

**MINNESOTA BOARD OF PHARMACY**

2829 UNIVERSITY AVE SE #530, MINNEAPOLIS, MN 55414-3251

Phone: (651) 201-2825 – Fax: (612) 617-2262

Relay Service: Metro Area (651) 297-5353 – Non-Metro Area 800-627-3529

E-Mail: [pharmacy.board@state.mn.us](mailto:pharmacy.board@state.mn.us) - Web: [www.pharmacy.mn.gov](http://www.pharmacy.mn.gov)

**APPLICATION FOR DRUG MANUFACTURER LICENSE**

LICENSE EXPIRES JUNE 1 OF EACH YEAR

**FEE:** If you manufacturer or ship the following drugs into the state of Minnesota ---  
Prescription only: - Fee \$235 ; Prescription & Non-Prescription – Fee \$235 ;  
Non-Prescription only and/or Veterinary – Fee \$210 Medical Gases – Fee \$185  
If you are licensed as a pharmacy in the state of Minnesota – Fee \$150

Make Check Payable to: Minnesota Board of Pharmacy

**NO RETURN OR REFUND OF FEES**

State of Minnesota Taxpayer Identification Number: Federal 41-6007162 - State 4405717

**NEW MANUFACTURER:** Date of proposed opening in Minnesota --

**CHANGE IN:** Date of proposed change --

- Ownership Formerly: \_\_\_\_\_
- Name Formerly: \_\_\_\_\_
- Address Formerly: \_\_\_\_\_
- Location/dimension Please attach copies of the plans or a sketch of the new location.

**FACILITY HOURS:** M-F \_\_\_\_\_ to \_\_\_\_\_ Saturday \_\_\_\_\_ to \_\_\_\_\_ Sunday \_\_\_\_\_ to \_\_\_\_\_

**PHONE NUMBER:** \_\_\_\_\_ **FAX NUMBER:** \_\_\_\_\_

**E-MAIL ADDRESS:** \_\_\_\_\_

**1. Print, type, or check all applicable boxes.**

Manufacturer Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

**2. Check the appropriate item and complete ownership information:**

Sole Proprietor;  Partnership;  Limited Liability Partnership;  Corporation;  Limited Liability Corp

Fill in: Name of Sole Proprietor, Partnership, or Corporation:

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

**Partnership or Limited Liability Partnership:** List all active and inactive partners. If a new partnership or limited liability partnership, please attach a copy of the partnership papers.

Name	Address	RPh?	% of Ownership

**Corporation or Limited Liability Corporation:** List all shareholders owning 20% or more of the voting stock, all officers and their titles. If a new Corporation or Limited Liability Corporation, please attach corporation papers.

Name	Address	RPh?	% of Ownership

List the state of incorporation: \_\_\_\_\_

List the number of shares of common or voting stock issued: \_\_\_\_\_

**All manufacturers should answer the following questions:**

**3. Qualifications of personnel:** (Production and Quality Control)

Name	Qualifications	Position

**4. Does the applicant have the required equipment necessary to comply with good manufacturing practice?**

Yes  No

**5. Is the facility registered with the FDA?**  Yes  No  Pending

**6. The FDA registration number is?** \_\_\_\_\_

**7. Categories of drugs proposed for handling:**  Medical Gases  Human Prescription Drugs  
 Veterinary Prescription Drugs  Human Non-prescription Drugs  Veterinary Non-prescription Drugs  
 Controlled Substance

**8. Are you licensed as a pharmacy in the state of Minnesota?**  No  Yes, License Number \_\_\_\_\_

**9. Please answer the following:**

- (a) On behalf of the owner, if the applicant is a sole proprietorship
- (b) On behalf of each partner, if the applicant is a partnership or a limited liability partnership
- (c) On behalf of the corporation, if the applicant is a corporation or a limited liability corporation, and on behalf of each officer, director, or shareholder owning 20% or more of the voting stock of the corporation.
  - a. Has the applicant habitually indulged in the illegal use of narcotics, stimulants, or depressant drugs; or habitually indulged in intoxicating liquors in a manner that could cause conduct endangering public health?  Yes  No
  - b. Has the applicant ever made application for a license to operate a pharmacy, drug manufacturing or wholesaling firm in this state or any other state?  Yes  No
    - (1) If yes, was the application denied by the Board of Pharmacy?  Yes  No
    - (2) If denied, for what reason? \_\_\_\_\_
    - (3) If the license was granted, was it later suspended, revoked, or placed on probation?  Yes  No
    - (4) Did the Board, in connection with violations, issue any warnings or reprimands?  Yes  No
    - (5) If yes, what was the nature of the violation? \_\_\_\_\_
  - c. Has the applicant had any products of its manufacture seized or recalled within the last two years because of FDA violations?  Yes  No If yes, specify: \_\_\_\_\_
  - d. List dosage forms the applicant proposes to manufacture. \_\_\_\_\_

- e. List dosage forms the applicant proposes to re-label. \_\_\_\_\_
- f. List dosage forms the applicant proposes to repackage. \_\_\_\_\_
- g. Has the applicant been convicted of theft of drugs or the unauthorized use, possession, or sale thereof  
 Yes     No
- h. Has the applicant been convicted in any court of a felony?     Yes     No

10. Federal Tax ID \_\_\_\_\_ If MN Resident, MN Tax ID \_\_\_\_\_

**11. MANUFACTURER LOCATED IN THE STATE OF MINNESOTA MUST COMPLETE THE FOLLOWING:**

1981 Laws, Chapter 346 requires that you supply us with information concerning your worker's compensation insurance, for this firm, prior to the issuance of the license. Please check the applicable box below:

- Self-insured, please attach a copy of the Certificate of Exemption from the Insurance Commissioner.
- I DO NOT employ anyone.
- I HAVE paid or otherwise compensated employees, therefore, I am furnishing the following information:

Insurance Company Name: \_\_\_\_\_  
 Street Address: \_\_\_\_\_  
 City, State, Zip Code: \_\_\_\_\_  
 Insurance Policy Number: \_\_\_\_\_ Date it Expires: \_\_\_\_\_

**12. ALL MANUFACTURERS LOCATED OUTSIDE THE BOUNDARIES OF THE STATE OF MINNESOTA:**

Please attach a copy of your current license from the state in which your facility is located and the most recent inspection report from that state or a letter explaining that your state does not require either licensure or inspections.

**13. THIS SECTION TO BE FILLED IN BY ALL FACILITIES:**

List the name, address, and phone number of a contact person at the facility:

Name \_\_\_\_\_ Phone Number: \_\_\_\_\_  
 Address: \_\_\_\_\_

**14. Please list address to which renewal application should be mailed, if different from the location listed in #1.**

Name: \_\_\_\_\_  
 Street Address: \_\_\_\_\_  
 City, State, Zip: \_\_\_\_\_

**15. The data you supply on this form will be used to assess your qualifications for licensure.** You are not legally required to provide this data, but we will not be able to grant the license without it. This data will constitute a public record, if and when the licensure is granted, and, at that time, copies may be issued to anyone.

I have read the above statement and I agree to supply the data on this form with full knowledge of the information provided in that statement. In addition, I, the undersigned, do hereby certify that all of the information contained in this application is true and correct and that the firm will be operated in compliance with all applicable laws and regulations.

**Name of applicant** – Please type or print      **Signature** of Owner, Partner or Administrative Officer      **Date**

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