

AIT: How to Stay Current with USP 797 and Practice Guidelines

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Learning Objectives

- Understand the most recent updates to USP 797, effective from November 1, 2023, particularly the new standards for compounding allergenic extracts.
- Identify compliance requirements for compounding personnel including training and testing requirements to comply with the updated USP 797 guidelines.
- Recognize facility and documentation standards including the design and maintenance of the Allergenic Extract Compounding Area (AECA) and the Primary Engineering Control (PEC) areas.

United States Pharmacopeia (USP)

Chapter 797 Overview



USP 797 published Nov 1, 2022 is the standards for preparing of compounded medication to ensure patient benefit and reduce risks such as contamination.

- Effective November 1, 2023

- Section 21: Compounding Allergenic Extracts

- Standards for compounding allergenic extracts and manipulating extracts when sterile transfer occurs

Why?

- Effective for treatment of allergic conditions in adults and children:

Allergic rhinitis

Allergic asthma

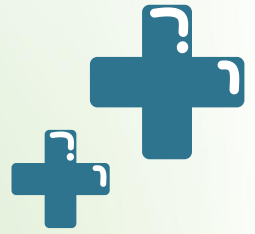
Allergic conjunctivitis

Atopic dermatitis

Insect allergy (Hymenoptera)

- Contamination is prevented by adequate training and the use of using aseptic technique
- Use of quality assurance checks throughout the mixing process is highly recommended

Compliance Topics



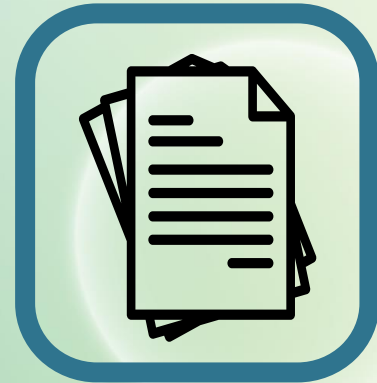
Personnel
Qualifications



Personal
Hygiene
and
Garbing



Facilities



Documentation



Who cares?

Allergists/Practices

- Dedication to high quality patient care & patient safety
- Eliminate errors
- Standardization
- Evidence based practice
- Meeting patient expectations

Outside Pressures

- FDA
- United States Pharmacopeia
- CMS
- Compounding related infections
- Expansion of nonstandard practices (direct to consumer, non-allergists)

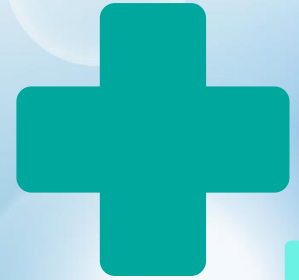
2012 Meningitis Outbreak



- Outbreak of rare CNS & other fungal infections (meningitis, paraspinal infections, joints)
- 64 deaths in 20 states- deadliest fungal meningitis outbreak in U.S. history
- >700 infected
- *Aspergillus fumigatus* first then predominantly *Exserohilum rostratum*
- CDC traced infections to 3 lots of preservative-free methylprednisolone acetate from NECC, Framingham, MA

Medication and Compounding Regulatory History

- 1906 Pure Food & Drug Act
- 1938 Food, Drug & Cosmetic Act (FDA, USP)
- 1962 Kefauver-Harris Amendment (safe/effective, IND)
- 1972 Drug Listing Act (NDC)
- 1992 First Sterile Comp. Standard-Dispensing Practices for Sterile Drug Prod. Intended for Home Use
- 1995 Sterile Drug Products for Home Use
- 1996 HIPAA
- 2003 FDA Modernization Act (labeling)
- 2004 USP 797
- 2008 USP 797 revision (allergen exemption)
- 2015 DRAFT FDA mixing guidance & USP 797 2nd revision proposal
- 2019 USP 797 2nd revision “Final” announced
- 2020 USP 797 2nd revision to 2008 allergen exemption
- 2022 USP 797 2nd revision finalized and released
- 2023 Nov 1 effective date for latest USP <797> revision



Behind the Scenes

- June 2016: AMA passes a resolution at the annual meeting:
- The AMA engages in efforts to convince USP to retain the current special rules for procedures in the medical office that could include but not be limited to allergen extract compounding in the medical office setting.
- October 2016: USP invites ACAAI & AAAAI leadership to engage in discussions in early 2017
- November 2016 – January 2017: Steering Committee (Drs. Mike Nelson, Tom Casale, Steve Kagan, and Jim Sublett) calls with USP
- February 02, 2017: Roundtable held at USP headquarters
- 2017-2019 Allergy representation at USP 797 Expert Panel meetings



Goal of USP 797 is to Prevent Patient Harm

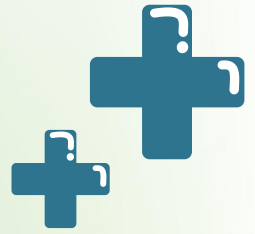
Provides minimum practice and quality standards for compounded sterile preparations based on current scientific information and best sterile compounding practices

- Standards for storage, packaging & preparation of compounded sterile products (CSPs)
- Adopted by many state pharmacy boards & The Joint Commission
- Includes considerations for both sterility and stability

Describe conditions and practices to prevent harm, including death, to patients that could result from:

- Microbial contamination (nonsterility)
- Excessive bacterial endotoxins
- Variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles or 10% for nonofficial articles
- Unintended chemical and physical contaminants
- Ingredients of inappropriate quality in compounded sterile preparations

Compliance Topics



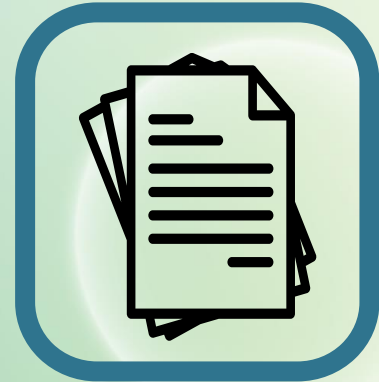
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Documentation



Extract mixing personnel must have:

- Completed training
- Completed a competency test
- Successful gloved fingertip test on three occasions then annually
- Successful media fill test once then annually

The screenshot shows the ACAAI website interface. At the top, there are logos for the American College of Allergy, Asthma & Immunology and allergist. Navigation links include Public website, Member website, Career center, Foundation, and College Learning Connection. A search bar is present with a SEARCH button. Below the navigation, there are dropdown menus for Course Catalog, Resources, Annual Meeting, MOC, FITs/Board Review, Webinars & More, and My Learning. The main content area displays the title "Allergen Extract Mixing Quiz: ACAAI Members 2023" and two tabs: OVERVIEW and REGISTER. A note states that the quiz is free for College members only. A course summary sidebar on the right shows the course opens on 01/01/2023 and expires on 12/31/2023, with a TAKE COURSE button and a 5-star rating.

Public website Member website Career center Foundation College Learning Connection

Course Catalog Resources Annual Meeting MOC FITs/Board Review Webinars & More My Learning

Main page Allergen Extract Mixing Quiz: ACAAI...

Allergen Extract Mixing Quiz: ACAAI Members 2023

OVERVIEW REGISTER

Note: This quiz is free for College members only. For the non-member version of the quiz, please go to <https://education.acaai.org/allergenextractquiznm>.

The Allergenic Extract Quiz is designed to train and test individuals preparing allergen extract treatment sets based on the 2019 USP Chapter <797> standards for allergen extract preparation.

Note to ACAAI members and non-members:
If you would like your non-member staff to take the quiz, please send them the following link: <https://education.acaai.org/allergenextractquiznm>

They will need to create a login (free). ACAAI members will receive a coupon code (emailed to you when you enroll in this quiz) for their staff to use in order to receive the 75% discount.

The American College of Allergy, Asthma and Immunology is here to help make sure your practice is compliant with current requirements.

Course summary

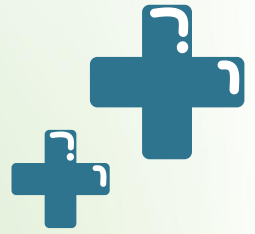
Course opens:	01/01/2023
Course expires:	12/31/2023

TAKE COURSE

Rating: ★★★★★

Bookmark course

Compliance Topics



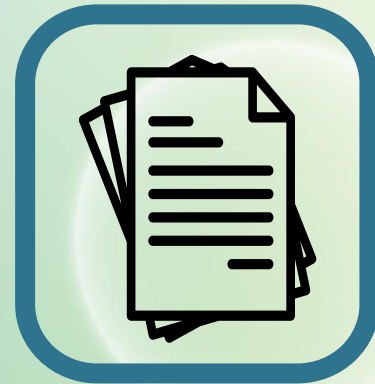
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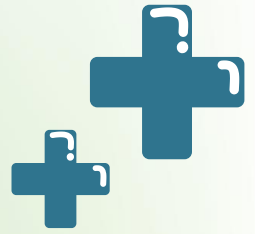


Garbing

- Face mask
- Sterile powder-free gloves
- Low-lint garment
- Head cover
- Facial hair cover if applicable



Compliance Topics



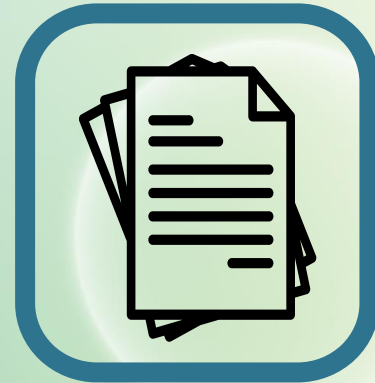
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AECA vs. PEC



AECA=allergenic extract compounding area

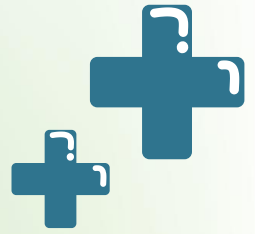
- Location considerations
- Visible and defined perimeter
- Surface cleaning daily and between sets
- Wall and doors cleaned monthly



PEC= ISO Class 5 Primary Engineering Control

- Location considerations
- Certification every 6 months
- All interior surfaces cleaned daily
- Horizontal surfaces cleaned between sets

Compliance Topics



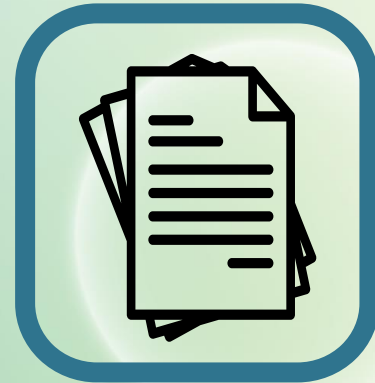
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Vial documentation

Beyond Use Date (BUD)

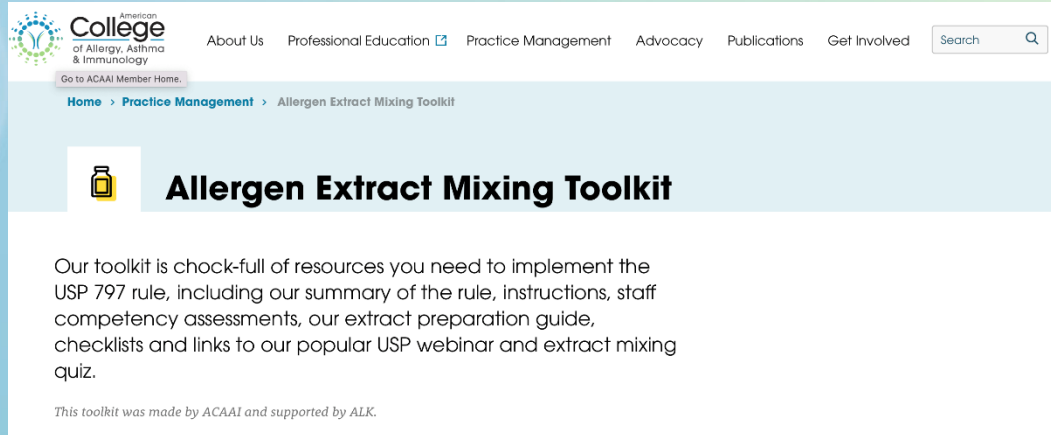
- No later than the earliest expiration date of any extract or diluent that is part of the set
- Cannot exceed 1 year

Labeling

- Name of patient
- Type and dilution
- BUD
- Storage conditions



Compounding documentation



The screenshot shows the website for the American College of Allergy, Asthma & Immunology. The header includes the college's logo and name, along with navigation links for About Us, Professional Education, Practice Management, Advocacy, Publications, and Get Involved. A search bar is located in the top right corner. Below the header, a breadcrumb trail reads: Home > Practice Management > Allergen Extract Mixing Toolkit. The main content area features a yellow icon of a vial and the title "Allergen Extract Mixing Toolkit". The text below the title states: "Our toolkit is chock-full of resources you need to implement the USP 797 rule, including our summary of the rule, instructions, staff competency assessments, our extract preparation guide, checklists and links to our popular USP webinar and extract mixing quiz." At the bottom of the content area, a small note reads: "This toolkit was made by ACAAI and supported by ALK."

- SOP's
- PEC certification if applicable
- Refrigerator temperature logs
- Training records

Individual Compounding Record documentation

- Each component's name, weight or volume, and strength
- Compounded sterile preparation's name, strength, dose
- Date and time
- Prescription, order, or lot number
- Total quantity compounded
- Final yield
- BUD and storage
- Results of quality control procedures
- Each component's vendor, lot, and exp date
- Individual involved and verifier



ACAAI / AAAAI Joint Message: November 2022

“We are pleased to report that thanks to the vigorous collective advocacy of the Allergy/Immunology community, the final standards for compounding of allergen extract mirror the proposed standards released in 2019. The ACAAI and AAAAI believe these standards to be reasonable and achievable.”

Immunotherapy Practice Parameter: 3rd Update (JACI 2011)

- Preparer qualifications
 - Task training, written test. media fill test
 - Antiseptic hand & surface disinfecting
 - Identify, measure, and mix ingredients
 - HCW training- RN, LPN, MA, tech, phys, APN
- Physician responsibility
 - Training & expertise in AIT
 - Ensures personnel trained, meet requirements, & use aseptic technique
 - Maintain documentation in file
 - General oversight & supervision
- Extract bacteriostasis
 - phenol ³0.25% or glycerin ³20%
- Prepare IAW manufacturer instructions
- Potency & beyond-use dates
 - Manufacturer & based on best data
- Mixing extracts
 - Based partially cross-reactivity
 - Separate high protease extracts
- Storage
 - 4-8°C in designated med. refrigerator
- Route
 - SQ or ID IAW pkg insert or alt. route if accepted standards of clinical practice
- Aseptic technique
 - Designate specific site w/ low traffic
 - 70% isopropanol (no dye, glycerin, etc.)
 - Hands to wrist (soap/water or 70% isopropanol or both)
 - Sanitize ampule necks & stoppers
 - Avoid contact contaminations
 - Inspect physical integrity at completion
- Labeling
 - Name, beyond use date
- Mixing log
 - Name, extract, date, BUD, lot numbers

Standardization of Prescription

Each prescription / immunotherapy record should contain:

- Two patient identifiers (i.e., Name and Date of Birth or Medical Record Number)
- Patient contact information
- Name of prescriber
- Date of prescription
- Name, concentration, and volume for each allergen
- Name and volume of diluents
- Schedule for administration (including adjustments for interruptions and reactions)



Standardization of Allergen Inclusion

- Use relevant allergens for each patient

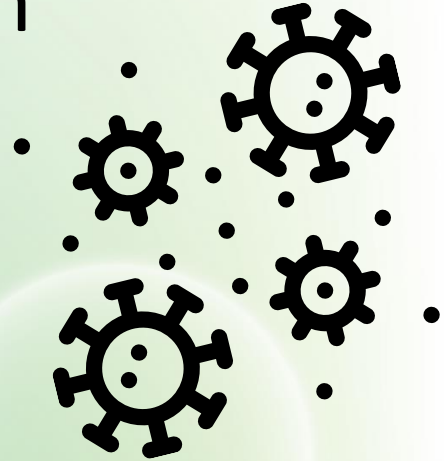
- Dose allergen extracts within minimum effective dose ranges

- Avoid combining extracts that may adversely affect overall potency

- Separate high protease extracts (mold, cockroach) from pollens

- Avoid mixing venom extracts with aeroallergen extracts

- Select and adjust doses of allergens using knowledge of cross-reactivity



What can you do?

- Follow USP <797> and Practice Parameter Standards

- Mix using established principles & training

- Ensure safe and aseptic vial preparation

- Eliminate errors & prioritize patient safety with quality checks

- Contribute to allergen extract safety studies
 - Respond to national immunotherapy safety survey for every practice
 - Report safety data from your own practices

- Help your Advocacy Council help you!



One Stop Supply Shop for College Members Only



Everything you need shipped in a temperature-controlled cooler that includes:

- The media fill kit(s)
- Gloved fingertip-thumb sampling plates
- Detailed instructions
- Incubation and reporting services

Receive a detailed report with the results to demonstrate your adherence with USP.

15% discount

<https://college.acaaai.org/resource/usp-compliant-testing-supplies/>

Eastern Allergy Conference– Takeaways

1. The standard is USP 797 Section 21.

- United States Pharmacopeia (USP) Chapter 797 rule is in effect as of November 1, 2023

2. USP 797 Section 21 is your blueprint for allergen extract mixing.

- Allergen extract mixing is part of USP 797 Section 21 which focuses on personnel training, facility standards, and documentation requirements.

3. Use resources to navigate USP 797 compliance.

- For example, the ACAAI has resources to assist you to get compliant including the toolkit and one day mixing courses (date: TBD).

Question Or Comment ?



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