

LICENSE APPLICATION INSTRUCTIONS
NON-RESIDENT PHARMACY ENGAGED IN COMPOUNDING/STERILE PREPARATIONS (CLASS E-S)

- Applicants will be notified of any items missing from the application within 4 to 6 weeks. Allow a minimum of 90 days from the time your application packet is complete (all missing items received), for review and final license issuance. Official review does not begin until all required items are received.
- Applications are considered withdrawn if missing items are not submitted to complete an application within one year of the original application submission date.
- **NOTICE: the application will be cancelled and a new application packet, including application fee, must be submitted, if a change in officer, owner, or location occurs while the application is under review by TSBP.**

1. **Pharmacy License Application – Submit Form [LIC-Class E S](#)**
The Pharmacist-in-Charge MUST have a Texas pharmacist license.

2. **Ownership Information:**

- **Partnership or individual – Submit Form [LIC-006](#); or**
- **Corporation or Limited Liability Company – Submit Form [LIC-007](#) with the following attachments:**
 - Certificate of Authority (Business Located Out-Of-State) issued by the state in which the corporation is located that indicates that the corporation or LLC is in good standing and authorized to do business in the resident state.
 - Articles of Incorporation (for Corporation) or Articles of Organization (for LLC)
 - Current Texas Franchise Tax Status. (If the Corp/LLC is registered w/TX Secretary of State)
- **Government owned – Submit Form [LIC-008](#).**
- If a closely-held corporation, a list of all owners.
- If a publicly-held corporation, a copy of the corporation's 10K Filing with the Security and Exchange Commission.

3. **Managing Officer Form(s) –**

Submit Form [LIC-021](#) Which provides information and questions regarding the “background” to be submitted by **each of the top four** Managing Officers. For each individual owner(s), managing officer(s) or partners that are not a Texas licensed pharmacist, attach copies of the following:

- Government-issued photo ID**
- Proof of SSN (copy of social security card or W2 form)**

4. **License Verification –**

Attach a written verification from the resident Board of Pharmacy which verifies the current status of license of the Pharmacist-in-Charge *and* the pharmacy. A copy of the license will NOT fulfill this requirement. The Board of Pharmacy verifying licensure may submit this direct to TSBP.

5. **Lease Agreement/Property Ownership –**

Attach a copy of lease agreement between the owner of the pharmacy and the owner of the building in which the pharmacy is located. The pharmacy address listed on the lease agreement must match the pharmacy address listed on all required forms. The tenant listed on the lease agreement must match the name of the pharmacy owner listed on all required forms. If you are subleasing the space, submit a copy of the sublease agreement along with the master lease agreement.

6. **Credit Worthiness Document –**

Provide a letter from a primary wholesaler with proof of credit worthiness.

7. **Inspection Report –**

Attach a copy of a pharmacy inspection report conducted within the within the last renewal cycle by one of the following approved vendors:

Accreditation Commission for Health Care, Inc. (ACHC)
139 Weston Oaks Court
Cary, North Carolina 27513
Contact: Jon Pritchett at 855-937-2242, extension 233.
<http://aisinspections.org/>

National Association of Boards of Pharmacy (NABP)
1600 Feehanville Drive
Mount Prospect, Illinois 60056
Contact: Erika P. Golder at 847-391-4574
<https://nabp.pharmacy/programs/verified-pharmacy-program/>

Superior Laboratory Services, Inc. (SLSI)
1710 Preston Road, Suite A
Pasadena, Texas 77503
Contact: Rick Meyer at 713-477-9247
<http://www.slsi.net/>

8. Pharmacy Application Supplemental Documents – Submit the following with your application:

- Labeled Blue prints or floor plans for the pharmacy, including a floor plan or design plan of the controlled environment for compounding sterile preparations;
- A minimum of 10 clearly labeled color photographs of the controlled environment for compounding sterile preparations, including equipment used for compounding sterile preparations; photos submitted should provide 360° view of sterile compounding area.
- A minimum of 10 clearly labeled color photographs of the pharmacy business location in general (e.g., pharmacy building showing neighboring businesses); include photos of areas facing the rear and sides of the building.
- Table of contents of the pharmacy's standard operating procedures (SOPs) for compounding sterile preparations;
- Documentation of special education or training for all pharmacy personnel who compound sterile preparations or supervise the compounding of sterile preparations at the pharmacy, as specified in [Board Rule 291.133](#). Include written record of initial and in-service training, education, and the results of written and practical testing and media-fill testing of pharmacy personnel.
- A complete list of all sterile preparations that are compounded by the pharmacy;
- If the pharmacy compounds sterile preparations for distribution/delivery to practitioners of the state for office-use/office-stock (for administration to patients in the practitioner's office), attach a copy of the regulatory citation (of the state in which the pharmacy is located) that authorizes compounding for practitioner office use;
- Documentation of the most recent airflow studies and air quality testing within the controlled environment used for compounding sterile preparations at the pharmacy;
- If the pharmacy is compounding high-risk sterile preparations, attach documentation to show that the pharmacy is routinely conducting the following tests of compounded sterile preparations: sterility, fungal and endotoxin.
- If the pharmacy has been inspected by the FDA, attach a copy of the inspection report.

SUBMIT THIS CHECKLIST AS A COVER SHEET WITH ALL ITEMS LISTED – KEEP COPIES FOR YOUR RECORDS