The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Health Professions Licensure

250 Washington Street, Boston, MA 02108



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# Non-Sterile Compounding Documents for Inspection

# Licenses/Registrations/Certifications:

* Massachusetts Drug Store Pharmacy License
* Massachusetts Controlled Substance Registration
* DEA Controlled Substance Registration Certificate
* Non-Resident Drug Store Pharmacy Licenses for all States Doing Business In
* Complex Non-Sterile Compounding License, as applicable
* Pharmacist, Pharmacy Intern, and Pharmacy Technician Licenses & Registration Cards
	+ Technician Trainee hours
* Other (DCP, FDA, etc.)

# Policy and Procedure Manual:

* Buildings and Facilities
* Personnel Training and Evaluation
* Personal Hygiene and Garbing
* Components
* Environmental Monitoring (e.g. Temperature, Humidity, etc.)
* Certification based tests for PECs and SECs, as applicable
* Equipment Management including maintenance, calibration, and cleaning intervals
* Safety Data Sheets and Spill Management
* Master Formulation Records and Compounding Records
* Labeling
* Proper Storage, handling, shipping, packaging, transportation, and delivery
* Final release checks and verification of non-sterile compounded preparations
* Quality control testing requirements and procedures (pH testing, capsule variance, etc.)
* Quality Assurance program including RCA and CAPA
* Change control
* Patient monitoring and adverse event reporting, including recalls of CSPs
* Response to broken, damaged, or spilled non-sterile compounded preparation
* Assignment of BUD
* Proper waste handling and disposal
* Hazardous Handling, as applicable

# Personnel Training, Competency, and Proficiency Tests:

* Training program design for new and veteran compounding personnel including didactic, observational, and return demonstration proficiency tests
* Hand hygiene and garbing competencies for compounding personnel and external staff members
* Cleaning and disinfection competencies for compounding personnel and external staff members
* Handling and transporting components and CNSPs
* Measuring and mixing
* Proper use of equipment and devices selected to compound CNSPs
* Documentation of the compounding process (e.g. Master Formulation Records, Compounding Records)
* Demonstrating knowledge and understanding of USP <795> Chapter
* Safety Data Sheets and Certificate of Analysis, as applicable

**Quality Related Documentation:**

* Environmental monitoring (e.g. Temperature, Humidity, and Pressures)
* Certification report for compounding environment and equipment
* Out of Specification reports for Environment, Personnel and Product including Investigations, Root Cause Analysis (RCA), Corrective Action Preventative Action CAPA and complaint handling
* Defective Drug Logs and Quality Related Event documentation.
* Compounding Master Formulation Records and Individual Compounding Records
* Cleaning and Disinfection Log(s)
* Extended Stability Analytical Testing Reports
* List of Non-Sterile Compounds Produced and/or Outsourced
* List of Non-Sterile Compounds Recalled, for any Reason
* Equipment records (e.g. calibrations, verification, and maintenance reports)
* References and Resources utilized to determine formulation and assignment of BUD