MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

By Robin O. Novak, RN CIC

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Objectives:

The learner will be able to:

- List the difference between a 503A and 503B pharmacy
- List items to evaluate when touring a compounding pharmacy
- List resources to learn more about compound pharmacies

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

IN THE NEWS

Did Compounded Antibiotic-steroid Formulation Cause Cataract Patients' Vision Problems?

So far, as many as 50 cataract patients have reported worsening visual acuity.

Published: April 27, 2017
Category: Outpatient Surgery > Cataract Surgery

http://www.outpatientsurgery.net/surgical-services/cataract-surgery/did-compounded-antibiotic-steroid-formulation-cause-cataract-patients-vision-problems--04-27-17

By RYAN JASLOW | CBS NEWS | August 12, 2013, 12:05 PM

Texas compounding pharmacy recalls drugs after 15 infections

The Food and Drug Administration announced Friday that it had tested 50 vials linked to the meningitis outbreak and found all 50 vials to be contaminated with mold or fungus. Dr. Jon LaPook reports on this and more troubling findings from the FDA.

Exophiala Infection from Contaminated Injectable Steroids Prepared by a Compounding Pharmacy -- United States, July--November 2002

https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5149a1.htm

Multistate Outbreak of Fungal Infection Associated with Injection of Methylprednisolone Acetate Solution from a Single Compounding Pharmacy – United States, 2012

Weekly
October 19, 2012 / 61(41);839-842

https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6141a4.htm

Investigation of compounding pharmacy lab reveals lapses in hospital's infection control

By KAISER HEALTH NEWS

Post a comment / May 20, 2016 at 11:56 AM

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Compounding definition:

FDA:

- Any manipulation of a sterile or non-sterile product intended to produce a sterile final product. The Food and Drug Administration (FDA) recognizes compounding as a part of pharmacy practice, which does not fall within the agency's authority.

USP <797>:

- Preparations prepared in accordance with manufacturer labeled instructions
- Preparations containing non-sterile ingredients or requiring non-sterile components and devices that must be sterilized before administration
- Biologicals, diagnostics, drugs, nutrients, or radiopharmaceuticals that possess either of the above two characteristics and include, but are not limited to, baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injection, irrigations, metered sprays,

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

USP <797>

Intent:

To prevent harm and fatality to patients that could result from microbial contamination, excessive bacterial endotoxins large content errors in strength of correct ingredients, and incorrect ingredients in compounding sterile products

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

503A Compounding- Traditional Compounder:

- Regulated by State board of pharmacy
- No mass compounding
- Restricted to providing compounded products to those with patient prescriptions only
- Ship within the state

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503B Compounding- Outsourcing facility:

- Regulated by FDA
- Provides large batch compounding
- Office-use is allowed
- Labeling requirements
- Ship across the U.S.

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Reasons to Compound:

- ✓ Limited resources – inventory storage
- ✓ Drug shortage
- ✓ Financial – Budget
- ✓ Pharmacy consultant with limited compounding experience
- ✓ Limited staff
- ✓ Inadequate compounding location within facility
- ✓ Quality expectations from payers
- ✓ Regulatory & accrediting agency recommendations
- ✓ Diminish risk of HAI

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Choosing a compounding pharmacy:

- Assess and identify ASC needs
  - Why do you need to utilize a compounding pharmacy?
  - What do you need compounded?
  - Is it available commercially?
  - What volume will you need?
  - What packaging options are needed?
  - What storage capacity is available at the ASC?

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Choosing a compounding pharmacy:

- √ Identify and contact vendors
  - √ Provide preparations and containers suitable for ASC setting
  - √ Request information
  - √ Request a proposal
  - √ Visit the facility

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Choosing a compounding pharmacy:

Information request:

- Facility history
- Volume of CSP/ month
- Regulatory/ licensure status
- Description of products/ services available
- Ordering process/ turn around time
- Pricing
- Customer support
- Enforcement/ accreditation actions
- Emergency preparedness
- Delivery options

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

What does the IP need to look for:

- Validate outliers in FDA 483 document are resolved as outlined

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/default.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1) There is inadequate HEPA-filter coverage or airflow over the area to which sterile product is exposed, specifically, on May 5, 2017, we observed a gap, approximately ¼ inches, across the back of the HEPA screen in the (b) (4) laminar air flow hood which is used to fill syringes of sterile drug products. The gap appears to be larger than the syringes being filled, causing them to be below the level of ISO 5 airflow.

2) Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated and were observed with exposed skin during aseptic processing.
   a. The sterile gowns used by the technician filling syringes of sterile drug products are buttoned using her bare hands before sitting with her entire upper body in the ISO 5 area with exposed skin around her eyes.
   b. The gowns worn by the pharmacist producing sterile drug products are non-sterile, including the sleeves that actually enter the ISO 5 area.
   c. Both types of gown are removed, hung on hooks in the ISO 8 area, and then re-used throughout the day.

3) There is no evidence that the (b) (4) preservative used to provide (b) (4) blanketing for glutathione sterile drug products is of an appropriate quality for its intended use.

4) Personnel failed to disinfect or change gloves frequently enough to prevent contamination. Specifically, on 06/05/2017, the pharmacist producing hydroxycobalamin donned sterile gloves and then touched more than 20 items in the ISO 7 cleanroom before spraying his gloves with (b) (4) and then placing them in the ISO 5 area to produce sterile product without changing his gloves.

Sporicidal agents are not used in your facility's cleanrooms and/or ISO 5 area.

Specifically, while conducting a walk through and observation of your firm's compounding on 7/10/17, we noted that your facility does not currently use a sporicidal agent while cleaning the ISO 5 area. We noted that during the cleaning process (b) (4) was used to clean the ISO 5 area, followed by (b) (4).

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

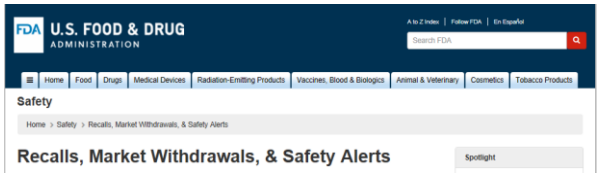
Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, your firm failed to establish a gowning procedure and aseptic processes that reduces the possibility of chemical and microbial contamination of compounded products manufactured in the ISO 5 laminar flow hood.
(a) On 6/20/17, we observed the compounding technician re-use a gowning jacket between multiple product compound preparations. As per the technician, your firm uses only one gown jacket during the daily routine compounding processes and disposes of it at the end of the day.
(b) On 6/20/17, we observed the compounding technician donning gloves inside the ISO 5 laminar flow hood, exposing the product contact surface areas to exposed skin.
(c) On 6/20/17, we observed the compounding technician introducing unfiltered air into a sterile bottle of Tacrolimus vet product through a syringe in order to create positive pressure.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically, you have not performed media fills that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.



Date	Brand Name	Product Description	Reason/ Problem	Company
06/29/2017	Ultra-Sten, D-Zine	Marketed as a dietary supplement	Presence of anabolic steroids	Hardcore Formulations
06/23/2017	Fagron Sterile Services	Succinylcholine Chloride 20mg/mL	Lack of Sterility Assurance	Fagron Sterile Services
06/22/2017	Advanced Pharma	Potassium Phosphate and Succinylcholine Chloride	Lack of Sterility Assurance	Advanced Pharma, Inc. d/b/a Avella of Houston
06/17/2017	Bristol-Myers Squibb	Eliquis (apixaban) 5 mg Tablets	Tablet Mix-Up	Bristol-Myers Squibb
06/16/2017	Alvogen	Clindamycin Injection USP	Lack of sterility assurance	Alvogen
06/15/2017	Hospira	8.4% Sodium Bicarbonate Injection, USP, NeutTM (Sodium Bicarbonate 4% additive solution), QUELICINTM (Succinylcholine Chloride Injection, USP) and Potassium Phosphates Injection, USP	Lack of Sterility Assurance	Hospira Inc, A Pfizer Company
06/15/2017	Advanced Pharma	Nitroglycerin products	Due to sub-potency	Advanced Pharma, Inc. d/b/a Avella of Houston
06/15/2017	Teva Pharmaceuticals USA, Inc	Paliperidone Extended-Release Tablets, 3mg	Potential for product to be below specification	Teva Pharmaceuticals USA, Inc
06/10/2017	Bristol-Myers Squibb	Eliquis (apixaban) 5 mg Tablets	Tablet Mix-Up	Bristol-Myers Squibb
06/09/2017	Tetracycline-ABC, Tetrastem, Diabecline and more	topical products	Concerns of Manufacturing Practices	Phillips Company

Accessed 6/29/17

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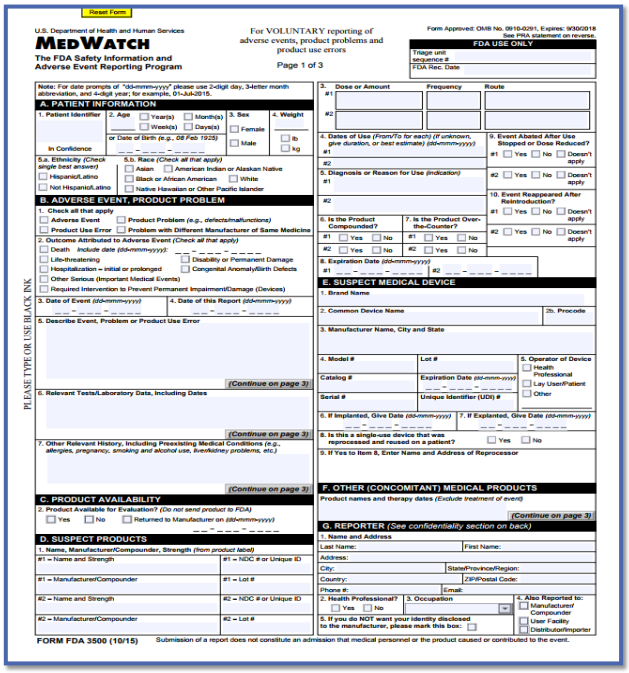
FDA RECALLS:

https://www.fda.gov/Safety/Recalls/default.htm



MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Medwatch Form

https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Choosing a compounding pharmacy:

Proposal Request:

- Standard terms of contract
  - Name, number of organization contact person
  - liability insurance
- Description of container systems, drug, strength, concentration etc.
- SOP
- Follow up documents for enforcement/ accreditation findings
- Handling and delivery procedure
- Statement that organization reserves right to cancel solicitation for services and reject any/ all proposals for any reason or for no reason
- Deadline date for proposal
- Date to initiate services

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Facility visit and tour:

- Condition of contract
- Environment
  - HEPA filtration
  - Uni-directional air flow: laminar airflow workbench, biological safety cabinet, compounding aseptic isolator, compounding aseptic containment isolator

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Facility visit and tour:

- Architecture
  - lighting
  - storage
  - buffer area
  - surfaces
  - ante room
- Automated compounding device
- Pressure differential, positive/ negative airflow
- BUD/ expiration

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Responsibility of compounding personnel:

- Educated, instructed and skilled
- Ingredients have correct identity, quality, and amount
- Properly stored open and partial containers
- Bacterial endotoxins minimized
- Proper and adequate sterilization used
- Equipment clean, accurate, appropriate
- Potential harm evaluated before dispensing
- Appropriate package for sterility and stability
- Maintain environment to preserve sterility of items
- Appropriate and complete labels
- BUD appropriate and validated
- Use of correct compounding procedures
- Method to rapidly identify and correct deficiencies
- Compounding is separate from quality evaluation

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Facility visit and tour:

- Cleaning/ disinfection
  - Germicidal detergent and water
    - 70% isopropyl alcohol
  - USP <797> appendix II

Table 3.
Minimum Frequency for Cleaning of Specific Sites (Reprinted with Permission from *USP* Chapter 797[15])

Site	Minimum Frequency
ISO Class 5 PEC	Beginning of each shift Before each batch Every 30 minutes when compounding After spills When surface contamination is known or suspected
Counters and easily cleanable work surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Facility visit and tour:

- Monitoring
  - Routine
  - Airborne particle test
  - Pressure differential/ displacement airflow
  - Temperature/ humidities
  - Surface disinfection sampling and assessment

Table 4.
Environmental Monitoring Requirements (Adapted from *USP* Chapter 797[15])

Parameter	Monitored By	Frequency
Temperature	Compounding personnel or facilities management staff (if electronic monitoring is centralized)	Documented daily (at a minimum)
Pressure differential or velocity across line of demarcation	Compounding personnel	Documented each shift (preferably), daily (at a minimum)
	Qualified certifier	At least every 6 months
Nonviable particles	Qualified certifier	At least every 6 months
Surface sampling	Compounding or laboratory personnel	Periodically, as defined by compounding and infection control personnel, at least every 6 months or after significant changes in procedures or cleaning practices
Electronic device sample of viable particles	Compounding personnel or qualified certifier	At least every 6 months

Table 5.
Controlled Temperatures (Data from *USP* General Notices and Requirements[58])

Storage Condition	Centigrade	Fahrenheit
Room temperature	20 to 25 °C	68 to 77 °F
Cold temperature (refrigerated)	2 to 8 °C	36 to 46 °F
Freezer (frozen)	−25 to −10 °C	−13 to 14 °F

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Facility visit and tour:

- Documentation
  - Results:
    - Non-viable particles: non living organisms that are shed i.e. dust, paper
    - Viable particles: living organisms i.e. bacteria, fungal spores
      - Require non-viable particles to travel
  - Sampling plan
    - Specific
    - New facility/ equipment
    - Every 6 months minimum
    - After facility/ equipment maintenance including remodel, renovation
    - Problems with product identification, preparation, employee technique or if CSP suspected of source of infection
    - Temperature monitoring

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

What does the IP need to look for:

- Request and view documents before tour
- Cleanliness
- PPE's
  - masks
  - gowns
  - gloves
  - shoe covers
  - hair covers

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

What does the IP need to look for:

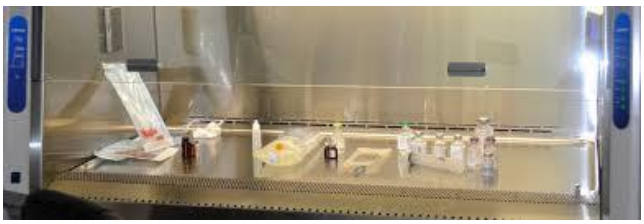
- Flow:
  - Traffic
  - Air

Airflow demonstration with smoke pencil

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

What does the IP need to look for:

- Flow:
  - Air



MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Table 110-3 Compounded Sterile Preparation Risk Levels

Category of CSP	Device Used	Surrounding Room	Limitations	BUD*
Immediate use	None	Ambient air	Simple mixing of no more than three sterile nonhazardous components	1 hour
Low-risk, 12-hour	ISO 5 hood†	Ambient air	Simple mixing of no more than three sterile components	12 hours
Low-risk	ISO 5 hood	ISO 7 clean room‡	Simple mixing of no more than three sterile components	48 hours at room temperature, 14 days under refrigeration, 45 days frozen
Medium-risk	ISO 5 hood	ISO 7 clean room	Mixing of all sterile components	30 hours at room temperature, 9 days under refrigeration, 45 days frozen
High-risk	ISO 5 hood	ISO 7 clean room	Includes any nonsterile component or exceeds the BUDs of other categories	24 hours at room temperature, 3 days under refrigeration, 45 days frozen

*The beyond-use date (BUD) is the time that administration of the CSP must begin following mixing of the CSP.

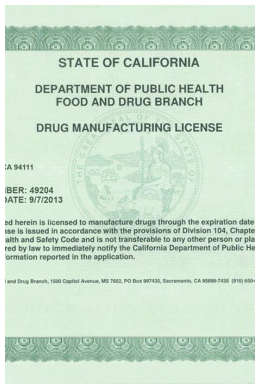
†ISO 5 hood is a properly certified laminar air flow workbench, BSC, compounding aseptic isolator, or compounding aseptic containment isolator.

‡Some isolators may be certified for use outside a clean room but must meet requirements detailed in USP <797>.

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

What does the IP need to look for:

- Document displays
  - Publicly posted
  - State license
  - Pharmacist license
  - Pharmacy tech certification


STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

DRUG MANUFACTURING LICENSE


PHARMACIST


Pharmacy Technician Certification Board

certifies that

Gerry [redacted]

Has met all requirements for certification and merits the designation of

Certified Pharmacy Technician (CPhT)

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

What does the IP need to look for:

- Medication supply and storage
- Packaging systems
- Transportation

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

Printed name and position/title of person assessed: _____
Name of facility or location: _____

Hand Hygiene and Garbing Practices: The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

_____ Presents in a clean appropriate attire and manner.
_____ Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante-areas.
_____ Brings no food or drinks into or stored in the ante-areas or buffer areas.
_____ Is aware of the line of demarcation separating clean and dirty sides and observes required activities.
_____ Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.
_____ Dons beard cover if necessary.
_____ Dons head cover assuring that all hair is covered.
_____ Dons face mask to cover bridge of nose down to include chin.
_____ Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.
_____ Dries hands and forearms using lint-free towel or hand dryer.
_____ Selects the appropriate sized gown examining for any holes, tears, or other defects.
_____ Dons gown and ensures full closure.
_____ Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly before donning sterile gloves.
_____ Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.
_____ Examines gloves ensuring that there are no defects, holes, or tears.
_____ While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.
_____ Removes PPE on the clean side of the ante-area.
_____ Removes gloves and performs hand hygiene.
_____ Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.
_____ Removes and discards mask, head cover, and beard cover (if used).
_____ Removes shoe covers or shoes one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. (Removes and discards shoe covers every time the compounding area is exited).

***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**

Signature of Person Assessed Printed Name Date

Signature of Qualified Evaluator Printed Name Date

- ❑ Hand hygiene/ Garbing evaluation
- ❑ Hand hygiene stations
- ❑ Hand hygiene

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

What does the IP need to look for:

- Products used for cleaning:
- Appropriate use
  - contact time
  - container lid closed
- Appropriate for area

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Appendix II. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties[1]

		Chemical Category of Disinfectant					
		Isopropyl alcohol	Accelerated hydrogen peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone-iodine)
Concentration Used		**60–95%**	**0.5%[3]**	**0.4–1.6% aq**	**0.4–1.6% aq**	**100–5000 ppm**	**30–50 ppm**
Microbial Inactivation[2]	Bacteria	+	+	+	+	+	+
	Lipophilic viruses	+	+	+	+	+	+
	Hydrophilic viruses	±	+	±	±	+	±
	M.tuberculosis	+	+	±	+	+	±
	Mycotic agents (fungi)	+	+	+	+	+	±
	Bacterial Spores	–	–	–	–	+	–
Important Chemical & Physical Properties	Shelf life >1 week	+	+	+	+	+	+
	Corrosive or deleterious effects	±	–	–	–	±	±
	Non-evaporable residue	–	–	+	+	–	+
	Inactivated by organic matter	+	±	+	±	+	+
	Skin irritant	±	–	+	+	+	±
	Eye irritant	+	–	+	+	+	+
	Respiratory irritant	–	–	–	–	+	–
	Systemic toxicity	+	–	+	+	+	+

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; – = no; ± = variable results.

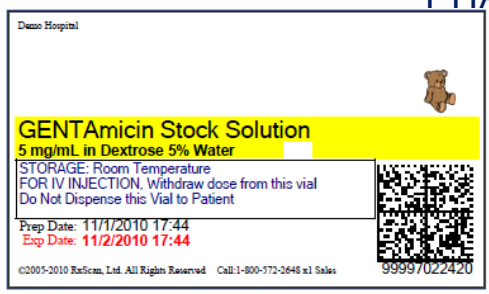
[1] Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA, "Antisepsis, disinfection and sterilization in the hospital and related institutions," *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, DC, 1995, pages 227-245.

[2] Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of ≤1 minute; inactivation of spores requires longer contact times (e.g., 5-10 minutes for 5,000 ppm chlorine solution against *C. difficile spores*). *Reference: Perez J, Springthorpe VS, Sattar SA, "Activity of selected oxidizing microbicides against the spores of Clostridium difficile: Relevance to environmental control," American Journal of Infection Control, August 2005, pages 320-325.*

[3] *Accelerated* hydrogen peroxide is a new generation of hydrogen peroxide-based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.

Cleaning Chemistr

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY



Label evaluation:

- Name of active ingredients
- concentration, strength, dosing
- Prep date, BUD
- Storage conditions
- ID of responsible compounding staff
- Control/ lot #
- Auxiliary labeling – precautions
- Device specific instructions

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Competencies:

- Aseptic technique
- Cleaning and disinfecting procedures
- Compounding of hazardous drugs, allergen extracts
- Use of sterile devices
- Use of compounding devices
- Ability to fill pump reservoirs
- End product testing and sterilization

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Quality Assurance

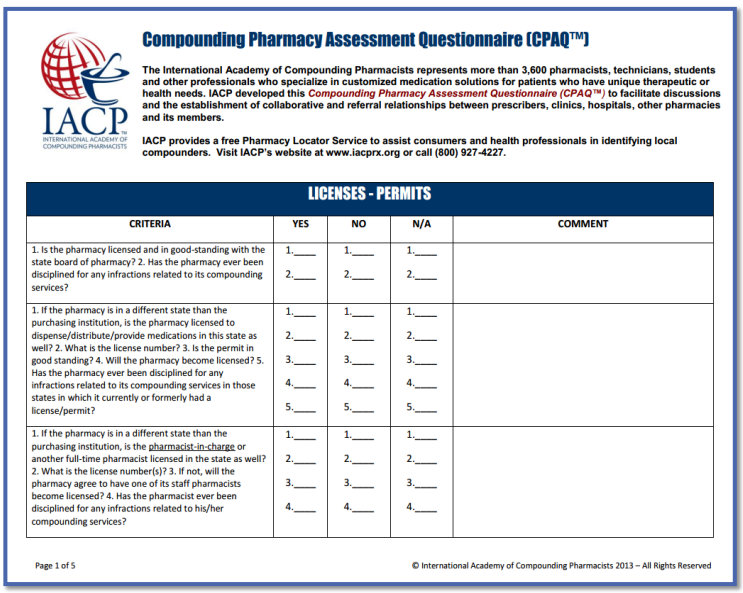
- Mechanism for monitoring, evaluating, correcting and improving activities and processes
- Review and analyze objective data
- Use data to develop action plans
- Actively correct problems detected, improve activities and processes
- Re-evaluation of corrective action to ensure effectiveness and sustainability
- Documentation

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

International Academy of Compounding Pharmacists (IACP)

2013 developed Compounding Pharmacy Assessment Questionnaire.

1. Licenses- Permits
2. Compounding services provided
3. Internal controls and quality assurance
4. Testing and verification



Compounding Pharmacy Assessment Questionnaire (CPAQ™)

The International Academy of Compounding Pharmacists represents more than 3,600 pharmacists, technicians, students and other professionals who specialize in customized medication solutions for patients who have unique therapeutic or health needs. IACP developed this *Compounding Pharmacy Assessment Questionnaire (CPAQ™)* to facilitate discussions and the establishment of collaborative and referral relationships between prescribers, clinics, hospitals, other pharmacies and its members.

IACP provides a free Pharmacy Locator Service to assist consumers and health professionals in identifying local compounders. Visit IACP's website at www.iacprx.org or call (800) 927-4227.

LICENSES - PERMITS				
CRITERIA	YES	NO	N/A	COMMENT
1. Is the pharmacy licensed and in good-standing with the state board of pharmacy? 2. Has the pharmacy ever been disciplined for any infractions related to its compounding services?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. If the pharmacy is in a different state than the purchasing institution, is the pharmacy licensed to dispense/distribute/provide medications in this state as well? 2. What is the license number? 3. Is the permit in good standing? 4. Will the pharmacy become licensed? 5. Has the pharmacy ever been disciplined for any infractions related to its compounding services in those states in which it currently or formerly had a license/permit?	1.____ 2.____ 3.____ 4.____ 5.____	1.____ 2.____ 3.____ 4.____ 5.____	1.____ 2.____ 3.____ 4.____ 5.____	
1. If the pharmacy is in a different state than the purchasing institution, is the pharmacist-in-charge or another full-time pharmacist licensed in the state as well? 2. What is the license number(s)? 3. If not, will the pharmacy agree to have one of its staff pharmacists become licensed? 4. Has the pharmacist ever been disciplined for any infractions related to his/her compounding services?	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	

Page 1 of 5

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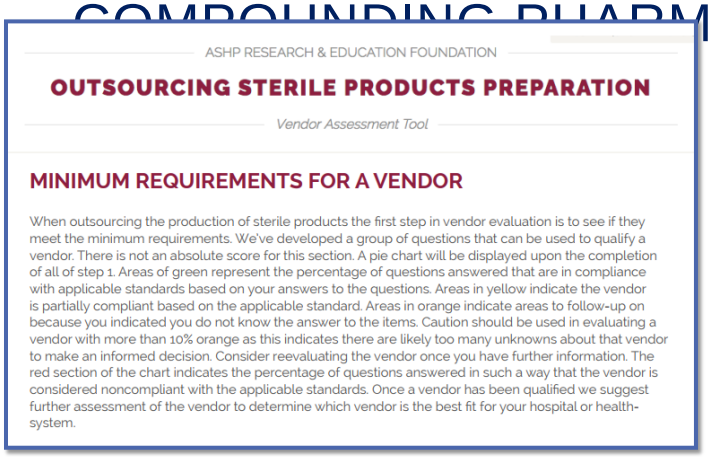

ASHP RESEARCH & EDUCATION FOUNDATION

OUTSOURCING STERILE PRODUCTS PREPARATION

Vendor Assessment Tool

MINIMUM REQUIREMENTS FOR A VENDOR

When outsourcing the production of sterile products the first step in vendor evaluation is to see if they meet the minimum requirements. We've developed a group of questions that can be used to qualify a vendor. There is not an absolute score for this section. A pie chart will be displayed upon the completion of all of step 1. Areas of green represent the percentage of questions answered that are in compliance with applicable standards based on your answers to the questions. Areas in yellow indicate the vendor is partially compliant based on the applicable standard. Areas in orange indicate areas to follow-up on because you indicated you do not know the answer to the items. Caution should be used in evaluating a vendor with more than 10% orange as this indicates there are likely too many unknowns about that vendor to make an informed decision. Consider reevaluating the vendor once you have further information. The red section of the chart indicates the percentage of questions answered in such a way that the vendor is considered noncompliant with the applicable standards. Once a vendor has been qualified we suggest further assessment of the vendor to determine which vendor is the best fit for your hospital or health-system.

Threshold questions:

1. 503A vs. 503B
2. Regulatory compliance
3. Quality and patient safety measures
4. Facility design and maintaining suitable facilities
5. Environmental and personnel monitoring
6. Equipment, containers, closures, and components
7. Production and process controls
8. Release testing, lab controls and stability/ expiration dating
9. Packaging and labeling
10. Medication safety features
11. Service excellence

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

- Accreditation manual
- 503A
  - Regulatory compliance
  - Personnel
  - Facilities and equipment
  - Chemicals, compounds, and completed compounded preparations
  - Compounding records
  - Beyond- Use- Dating, potency, and sterility
  - Completed compounded preparations
  - Prescriber communication and patient education
  - Total quality management

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

ASC Responsibilities:

- Shipping and receiving
- Verification
- Storage
- Documentation
- Practice aseptic technique
- Safe injection practices
  - Appropriate use of SDV and MDV
- Report quality issues

MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

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MEASURES USED TO EVALUATE A COMPOUNDING PHARMACY

Questions?

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