# New Mexico Board of Pharmacy

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## COMPOUNDING ALLERGENIC EXTRACTS CLINIC INSPECTION FORM

CLINIC NAME: _____DATE: _____PHONE:_____
ADDRESS: _____ CITY: _____ ZIP: _____
CLINIC TYPE: Class A___(more than 12,500 units dispensed annually) Class B1___(1 to 2,500 units annually) Class B2___(2,501 to 7,500 units) Class B3___(7,501-12,500 units)
Class C ___ (administration only)
NMCS No._____ DEA No._____ Clinic No._____
Exp. Date_____ Exp. Date_____ Exp. Date_____
Consultant Pharmacist_____ Appropriate Visits: Yes____ No_____
Chart Reviews Done: Yes_____ No_____ Appropriate: Yes____ No_____
Log of All Visits and Activities: Yes_____ No_____
Supportive Personnel: Yes_____ No_____ Storage of Medications Appropriate: Yes___ _No_____
Receipt Records Kept: Yes_____ No_____ Schedule II Records Appropriate: Yes____ No_____
Schedule III, IV & V Receipt Records Appropriate: Yes_____ No_____
Samples Kept: Yes_____ No_____ Appropriate Receipt Records: Yes____ No_____
Drug Source: _____
Controlled Substance Inventory Done: Yes_____ No_____ Date:_____
Repacking Done: Yes_____ No_____ Appropriate Record: Yes_____ No_____
Appropriate Label: Yes_____ No_____
Dispensing or Distributing Done: Yes_____ No_____ Labeling Appropriate: Yes____ No_____
Counseling Done: Yes_____ No_____ Appropriate: Yes____ No_____
Written Information Provided: Yes___ No___ Pharmacist Phone Number Provided: Yes____ No_____
Disposition Records of Unwanted or Outdated Drugs Adequate: Yes_____ No_____
Adequate Reference Materials: Yes_____ No_____
Policy and Procedures Manual Adequate: Yes____ No____ Date Signed & Reviewed: _____
List of Pharmacy Personnel___ Function of Pharmacy Personnel___ Clinic Objectives___
Formularies____ Security ____Sanitation___ Licensing___ Reference Materials___ Drug Storage___
Packaging and Repacking___ Dispensing & Distributing___ Supervision__ Labeling & Relabeling___
Destruction & Returns___ Scope of Practice__ Drug & Device Procuring__
Receiving of Drugs/Devices__ Delivery of Drugs/Devices__ Record Keeping__ Samples__
Board of Pharmacy Inspection Form Posted: Yes____ No____ All License Current: Yes_____ No_____

1. A designated person (s) with training and expertise in allergen immunotherapy is responsible for ensuring that personnel who will be preparing allergenic extract prescription sets are trained, evaluated, and supervised. . . . . YES NO

2. Before beginning to independently prepare allergenic extracts (AE), all compounding personnel must complete training and be able to demonstrate knowledge of principles and skills for sterile compounding. . . . . YES NO

3. Annual personnel training and competency must be documented. Personnel must demonstrate knowledge and competency in these procedures by passing written or electronic testing before they can be allowed to compound allergenic extract prescription sets. . . YES NO.

4. Before being allowed to independently compound, all compounders must successfully complete gloved fingertip and thumb sampling on both hands no fewer than 3 separate times. Each fingertip and thumb evaluation must occur after performing separate and complete hand hygiene and garbing procedures. After the initial competency evaluation, compounding personnel must successfully complete gloved fingertip and thumb sampling on both hands at least every 12 months thereafter. . YES NO

5. Compounding personnel must have their sterile technique and related practices evaluated at least every 12 months as demonstrated by successful completion of a media-fill test. If compounding outside of a PEC, the post-media-fill surface sample is not required. . . . . YES NO

6. Personnel who fail competency evaluations must successfully pass reevaluations in the deficient areas before resuming compounding of AE prescription sets. The designated person must identify the cause of failure and determine appropriate retraining requirements. . . . . YES NO

7. Personnel who have not compounded an allergenic extract prescription set in more than 6 months must be evaluated in all core competencies before resuming compounding duties. . . YES NO

8. Before beginning compounding of allergenic extract prescription sets, personnel must perform hand hygiene and garbing procedures according to the facility's SOPs. . . . YES NO

9. The minimum garb requirements include:
○ A low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gowns)
○ A low-lint, disposable head cover that covers the hair and ears and, if applicable, a disposable cover for facial hair
○ Face mask
○ Sterile powder-free gloves
. . . . . YES NO

10. Throughout the compounding process, personnel must apply sterile 70% IPA onto all surfaces of the gloves and allow them to dry thoroughly. . . . . YES NO

11. The compounding process must occur in an ISO Class 5 PEC or in a dedicated allergenic extract compounding area (AECA). The PEC or AECA used to compound allergenic extract prescription sets must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality. 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. The PEC or the work surfaces in the AECA must be located at least 1 m away from a sink. 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. . . . YES NO

12. If used, the PEC must be certified at least every 6 months. . . . YES NO N/A

13. If used, a visible perimeter must define the AECA.
○ Access to the AECA during compounding must be restricted to authorized personnel.
○ During compounding activities, no other activity is permitted in the AECA.

○ The surfaces of walls, floors, fixtures, shelving, counters, and cabinets in the AECA must be cleanable.
○ Carpet is not allowed in the AECA.
○ Surfaces should be resistant to damage by cleaning and disinfecting agents.
○ The surfaces in the AECA upon which the allergenic extract prescription sets are prepared must be smooth, impervious, free from cracks and crevices, and non-shedding to allow for easy cleaning and disinfecting.
○ Dust-collecting overhangs such as utility pipes, ledges, and windowsills should be minimized. If overhangs or ledges are present, they must be easily cleanable.
○ The AECA must be designed and controlled to provide a well-lighted working environment, with temperature and humidity controls for the comfort of compounding personnel wearing the required garb.
. . . . . YES NO N/A

14. In a 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. Apply sterile 70% IPA to the horizontal work surface between each prescription set. . . . YES NO N/A

15. In an 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. Apply sterile 70% IPA to the horizontal work surface between each prescription set.
○ If present, 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.
○ Ceilings within the perimeter of the AECA must be cleaned and disinfected when visibly soiled and when surface contamination is known or suspected. . . . . YES NO N/A

16. Vial stoppers on packages of conventionally manufactured sterile ingredients must be wiped with sterile 70% IPA to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extract prescription sets. . . . . YES NO

17. The BUD for the prescription set must be no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set, and the BUD must not exceed 1 year from the date the prescription set is mixed or diluted. . . . YES NO N/A

18. The label of each vial of an allergenic extract prescription set must display the following prominently and understandably:
○ Patient name
○ Type and fractional dilution of each vial, with a corresponding vial number
○ BUD
○ Storage conditions
. . . . . YES NO

19. • All facilities where allergenic extract prescription sets are prepared must have and maintain 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)
○ Compounding records for individual allergenic extract prescription sets
○ Information related to complaints and adverse events including corrective actions taken
○ Investigations and corrective actions

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20. Official response within 30 days . . . . . YES NO

COMMENTS

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Official State Drug Inspector