

**Licence No.: 1364 RRRRR**  
**Licence Issued: May 9, 1990**

**Licence Revised: July 12, 1993**  
**October 30, 1995**  
**June 5, 1998**  
**March 9, 2000**  
**June 19, 2003**

**IN ACCORDANCE WITH THE ENVIRONMENT ACT (C.C.S.M. c. E125)**  
**THIS LICENCE IS ISSUED PURSUANT TO SECTIONS 10(1) AND 14(2) TO:**

**BIOVAIL CORPORATION INTERNATIONAL: "the Licencee"**

for the operation of the Development being a pharmaceutical manufacturing facility, including all related activities, located at the junction of Hespeler Street North and Provincial Trunk Highway No. 52 East in the City of Steinbach in accordance with a proposal received on April 27, 1999, and the Notice of Alteration dated April 8, 2002, and subject to the following specifications, limits, terms and conditions:

**DEFINITIONS**

In this Licence,

**"accredited laboratory"** means an analytical facility accredited by the Standard Council of Canada (SCC), or accredited by another accrediting agency recognized by Manitoba Conservation to be equivalent to the SCC, or be able to demonstrate, upon request, that it has the quality assurance/quality control (QA/QC) procedures in place equivalent to accreditation based on the international standard ISO/IEC 17025, or otherwise approved by the Director;

**"affected area"** means a geographical area, excluding the property of the Development;

**"development scale equipment"** means equipment used in the development of pharmaceutical products and includes:

- a. portable tablet coaters with a drum diameter of 36 inches or less;
- b. fluid bed granulator/coater/dryer units identified as Niro MP 4/5 and Niro MP 4 located in rooms 330 and 955 at the Development, or units serving the same function with smaller granulating/coating/drying capacity; and
- c. portable Skerman Pan coaters or equivalents;

**"noise nuisance"** means a continuous or repeated noise in an affected area, which is offensive, obnoxious, troublesome, annoying, unpleasant or disagreeable to a person:

- a. residing in an affected area;
- b. working in an affected area; or
- c. present at a location in an affected area which is normally open to the members of the public;

if the noise

- d. is the subject of at least 5 written complaints, received by the Director in a form satisfactory to the Director, and within a 90 day period, from 5 different persons falling within clauses a), b), or c), who do not live in the same household; or
- e. is the subject of at least one written complaint, received by the Director in a form satisfactory to the Director, from a person falling within clauses a), b), or c), and the Director is of the opinion that if the unwanted sound had occurred in a more densely populated area there would have been at least 5 written complaints received within a 90 day period from 5 different persons who do not live in the same household;

**"odour nuisance"** means a continuous or repeated odour, smell or aroma, in an affected area, which is offensive,

obnoxious, troublesome, annoying, unpleasant, or disagreeable to a person:

- a. residing in an affected area;
- b. working in an affected area; or
- c. present at a location in an affected area which is normally open to the members of the public;

if the odour, smell or aroma

- d. is the subject of at least 5 written complaints, received by the Director in a form satisfactory to the Director, and within a 90 day period, from 5 different persons falling within clauses a), b), or c), who do not live in the same household; or
- e. is the subject of at least one written complaint, received by the Director in a form satisfactory to the Director, from a person falling within clauses a), b), or c), and the Director is of the opinion that if the unwanted odour, smell or aroma had occurred in a more densely populated area there would have been at least 5 written complaints received within a 90 day period from 5 different persons who do not live in the same household;

**"opacity"** means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background;

**"particulate matter"** means any finely divided liquid or solid matter other than water droplets;

**"particulate residue"** means that part or portion of an atmospheric emission which is deposited onto a surface;

**"point source"** means any point of emission from a Development where pollutants are emitted to the atmosphere by means of a stack; and

**"stack"** means a duct, pipe, chimney, vent, opening, or other structure through which pollutants are emitted to the atmosphere.

### **GENERAL TERMS AND CONDITIONS**

This Section of the Licence contains requirements intended to provide guidance to the Licencee in implementing practices to ensure that the environment is maintained in such a manner as to sustain a high quality of life, including social and economic development, recreation and leisure for present and future Manitobans.

1. The Licencee shall implement a high standard of equipment maintenance and good housekeeping and operational practices with respect to the Development, at all times.
2. The Licencee shall reduce the production and dissemination of wastes by initiating and maintaining waste reduction and waste recycling programs.
3. The Licencee shall, upon the request of the Director and in addition to any of the limits, terms or conditions specified in this Licence:
  - a. sample, monitor, analyze and/or investigate specific areas of concern regarding any segment, component or aspect of pollutant storage, containment, treatment, handling, disposal or emission systems, for such pollutants or ambient quality, aquatic toxicity, leachate characteristics and discharge or emission rates, for such duration and at such frequencies as may be specified;
  - b. determine the environmental impact associated with the release of any pollutants from the said Development; or
  - c. provide the Director, within such time as may be specified, with such reports, drawings, specifications, analytical data, descriptions of sampling and analytical procedures being used, bioassay data, flow rate measurements and such other information as may from time to time be requested.

4. The Licencee shall, unless otherwise specified in this Licence:
  - a. carry out all sampling of, and preservation and analyses on, water, soil or air samples in accordance with methodologies approved by the Director;
  - b. ensure that all analytical determinations are undertaken by an accredited laboratory; and
  - c. report the results to the Director within 60 days of the samples being taken.
5. The Licencee shall provide to the Director, upon request, all information required under this Licence, in writing and in such form and content (including number of copies), as may be specified by the Director.
6. The Licencee shall notify the Director of an intended alteration of process, which may effect in any manner a waste discharge or emission, prior to implementing such alteration.

### **SPECIFICATIONS, LIMITS, TERMS AND CONDITIONS**

#### **Respecting Air Emissions**

7. The Licencee shall not emit from the Development:
  - a. particulate matter in any air emission that:
    - i. exceeds 0.23 grams per dry standard cubic metre calculated at 25 degrees Celsius and 760 millimetres of mercury, corrected to 12 percent carbon dioxide for processes involving combustion, from any point source of the Development;
    - ii. exhibits a visible plume with an opacity of greater than 5 percent at any point beyond the property line of the Development; or
    - iii. results in the deposition of visible particulate residue at any time beyond the property line of the Development; or
  - b. particulate matter from any point source with an opacity that equals or exceeds:
    - i. 20 percent as the average of any 24 consecutive opacity observations taken at 15 second intervals;
    - ii. 20 percent for more than 16 individual opacity observations within any 1 hour period; or
    - iii. 40 percent for any individual opacity observation.
8. The Licencee shall not cause or permit a noise nuisance to be created as a result of the operation or alteration of the Development, and shall take such steps as the Director may require to eliminate or mitigate a noise nuisance.
9. The Licencee shall not cause or permit an odour nuisance to be created as a result of the operation or alteration of the Development, and shall take such steps as the Director may require to eliminate or mitigate an odour nuisance.

#### **Respecting Air Emission Management**

10. The Licencee shall not operate any process equipment, excepting development scale equipment, which uses a chemical listed in Clause 16 of this Licence unless:
  - a. there is emission collection equipment specifically designed to collect all emissions from the process equipment and said collection equipment is fully operational and in service at the time of operation of the process; and
  - b. the collected emissions are directed to a fully operational air pollution control device which is in service and is suitable for the treatment or removal of potential pollutants of concern.
11. The Licencee shall configure, maintain and operate the emission collection equipment and the air pollution

control device as proposed in the proposal dated April 27, 1999, and subsequent updates, to the manufacturers specifications.

12. The Licencee, unless otherwise approved by the Director, shall not operate any process equipment, excepting development scale equipment, between January 1 and December 31 of any year with the emissions bypassing the air pollution control device, for greater than forty eight (48) hours.
13. The Licencee shall maintain a daily record of mass balance of untreated emissions from the Development, for those compounds listed in Clause 16 of this Licence, and if this daily mass balance indicates that the cumulative untreated emissions between January 1 and December 31 of any year are in danger of exceeding 4500 kilograms, shall immediately notify the Director in writing or by facsimile.
14. The Licencee, where the conditions of Clause 12 of this Licence are exceeded and excepting development scale equipment, shall:
  - a. cease the process as soon as is possible; and
  - b. discontinue any further processing until the air pollution control device is fully operational and in service.

### **Respecting Monitoring, Recordkeeping and Notification**

15. The Licencee shall conduct monitoring and perform analyses of emissions to air and to the sanitary sewer for parameters and in the time frame that may be specified by the Director.
16. The Licencee shall maintain a monthly inventory log book of the quantities of the following chemicals used at the Development:
  - a. methanol;
  - b. isopropanol;
  - c. ethyl alcohol; and
  - d. denatured ethanol.
17. The Licencee shall maintain the inventory log book required pursuant to Clause 16 of this Licence such that the monthly quantities of the latest 24 months of records are made available for inspection by an Environment Officer, and shall supply a copy of any part or portion of the inventory log book to the Director upon request.
18. The Licencee shall:
  - a. notify the Director of any chemicals proposed to be used in the operation and not listed in Clause 16 of this Licence; and
  - b. receive approval from the Director prior to using the new chemical.
19. The Licencee shall maintain a log book of all maintenance activities and down time of the air pollution control device. The log book shall be available upon request for inspection and shall contain, at minimum, the following:
  - a. date/time of log entry;
  - b. nature of maintenance / event;
  - c. time and duration of maintenance / event;
  - d. if there is down time which coincides with processing activity, the accumulated downtime for the 7day/calendar month/year period as applicable; and
  - e. signature of responsible employee.
20. The Licencee shall notify the Director, by facsimile or other acceptable means, within one working day of any shutdown of the air pollution control device where the processing was continued. Such notification shall include

the actual time of the processing where the emissions were not treated by the air pollution control device; the reason for the shutdown of the air pollution control device; and the corrective measures and other actions taken.

**Respecting Disposal of Process Wastes**

21. The Licencee shall dispose of any chemicals and other waste pharmaceutical product not reused in the plant operation in a manner acceptable to the Director.

**REVIEW AND REVOCATION**

- A. Environment Act Licence No. 1364 RRRR is hereby rescinded.
- B. If in the opinion of the Director the Licencee has exceeded or is exceeding the specifications, limits, terms or conditions set out herein, the Director may revoke, temporarily or permanently, this Licence.

"original signed by"  
**Larry Strachan, P. Eng.**  
**Director**  
**Environment Act**

**Client File No: 3128.00**