

Allergen Immunotherapy Extract Preparation Guidelines

1. Qualifications of extract preparation personnel:

- Compounding personnel must pass a written test on aseptic technique and extract preparation.
- Compounding personnel must be trained in preparation of allergenic products.
- Compounding personnel must annually pass a media-fill test, as described in Addendum A.*
- Compounding Personnel who fail written or media-fill test would be reinstructed and re-evaluated.
- Compounding Personnel must be able to demonstrate understanding of antiseptic hand cleaning and disinfection of mixing surfaces.
- Compounding Personnel must be able to correctly identify, measure, and mix ingredients.
- Compounding personnel should be appropriately trained health professionals including, but not limited to, registered nurses, licensed practical nurses, medical technicians, medical assistants, physician assistants, advanced practice nurses and physicians.

2. Physician responsibility:

A physician with training and expertise in allergen immunotherapy is responsible for ensuring that compounding personnel are instructed and trained in preparation of immunotherapy using aseptic technique as defined below and that they meet the requirements of these guidelines. Evidence of such compliance shall be documented and maintained in personnel files. The physician is responsible for providing general oversight and supervision of compounding.

3. Bacteriostasis:

Allergen extract dilutions must be bacteriostatic, meaning that they must contain phenol concentrations of at least 0.25%, or if phenol concentration is less than 0.25%, the extract must have a glycerin concentration of at least 20%.

4. Dilutions prepared in accordance with manufacturer's instructions:

Allergen extracts must be diluted in accordance with antigen manufacturer's instructions.

5. Potency:

The manufacturer's expiration dates must be followed. Beyond-use dates for allergy extract dilutions should be based on best available clinical data.

6. Mixing of extracts with high and low proteolytic enzymes—cross-reactivity of antigens:

Separation of aqueous extracts with high proteolytic enzyme activities from other extracts is recommended.

7. Storage:

Extracts should be stored at 4°C to reduce the rate of potency loss or according to manufacturer's directions. Extracts beyond the expiration date of the manufacturer are to be discarded. Storage must be in a designated refrigerator for medications and not used for food or specimens.

8. Subcutaneous injection:

Allergen extracts can only be administered intradermally or through subcutaneous injection unless the FDA-approved package insert or accepted standards of clinical practice permit another route of administration.

9. Aseptic technique:

Preparation of allergy immunotherapy shall follow aseptic manipulations defined as:

- The physician must designate a specific site, such as a countertop, in an area of the practice facility where personnel traffic is restricted and activities that may contribute to microbial contamination (e.g., eating, food preparation, placement of used diagnostic devices, materials, and soiled linens) are prohibited.
- The extract preparation area must be sanitized with 70% isopropanol that does not contain added ingredients, such as dyes and glycerin.
- Extract preparation personnel must thoroughly wash hands to wrists with detergent or soap and potable water. Substitution of hand washing by treatment with sanitizing agents containing alcohol and/or 70% isopropanol is acceptable.
- Necks of ampules to be opened and stoppers of vials to be needle punctured must be sanitized with isopropanol.
- Direct contact contamination of sterile needles, syringes, and other drug administration devices and sites on containers of manufactured sterile drug products from which drugs are administered must be avoided. Sources of direct contact contamination include, but are not limited to, touch by personnel and non-sterile objects, human secretions, blood, and exposure to other non-sterile materials.
- After mixing is complete, visual inspection is to be performed for physical integrity of the vial.

10. Labeling:

Immunotherapy vials are to be clearly labeled with the patient's name and beyond-use date of the vial.

11. Mixing log:

A mixing log is to be kept with information on the patient's name, extract used for mixing, mixing date, expiration date and lot numbers.

12. Policy and procedure manual:

Practices preparing allergy extracts must maintain a policy and procedure manual for the procedures to be followed in mixing, diluting, or reconstituting of sterile products and for the training of personnel in the standards described above.

***Addendum A:**

Example of a media-fill test procedure. This or an equivalent test is performed at least annually by each person authorized to compound allergen immunotherapy extracts under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of allergen immunotherapy extracts. Once begun, this test is completed without interruption. A double-concentrated media such as from Valiteq is transferred in ten 0.5-mL increments with a sterile syringe to a sterile 10-cc vial. Five mL of sterile water (preservative free) is added. This is the "concentrate." The vial is incubated within a range of 20-35°C for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days.