involved have read the policies and procedures before compounding sterile preparations. COMAR 10.34.19.12B

Documentation of communication of policy and procedure for additions and deletions.

The storage and handling of products and supplies. COMAR 10.34.19.12C(6)(b)

The storage and delivery of final preparation. COMAR 10.34.19.12(6)(b) and (f)

Media fill process verification testing. COMAR 10.34.19.12C(11)

Fingertip touch testing. COMAR 10.34.19.15C

The criteria for Beyond Use Dating (BUD). COMAR 10.34.19.12C(6)(e)

Personnel access and movement of materials into and near the compounding area. COMAR 10.34.19.12C(2)

The use and maintenance of environmental control devices used to create the critical area for manipulation of sterile preparations (e.g. laminar air flow workstations, biological safety cabinet, ISO Class 7 clean room, and/or CAIs. COMAR 10.34.19.12C(3)

A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants (pharmacies subject to an institutional infection control policy may follow that policy).

The method used to monitor the environment for bacterial microorganisms. COMAR 10.34.19.12C(4)

The disposal of packaging materials, used syringes, containers, and needles to avoid accumulation and maintain sanitation in the controlled area. COMAR 10.34.19.12C(18); COMAR 10.34.19.15F

YES NO N/A

Written policies and procedures for the use of established master formulas and worksheets for sterile batch compounding, if applicable.

Established sterilization procedures including documentation of results, if applicable. COMAR 10.34.19.12C(4)

End-product evaluation and testing, if applicable. COMAR 10.34.19.12C(11); COMAR 10.34.19.15H

5. DISPOSAL OF WASTE MATERIAL

YES NO N/A

Pharmacies compounding sterile preparations shall have written policies and procedures for disposal of infectious materials and/or materials containing cytotoxic residue or hazardous waste. COMAR 10.34.19.12C(18)

Procedures must include cleanup of spills and shall be in conformance with local health jurisdictions. COMAR 10.34.19.12C(4)

6. SECURITY

YES NO N/A

The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (If yes, briefly describe how access is restricted.) COMAR 10.34.05.02

The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02

Opening Inspection:

Pass

Fail

Inspectors Comments:

Inspector Signature _____

Pharmacist Name: _____ License #: _____
(Print)

Received a copy of the inspection report on _____

Date and Signature of the Pharmacist