Application to ADD-ON a Compounding and Repackaging Pharmacy Licence

A completed application and required floor planes (see page 6 of this application) must be submitted to the ACP office a minimum of 60 days prior to the proposed effective date.

Section One: Pharmacy Demographics

Proposed Effective Date for Compounding Services to Begin: _____

_____
Operating name of the pharmacy **Licence #**

_____
Physical address – PO Box # not acceptable here

_____
City Postal code

_____
Phone # - include area code Fax # - include area code Toll-free # (if applicable)

_____
Website address (if applicable)

Pharmacy hours: Monday-Friday _____ Saturday _____ Sunday/Holidays _____

The number of hours per week the pharmacy will be open to the public: _____

The number of hours per week the licensee, on average, will be present at this pharmacy: _____

Section Two: Proprietor's Agent Information and Undertaking

A Proprietor's Agent is either the owner or the designated representative of the owner(s) / corporation who fulfils the responsibilities and obligations of a proprietor under the legislative framework

_____
Name of Proprietor's Agent (please print clearly) *(ACP Registration # if applicable)*

_____
Position and/or relationship to proprietor

_____
Phone Number *Email Address (please print clearly)*

Proprietor's Agent Undertaking (this section must be completed by the proprietor's agent)

As the proprietor or as the representative acting on behalf of the proprietor, I undertake to act in accordance with *Pharmacy and Drug Act*, any order made under the *Act*, the code of ethics and the standards for the operation of licensed pharmacies.

_____
Signature

Dated at _____ this _____ day of _____, 20____
(name of city or town) *(date i.e. 25th)* *(month)* *(year)*

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Section Three: Compounding Services

All pharmacies must have an area for compounding drugs and be equipped to provide compounding services.

Non-sterile compounding

Prior to completing the following section you must:

1. Review the Standards for Pharmacy Compounding of Non-sterile Preparations and the Guidance Document for Pharmacy Compounding of Non-sterile Preparations and other related documents.
2. Determine the active pharmaceutical ingredients (APIs) that the pharmacy will use to compound. For each API, refer to the National Institute for Occupational Safety and Health (NIOSH) list and the Safety Data Sheet (in particular, Sections 2 and 8) to determine the level of risk to personnel, the appropriate personal protective equipment, and the engineering controls required for the pharmacy. When there is uncertainty as to the level of risk, you must adhere to the higher standard. Retain copies of all Safety Data Sheets and the assessments of risk.

What APIs will the pharmacy use during compounding?

Check One	Ingredients/Compounds	Physical requirements*
❒Yes ❒ No	Hazardous drugs which are classified by NIOSH as Group 1	**Level C** • Separate room • Appropriate containment device (C-PEC) for materials being compounded • Well-ventilated with appropriate air exchange • Negative pressure
❒Yes ❒ No	Hazardous materials classified by WHMIS as a health hazard, such as those very irritating to the respiratory track, the skin, and the mucous membrane	
❒Yes ❒ No	Drugs which are classified by NIOSH as Group 2 or 3 where large quantities of APIs are used routinely	
❒Yes ❒ No	Complex compounds as defined in USP <795>	When there is uncertainty as to the level of risk, then you must adhere to the higher standard (e.g., Level C). **Level B** • Separate room (ventilated or with containment device) • Larger workspace and appropriate equipment • Environment conducive to little or no interruptions • Greater protection from cross contamination • May require a ventilated containment device when certain powders, aromatic products or hazardous products are compounded **Level B** is limited to when, based on the assessment of risk, • the requirements will provide an environment that is safe for the compounding personnel, and • you can justify and provide evidence on how the risk is low and can be mitigated. **Risk mitigation and rationale must be documented in the risk assessment.**
❒Yes ❒ No	Small quantities of ingredients or preparations which require ventilation	
❒Yes ❒ No	Simple and moderate compounds as defined in USP <795>	When there is uncertainty as to the level of risk, then you must adhere to the higher standard (e.g., Level B). **Level A** • Separate space designated for compounding

* Requirements are excerpts from the Standards for Pharmacy Compounding of Non-sterile Preparations and must not be read in isolation. Refer to the standards for complete requirements.

Your accompanied floor plan must indicate the location of the engineering controls (e.g., fume hood, eyewash station, safety shower) required for the pharmacy based on the APIs with which you will be compounding, the corresponding Safety Data Sheets, and your assessments of risk. This information, along with compounding policies and procedures, master formulation records, and a quality assurance program, must be available upon request during the pre-opening inspection.

Sterile compounding

If your pharmacy will be compounding sterile preparations, you must comply with the Model Standards for Compounding Hazardous and Non-Hazardous Sterile Preparations.

Will the pharmacy be compounding sterile preparations? ❒ Yes ❒ No

If yes, indicate risk level(s)/use: ❒High ❒Medium ❒Low ❒Immediate use

- Risk levels are per the Model Standards

Will the pharmacy be compounding *hazardous* sterile products? ❒ Yes ❒ No

If yes, indicate microbial risk level(s): ❒High ❒Medium ❒Low

- Risk levels are per the Model Standards

Alberta College of Pharmacy

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Section Three: Pharmacy Staff

Identify ALL regulated members (pharmacists, interns, students, technicians and provisional technicians) that are currently employed at this pharmacy location. Assistants are not regulated members. The licensee (manager) is responsible for notifying ACP of future staff changes via e-mail at pharmacy@abpharmacy.ca

Note: Ensure the below list is accurate and complete as ACP will add/remove employees to/from the pharmacy file accordingly

ACP Registration #	Name	Pharmacist, Intern, Student, Technician, or Provisional technician	Licensee Yes/No

Section Four: Licensee Undertaking

Licensee Undertaking and Application (this section must be completed by the pharmacy licensee)

I hereby make application for a pharmacy licence under the *Pharmacy and Drug Act* to operate a pharmacy. In making this application, I undertake to personally manage, control and supervise the practice of pharmacy in the pharmacy and to comply with the *Act*, any condition imposed on the licence, any order made under the *Act*, the code of ethics and the standards for the operation of licensed pharmacies.

Licensee Signature: _____Licensee Registration #_____

Dated at _____this _____ day of _____, 20____
(name of city or town) *(date i.e. 25th)* *(month)*

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Section Five: Ownership Information

Please check (✓) one

❒ Sole Proprietorship
(a business owned by one individual, which is **not** organized as a corporation)

❒ Partnership
(a business owned by two or more people which is **not** organized as a corporation)

❒ Corporation
(a business that is a separate legal entity chartered under provincial or federal laws with owners that are called shareholders)

_____
name of the sole proprietor, partnership, or corporation – If partnership, include information for all partners

mailing address

city *province* *postal code*

Contact Person(s) for the partnership or proprietor's representative as designated by the corporation

phone # - include area code *fax # - include area code* *toll-free # (if applicable)*

email address *website address (if applicable)*

Shareholder Information

List those partners and/or shareholder holding 20% or more voting shares

Shareholder's or Partner's name *% of shares*

mailing address

city *province* *postal code*

phone # - include area code *cell phone # - include area code* *email address*

Shareholder's or Partner's name *% of shares*

mailing address

city *province* *postal code*

phone # - include area code *cell phone # - include area code* *email address*

Shareholder Information continued

Shareholder's or Partner's name *% of shares*

mailing address

city *province* *postal code*

phone # - include area code *cell phone # - include area code* *email address*

Shareholder's or Partner's name *% of shares*

mailing address

city *province* *postal code*

phone # - include area code *cell phone # - include area code* *email address*

Shareholder's or Partner's name *% of shares*

mailing address

city *province* *postal code*

phone # - include area code *cell phone # - include area code* *email address*

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You must submit a copy of the pharmacy floor plan(s) with this completed application. The floor plans must comply with the below floor plan requirement guide. An incomplete document or floor plans that do not comply with this guide will not be reviewed.

Criteria	✓
Is the floor plan **clear, accurate and legible**?	
Is the floor plan **drawn to scale**?	
Does the floor plan include **exact measurements (in ft.) of all dimensions** (e.g., walls and entry points) so that the area of the dispensary and patient services area may be easily calculated?	
Does the floor plan clearly identify the • dispensary[1], • patient services area[2], and • surrounding public area[3]?	
Does the floor plan clearly **indicate the size (in square feet)** of the • dispensary (must be at least 193.8 ft^2 (18 m^2) in area), • patient services area, and • total prescription department (a prescription department (dispensary + patient services area) must be at least 355.2 ft^2 (33 m^2) in area) Premises/rooms shared with other businesses (e.g., waiting room) are considered a public area and do not count towards the overall size of the prescription department.	
Does the floor plan clearly **indicate all entry points into the dispensary**? • Indicate whether there is a gate, lift-up countertop, or door. • You cannot have the only access to the dispensary be through a counselling room or office.	
Does the floor plan clearly identify the following within the dispensary? • **a counter** with at least 16.1 ft^2 (1.5 m^2) of uninterrupted work space (i.e., free of computer terminals, phones, etc.) • **working aisles** that are at least 3 ft. (90 cm) wide • adequate **shelving and storage** • **compounding area,** in accordance with the compounding standards o **location of the sink and heat source** for compounding o any fume hoods, eyewash stations, safety showers, as applicable • **refrigerator** (bar refrigerator units are not acceptable) • **lockable drug locker or cupboard** • **computer terminal(s)**	
Does the floor plan clearly **identify a semi-private area** for receiving prescriptions (e.g., a service counter with suitable visual and sound barriers and away from patient waiting- or high-traffic areas)?	
Does the floor plan clearly **identify any private area(s)** used for injection services (must be publicly and wheelchair accessible)?	
Does the floor plan clearly **indicate any security grilles** used to secure the dispensary?	
Does the floor plan clearly identify all areas intended for pharmacy use?	
If sharing premises, have you included an additional floor plan depicting the overall facilities, space and layout of the premises? • If the pharmacy shares a premise, the prescription department must operate as a lock and leave.	

[1] "dispensary" means the area of a licensed pharmacy that is not accessible to the public and in which pharmacists
- dispense, provide for sale, and sell drugs referred to in sections 31 and 32 of the *Pharmacy and Drug Act* (PDA), and
- compound drugs referred to in sections 31, 32 and 33 of the Act;

[2] "patient services area" means the area of a licensed pharmacy located outside and adjacent to the dispensary where
- patients receive pharmacy services from pharmacists, and
- drugs referred to in section 33 of the Act may be provided for sale;

[3] "public area" means the area of a licensed pharmacy located outside the prescription department.

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_____ _____

Pharmacy Name *Licence #*

Section Seven: Fee Payment

❒ Provision of Compounding and Repacking Services…….... **$643.65 ($613.00 plus $30.65 GST)**

Payment Options

❒ Cheque # _____ (Make cheque payable to the Alberta College of Pharmacy)

❒ Credit Card - Visa or MasterCard Only

Credit Card Information

Credit Card Number _____ _____ _____ _____

Name on Credit Card _____

Expiry Date (MM/YY) _____ Security Code (3 digits on back of card) _____

Cardholder's signature _____ Date _____

Cardholder's phone # _____ Cell # _____

Area code-phone # Area code-phone #

For Office Use Only

Date Transaction Processed: _____