



COMMONWEALTH OF VIRGINIA

Board of Pharmacy

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APPLICATION FOR AN OUTSOURCING FACILITY PERMIT

Check Appropriate Box(es):

- | | | | |
|---|----------|--|----------|
| <input type="checkbox"/> New ³ | \$270.00 | <input type="checkbox"/> Change of Pharmacist-In-Charge ² | \$50.00 |
| <input type="checkbox"/> Change of Ownership ² | \$50.00 | <input type="checkbox"/> Change of Location ³ | \$150.00 |
| <input type="checkbox"/> Change of Facility Name ² | No Fee | <input type="checkbox"/> Remodeling ³ | \$150.00 |
| <input type="checkbox"/> Reinstatement ^{1, possibly 3} | _____ | | |

¹ If reinstatement, due to: Lapse of Permit or Suspension or Revocation of a Permit

Application fees are not refundable. Applications are valid for one year from the date of receipt.
The required fees must accompany the application. Make check payable to "Treasurer of Virginia".

Applicant—Please provide the information requested below. (Print or Type) Use full name, not initials.

Name of Outsourcing Facility		Area Code and Telephone Number (currently working number)	
Street Address		Area Code and Fax Number	
City		State	Zip Code
If a current outsourcing facility permit is held, indicate the permit number 02		If a current pharmacy permit is held, indicate the permit number 0201-	
(Print) Name of the Pharmacist-In-Charge (PIC) (if change of PIC, list incoming)		Effective Date of Change (if change of PIC, date assuming role as PIC) ²	
Email address for PIC:		License Number of the PIC 0202-	
Signature of the Pharmacist-In-Charge (PIC) (if change of PIC, incoming signature)		Date	
Expected Hours of Operation		Expected Opening, Moving, or Completion Date	Requested Inspection Date ³

³ A 14-day notice is required for scheduling an opening or change of location inspection. Drugs may not be stocked prior to inspection and approval. An inspector will call prior to the requested date to confirm readiness for inspection. If the inspector does not call to confirm the date, the responsible party should call the Enforcement Division at 804-367-4691 to verify the inspection date with the inspector.

FOR OFFICE USE ONLY:

Date processed:		Check No:		Receipt No:		Application No:	
Assigned Inspection Date ³ :		Date Inspected:		Reviewed By:		Date Reviewed:	
Date Issued:		Permit Number 02		USP or cGMP		Date Scanned to Enforcement:	
						Date Scanned to MLO:	

OWNERSHIP TYPE—check one:	Corporation <input type="checkbox"/>	Partnership <input type="checkbox"/>	Individual <input type="checkbox"/>	Other <input type="checkbox"/>
Name of ownership entity if different from name of application:				
Street Address:			Phone No.	
City:	State:	Zip Code:		
State(s) of incorporation:				

List all other trade or business names used by this facility	
Name: _____	Name: _____
Name: _____	Name: _____

LIST OF OWNERS/OFFICERS AND RESIDENCE ADDRESSES, OR LIST IS ATTACHED <input type="checkbox"/>	
Name: _____	Title: _____
Residence Address: _____	
Name: _____	Title: _____
Residence Address: _____	

Please Answer the Following Questions:

1. Does the outsourcing facility engage in the HIGH-RISK compounding of sterile drug products?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2. Does the outsourcing facility engage in the MEDIUM-RISK compounding of sterile drug products?	Yes <input type="checkbox"/> No <input type="checkbox"/>
3. Does the outsourcing facility engage in the LOW-RISK compounding of sterile drug products?	Yes <input type="checkbox"/> No <input type="checkbox"/>
4. Does the outsourcing facility engage in the compounding of NON-STERILE drug products?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5. Does the outsourcing facility dispense compounded drugs pursuant to valid prescriptions? If yes, a pharmacy permit is also required. Outsourcing facilities which share the same space with a pharmacy must perform all compounding in compliance with cGMPs.	Yes <input type="checkbox"/> No <input type="checkbox"/>

<p>ADDITIONAL REQUIRED INFORMATION: The requested documentation must be submitted with the application in order to grant an outsourcing facility permit.</p> <ol style="list-style-type: none"> 1. A legible copy of this outsourcing facility's current, unexpired, unrestricted FDA registration. 2. A copy of the current outsourcing facility inspection report, conducted no more than 1 year prior to the date of submission of this application, in compliance with §54.1-3434.05 of the Virginia Drug Control Act and indicating compliance with current good manufacturing practices (cGMPs). Corrective action addressing any identified deficiencies must be submitted with the inspection report, along with any correspondence with a regulatory body regarding the corrective action. 3. A list of pharmacists practicing at this outsourcing facility other than the PIC.
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