

Prepping for Practice: AIT, USP and Tools for a Successful Start

Mohamed Yassin, MD, FAAAAI, FAAAAI
Allergy, Asthma, and Pulmonary Associates
1511 Northway Drive, Saint Cloud, MN
mohamed.satti.yassin@gmail.com

1

Disclosure

Nothing to disclose

2

Allergy Immunotherapy (AIT)

- AIT was first introduced as a treatment for "hay fever" in 1911 by British physicians (Timothy Grass) which showed 100-fold improvement
- In the 1960s, the benefit of AIT was shown to be specific to the allergen used in treatment, and major allergens in specific pollens were identified in the first double-blind, randomized, controlled trials using sham injections

3

Indications of Allergy Immunotherapy (AIT)

- The first question; Does the patient have a disorder that responds to immunotherapy?
- SCIT using preparations of aeroallergens may be indicated in the management of the following disorders:
 - Allergic rhinitis and/or allergic conjunctivitis, including:
 - Seasonal allergic rhinitis and/or conjunctivitis
 - Perennial allergic rhinitis and/or conjunctivitis
 - Both seasonal and perennial allergic rhinitis and/or conjunctivitis
 - Allergic asthma: Seasonal allergic asthma and Perennial allergic asthma
 - Both allergic rhinitis and/or allergic conjunctivitis and allergic asthma

4

Indications of Allergy Immunotherapy (AIT)

- The second question; *Is the allergen(s) clinically important?* — A patient is a candidate for allergen immunotherapy only if it has been established that there is a clinically important allergic component to his/her disease. For patients with the disorders listed above, clinical relevance is established by the presence of both of the following:
- Symptoms upon natural exposure to the allergen – It is sometimes easy to determine if patients have symptoms upon exposure (eg, symptoms upon intermittent exposure to cats), although in other situations, it is inferred when the patient has known exposure to an allergen and a temporal pattern of symptoms that is consistent with occurrence of that allergen, such as rhinitis and conjunctivitis during tree pollen season.
- And: The presence of specific immunoglobulin E (IgE) to that allergen, demonstrated either through allergen skin testing or serum tests for allergen-specific IgE.

5

Indications of Allergy Immunotherapy (AIT)

- The third question; Have other measures been maximized? — The clinician should ensure that the patient has maximized environmental control measures and is on an optimal medication regimen
- Pharmacologic management. Medications are relatively easy for most patients to use, and when effective, they provide relief more rapidly than immunotherapy.

6

Indications of Allergy Immunotherapy (AIT)

- The fourth question; Is current management suboptimal?
- Consider a trial of allergen immunotherapy in patients with significant allergic disease, for whom management is suboptimal for any of the following reasons:
 - Persistent symptoms on a seasonal and/or perennial basis
 - An inadequate or partial response to environmental control and pharmacotherapy
 - Noncompliance with maintenance medication regimen or suboptimal use of medication devices (eg, nasal sprays or inhalers)
 - Side effects related to medication use
 - Cost burden associated with chronic medication use

7

Why Is It Important To Be Diligent In Selecting The Appropriate Patient for AIT?

- It is ethical
- It is highly rewarding for both the doctor and the patient
- You will have great compliance and low rate of AIT drop out
- You will slowly but surely build a successful practice; the strong advertisement is the positive word from a satisfied patient
- You will have a great reputation in town

8

United States standardized extracts: Effective and ineffective doses and major allergen content

Allergen	Effective doses*	Ineffective doses*	Labeling of United States standardized extracts	Average major allergen content [¶]
Short ragweed	4 to 24 mcg Amb a 1	0.6 and 2 mcg Amb a 1	1:10 w/v (100,000 AU/mL)	520 mcg/mL Amb a 1
<i>Dermatophagoides pteronyssinus</i>	3.25 to 12 mcg Der p 1	0.7 mcg Der p 1	10,000 AU/mL	67 mcg/mL Der p 1
<i>Dermatophagoides farinae</i>	10 mcg Der f 1	Not determined	10,000 AU/mL	65 mcg/mL Der f 1
Timothy grass	15 and 20 mcg Phl p 5	2 mcg Phl p 5	100,000 BAU/mL	660 mcg/mL Phl p 5
Bermuda grass	Not determined	Not determined	10,000 BAU/mL	225 mcg/mL Cyn d 1
Cat hair or pelt	11 to 17 mcg Fel d 1	3 mcg Fel d 1	10,000 BAU/mL	40 mcg/mL Fel d 1

w/v: weight/volume; AU: allergy unit; BAU: bioequivalent allergy unit.

* Effective and ineffective doses are based upon double-blind, placebo-controlled studies.^[1]

[¶] Mean values. Individual lots of extracts may vary considerably from these values.^[2]

References:

1. Nelson HS. Subcutaneous injection immunotherapy for optimal effectiveness. *Immunol Allergy Clin North Am* 2011; 31:211.
2. Plunkett G, ALK-Abello, Round Rock, Texas, personal communication. Values are based on analysis of dozens of extracts from all manufacturers in the US, 2011.

9

United States nonstandardized extracts: Effective and ineffective doses and major allergen content

Allergen	Effective doses*	Ineffective doses*	Labeling of United States nonstandardized extracts	Average major allergen content [¶]
Dog (acetone precipitated)	15 mcg Can f 1	3 mcg Can f 1	1:100 w/v	140 mcg/mL Can f 1
Dog (aqueous)	15 mcg Can f 1	3 mcg Can f 1	1:10 w/v	5 mcg/mL Can f 1
Birch	3.25 to 15 mcg Bet v 1	Not determined	1:10 w/v	390 mcg/mL Bet v 1
Olive	Not determined	Not determined	1:10 w/v	430 mcg/mL Ole e 1
Sagebrush	Not determined	Not determined	1:10 w/v	1300 mcg/mL Art v 1
<i>Alternaria alternata</i>	1.6 and 8 mcg Alt a 1	Not determined	1:20 w/v	<0.01 to 6.1 mcg/mL Alt a 1
<i>Aspergillus fumigatus</i>	Not determined	Not determined	1:20 w/v	<0.01 to 64 mcg/mL Asp f 1
German cockroach	Not determined	Not determined	1:20 w/v	8 to 66 mcg/mL Bla g 2

w/v: weight/volume.

* Effective and ineffective doses are based upon double-blind, placebo-controlled studies.^[1]

[¶] Mean values. Individual lots of extracts may vary considerably from these values.^[2]

References:

1. Nelson HS. Subcutaneous injection immunotherapy for optimal effectiveness. *Immunol Allergy Clin North Am* 2011; 31:211.
2. Plunkett G, ALK-Abello, Round Rock, Texas, personal communication. Values are based on analysis of dozens of extracts from all manufacturers in the US, 2011.

10

Recommended dosing with United States standardized extracts^[1]

Allergen	Extracts available	Dosing by average major allergen content ^[2]	Dosing recommended in practice parameters
Short ragweed	1:10 w/v (100,000 AU/mL)	2500 AU	1000 to 4000 AU
<i>Dermatophagoides pteronyssinus</i>	3000, 5000, 10,000, and 30,000 AU/mL	1000 AU	500 to 2000 AU
<i>Dermatophagoides farinae</i>	3000, 5000, 10,000, and 30,000 AU/mL	1500 AU	500 to 2000 AU
Cat hair or pelt	5000 and 10,000 BAU/mL	3750 BAU	1000 to 4000 BAU
Timothy grass	100,000 BAU/mL	3000 BAU	1000 to 4000 BAU
Bermuda grass	10,000 BAU/mL	1000 BAU	300 to 1500 BAU

w/v: weight/volume; AU: allergy unit; BAU: bioequivalent allergy unit.

Reference:

1. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol* 2011; 127:S1-S5.
2. Nelson HS. Subcutaneous injection immunotherapy for optimal effectiveness. *Immunol Allergy Clin North Am* 2011; 31:211.

11

Preparation of allergen immunotherapy extracts for subcutaneous immunotherapy (SCIT): Overview

Allergens	Effective doses	Available extracts (in United States)	Dosing recommended in practice parameters	Amount to add to 10 mL vial (maintenance solution) (maintenance dose = 0.5 mL)	Mixing limitations
<i>Dermatophagoides pteronyssinus</i>	3.25 to 12 mcg Der p 1*	10,000 AU/mL	500 to 2000 AU	2 mL (to deliver 1000 AU per dose)	Do not mix with fungal or cockroach
<i>Dermatophagoides farinae</i>	10 mcg Der f 1*	10,000 AU/mL	500 to 2000 AU	2 mL (to deliver 1000 AU per dose)	Do not mix with fungal or cockroach
Short ragweed	4 to 24 mcg Amb a 1*	1:10 w/v (100,000 AU/mL)	1000 to 4000 BAU	0.5 mL (to deliver 2500 BAU per dose)	Do not mix with fungal or cockroach
Timothy grass	15 and 20 mcg Phl p 5*	100,000 BAU/mL	1000 to 4000 AU	0.6 mL (to deliver 3000 BAU per dose)	Do not mix with fungal or cockroach
Bermuda grass	Not determined	10,000 BAU/mL	300 to 1500 BAU	2 mL (to deliver 1000 BAU per dose)	Do not mix with fungal or cockroach
Cat hair or pelt	11 to 17 mcg Fel d 1*	10,000 BAU/mL	1000 to 4000 BAU	6 mL (to deliver 3000 BAU per dose)	Do not mix with fungal or cockroach

12

Preparation of allergen immunotherapy extracts for subcutaneous immunotherapy (SCIT): Overview

Dog (acetone-precipitated)	15 mcg Can f 1*	1:100 w/v	0.04 to 0.19 mL, 1:100 w/v	2 mL	Do not mix with fungal or cockroach
Birch	3.25 to 15 mcg Bet v 1*	1:10 to 1:40 w/v, 10,000 to 40,000 PNU/mL	1:100 w/v or 4000 PNU	1 mL	Do not mix with fungal or cockroach
Olive	Not determined	1:10 to 1:40 w/v, 10,000 to 40,000 PNU/mL	1:100 w/v or 4000 PNU	1 mL	Do not mix with fungal or cockroach
Sagebrush	Not determined	1:10 to 1:40 w/v, 10,000 to 40,000 PNU/mL	1:100 w/v or 4000 PNU	1 mL	Do not mix with fungal or cockroach
<i>Alternaria alternata</i>	1.6 and 8 mcg Alt a 1*	1:10 to 1:40 w/v, 10,000 to 40,000 PNU/mL	Highest tolerated dose	Variable depending on potency of the stock extract	Do not mix with pollens, dust mite, danders, or cockroach
<i>Aspergillus fumigatus</i>	Not determined	1:10 to 1:40 w/v, 10,000 to 40,000 PNU/mL	Highest tolerated dose	Variable depending on potency of the stock extract	Do not mix with pollens, dust mite, danders, or cockroach
Cockroach	Not determined	1:10 to 1:40 w/v, 10,000 to 40,000 PNU/mL	Highest tolerated dose	Variable depending on potency of the stock extract	Do not mix with pollens, dust mite, danders, or molds

13

The new USP 797 Compounding Rules:
Implementation Date 11/1/2023

14

US Pharmacopeia (USP)

- Founded in 1820
- USP is an independent, scientific nonprofit organization focused on building trust in the supply of safe quality medicines
- USP standards apply to any physician compounding AIT in the office
- USP 797 section 21 (if you are compounding individual patient vial sets)
- Some allergists/immunologists prefer to administer immunotherapy doses drawn directly from a stock dilution of an individual allergen extract or mixture of allergens and inject the extract into the patient (shared- patient vials). In such cases, the physician needs to comply with the whole USP 797
- The new rules are the **minimum standards** to be followed for the preparation of compounded sterile preparations (CSPs)

15

Where Can You Compound Extracts?

- You have two options:
 - ISO Class 5 **PEC** (Primary **E**ngineering **C**ontrol)
 - Dedicated **A**llergenic **E**xtracts **C**ompounding **A**rea (**AECA**)

16

(BOTH), Room with ISO Class 5 PEC And Dedicated Allergenic Extracts Compounding Area (AECA)

- The impact of activities that will be conducted around or adjacent to the PEC or AECA must be considered carefully when designing such an area.
- Away from unsealed windows, doors that open to the outside
- Restricted traffic and no other activities in the area while compounding
- Neither a PEC nor an AECA may be located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality
- One meter away from the sink
- Temperature and humidity controlled
- No carpet

17

ISO Class 5 PEC (Primary Engineering Control) (PEC)

18

ISO Class 5 PEC (Primary Engineering Control) (PEC)

- ISO Class 5 PEC (Primary Engineering Control) (PEC)
 - ISO class 5 certified hood
 - External venting not required
 - Certification every 6 months

19

ISO Class 5 PEC (Primary Engineering Control) (PEC)

- ISO Class 5 PEC (Primary Engineering Control) (PEC) **Certification:**
- **Before** a compounding area is used to compound either Category 2 (Allergenic Extracts), it must be independently certified using the USP requirements when applicable, manufacturer specifications.
- Certification indicates that the compounding area is meeting its design and air quality specifications
- Certification of the classified areas including the PEC must be performed initially, and recertification must be performed **at least every 6 months**

20



21

Dedicated Allergenic Extracts
Compounding Area (AECA)

22

Dedicated Allergenic Extracts Compounding Area (AECA)

- A visible perimeter **must** define the AECA
- Access to the AECA during compounding must be **restricted to authorized personnel** (Compounders)
- During compounding activities, **no other activity is permitted** in the AECA
- **Compounding surface** must be cleanable, resist damage from disinfectants and cleaners, smooth, impervious, free from cracks and crevices, and non-shedding (lamine, composite, glass, stainless steel)
- **The surfaces of walls, floors, fixtures, shelving, counters, and cabinets in the AECA must be cleanable.**
- The AECA must be designed and controlled to provide a **well-lighted** working environment, with temperature and humidity controls

23

Cleaning and Disinfecting For Compounding Extracts

- **PEC:**
 - All **interior surfaces of the PEC** must be cleaned and disinfected each day of use before compounding begins and when surface contamination is known or suspected. (use EPA approved cleaning/disinfecting agent)
 - Apply sterile 70% IPA to the horizontal work surface **between each prescription set**
 - **Extract Prescription sets and Vial stoppers** on packages of conventionally manufactured sterile ingredients must be wiped with sterile 70% IPA, allow to dry before they are used.

24

Cleaning and Disinfecting For Compounding Extracts

- **AECA:**
- **All work surfaces in the AECA** where direct compounding is occurring must be cleaned and disinfected each day of use before compounding begins and when surface contamination is known or suspected
- Clean horizontal work surface with 70% IPA ***between each prescription set***
- **Walls, doors, and door frames within the perimeter** of the AECA must be cleaned and disinfected monthly and when surface contamination is known or suspected.

25

Cleaning and Disinfecting For Compounding Extracts

- **AECA:**
- **Ceilings** within the perimeter of the AECA must be cleaned and disinfected **when visibly soiled and when surface contamination is known or suspected.**
- Dust-collecting overhangs such as utility pipes, ledges, and windowsills **should be minimized. If overhangs or ledges are present, they must be easily cleanable**

26

Where Should You Compound Extracts? PEC or AECA?

PEC

- All **interior surfaces of the PEC** must be cleaned and disinfected before compounding begins
- Certification every 6 months

AECA

- A **visible perimeter must define the AECA**
- **Compounding surface**; smooth, impervious, free from cracks and crevices, and non-shedding
- The surfaces of **walls, floors, fixtures, shelving, counters, and cabinets** in the AECA must be cleanable
- **Walls, doors, and door frames within the perimeter** of the AECA must be cleaned and disinfected monthly

27

Where Should You Compound Extracts? PEC or AECA?

PEC

AECA

- **Ceilings** within the perimeter of the **AECA** must be cleanable
- Dust-collecting overhangs such as utility pipes, ledges, and windowsills **should be minimized and If overhangs or ledges are present, they must be easily cleanable**

28

Personnel Hygiene and Garbing for Compounding Allergenic Extract Prescription Sets

29

Personal Hygiene and Garbing

- At a minimum, individuals must:
- Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)
- Remove all cosmetics because they shed flakes and particles
- Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the CSP. Cover any jewelry that cannot be removed.

30

Personal Hygiene and Garbing

- Do not wear ear buds or headphones.
- Do not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area.
- Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail polish, artificial nails, and extenders must not be worn

31

Personal Hygiene and Garbing

- Perform hand hygiene:
 - Clean underneath fingernails under warm running water using a disposable nail cleaner.
 - Wash hands and forearms up to the elbows with soap and water for at least 30 s.
 - Dry hands and forearms up to the elbows completely with low-lint disposable towels or wipers.

32

Personal Hygiene and Garbing

- Minimum garbing includes:
 - Powder free sterile gloves
 - Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck
 - Face mask
 - Low-lint disposable cover for the head, hair, ears
 - If applicable, disposable cover for facial hair

33

Sequence of Personal Hygiene and Garbing

- **First:** donning of head and facial hair covers (e.g., beard covers in addition to facemasks), wipe glasses if applicable. Eye shields are optional
- **Next:** hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (**brushes is not recommended**). Hands and forearms to the elbows will be **completely dried using either lint-free disposable towels or an electronic hand dryer.**
- **Next:** non-shedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned. **If reusable gowns are worn, they should be laundered appropriately**

34

Sequence of Personal Hygiene and Garbing

- **Next:** prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a **waterless alcohol-based surgical hand scrub with persistent activity**. Hands are allowed to dry thoroughly before donning sterile gloves. Powder free Sterile gloves shall be **the last item donned before compounding begins**.
- Gloves become **contaminated** when they contact nonsterile surfaces during compounding activities. **Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly**

35

Personnel Qualifications

- Designated person (Expert) function; ensuring proper training and supervision of all compounding personnel
- Complete training before starting compounding
- Annual personnel training:
 - Written exam
 - Gloved fingertip and thumb sampling (X3) then yearly
 - Media fill test initially then yearly
- Important rule: If you do not compound for 6 months, must re-do all the annual training

36

Gloved Fingertip and Thumb Sampling

- One sampling device per hand (plates or slides) containing general microbial growth agar such as tryptic soy agar supplemented with neutralizing agent (lecithin, tween, polysorbate 80)
- Label:
 - Personnel name, date and time, right or left
- Don't disinfect gloves before testing



37

Gloved Fingertip and Thumb Sampling

- Use one sampling media device (e.g., plates, paddles, or slides) per hand, containing general microbial growth agar (e.g., trypticase soy agar [TSA]) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) as this agar supports both bacterial and fungal growth.
- Label each media device with a personnel identifier, right or left hand, and the date and time of sampling.
- Do not apply sterile 70% isopropyl alcohol (IPA) to gloves immediately before touching the media device because this could cause a false-negative result. Using a separate media device for each hand, collect samples from all gloved fingertips and thumbs from both hands by rolling fingertip pads and thumb pad over the agar surface.
- Incubate the media device at 30°–35° for no less than 48 h and then at 20°–25° for no less than 5 additional days. Samples must be incubated in an incubator. Handle and store media devices to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading (e.g., invert plates).
- Record the number of cfu per hand (left hand, right hand).
- Determine whether the cfu action level is exceeded by counting the total number of cfu from both hands.

38

Gloved Fingertip and Thumb Sampling

- Incubate sampling device at 30-35 degrees for no less than 48 hours and then at 20°-25° for no less than 5 additional days
- Store media devices inverted during incubation to prevent condensate from dropping onto the agar and affecting the accuracy of the colony-forming units

39

Gloved Fingertip and Thumb Sampling

- Successful completion of the initial gloved fingertip and thumb test is defined as **zero (0) colony-forming units** (cfu); subsequent gloved fingertip and thumb sampling after media-fill testing is defined as ≤ 3 cfu (total for both hands)
- <https://www.youtube.com/watch?v=F9K8DAupOFg>

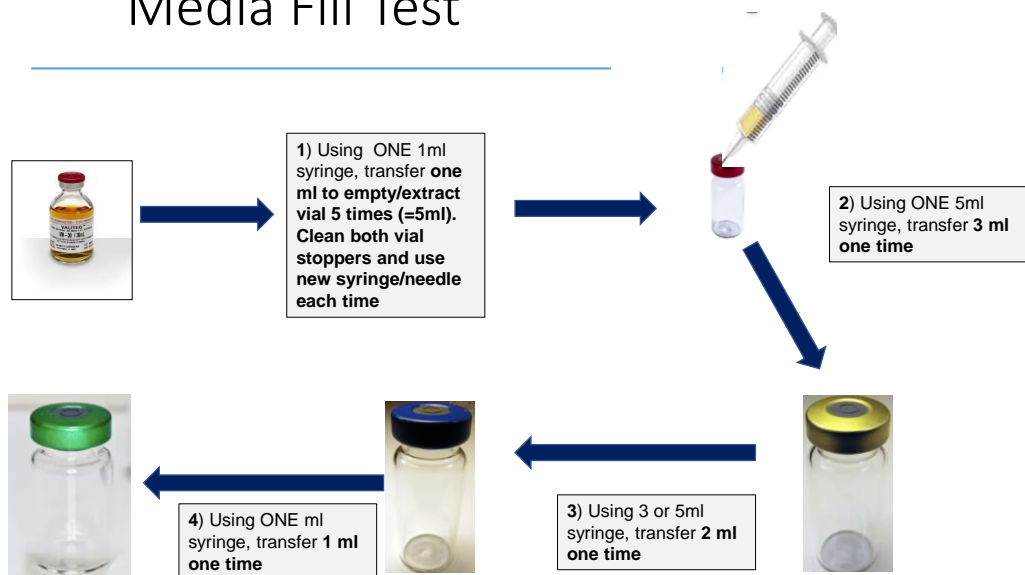
40

Media Fill Test

- Start with sterile components (clean the hood, area, ...)
- Manipulate in manner that simulates sterile to sterile compounding
- Transfer the sterile soybean – casein media into the same type of container closure system
- Do not dilute the media
- Incubate for 7 days at 20-25 degrees followed by 7 days at 30-35 degrees
- Failure; visible turbidity or other visual manifestations of growth on or before 14 days

41

Media Fill Test



42

Treatment Vial Labeling

- Patient name
- Type
- Dilution
- Storage requirement
- Beyond Use Date (BUD)

43

Expiration Vs Beyond Use Date (BUD)

- An expiration date is the last date a manufacturer can guarantee the potency and safety of a medication
- **A beyond-use date is the last date you can safely use a compounded medication.** It's determined based on several factors by the physician/pharmacy/technician making the medication.

44

Beyond Use Date (BUD)

- **USP 797:** BUDs for CSPs that are prepared strictly in accordance with manufacturers' product labeling shall be those specified in that labeling or **from appropriate literature sources or direct testing**.
- BUD - no later than the expiration of the earliest expiration date of any component (any extract, HSA)
- Maximum BUD for 1:1 (V:V) extracts: one year from the date the prescriptive vial/set is mixed
- What about more dilute extracts?

45

Beyond Use Date (BUD): More Dilute Extracts

- It is not one year, and it depends on:
 - Glycerinated vs aqueous extracts
 - The diluent used (HSA, Normal saline with phenol, 10% glycerin HSA)
 - Storage temp
- Immunotherapy extracts more dilute than 1: 100 (wt:vol) should not be used beyond 3 months. (ref; Dr. Richard Weber, chapter 20, pharmacology)

46

Stability of major allergens in dilute solutions

Extract	Diluent	1:125 v/v			1:625 v/v		
		3 months	6 months	12 months	3 months	6 months	12 months
Grass	HSA	60	76	51	79	74	54
	NSP	54	60	16	29	24	6
Bermuda	HSA	73	67	43	68	51	34
	NSP	62	53	9	26	16	0
Birch	HSA	93	79	75	76	63	49
	NSP	82	41	34	41	21	13

Numbers represent percent of original potency.

v/v: volume/volume; HSA: normal saline with 0.03% human serum albumin (HSA); NSP: normal saline phenol.

Data from: Plunkett G. Stability of allergen extracts used in skin testing and immunotherapy. Curr Opin Otolaryngol Head Neck Surg 2008; 16:285.

47

Beyond Use Date (BUD): Extract Mixes

- It is not one year, Even if the individual stock extracts have longer expirations
- Example: Tree mix (Birch, Maple, Oak) all individual extracts expiration is January 2026, Your new mix "BUD" will be a year from the preparation day.

48

Shipping and Transport of Treatment Vials

- Package and transport treatment vials in a mode that will prevent damage and maintain sterility and stability condition
- When shipping, use appropriate container that will preserve stability (temperature controlled) and label the exterior **must** include specific handling instructions and temperature requirement.

49

Preparing Allergen Extracts: Payer Documentation

- Some commercial payers are already requiring allergy practices to submit documentation as outlined in the USP 797 Guidelines even though they do not officially take effect until November 1
 - Payment denials for 95165 are increasing, and are typically tied to extract vial labeling
 - Practices are reporting difficulties disputing denials
- All allergen extract vials must include:
 - Patient name
 - Type and fractional dilution of each vial with a corresponding vial number
 - BUD
 - Storage conditions
- Claims for allergen extract vial preparation **MUST** include evidence of proper vial labeling noted above

50

Documentation for Compounding Allergenic Extract Prescription Sets

- All facilities where allergenic extract prescription sets are prepared **must have and maintain written or electronic documentation** to include, but not limited to, the following:
- **SOPs** describing all aspects of the compounding process
- **Personnel training records, competency assessments, and qualification records including corrective actions for any failures**
- **Certification reports of the PEC**, if used, including corrective actions for any failures
- **Temperature logs** for refrigerator(s)
- **CRs** for individual allergenic extract prescription sets

51

Documentation for Compounding Allergenic Extract Prescription Sets

Compounding records / log must include the following:

- Name, strength or activity, and dosage form of the CSP
- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription, order, or lot number)
- A method to identify the individuals involved in the compounding process and individuals verifying the final CSP
- Name of each component
- Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient (Mixes; trees weeds,...)

52

Documentation for Compounding Allergenic Extract Prescription Sets

Compounding records / log must include the following:

- Volume of each component
- Strength or activity of each component
- Total quantity compounded.
- Final yield (e.g., quantity, containers, number of units)
- Assigned BUD and storage requirements.
- Results of QC procedures (e.g., visual inspection)
- If applicable, the CR must also include: MFR reference for the CSP

53

Why Should We Comply With the USP 797?

- USP 797 applies to **everyone involved in sterile compounding: pharmacists, nurses, physicians and pharmacy technicians**
- The intent of USP 797 is **to prevent patient harm and death through minimum practice and quality standards expected of any entity or individual involved in storage, handling, preparation and transportation of CSPs** (compounded sterile preparations)
- Legal implications: The new USP chapter 797, Pharmaceutical Compounding: Sterile Preparations, **will become enforceable by regulatory agencies on November 1, 2023.**

54

AAAAI Compounding/USP 797 Resources

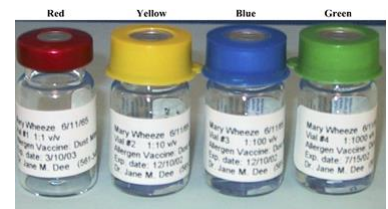
- The Compounding Corner

(<https://education.aaaai.org/compounding-corner>)

- Extract preparation facility requirements, detailed hygiene and garbing protocols, training module for clinicians and staff, and more
- Coming soon: Allergen extract compounding quiz, documentation checklist



- Practice Management Resource Guide Chapter 9: Subcutaneous Allergen Immunotherapy Extract Preparation for Aeroallergens and Venom
- Practice Parameter on Immunotherapy



55

AAAAI Practice Management Workshop July 28-30 – Minneapolis, MN

- Discounted registration for FIT (\$100) and NAIA (\$350) members
- Unique interactive educational experience
- Sessions geared towards new allergists:
 - Preparing Allergen Immunotherapy Extracts
 - Mastering the Art of Contract Negotiation
 - Practice Management Basics
 - Coding and Billing Basics



Register at <https://www.aaaai.org/Practice-Management/Practice-Management-Workshop/Practice-Management-Workshop>

56

Questions?