



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

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