Saskatchewan Association of Naturopathic Practitioners
Policies and Procedures

In-Office Preparation and Compounding of Naturopathic Medicines – *Adopted April 5, 2009*

The Saskatchewan Association of Naturopathic Practitioners (SANP) has established the following policy for the safe storage, handling and preparation or compounding of bulk and finished medicines in order to protect the health and safety of the patient, the naturopathic doctor and his/her personnel.

Definition: For the purpose of this policy, preparation and compounding pertain only to medicines that a naturopathic doctor may legally prepare in-office for the treatment of his/her patients.
Compounding means the mixing together of two or more ingredients.
Bulk product includes but is not limited to: tinctures (herbal, homeopathic), herbal powders or loose herbs, fluid/solid extracts, creams, salves, ointments.
Finished products include but are not limited to nutritional supplements (vitamins, minerals, concentrated foods, oils etc.), herbal medicines, homeopathic medicines, lotions, salves etc., that are normally for resale. Registrants may choose to repackage these products to provide patients with samples, or to provide the specific amount required by the patient.
Manufacturer means a company or person who produces or processes a natural health product for the purpose of sale, but does not include a healthcare practitioner who, at the request of a patient, compounds a medicine for the purpose of sale to that patient. This policy does not apply to manufacturers of natural health products who are subject to federal guidelines.
Refer to www.healthcanada.ca/nhpd

Intent: To assist Registrants in developing, achieving and maintaining minimum standards for the preparation and compounding of medicines in naturopathic practice.

Precaution: Prior to the preparation of any medicine, the Registrant shall ensure that the patient has no known allergic/adverse reaction(s) to any of the ingredients.

Suppliers: Registrants are expected to ensure that products they dispense are of good quality and are produced by reputable manufacturers.

Compounding Area: The area in which a medicine is prepared shall be designed, constructed and maintained in a manner that:

a. permits the operations to be performed under sanitary and orderly conditions;
b. permits effective cleaning of all relevant surfaces to prevent contamination of the medicine.

Clean Work Field:
Compounding of medicines should ideally be performed in a location that is separate from any lab testing materials or samples. Areas used for multiple purposes must be properly cleaned before and after the preparation of a medicine.

Tools and Receptacles:

The tools and receptacles with which a medicine is prepared shall be designed, constructed, maintained, arranged, and used in a manner that:

a. permits the effective cleaning of all relevant surfaces;
b. prevents contamination of the medicine;
c. permits them to function in accordance with their intended use.

Any equipment (e.g. graduated cylinder, pipette, funnel, measuring cup, etc.) used in transferring or preparing the medicine should be cleaned with a sanitizing agent prior to the preparation, or should be a single-use, disposable piece of equipment.

Packaging:
All packaging used for medicines must be PVC-free, food grade, and stored in such a way as to avoid contamination.

Storage:
All medicines must be stored in a controlled-access area and in such a way as to avoid contamination.

Personnel:
Every medicine shall be prepared by personnel who have had the training necessary to prepare the medicine safely, having regard to the duties and responsibilities involved.

Every person who prepares a medicine shall follow written sanitation guidelines that shall be clearly posted for all personnel working in the area and shall include:

- *cleaning procedures for the area where the medicine is prepared and for the tools and receptacles used in the preparation of the medicine*
- *instructions for the sanitary compounding of medicines and the handling of materials used in their preparation*
- *minimum requirements of health, hygienic behaviour and appropriate clothing for personnel*

No person who is infected with or is a carrier of a disease in a communicable form, or who has an uncovered, open lesion on any exposed surface of the body, shall have access to any area where a medicine is being prepared during any stage of its preparation.

Every person who prepares a medicine shall have written instructions for proper hygiene and cleaning of tools and materials for preparing the medicine (see appendix A for sample guidelines). Hygienic handling includes:

- *Washing hands with sanitizing agent and wearing disposable gloves (optional) before any medicine is prepared*
- *Clean work field – cleaned with a sanitizing agent before preparation.*

Quality Assurance:
Every person in whose office medicines are prepared shall maintain:

a. a program of self-inspection, designed to ensure that any medicine prepared on the premises is prepared in accordance with the requirements of this policy (see appendix B for sample self-inspection program);
b. a system whereby no medicine shall be made available for sale unless the sale is to a patient and is approved by the Registrant.

c. a system whereby no medicine shall be made available for sale unless the expiry date on the package is at least 1 month past the date on which the patient is expected to be finished taking the medicine. No expired medicines shall be made available for sale.

Record Keeping:

a. Every Registrant shall maintain a log book (see Appendix C for sample log book) containing a record of the distribution of each medicine compounded that enables the Registrant to recall any compounded medicine from patients. These records shall be retained for a period of at least one year.
b. Every Registrant shall maintain records of regular self-inspection and any action taken in connection with that program, and retain those records for a period of at least one year.
c. Where a complaint respecting the quality of a medicine is received the complaint must be forwarded to the supplier's Quality Assurance personnel. A record of the complaint and of the investigation of the
d. complaint shall be retained by the Registrant for a period of at least one year and a copy placed in the patient's file

Labeling:

Please refer to the Board's policy on ***Dispensing of Medicines and Devices*** for information on labeling.

APPENDIX A

Example of Written Guidelines
For Personnel

1. No person who is infected with or is the carrier of a disease in a communicable form shall have access to the area where medicine is being prepared.
2. Confirm that patient has no known allergic or adverse reaction to ingredients.
3. Cover any open lesion on any exposed surface of the body.
4. Ensure area is clear of possible contaminants, e.g. body fluid samples.
5. Wash hands with warm soapy water or hand sanitizer.
6. Wear disposable, non-latex, talc-free gloves (optional)
7. Wear clean lab coat (optional).
8. Clean work field with sanitizing agent (name your preferred product here).
9. Check receptacles for damage (cracks/chips) and only use items that are in good condition.
10. Wash receptacles in clean, soapy water or sanitizing agent (or use single-use, disposable receptacles).
11. Inspect tools and materials and arrange in an orderly fashion for effective and efficient compounding.
12. Check expiry date on products to be compounded.
13. When finished compounding, clean and sanitize all tools and receptacles and restore to shelf (storage area).
14. Clean and sanitize work field.
15. Record patient's name, medications and date in log book.

APPENDIX B
Example of Self-Inspection Record

Set aside a regular time and day of the week or month for consistent self-inspection, e.g. Monday morning 9:30 – 10:00 am or the first Monday of every month

1. Check storage space to ensure all receptacles, tools, medicines, packaging are safely stored away from possible contaminants. Date _____ Initial _____
2. Inspect receptacles for chips, cracks, damage. Discard and replace as necessary.

Name of item replaced _____ Date _____ Initial _____

3. Check disposable glove supply. Date _____ Initial _____
4. Check sanitizer supply. Date _____ Initial _____
5. Check medicine supplies and expiry dates. Date _____ Initial _____
6. Check packaging for supply and possible contaminants. Date _____ Initial _____
7. Check labeling supplies. Date _____ Initial _____
8. Check log book entries for completeness.
9. Post or file completed self-inspection record in an appropriate location.

APPENDIX C
Example Log Book

DATE	PATIENT'S NAME	MEDICINES COMPOUNDED	EXPIRY DATES	LOT #
		1. 2. 3.	1. 2. 3.	1. 2. 3.
		1. 2. 3.	1. 2. 3.	1. 2. 3.
(etc.)				