



South Carolina Department of Labor, Licensing and Regulation

**South Carolina Board of Pharmacy**

110 Centerview Dr. • Columbia • SC • 29210

P.O. Box 11927 • Columbia • SC 29211-1927

Phone: 803-896-4700 • Contact.pharmacy@llr.sc.gov • Fax: 803-896-4596

llr.sc.gov/bop

## **INSTRUCTIONS OUTSOURCING FACILITY PERMIT APPLICATION**

An Outsourcing Facility permit is required if a facility compounds

- sterile drugs without a prescription or
- sterile and non-sterile drugs without a prescription

**and** is registered with the FDA as a 503B Outsourcing Facility.

The outsourcing facility must also:

- (a) hold a current S.C. Pharmacy permit or  
current S.C. Non-dispensing Drug Outlet permit as a manufacturer

or (b) apply for a Pharmacy permit or Non-dispensing Drug Outlet permit  
concurrently with this application

The permit holder for the outsourcing facility is responsible for the supervision and control of compounded drugs and must be a licensed pharmacist.

Using false, fraudulent, forged statement or document, or committing a fraudulent, deceitful or dishonest act or omitting a material fact in obtaining licensure is grounds for discipline or permit denial.

Submit the completed application with the following items: (If an item is not applicable, please indicate N/A)

\_\_\_\_\_ Non-refundable application fee of \$280 payable to SC Board of Pharmacy

\_\_\_\_\_ Copy of FDA inspection, any 483(s) issued and facility's response

\_\_\_\_\_ Copy of current DEA registration and/or copy of state controlled substance registration

\_\_\_\_\_ Letter describing in detail the nature of your business

\_\_\_\_\_ List of pharmacists practicing at this outsourcing facility other than the PIC



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OUTSOURCING FACILITY PERMIT APPLICATION

\$280 application fee payable to SC Board of Pharmacy

Table with 2 columns: FOR BOARD USE ONLY, and empty cells for Date paid, Amount paid, Check #

- Checkboxes for New Facility, Change to Existing Permit, Change of Ownership, Change of Name, Change of Location, and Federal Tax Id #.

Facility name: \_\_\_\_\_

dba name: \_\_\_\_\_ Address: \_\_\_\_\_

City: \_\_\_\_\_ County: \_\_\_\_\_ Zip code: \_\_\_\_\_

Phone: \_\_\_\_\_ Website: \_\_\_\_\_

Contact person at this site: \_\_\_\_\_ Name Title Email

Mailing address where all correspondence regarding licensure will be sent if other than facility above:

Contact Person: \_\_\_\_\_ Email: \_\_\_\_\_

Facility name: \_\_\_\_\_ Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

TYPE OF COMPOUNDING ACTIVITY

1-Does the outsourcing facility engage in HIGH-RISK compounding of sterile drug products? YES NO

2-Does the outsourcing facility engage in MEDIUM-RISK compounding of sterile drug products? YES NO

3-Does the outsourcing facility engage in LOW-RISK compounding of sterile drug products? YES NO

4-Does the outsourcing facility engage in the compounding of NON-STERILE drug products? YES NO

5-Does the outsourcing facility dispense compounded drugs pursuant to valid prescriptions? YES NO

\*If YES, a pharmacy permit is required. Outsourcing facilities which share the same space with a pharmacy must perform all compounding in compliance with cGMPs.

6-Has your facility been inspected by the FDA? YES NO

7-If inspected by the FDA, was your facility issued a 483? YES NO

If YES, attach a copy of the FDA Form 483 and your company's response to the issues noted.

8-Provide licensure information for the pharmacist responsible for overseeing compounding at your facility.

Name: \_\_\_\_\_ License #: \_\_\_\_\_ Expiration date: \_\_\_\_\_

9-Which of the following entities do you sell/ship product to? Check all that apply.

- Checkboxes for retail pharmacies, hospital pharmacies, permitted clinics/surgical centers, practitioners (MD, DMD, DVM, APRN, PA-C), and other.

**10-Has any license or permit held by the applicant, permit holder, or by any owner or corporate officer been disciplined, denied, refused or revoked for violations of any pharmacy laws or drug laws in South Carolina or any other state?**  YES\*  NO

\*If Yes, attach a full written explanation and copies of applicable court documents.

**OWNERSHIP: Check appropriate box and provide complete**

**sole proprietorship** Name of business entity: \_\_\_\_\_

Name	Address	DOB

**partnership** Name of partnership: \_\_\_\_\_

Partner name	Address	DOB

**Corporation** Name of Corporation: \_\_\_\_\_

State of Incorporation: \_\_\_\_\_ Name of Parent Company \_\_\_\_\_

Name of Corp officer	Title	DOB	Address	% of Stock ownership
1				
2				
3				

**ATTESTATION**

*I declare that I have read and approve the foregoing and the statements are true and correct to the best of my knowledge and belief; I will comply with the Code of Laws of the South Carolina Pharmacy Practice Act; and I understand I am responsible for any violations occurring during my tenure.*

\_\_\_\_\_  
Signature of person acting as Permit Holder

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print name and title of Permit Holder

\_\_\_\_\_  
Email address of Permit Holder or contact person

*I declare that I have read and approve the foregoing and the statements are true and correct to the best of my knowledge and belief; I will comply with the Code of Laws of the South Carolina Pharmacy Practice Act; and I understand I am responsible for any violations occurring during my tenure.*

\_\_\_\_\_  
Signature of pharmacist responsible for compounding

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print name of pharmacist

\_\_\_\_\_  
Email address

**INSPECTION:** Your application will be processed and assigned to a Board of Pharmacy inspector. The Inspector will contact you several weeks prior to the listed expected opening date for submission of policies and procedures and a status update.

Mail completed application and non-refundable \$280 application fee payable to S.C. Board of Pharmacy to:  
Mailing address: PO Box 11927 Overnight/physical address: 110 Centerview Drive, Suite 201  
 Columbia SC 29211-1927 Columbia, SC 29210