USP 797 Compliance Tool

Name: _____ Date: _____ Score: _____

Minimum acceptable score: 90% compliance with procedures and techniques

	Observed Technique	Points	
		Possible	Achieved
Preparation for Compounding			
1	All personal hygiene and gowning requirements are observed. Jewelry removed. No food or beverages in compounding area.	5	
2	All equipment preparation, cleaning and sanitizing, calibration and documentation are completed.	5	
3	Any required calculations are completed accurately.	5	
4	Materials are properly staged, including:		
	a. Appropriate tools are selected (correct syringe and needle size, correct type of dispensing pins, etc.)	3	
	b. Label information is verified (identify, concentration, expiration dates)	3	
	c. Components are checked for acceptability (no precipitates, discoloration, container damage, etc.)	3	
	d. Components are pre-cleaned and sanitized as necessary.	3	
5	Materials are arranged correctly in the LAFW.	5	
6	Proper planning of the compounding operation is exhibited to assure smooth operation and minimum disruption.	4	
7	Data entry into automated compounder is correct, or correct technique and volumes are transferred by alternate bulk-transfer method.	3	
Manipulative Technique			
8	All critical sites are disinfected correctly, including no re-use of swabs, and alcohol is allowed to dry prior to compounding.	5	
9	Gloves are disinfected frequently (at least every three or four manipulations, immediately before opening the ampule, and whenever they are removed from, or returned to the LAFW) and alcohol is allowed to dry.	5	

10	The work surface is cleaned and disinfected prior to compounding, between procedures, and whenever debris accumulates, or spills occur.	5	
11	No critical sites are touch-contaminated (no touching of needles or septa, dispensing pin cap sterile surfaces, etc.).	5	
12	First air is maintained to all critical sites at all times, and work is not conducted immediately over disinfected critical sites.	5	
13	Reconstituted powder completely dissolved, without excessive shaking; no foaming.	3	
14	Ante-coring techniques are incorporated, and previously made holes in septa are not re-entered.	4	
15	Final measurements are made before withdrawal of the needle from the septum, and no material is discharged into the work zone.	5	
16	All syringes and materials are prepared before opening the ampule.	1	
17	Ampule contents are drawn up immediately after the ampule is opened.	1	
18	The neck of the ampule is cleaned and disinfected prior to opening, and alcohol is allowed to dry.	2	
19	Ampule contents are filtered.	2	
20	No talking or laughing is directed at the LAFW.	3	
21	Excessive or erratic hand or body movements are avoided, and the body (head, shoulders, etc.) does not intrude into the LAFW.	3	
22	Clean compounding components, waste, and product are kept separate and the work zone is free from clutter, debris, and spilled drug.	3	
Post-Compounding			
23	All products and stored multi-dose vials are properly labeled in the same manner as drug products (initials of personnel, date of compounding or opening, volume and identity of diluent, dispensing pins are properly capped, etc.).	3	
24	The LAFW is cleaned and disinfected upon completion of operations and removal of the end product.	3	
25	Waste materials are disposed of properly in accordance with policy.	3	

Assessment Performed By:_____ Date:_____

Observations: Please give criterion number and describe errors for all point deductions.

Participant Comments:

Participant Signature: _____ Date: _____

Sample Test						Results	
Test Date	**Sample #**	**Prepared By**	**Hood #**	**Media Lot #**	**Incubation Temperature**	**Colony Forming Units (CFUs)**	**Comments**

Sample Test						Results	
Test Date	**Sample #**	**Prepared By**	**Hood #**	**Media Lot #**	**Incubation Temperature**	**Colony Forming Units (CFUs)**	**Comments**

Hot Off the Press: Final Standards for Allergen Extract Compounding under USP Chapter 797

Under the new standards, to continue in-office compounding of individual treatment sets for allergen immunotherapy, otolaryngic allergy practices will, beginning Dec. 1, need to comply with the following:

1. Personnel Qualifications

- Designate one person to oversee and evaluate compounding personnel.
- Provide training and testing on principles and procedures for new staff and annual evaluation for others for sterile compounding, garbing, hygiene, gloved fingertip and thumb sampling and media fill tests.
- Ensure that compounding personnel wear powder-free sterile gloves; non-cotton, low-lint sleeved garments that gather at the wrist and close at the neck; face mask and disposable cover for head and facial hair.

2. Facilities

- Compounding must occur in either (1) an ISO Class 5 Primary Engineering Control (PEC) OR (2) in a dedicated Allergenic Extracts Compounding Area (AECA), either of which must not be within one meter from a sink and can't be near unsealed windows, doors to the outside, or high traffic or other areas that present environmental control challenges such as bathrooms or kitchens.
- If used, a PEC must be certified every 6 months, and cleaned and disinfected before and after each compounding, and surface must be disinfected between each prescription set.
- An AECA must have a visible perimeter and meet the following conditions:
  - o Access restricted to authorized personnel.
  - o No other activity permitted during compounding.
  - o All surfaces must be cleanable and kept clean.
  - o No carpet is allowed.
  - o No surfaces that can be damaged by cleaning and sanitizing agents.
  - o Surfaces must be smooth, impervious, non-shedding, and free of cracks or crevices.
  - o Overhangs should be avoided or must be easily cleaned.
  - o Well lit, and temperature and humidity controlled for comfort of compounding personnel.
  - o Work surface must be cleaned and disinfected before and after each compounding session, and disinfected between each new set, as well as at the time of any spill or contamination.
- Vial stoppers on packages of conventionally manufactured sterile ingredients must be disinfected with 70% IPA wipes before each use.
- Walls, doors, and door frames within and AECA must be disinfected monthly and when contamination is suspected.
- Ceilings in the AECA must be cleaned and disinfected when visibly soiled.

3. Documentation

- Labels on prescription sets must include patient name, type and fractional dilution with corresponding vial number, beyond use date, and required storage conditions.
- Standard Operating Procedures manuals describing required compounding process.
- Training, assessment results, evaluations, and qualification records for all compounding personnel, including any corrective actions following assessments and evaluations.
- Certification reports for PEC, if used.
- Temperature logs for refrigeration.
- Compounding records for individual extract prescription sets.
- Information on any complaints and adverse events.
- Investigations and corrective actions following any complaints and adverse events.

To download a copy of USP 797 go to: **https://www.usp.org/compounding**

Final Standards for Allergen Extract Compounding under USP Chapter 797

Glossary *

- **Allergenic extract prescription set:** Combinations of licensed allergenic extracts which would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
- **Allergenic extracts:** Biological substances used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
- **Allergenic extracts compounding area (AECA):** A designated, unclassified space, area, or room with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
- **Aseptic processing:** A method by which separate, sterile components (e.g., drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g., by membrane filtration, autoclave).
- **Aseptic technique:** A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
- **Compounding:** The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication.
- **Garb:** Items such as gloves, garments (e.g., gowns, coveralls), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
- **Gloved fingertip and thumb sampling:** Process to evaluate a compounder's competency in correctly performing hand hygiene and garbing.
- **Media-fill test:** A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.

* Glossary descriptions extracted from the 2019 release of the USP General Chapter <797> Pharmaceutical Compounding -Sterile Preparations. Download a copy of USP 797: https://www.usp.org/compounding

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USP 797 Compliance Training and Media Fill Test Workshop at the 2019 AAOA Advanced Course

Join us at the 2019 AAOA Advanced Course in Allergy and Immunology in Austin, TX, December 12-14, 2019 for an optional paid workshop on USP 797 Compliance Training and Media Fill Test!

The USP guidelines are due to go in effect by December 1, 2019. Take advantage of this opportunity to have your staff review compliance training (note: laptop/tablet required) and check that box for the year. The AAOA is rolling out its new online compliance training module to help you and your staff ahead of the curve and make sure everyone is practicing within the new USP 797 protocol. In addition to USP compliance, we are offering a media fill kit to complete the compounding training.

When: December 12, 2019
Where: 2019 AAOA Advanced Course
JW Marriott
Austin, TX

Cost: $125 per AAOA member
$300 per non member

AMERICAN ACADEMY OF OTOLARYNGIC ALLERGY, INC.
Specialty Physicians Dedicated to the Quality Care of Patients with Allergic Disease
11130 SUNRISE VALLEY DRIVE, SUITE 100 RESTON, VA 20191 202.955.5010 / PHONE 202.955.5016 / FAX WWW.AAOALLERGY.ORG

Media-Fill Test Vendors

The allergen immunotherapy extract preparation guidelines recommend that all individuals who prepare extract vials successfully complete an annual technical drill called a media-fill test. This is an actual, physical demonstration that the staff person can transfer material, in a sterile fashion, from one vial to another.

Following is a list of vendors who supply Media-Fill tests. The American Academy of Allergy does not recommend or endorse any specific company, this information is provided for information only.

Acute Care Pharmaceuticals
(888) 909-7700
http://www.pharma-choice.com

Hardy Diagnostics
(805) 346-2766 or (800) 266-2222
http://hardydiagnostics.com

Q.I.medical, Inc.
(530) 272-8700
http://www.qimedical.com

VALITEQ (Allerteq 1; Allerteq 4; Attack II Kit)
(800) 433-7698
http://www.valiteq.com