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| **DATE(S) OF INSPECTION:** | **ISP# -** | | | |
| **PHARMACY DBA NAME:** |  | | | |
| **STORE NUMBER:** |  | | | |
| **STREET ADDRESS:** |  | | | |
| **CITY / STATE / ZIP:** |  | | | |
| **TELEPHONE:** |  | | | |
| **FAX:** |  | | | |
| **EMAIL:** |  | | | |
|  |  | | | |
| **PHARMACY LIC. NUMBERS:** |  | | | |
| **PHARMACY LIC. EXPIRATION:** |  | | | |
|  |  | | | |
| **MANAGER OF RECORD (MOR):** |  | | | |
| **MOR LIC. NUMBER:** |  | | | |
|  |  | | | |
| **COMPOUNDING INVESTIGATIONAL MEDICATION(S):** | **YES** | **NO** | | |
| **COMPOUNDING DIETARY / NUTRITIONAL**  **SUPPLEMENTS:** | **YES** | **NO** | | |
| **HIGHEST STERILE COMPOUNDING RISK LEVEL:** | **LOW** | **MEDIUM** | **HIGH** | |
| **DAILY PHARMACY VOLUME (STERILE**  **COMPOUNDING):** |  | | | |
|  |  | | | |
| **HOURS OF OPERATION:** | **M – F:** | **SAT:** |  | **SUN:** |



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| **A. Regulatory Requirements** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **1** | Compounder is appropriately licensed |  |  |  |  |
| **2** | If compounder prepares a significant number of non  patient specific preparations (e.g. > 5% of the compounders volume), the compounder is registered  as a drug manufacturer with the FDA, if required. |  |  |  |  |
| **3** | If compounder prepares non patient-specific  controlled substances, the compounder is registered as a drug manufacturer with the DEA. |  |  |  |  |
| **4** | All pharmacists are licensed in the state in which  they are practicing. |  |  |  |  |
| **5** | All pharmacy technicians are licensed or registered  in the state in which they are practicing. |  |  |  |  |
| **6** | Compounder meets or exceeds state required  pharmacist-to-pharmacy technician ratios for the state in which the compounding center is located. |  |  |  |  |
| **7** | If an FDA-approved product is commercially  available (not on backorder), the compounder does not prepare the same drug formulation using non- sterile powders or other components. |  |  |  |  |
| **8** | Compounder meets regulatory requirements for  handling of hazardous agents. |  |  |  |  |



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| **B. Quality Requirements** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **9** | A quality assurance program for compounding  includes at least the following separate, but integrated components: (1) training; (2) standard  operating procedures; (3) documentation; (4)  verification; (5) testing; (6) cleaning and disinfecting; (7) containers, packaging, repackaging,  and storage. |  |  |  |  |
| **10** | Compounder can provide documentation that  confirms competency (hand hygiene and garbing, aseptic technique and related practices, and cleaning  and disinfection procedures) is evaluated prior to  compounding of actual drug preparations and on at least an annual basis. |  |  |  |  |
| **11** | Compounder can provide documentation that  confirms that the compounder tests aseptic techniques by preparing media fill units per USP Chapter <797> standards.  ***(Pre-qualification & On-going)***  **Low and Medium Risk*:*** Once and then annually  **High Risk:** Once and then semi-annually |  |  |  |  |
| **12** | Compounder can provide documentation that  personnel are complying with gowning, gloving, and glove fingertip processes that are consistent with USP chapter <797> standards.  ***(Prequalification & Ongoing)***  **Low and Medium Risk:** Glove fingertip test three times initially then annually.  **High Risk:** Glove fingertip test three times initially then semi-annually. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **13** | Compounder provides detailed reports on the  incidence of positive media test results and positive gloved finger tip samples and the follow-up retests after corrective action is completed. |  |  |  |  |
| **14** | Compounder applies USP <797> Standard BUDs to  all CSPs. |  |  |  |  |
| **15** | Compounder provides customers with substantial  evidence (peer reviewed studies or validated study) that supports extended expiration dating for  compounded sterile preparations when BUD limits  in USP <797> are exceeded. |  |  |  |  |
| **16** | Compounder has a policy that requires validation of  new or changed facilities, equipment, processes, container types, for sterility, and repeatability. |  |  |  |  |
| **17** | There is a mechanism to promptly address  equipment problems. |  |  |  |  |
| **18** | A written environmental sampling plan is developed  based on the compounding activities performed, locations to be monitored, the device used to monitor, the frequency of collection, and procedures if readings exceed established thresholds. |  |  |  |  |
| **19** | **Viable and Non-Viable Air**  Sampling occurs minimally every 6 months.  Volumetric sampling is required. Fungal testing is required for high risk compounding. |  |  |  |  |
| **20** | **Viable Surface**  Sampling occurs minimally every 6 months. Fungal testing is required for high risk compounding. |  |  |  |  |
| **21** | Sampling data is baselined and evaluated on a  routine basis. Trending analysis is required. |  |  |  |  |
| **22** | Compounder has action and alert limits for  environmental monitoring. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **23** | Facility personnel completing environmental  monitoring are appropriately trained and certified if necessary. |  |  |  |  |
| **24** | Compounder develops and implements methods for  improving quality based on analyzed data. |  |  |  |  |
| **25** | Compounder evaluates and continuously monitors  the methods used for the packaging, handling, and transport of CSPs. |  |  |  |  |
| **26** | Compounder evaluates and continuously monitors  the storage of CSPs to ensure compliance with appropriate storage conditions. |  |  |  |  |
| **27** | Drug storage refrigerators, freezers and medication  storage areas have daily monitoring and documentation of temperatures. |  |  |  |  |
| **28** | Personnel inspect all drug storage areas routinely to  ensure drugs are stored separately from food. |  |  |  |  |
| **29** | Solutions, medications, equipment, and supplies (in  all areas) are stored according to the manufacturer or USP requirements and are inspected routinely  (per P&P) for proper conditions of light, temperature, moisture, and ventilation |  |  |  |  |
| **30** | Outdated and unused CSPs are segregated in a  separate area for return and disposal per P&P. |  |  |  |  |
| **31** | Personnel determine whether a CSP not  administered as originally intended can be used for an alternate patient or under alternate conditions |  |  |  |  |



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| **C. Compounding Environment** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **32** | The space provides for orderly placement of  equipment and materials to prevent mix-ups between ingredients, containers, labels, in-process  materials, finished preparations. |  |  |  |  |
| **33** | Procedures are implemented to prevent cross-  contamination. |  |  |  |  |
| **34** | Areas used for **sterile** preparation are separate and  distinct from areas used for **non-sterile** preparation. |  |  |  |  |
| **35** | The compounding area is well-lighted. |  |  |  |  |
| **36** | Heating, ventilation and air conditioning systems  are controlled. A constant temperature is maintained 24 hours per day, 7 days per week. |  |  |  |  |
| **37** | The bulk storage area is adequately arranged, proper  temperature and humidity maintained and suitably controlled. |  |  |  |  |
| **38** | Hot and cold potable water is supplied for hand and  equipment washing in the compounding area. Soap or detergent and single-use towels or driers are readily available. |  |  |  |  |
| **39** | The compounding areas are maintained in a clean  and sanitary condition. |  |  |  |  |
| **40** | In case of modular construction methods, a surface  material such as fiberglass-reinforced plastic (FRP) should be used. |  |  |  |  |
| **41** | Ceilings are smooth, impervious, free from cracks  and non-shedding (plastic covered clean room grade ceiling tiles). All tiles must be sealed. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **42** | Floors are smooth, impervious, free from cracks and  non-shedding. Floor are overlaid with wide sheet vinyl and heat welded seams and coving to the sidewall. |  |  |  |  |
| **43** | Fixtures are smooth, impervious, free from cracks  and non-shedding. All fixtures mounted to wall in a way that "seals" any space between wall and fixture. |  |  |  |  |
| **44** | Shelving is smooth, impervious, free from cracks  and non-shedding. |  |  |  |  |
| **45** | Counters are smooth, impervious, free from cracks  and non-shedding (all exposed surfaces including underside). |  |  |  |  |
| **46** | Cabinets are smooth, impervious, free from cracks  and non-shedding. |  |  |  |  |
| **47** | Ceiling to wall junctures are coved or caulked to  avoid cracks. |  |  |  |  |
| **48** | Inlaid ceiling panels are impervious and  hydrophobic. |  |  |  |  |
| **49** | There are no dust-collecting overhangs. |  |  |  |  |
| **50** | There are no windowsills. |  |  |  |  |
| **51** | Exterior lens surface of ceiling light fixtures are  smooth, mounted flush, and sealed. |  |  |  |  |
| **52** | There are no sinks in primary and secondary  compounding areas. |  |  |  |  |
| **53** | There are no floor drains in primary and secondary  compounding areas. |  |  |  |  |
| **54** | Carts are made of stainless steel wire or sheet metal.  A minimum of two stainless steel carts with cleanable castors are essential. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **55** | Carts have cleanable casters and are mobile. |  |  |  |  |
| **56** | All surfaces are designed to provide effective  cleaning. |  |  |  |  |
| **57** | All surfaces are resistant to damage by cleaning  agents. |  |  |  |  |
| **58** | There are no cardboard containers in buffer area at  any time. |  |  |  |  |
| **59** | There are no electronics (computers, printers, radios  and refrigerators) in the buffer area at any time. |  |  |  |  |
| **60** | Trash is disposed of in a safe, sanitary and timely  manner. |  |  |  |  |
| **61** | All components, containers and equipment are  stored off the floor in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area. |  |  |  |  |
| **62** | The equipment generally is of appropriate design  and size for the compounding that is performed. |  |  |  |  |
| **63** | All equipment is of appropriate design such that the  surfaces that contact pharmaceutical components, in-process materials or finished preparations is not  reactive, additive or adsorptive. |  |  |  |  |
| **64** | All equipment is thoroughly cleaned immediately  after use to avoid cross-contamination. |  |  |  |  |
| **65** | Equipment is stored to prevent it from  contamination and is located to facilitate its use, maintenance, and cleaning. |  |  |  |  |
| **66** | Equipment used for allergenic ingredients is  appropriately handled, cleaned and stored immediately after use. |  |  |  |  |
| **67** | All work surfaces are cleaned of loose materials and  residue from spills before compounding. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **68** | Floors in the buffer area and ante area must be  mopped daily with a cleaning and disinfecting agent at a time when no aseptic compounding is in progress. |  |  |  |  |
| **69** | Daily cleaning and sanitizing of workspaces  including all buffer room carts, equipment, workbenches, work surfaces, and floors is an  important responsibility of compounding personnel.  Cleaning is documented. |  |  |  |  |
| **70** | Storage shelving in buffer and ante areas are  emptied of all supplies, cleaned, and sanitized at planned intervals (at least monthly). Walls and  ceilings in buffer and ante areas are cleaned monthly as well. |  |  |  |  |
| **71** | Facility has reviewed and approved all cleansing  and sanitizing agents (considering compatibilities, effectiveness, and presence of inappropriate or toxic  residues) |  |  |  |  |
| **72** | Mops, wipes, sponges, and other cleaning materials  must be non-shedding and dedicated for use only in the sterile compounding area (buffer room). |  |  |  |  |
| **73** | Cleaning tools are replaced as soon as they are  identified as unsuitable for use |  |  |  |  |
| **74** | Ideally, all cleaning materials are disposable and  discarded after one use. |  |  |  |  |
| **75** | Trash is collected in suitable plastic bags and  removed on a daily basis with minimal agitation |  |  |  |  |
| **76** | All equipment is clean, properly maintained and  validated at appropriate intervals. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **77** | PECs need to be cleaned and disinfected at the  beginning of each shift, before each batch, at least every 30 minutes during compounding, when surfaces are visibly soiled, and when surface contamination is known or even suspected. |  |  |  |  |
| **78** | Clean and disinfect all interior working surfaces of  LAFW from top to bottom, back to front, away from the HEPA filter. Cleaning is performed with sterile water, and disinfecting with sterile 70% isopropyl alcohol or similar antimicrobial, residue-free sanitizing agent. |  |  |  |  |
| **79** | Nothing should be permitted to come in contact with  the HEPA filter. This includes cleaning solutions, aspirate from syringes, or glass from ampules,  which should not be broken towards the filter. |  |  |  |  |



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| **D. Engineering Controls** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **80** | PEC/SEC certification is in date. |  |  |  |  |
| **81** | PEC/SEC is certified every 6 months or sooner if  recommended by manufacturer. |  |  |  |  |
| **82** | PEC: e.g., airflow workbench (LAFW) and  Biological safety cabinets (BSCs) provide ISO Class 5 air quality. |  |  |  |  |
| **83** | PECs are located in ISO Class 7 buffer room  (cleanroom) |  |  |  |  |
| **84** | Buffer room (secondary engineering control) is  designed to reduce the risk of contaminants being blown into primary compounding area (PCA). To be considered a clean room, buffer area must meet specific air quality, HEPA filtration, air changes per hour, and room pressure differentiation criteria (provide at least ISO Class 7 air quality). The buffer room provides ISO Class 7 air quality. |  |  |  |  |
| **85** | Within the buffer area, PEC should be kept away  from excess traffic, doors, air vents, or anything that could introduce contaminates into the workbench. |  |  |  |  |
| **86** | Anteroom is separate from buffer area. |  |  |  |  |
| **87** | Anteroom provides ISO Class 8 air quality, or ISO  Class 7 air quality, depending on the connecting buffer area. |  |  |  |  |
| **88** | Anteroom area should store adequate amount of  gowning supplies but should not be part of high traffic area or corridor. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **89** | Anteroom is used to un-carton and sanitize all  supplies to be taken into buffer area. |  |  |  |  |
| **90** | Hand sanitizing and gowning activities occur in  anteroom |  |  |  |  |
| **91** | Faucet handles are designed to be hands-free |  |  |  |  |
| **92** | Buffer area can be accessed without the use of  hands |  |  |  |  |
| **93** | For facilities that compound only low and/or  medium risk preparations, ante room can be in the same area as buffer room, separated by line of demarcation. However, a separate ante room is still recommended. |  |  |  |  |
| **94** | For high risk compounding, there must be a separate  ante room. |  |  |  |  |
| **95** | All supplies brought into buffer area are non-  permeable, non-shedding, and resistant to disinfectants. |  |  |  |  |
| **96** | Materials exposed to patient care areas are kept out  of buffer area. |  |  |  |  |



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| **E. Compounding Procedures** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **97** | There is no smoking, food, drink, or chewing gum  allowed in the buffer area at any time. |  |  |  |  |
| **98** | No jewelry on the hands or wrist or any visible  piercings may be worn when working within a LAFW nor in buffer area. |  |  |  |  |
| **99** | No make up may be worn in the buffer area as it can  shed particles. |  |  |  |  |
| **100** | Before putting on gloves, the nails should be  cleaned, and the hands, wrists, and forearms should be washed thoroughly for at least 30 seconds with warm water and antimicrobial skin cleanser. |  |  |  |  |
| **101** | Compounding personnel must appropriately utilize  gowns, masks, gloves, hair covers, and shoe covers. |  |  |  |  |
| **102** | Place only essentials in LAFW. No paper, pens,  labels, or trays may be placed in the workbench |  |  |  |  |
| **103** | Objects that shed particles are not brought into the  buffer area (cardboard cartons, paper towels, and cotton items). |  |  |  |  |
| **104** | Clean and disinfect all interior working surfaces of  LAFW from top to bottom, back to front, away from the HEPA filter. |  |  |  |  |
| **105** | Compounding personnel check the quality, purity,  amount, and identity of all ingredients |  |  |  |  |
| **106** | Correct compounding procedures are used |  |  |  |  |
| **107** | During compounding, periodically disinfect gloves  with sterile 70% isopropyl alcohol and allow them to dry thoroughly before continuing. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **108** | Open and partially used containers are properly  labeled and stored. |  |  |  |  |
| **109** | Packaging is appropriate for sterility and stability |  |  |  |  |
| **110** | Product labels are appropriate and complete for safe  use |  |  |  |  |
| **111** | Products are visually inspected for physical integrity  during and after compounding, and a final check of the CSP is performed. |  |  |  |  |
| **112** | Deficiencies in compounding procedures can be  rapidly identified and corrected. |  |  |  |  |
| **113** | Completed compounded products are maintained in  a separate area away from the active compounding area. |  |  |  |  |
| **114** | Not more than two entries into any one sterile  container or sterile administration device |  |  |  |  |
| **115** | Compounding activities only involve closed or  sealed packaging systems. |  |  |  |  |



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| **F. Records Management** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **116** | The record keeping requirements of the state are  followed. |  |  |  |  |
| **117** | Compounding records and documents are  maintained for the time period required by the state. |  |  |  |  |
| **118** | PEC/SEC certification records are maintained and  readily available. |  |  |  |  |
| **119** | A detailed formulation record is maintained for each  sterile compounded preparation and includes: name of preparation, strength and dosage form; all  ingredients and their quantities; equipment used for  the preparation; admixing instructions to include order of mixing, temperatures, duration of mixing  and other pertinent factors; assigned beyond-use  date; container used; storage requirements; quality control procedures. |  |  |  |  |
| **120** | Procedures are developed for the facility,  equipment, personnel, preparation, packaging and storage of compounded preparation to ensure  accountability, accuracy, quality, safety, and uniformity in compounding. |  |  |  |  |
| **121** | A procedure is defined for recalls. The recall file  should be maintained with information concerning any applicable recalled products affecting the  pharmacy. |  |  |  |  |
| **122** | Compounder provides pedigree information that  documents that they do not purchase products outside of traditional drug distribution networks or  through secondary wholesalers. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **123** | Compounder provides quality control history and  quality assurance trend reports on a regular basis and upon request. |  |  |  |  |
| **124** | Compounder provides documentation that confirms  that sterile media used are certified by the manufacturer to be sterile and guaranteed to promote growth. |  |  |  |  |
| **125** | Compounder has documented processes and  procedures (including shipping validation studies) to ensure that preparations leaving the site retain their integrity and stability through the shipping cycle. |  |  |  |  |
| **126** | Didactic training, visual process validation and  written assessment of personnel is documented. |  |  |  |  |
| **127** | Documentation is available that cleaning methods  and agents are effective in preventing contamination of the sterile preparations area. |  |  |  |  |



I have participated in a sterile compounding audit and have reviewed the audit report with the inspectors.

Plan of Correction Issued: Yes No

If yes, I will provide a plan of correction for all findings within 15 business days.

### Print Name: Signature:

**Title: License Number:**

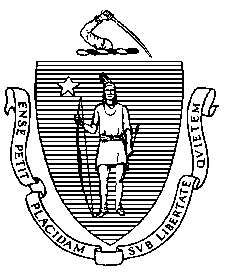
**Inspector: Date:**

**Inspector: Date:**

**Inspector: Date:**

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| **Comments:** |
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The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health



## Bureau of Health Professions Licensure

239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER

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MARYLOU SUDDERS

Secretary

MONICA BHAREL, MD, MPH

Commissioner

**Massachusetts Board of Registration in Pharmacy Sterile Compounding Documents for Inspection**

# Licenses:

* 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 Massachusetts
* Sterile Compounding License, as applicable
* Institutional 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:

* Personnel Monitoring (e.g. Aseptic Media Fills, Gloved Finger Tip Sampling, etc.)
* Environmental Monitoring (e.g. Air, Surface, Non-Viable)
* ISO Classified Area Monitoring (e.g. Certification based tests for PECs and SECs) Proper Storage, handling, shipping, packaging, transportation, and delivery
* Final release checks and verification of CSPs
* Quality assurance program including RCA and CAPA
* Change control, validation of new or changed facilities, equipment, or processes Hand hygiene and garbing processes
* Aseptic technique
* Patient monitoring and adverse event reporting, including recalls of CSPs Maintenance, calibration, and cleaning intervals
* Response to broken, damaged, or spilled CSPs Compounding procedures specific to each risk level
* Sterilization and depyrogenation processes, as applicable Sterility and endotoxin testing, as applicable
* Assignment of BUD
* Proper waste handling and disposal

# Personnel Training, Competency, and Proficiency Tests:

* Training program for new and veteran compounding personnel
* Aseptic manipulation proficiencies for compounding personnel
* Gloved finger tip/thumb proficiencies for compounding personnel and external staff members (Initial and Ongoing)
* Hand Hygiene and Garbing competencies for compounding personnel and external staff members
* Cleaning and Disinfection competencies for compounding personnel and external staff members

# Quality Related Documentation:

* Environmental monitoring results including trending analysis and sampling map
* Certification report for compounding environment
* Example of Out of Specification reports for Environment, Personnel and Product including Root Cause Analysis (RCA) and Corrective Action Preventative Action CAPA.
* Compounding Master Formulation Record and Individual Compounding Record
* Logs: Cleaning and Disinfection, Pressure Differentials, Temperature and Humidity, Incubator
* Cleaning and Disinfection chemicals, activity, contact time, ready-to-use (RTU) or dilution (Instructions required)
* Sterility and Endotoxin Testing
* Report Extended Stability
* Analytical Testing Reports
* List of CSPs Produced and/or Outsourced
* List of CSPs Recalled, for any Reason