Health Canada Santé Canada

EVIDENCE FOR HOMEOPATHIC MEDICINES

NATURAL HEALTH PRODUCTS DIRECTORATE

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Canada

“Our mission is to help the people of Canada maintain and improve their health, while respecting individual choices and circumstances.”

Health Canada

“Our role is to ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.”

Natural Health Products Directorate

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Contact the Natural Health Products Directorate

Natural Health Products Directorate
Health Canada
2936 Baseline Rd., Tower A
Ottawa, Ontario
K1A 0K9

www.healthcanada.gc.ca/nhp

Telephone: 1-888-774-5555
Fax: (613) 948-6810
Email: NHPD_DPSN@hc-sc.gc.ca

ABOUT THIS GUIDANCE DOCUMENT

The *Natural Health Products Regulations* (the Regulations) require all homeopathic medicines to have a licence before being sold in Canada. Licence holders are issued a product number which must appear on the label of their product. The product number for homeopathic medicines is preceded by DIN-HM. To obtain a DIN-HM, a Product Licence Application (PLA) form must be completed by applicants. These applications are assessed by the Natural Health Products Directorate (NHPD), which is responsible for issuing product licences for all natural health products (NHPs). The NHPD uses evidence submitted by applicants to critically assess the safety, efficacy and quality of NHPs prior to approving them for sale in Canada.

The legal requirements for NHPs in Canada are found in the Regulations. This guide is based on the Regulations and is intended to be used as a tool when applying for a product number (DIN-HM) for a homeopathic medicine. The NHPD reserves the right to request information, material or changes related to a Product Licence Application (PLA) that may not be indicated in this guide.

To complete a PLA form, applicants will need to consult this document as well as the *Product Licensing Guidance Document* and the *Guide for Completing the Product Licence Application Form*, which is attached to the PLA form. The *Guide for Completing the Product Licence Application Form* provides line-by-line instructions for filling out all types of PLA forms whereas this guide outlines areas of the PLA form which are specific to homeopathic medicines. A copy of the PLA form can be found at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html. Applicants may also need to consult the document entitled *Evidence for the Safety and Efficacy of Finished Natural Health Products* and the *Labelling Guidance Document*.

The information in this document applies to all applications submitted for a homeopathic medicine product licence, including those that already have a DIN issued by Health Canada.

In addition to a product licence, all businesses in Canada which manufacture, package, label and/or import homeopathic medicines for sale must also have a site licence as of January 1, 2006. To apply for a site licence, applicants must submit a complete submission package including the site licence application form to NHPD for assessment. For more information, please see .

This guide should be read in parallel with the *Natural Health Product Regulations*, which came into effect on January 1, 2004. An electronic version of the Regulations is available on the Internet at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/prodnatur/index_e.html. This guide refers to other NHPD documents found on the Internet at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index_e.html. Definitions of terms used in the guide are provided in the Glossary.

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1.0 GENERAL INFORMATION

1.1 Definition of a Homeopathic Medicine

To be considered a homeopathic medicine, a product must meet two criteria. It must be:

1) Manufactured from, or contain as medicinal ingredients, only substances referenced in a homeopathic monograph in one of the following homeopathic pharmacopoeias, as they are amended from time to time:

   - *Homeopathic Pharmacopeia of the United States* (HPUS)
   - *Homöopathisches ArzneiBuch* (HAB) or *German Homeopathic Pharmacopoeia* (GHP)
   - *Pharmacopée française* or *French Pharmacopoeia* (PhF)
   - *European Pharmacopoeia* (Ph.Eur.)
   - *Encyclopedia of Homeopathic Pharmacopoeia* (EHP)

2) Prepared in accordance with the methods outlined in one of the homeopathic pharmacopoeias listed above, as they are amended from time to time.

1.1.1 Homeopathic Medicines Eligible for a DIN-HM

Provided the medicinal ingredients are found in one of the aforementioned pharmacopoeias and are not prohibited in the Regulations, homeopathic medicines manufactured from the following are eligible for a licence:

- Substances listed on Schedule D of the *Food and Drugs Act* (Biologics, see **Appendix 5**).
- Substances exempted from the *Tobacco Act* because they are subject to the *Food and Drugs Act*, such as homeopathic *tabacum* and *nicotinum* (see **Appendix 5**).
- Substances listed on Schedule F of the *Food and Drug Regulations* (Prescription Drugs, see **Appendix 5**).
- Any substance derived from an animal material. If animal material is contained in the product or was used in the manufacturing of the product, the application must include a completed Animal Tissue Form for each animal material. This form can found at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html.
- Substances used to manufacture nosodes, isodes, sarcodes, and allersodes.

1.1.2 Homeopathic Medicines Eligible for a DIN-HM Above a Specific Homeopathic Potency

Due to the potential toxicity of certain medicinal ingredients, some homeopathic medicines will only be authorized for sale if they meet a minimum homeopathic potency established by the NHPD.

- *Aristolochia spp*. and *Asarum spp.* must be potentized to 12 CH (or equivalent dilution) or higher. Note that *Cocculus indicus*, *Clematis recta* and *Menispermum canadense* are not affected by any restrictions related to *Aristolochia spp*. and *Asarum spp*.

- Substances on the restricted and/or prohibited substance list in the *Natural Health Products Compliance Guide.* As a general rule, NHPD will consider applications for products made from these substances only if the homeopathic potency is 12 CH (or equivalent dilution) or higher.
- Homeopathic medicines listed in the HPUS with "N/A" as the OTC limit must be 12 CH (or equivalent dilution) or higher.
- Homeopathic medicines with no minimum homeopathic potency in any accepted homeopathic pharmacopoeia must be 12 CH (or equivalent dilution) or higher.

For the above substances, homeopathic potencies below 12 CH will be considered if sufficient evidence is provided to demonstrate that any risk is mitigated at lower homeopathic potencies.

1.1.3 Homeopathic Medicines Not Eligible for a DIN-HM

The Regulations do not apply to homeopathic medicines manufactured from substances on the following lists:

- Schedules I to V of the *Controlled Drugs and Substances Act*
- Schedule C of the *Food and Drugs Act* (Radiopharmaceuticals)

See **Appendix 6** for these schedules and lists.

Homeopathic medicines intended for injectable use are also excluded from the *Natural Health Products Regulations.*

Products containing medicinal ingredients not found in any of the five accepted pharmacopeia are not eligible for a DIN-HM. Applicants may apply for a Natural Product Number (NPN) for these products, in which case the evidence requirements outlined in the *Safety and Efficacy* guidance document must be met.

1.1.4 Combination Homeopathic Medicines

A combination (multiple-ingredient) homeopathic medicine is defined as a homeopathic medicine manufactured from two or more medicinal ingredients. While homeopathic medicines with a single medicinal ingredient are not permitted to make any claim other than "Homeopathic Medicine," "Homeopathic Remedy," "Homeopathic Preparation" or "Homeopathic Drug," combination homeopathic medicines may make specific claims if supported by homeopathic references.

In combination homeopathic medicines with a specific recommended use or purpose (see **chapter 8** for an explanation of specific recommended use or purpose), the homeopathic potency of all medicinal ingredients must generally be between the minimum homeopathic potency outlined in the most current editions of the accepted homeopathic pharmacopoeia and 30 CH or its equivalent. That is, 30 CH or its equivalent is the maximum homeopathic potency for homeopathic medicines with a specific recommended use or purpose.

An applicant may submit a Product Licence Application for a homeopathic medicine above 30 CH with a specific recommended use or purpose, if evidence is provided to support the safety of the proposed homeopathic potency. The NHPD will evaluate these on a case-by-case basis.

Products containing a combination of homeopathic and non-homeopathic medicinal ingredients will not be evaluated as homeopathic medicines. Instead, they will be evaluated as NHPs eligible for a Natural Product Number (NPN).

1.2 Information Required for all Natural Health Products

The following Recommended Conditions of Use, as defined in the Regulations, must appear on the label of all homeopathic medicines. They provide the necessary information to enable consumers to make an informed choice regarding a NHP. They include the product's:

- recommended use or purpose;
- dosage form;
- recommended route of administration;
- recommended dose;
- recommended duration of use, if any; and
- risk information, including cautions, warnings, contra-indications or known adverse reactions associated with its use

Please refer to **chapter 7.4.1** for an explanation of each of these elements. Evidence to support each of the Recommended Conditions of Use must be provided by the applicant with their completed Product Licence Application form.

1.3 Evidence to Support the Use of Homeopathic Medicines

Applicants are responsible for submitting evidence to support the safety, efficacy and quality of a homeopathic medicine, as per Section 5(g) of the Regulations. The evidence submitted must support the proposed Recommended Conditions of Use (see **chapter 1.2**) of the homeopathic medicine.

There are two categories of homeopathic medicines:

- homeopathic medicines that state a specific recommended use or purpose, and
- homeopathic medicines that do not state a specific recommended use or purpose (see **chapter 7.4.1** for a definition of each category).

The evidence required will vary depending on which category the homeopathic medicine falls into (specific or non-specific recommended use or purpose) as outlined in **chapter 8**. Information supporting the recommended conditions of use must be provided by referencing evidence such as clinical trials and/or published homeopathic references. See **Appendix 1** for a list of sample references.

For homeopathic medicines that already have a DIN (i.e. transitional DIN applications), further evidence to support the safety and efficacy of the product is not necessary as long as the product has not changed in any way from what was previously approved by Health Canada. Evidence may need to be provided, however, to support the safety of the product's non-medicinal ingredients. Please see **chapter 3** for the submission requirements for transitional DIN applications.

1.4 Safety of Homeopathic Medicines

Homeopathic medicines that state a specific recommended use or purpose must be suitable for self care and not require the supervision of a health care practitioner. Homeopathic medicines that do not state a recommended use or purpose are considered to have a non-specific recommended use or purpose. These medicines are generally used for self-care by consumers who have knowledge of homeopathic medicines. However, they may still state a direction of use to the effect of, "To be used as directed by a health care practitioner."

The term "self-care" refers to the activities individuals undertake for the prevention, treatment, and symptomatic relief of diseases, injuries or chronic conditions that individuals can recognize and manage on their own behalf, either independently or with participation from a health care practitioner. This includes the use of NHPs that are safe, effective and of high quality.

2.0 SUBMISSION REQUIREMENTS FOR HOMEOPATHIC MEDICINES

Listed below are the items and/or information that must be included in all homeopathic medicine submissions to the NHPD which do not currently hold a DIN.

- Cover letter describing the type of application being submitted and contents of the submission package (see **chapter 5**).
- Completed Product Licence Application form. Product Licence Application forms may be found at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html. Samples of completed Product Licence Application forms may be found in **Appendix 2** and **Appendix 3**.
- For each medicinal ingredient, a photocopy of the monograph from the pharmacopoeia to which the applicant attests (see **chapter 7.1**, Standard or Grade).
- For homeopathic medicines with a specific use or purpose, photocopied and underlined evidence from at least one homeopathic reference to support the recommended use or purpose of each medicinal ingredient (see **chapter 7.4.1** for an explanation of a specific recommended use or purpose). Product Licence Applications for homeopathic medicines with a non-specific use or purpose do not need to be accompanied by evidence supporting their use.
- Evidence to support the safety of non-medicinal ingredients. This is only required when a non-medicinal ingredient is not listed on the NHPD's List of Accepted Non-Medicinal Ingredients (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/nmi-imn_list1_e.html). For the NHPD definition of a non-medicinal ingredient, please refer to the chapters on non-medicinal ingredients and combination products in the document *Evidence for the Safety and Efficacy of Finished Natural Health Products* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html).
- Quality Summary Report (see **chapter 9**).
- Proposed label text (see **chapter 10**).
- A separate Animal Tissue Form for each animal material contained in the product or used in the manufacturing of the product. (See **Appendix 4** for a sample of a completed animal tissue form.) Animal Tissue Forms may be found at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html

3.0 SUBMISSION REQUIREMENTS FOR TRANSITIONAL DIN APPLICATIONS

Transitional DIN products are those which were issued a DIN (Drug Identification Number) by the Therapeutic Products Directorate under the *Food and Drug Regulations* before the *Natural Health Products Regulations* came into effect. Because Health Canada has already assessed and approved the safety and efficacy of these products under the *Food and Drug Regulations*, applicants are not required to submit evidence to support the safety and efficacy of these homeopathic medicines.

Listed below are the items and/or information that must be included in a transitional DIN homeopathic medicine application for assessment by the NHPD.

- Cover letter describing the type of application being submitted and contents of the submission package (see **chapter 5**).
- Completed Product Licence Application form. Product Licence Application forms can be found at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html. Samples of completed Product Licence Application forms are in **Appendix 2** and **Appendix 3**.
- Evidence to support the use of non-medicinal ingredients. This is only required when a non-medicinal ingredient is not listed on the NHPD's list of Accepted Non-Medicinal Ingredients (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/nmi-imn_list1_e.html). For the NHPD definition of a non-medicinal ingredient, please refer to the chapters on non-medicinal ingredients and combination products in the document *Evidence for the Safety and Efficacy of Finished Natural Health Products* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html).
- Quality Summary Report (see **chapter 9**)
- Proposed label text (see **chapter 10**)
- A separate Animal Tissue Form for each animal material contained in the product or used in the manufacturing of the product. (See **Appendix 4** for a sample of a completed animal tissue form.) Animal Tissue Forms may be found at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html

4.0 PART 1 OF THE PRODUCT LICENCE APPLICATION FORM – APPLICANT AND CONTACT INFORMATION

For information on completing this chapter of the product licence application form, please consult the *Guide for Completing the Product Licence Application Form*.

5.0 PART 2 OF THE PRODUCT LICENCE APPLICATION FORM – SUBMISSION TYPE

Section A – Product Licence Application

For homeopathic medicines that do not already have a Drug Identification Number (DIN), check the box entitled Homeopathic.

For homeopathic medicines that currently hold a valid Drug Identification Number (DIN), check the box Homeopathic DIN. As well, the DIN must be written in the space provided.

When changes (i.e. an amendment or a notification) are made to a product that currently holds a DIN-HM, enter the DIN-HM in the space provided.

Section B – Monograph Revisions Affecting an Existing Product Licence

Not applicable to homeopathic medicines.

Sections C and D – Product Licence Amendment and Notification

For information on completing this section of the product licence application form, please consult the *Product Licensing Guidance Document*.

Section E – Submission Content

List the supporting documents included with the submission package. For homeopathic medicines, please also check “other” and indicate in the space next to it the monographs being submitted with the application; for example, HAB monographs.

See **chapters 2.0** and **3.0** for the submission requirements for homeopathic medicines and transitional-DIN homeopathic medicines.

Section F – Reference Submission

For information on completing this section of the product licence application form, please consult the *Guide for Completing the Product Licence Application Form.*

Section G – NHPD Master File

Not applicable to homeopathic medicines.

6.0 PART 3 OF THE PRODUCT LICENCE APPLICATION FORM – SITE INFORMATION

As per Section 22 of the Regulations, the following information relates to sites involved in the manufacturing, packaging, labelling and/or importing of homeopathic products.

6.1 General Information Pertaining to Site Licensing

As of January 1, 2006, every Canadian manufacturer, packager, labeller or importer of NHPs (including homeopathic medicines) is required to have a valid site licence number prior to the product being made available for sale in Canada.

Note that distributors who distribute products from a manufacturer, packager, labeller and/or importer that is authorized by a site licence to conduct the activity, do not require a site licence but are recommended to follow Good Manufacturing Practices themselves.

To apply for a site licence, applicants must provide a complete Site Licence Application to NHPD for assessment. The following documents must be submitted with the Site Licence Application form: Quality Assurance Report, Supplementary Quality Assurance Report (for homeopathic medicines), and Quality Assurance Person's Qualifications.

For further information on the site licensing process, please refer to the *Site Licence Guidance Document* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/slgd-drle_e.html). The *Site Licence Guidance Document* is intended for manufacturers, packagers and/or labellers of NHPs within and outside of Canada, and for Canadian importers of NHPs for sale in Canada.

6.2 Product Licence Application Instructions – Site Information

For information on completing this section of the product licence application form, please consult the *Guide for Completing the Product Licence Application Form.*

For Transitional DIN homeopathic medicines that are presently on the market, the licensee must provide the relevant site information within 30 days of the DIN-HM being issued.

7.0 PART 4 OF THE PRODUCT LICENCE APPLICATION FORM – PRODUCT INFORMATION

Primary Brand Name (Mandatory)

For information on completing this section of the product licence application (PLA) form, please consult the *Guide for Completing the Product Licence Application Form.*

7.1 Part 4, Section A – Medicinal Ingredients

7.1.1 Product Licence Application Form Instructions (Medicinal Ingredients)

Mandatory Information in Part 4, Section A

All fields in Section 1 are described below. However, only the following are mandatory:

- Standard or Grade (not denoted with an asterisk but mandatory for homeopathic medicines);
- Proper Name;
- Quantity (homeopathic potency);
- Synthetic;
- Animal Tissue;
- Source Information; and
- Method of Preparation (not denoted with an asterisk but mandatory for homeopathic medicines).

Standard or Grade (Mandatory)

A monograph from one of the accepted homeopathic pharmacopoeias must be referenced for each medicinal ingredient. Enter into this box the acronym for the homeopathic pharmacopoeia referenced. Please refer to the acronyms in **chapter 1.1**.

NHPD Compendial Monograph

Not applicable to homeopathic medicines. Please leave this column blank.

Proper Name (Mandatory)

For homeopathic medicines, the proper name can be the name appearing at the top of the monograph of the pharmacopoeia listed in “Standard or Grade”.

The proper name can also be determined as outlined below:

- **Plant or plant material, alga, fungus, bacterium, non-human animal material or probiotic:** the current scientific name of its genus and, if any, its specific epithet (i.e. Latin binomial) or a verified, unambiguous synonym of the scientific name.
  Example: *Allium cepa*

- **Mineral or chemical:** Any unambiguous name.
  Example: Sodium chloride
- **Vitamin:** A name set out for that vitamin in Item 3 of Schedule 1 of the Regulations.
  Example: Biotin, folate, niacin, pantothenic acid, vitamin A, thiamine, riboflavin, vitamin B_6, vitamin B_{12}, and vitamins C, D and E
- **Nosode:** The current Latin binomial of the disease-causing agent.
  Example: *Bordetella pertussis*
- **Sarcode:** The name of the tissue used.
  Example: Thyroid

Common Name

For homeopathic medicines, the common name of a medicinal ingredient can be the same as the proper name or can be any French or English name by which it is commonly known, provided it is a name listed in the accepted homeopathic pharmacopoeia being attested to.

The common name is not required on the PLA form if it is the same as the proper name, in which case the name must be printed only once on the label. If the common name is different from the proper name, both names must appear on the label.

Quantity per Dosage Unit (Homeopathic Potency) (Mandatory)

The term “quantity”, as it appears on the PLA form, refers to the amount of medicinal ingredient per dosage unit. A statement of quantity is required for all medicinal ingredients. Enter the homeopathic potency (e.g. 12 CH) in the column entitled “quantity” on the PLA form. Do not enter the homeopathic potency in the column entitled “potency”.

For homeopathic medicines containing a single medicinal ingredient, one DIN-HM may apply to more than one homeopathic potency. In these cases, only the lowest homeopathic potency need be entered on the PLA form for evaluation. The DIN-HM assigned will apply to all homeopathic potencies higher than the one approved.

If the applicant would also like to indicate an amount (in millilitres, milligrams, etc.) for a medicinal ingredient, in addition to a homeopathic potency, he/she should refer to the information under “Potency.”

Note that Hahnemanian and Korsakovian dilutions are considered interchangeable for product licensing purposes.

Minimum Homeopathic Potency

The medicinal ingredients in some homeopathic medicines are potentially toxic at material doses. The serial dilutions involved in the manufacture of a homeopathic medicine are a factor which mitigates the risk of toxicity from these medicinal ingredients. Minimum homeopathic potencies have been established in some jurisdictions to ensure that such medicinal ingredients do not exceed a safe dose.

- In the HPUS, the minimum homeopathic potency appears on each homeopathic monograph as the over-the-counter (OTC) limit
- Under German regulation, the minimum homeopathic potency for registration of homeopathic products is generally D4.

Where the medicinal ingredient appears as a monograph in both the HPUS and the HAB, and there is a discrepancy between the minimum homeopathic potencies, NHPD will accept the lowest of the two, as long as the methods of preparation are equivalent.

If no minimum homeopathic potency is provided for the medicinal ingredient in any accepted homeopathic pharmacopoeia, and there is concern about the safety of the starting material, the minimum homeopathic potency will be 12 CH (or equivalent dilution).

Applications for a product with a medicinal ingredient having a homeopathic potency below 12 CH for which there is no minimum homeopathic potency in an accepted pharmacopoeia will be evaluated on a case-by-case basis to ensure any safety concerns are addressed.

Synthetic (Mandatory)

Indicate if the source material is synthetic (e.g. chloroform). Each synthetic medicinal ingredient must comply with the quality specifications of the accepted pharmacopoeia that is referenced.

Animal Tissue (Mandatory)

Indicate if animal material was used as source material for the medicinal ingredient. For example, animal tissue was used in the preparation of *Lac caninum* because its source is the secretion of the mammary glands of a lactating dog. Since animal tissue was used, an Animal Tissue Form will need to be completed (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html).

A separate Animal Tissue Form must be submitted for **each** animal material used. (See **Appendix 4** for a sample of a completed animal tissue form.)

A copy of the Animal Tissue Form can be found at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html.

Potency

This field of the PLA form is applicable to homeopathic medicines only if a homeopathic manufacturer would also like to indicate an amount (in millilitres, milligrams, etc.) for a medicinal ingredient, in addition to a homeopathic potency. Please enter the amount (mL, mg, %, etc.) in the sub-column “amount” and repeat the homeopathic potency in the sub-column “constituent.”

For example: Potency amount: 25 mg
Potency constituent: of D3 dilution

Please note that the homeopathic potency of each ingredient must still be filled out in the "quantity" section.

Source Information (Mandatory)

The source is the substance from which the medicinal ingredient was derived. Source information is drawn from the information contained in the homeopathic monograph submitted for each medicinal ingredient.

- **Plant or Plant Material** - The source material is the part of the plant used or whole plant, if applicable, and the common name of the organism if not adequately captured in the medicinal ingredient name.
- **Animal material (excluding sarcodes)** - The source material is the part of the animal used or whole organism, if applicable, and the common name of the organism if not adequately captured in the medicinal ingredient name.
- **Mineral/Chemical** – The source material is the name of the mineral or chemical as written on the homeopathic monograph.
- **Nosode** – The source material is the description found in the homeopathic monograph submitted with the PLA form.
- **Sarcode** – The source material is the type of animal plus the part used, as described in the homeopathic monograph submitted with the PLA form.

Table 1: Examples of source material for homeopathic medicines.

Category	**Medicinal Ingredient Proper Name**	**Source Material (homeopathic pharmacopoeial definition)**
Plant or Plant Material	*Lycopodium clavatum*	(Part of the plant) spores
Animal Material (Excluding sarcodes)	*Lachesis mutus*	(Part of the animal) venom
Mineral/ Chemical	Hydrocyanicum acidum or Hydrogen cyanide	(The name of the mineral or chemical as written on the homeopathic monograph.) Hydrogen cyanide
Nosode	Medorrhinum	(Summary of the description as stated in the referenced homeopathic pharmacopoeia) Sterilized extract of purulent urethral secretions from blennorrhagia , containing *Neisseria gonorrhoeae*
Sarcode	Thyroidinum	(Animal source plus part) Bovine thyroid

Extract

Not applicable to homeopathic medicines. Please leave these columns blank.

Method of Preparation (Mandatory)

For each medicinal ingredient, indicate the acronym for the homeopathic pharmacopoeia being referenced as well as the method number/class (e.g. HAB Method 4a).

An applicant is permitted to reference a method of preparation from one homeopathic pharmacopoeia even if the medicinal ingredient does not appear in that same pharmacopoeia (e.g. HPUS medicinal ingredient that uses a HAB method of preparation). By stating the method used, the applicant is attesting that the pharmacopoeial method that is followed is appropriate for the MI being used. These applications will be evaluated on a case-by-case basis.

7.2 Part 4, Section B – Non-medicinal Ingredients

7.2.1 General information (Non-Medicinal Ingredients)

Acceptable Non-Medicinal Ingredients

Non-medicinal ingredients are any ingredients that are added to the starting material (e.g. plant, chemical, mineral) to confer suitable form and consistency and that are contained in the final product. Non-medicinal ingredients may include, but are not limited to, capsule components, diluents, binders, lubricants, disintegrators, colouring agents and flavours. All non-medicinal ingredients that appear in a homeopathic medicine must be listed on the PLA form and must meet the specifications outlined in any of the accepted homeopathic pharmacopoeia, as they are amended from time to time.

Non-medicinal ingredients not listed in one of the accepted homeopathic pharmacopoeias may be permitted if the meet the criteria outlined in the *Product Licensing Guidance Document* (chapter 4.4).

7.2.2 Product Licence Application Form Instructions (Non-Medicinal Ingredients)

Mandatory Information in Section B

All fields in Section 2 are described below. However, only the following are mandatory:

- Common Name;
- Purpose; and
- Animal Tissue Used (Note that lactose is considered an animal tissue and requires a completed Animal Tissue Form).

Note: Information to complete other fields in this section may be required if the non-medicinal ingredient is not on the NHPD List of Accepted Non-Medicinal Ingredients or is outside the specified limitations given for item on the list.

For detailed information on completing this section of the product licence application form, please consult the *Product Licensing Guidance Document* and the *Guide for Completing the Product Licence Application Form*.

7.3 Part 4, Section C – Ingredient(s) used in processing

For detailed information on completing this section of the PLA form, please consult the *Product Licensing Guidance Document* and the *Guide for Completing the Product Licence Application Form*.

7.4 Part 4, Section D – Recommended Conditions of Use

7.4.1 Product Licence Application Form Instructions – Part 4, Section D

Mandatory Information in Section D

All fields in Section 3 are described below. Only the following fields are mandatory:

- Recommended Use or Purpose;
- Dosage Form;
- Sterile;
- Route of Administration;
- Duration of Use, if any (not denoted with an asterisk on the PLA form and is only required for homeopathic medicines with a specific recommended use or purpose);
- Sub-Population Group;
- Amount to be Taken at One Time: No. of Dosage Units and Dosage Unit;
- Cautions and Warnings;
- Contraindications; and
- Known Adverse Reactions.

Recommended Use or Purpose (mandatory).

For the purpose of product licensing, homeopathic medicines will be classified into one of two categories based on the homeopathic medicine's recommended use or purpose (claim).

The two categories are:

- homeopathic medicines with a ***non-specific*** recommended use or purpose; and
- homeopathic medicines with a ***specific*** recommended use or purpose.

Homeopathic Medicines With a Non-specific Recommended Use or Purpose

No recommended use or purpose (claim) is permitted for these homeopathic medicines. The terms "Homeopathic Medicine", "Homeopathic Preparation", "Homeopathic Drug" or "Homeopathic Remedy", must appear on the label in place of any claim.

These homeopathic medicines may be single or combination homeopathic medicines (see **chapter 1.1.4**).

Any homeopathic potency is acceptable for these homeopathic medicines as long as the homeopathic potency of each medicinal ingredient is equal to or higher than the minimum homeopathic potency defined in acceptable homeopathic pharmacopoeia. Refer to **chapter 7.1.1** for more information on minimum homeopathic potency.

Table 2 describes the allowable homeopathic potencies for homeopathic medicines with non-specific claims.

Homeopathic Medicines With a Specific Recommended Use or Purpose

An applicant may propose a specific recommended use or purpose if:

- The homeopathic medicine contains two or more medicinal ingredients.
- The claim is supported by homeopathic references. For information on the evidence requirements for homeopathic medicines, please see **chapter 8**. A list of sample references may be found in **Appendix 1**.

The claim must identify a specific symptom or set of symptoms that the homeopathic medicine is intended to treat. The applicant must ensure that the claim does not include any condition listed on Schedule A of the *Food and Drugs Act*. (http://laws.justice.gc.ca/en/F-27/240957.html). The claim must appear on the label using specific, current and unambiguous terms. The claim may also be followed by wording to the effect of, "…or to be used as directed by a health care practitioner".

The homeopathic potency of all medicinal ingredients in homeopathic medicines with a specific recommended use or purpose must generally be between the minimum homeopathic potency outlined in the most current editions of the accepted homeopathic pharmacopoeia and 30 CH or its equivalent. That is, 30 CH or its equivalent is the maximum homeopathic potency for homeopathic medicines with a specific recommended use or purpose.

An applicant may submit a PLA for a homeopathic medicine above 30 CH with a specific recommended use or purpose, if sufficient evidence is submitted to support the safety of the proposed homeopathic potency. The NHPD will evaluate these on a case-by-case basis.

Table 2 summarizes the allowable homeopathic potencies for homeopathic medicines with specific claims.

Table 2: Summary of Allowable Homeopathic Potencies by Category

Minimum homeopathic potency	***Non-specific* claim (Single or combination medicine)**	***Specific* claim (Combination medicine only)**
Stated in an accepted pharmacopoeia	Lower limit: as stated in the pharmacopoeia Upper limit: no upper limit	Lower limit: as stated in the pharmacopoeia Upper limit: 30 CH
NOT stated in an accepted pharmacopoeia	Lower limit: 12 CH Upper limit: no upper limit	Lower limit: 12 CH Upper limit: 30 CH

Dosage Form (Mandatory)

Acceptable dosage forms for homeopathic medicines are those outlined in the accepted homeopathic pharmacopoeia. Dosage forms include, but are not limited to:

- powder;
- granule;
- pellet/globule/pilule;
- tablet;
- solution;
- ointment/cream/lotion/gel;
- syrup; or
- suppositories.

Please note that Appendix 8 of the *Product Licensing Guidance Document* defines dosage forms.

All dosage forms must meet regulatory requirements, such as those related to quality and good manufacturing practices.

Sterile (Mandatory, where applicable)

Indicate if the homeopathic medicine will be a sterile product. Homeopathic medicines designed for ophthalmic purposes are required to be sterile. Please refer to the *Good Manufacturing Practices Guidance Document* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf_e.html) for the requirements for manufacturing and packaging of sterile products.

Route of Administration (Mandatory)

Indicate the route by which the homeopathic medicine is to be delivered.

Routes of administration for homeopathic medicines include, but are not limited to: oral, sublingual, nasal, ophthalmic and topical. The conditions of preparation for homeopathic medicines for nasal (inhalation) and ophthalmic uses shall be in accordance with the specifications outlined in the most current edition of the *Homeopathic Pharmacopeia of the United States* or the *European Pharmacopoeia*.

Homeopathic medicines marketed for injectable use (i.e. employing any route of administration requiring puncturing of the dermis) are not covered under the Regulations (as stated in Schedule 2, item 5), and will therefore not be eligible for DIN-HMs. Injectable drug products are regulated under the *Food and Drug Regulations*.

Duration of Use (Mandatory for products with a specific recommended use or purpose)

This refers to a time frame during which it is safe to consume the product without causing health concerns.

Non-specific Recommended Use or Purpose

A duration of use statement indicating a specific time frame is optional.

Specific Recommended Use or Purpose

A duration of use statement, indicating a specific time frame, is required.

Applicants are advised to establish a duration of use that is appropriate to the condition and/or symptoms stated as the recommended use or purpose. The duration of use should take into consideration the following:

- For some conditions, it is expected that symptoms improve more slowly than for other conditions (homeopathic medicines may be taken for prolonged periods).
- The persistence and/or worsening of symptoms associated with some conditions will warrant consultation with a health care practitioner.
- The development of new symptoms may warrant consultation with a health care practitioner.

Therefore, statements such as “Consult a health care practitioner if symptoms persist or worsen” or “Consult a health care practitioner if symptoms do not improve within 7 days” would be acceptable for the Duration of Use.

Recommended Dose

The information below regarding recommended dose applies to all homeopathic medicines, irrespective of the recommended use or purpose.

Sub-population Group (Mandatory)

Enter the group to which the homeopathic medicine is targeted. Most often, this will be “adults”, but may also be “children”, “infants”, “seniors”, “men” or “women.” If the homeopathic medicine is targeted to children or infants, the age group(s) must be indicated as well. The following age categories are recommended in most cases: infants 1-11 months; children 1-5 years; children 6-11 years; adults and children 12 and over.

Amount to be Taken at One Time (Mandatory)

No. of Dosage Units: Indicate the amount of product to be taken at one time (e.g. 3).
Dosage Unit: Indicate the unit (e.g. pellet)

For non-discrete dosage forms (e.g. powder, liquid, cream), the dosage unit may be expressed as teaspoon, mL, grams, scoop, dropper, etc.

Example - liquid:
No. of Dosage Units: 2
Dosage Unit: teaspoons (5mL)

Example- topical cream:

No. of Dosage Units: apply sparingly
Dosage Unit: cream

Frequency

Indicate how often the product should be taken. Example: Three times a day.

Applicants are not permitted to include the term “or as needed” (e.g. four times per day or as needed”) as part of the dose frequency (this limitation is not applicable to topical products). A statement to the effect of “four times per day, or as directed by a health care practitioner” would be acceptable.

Recommended Doses

The following table outlines recommended doses for several common dosage forms. The recommended dose for solid dosage forms is the same for adults, seniors and children. The recommended dose for liquid forms differs for adults and children.

Directions for Use

Enter any additional information that may help the consumer receive maximum benefit from the product. For example:

- “Take at least one hour before or after eating.”
- The dosing specifications for acute conditions (see Table 3).
- “Dissolve tablet in water before administering.”

For children 0-2 years old, the directions for use should include instructions to dissolve the solid dosage form (e.g. granules, globules, tablets) in a small amount of water.

Table 3: Dosage forms and their suggested recommended dose.

DOSAGE FORM	SUB-POPULATION	AMOUNT	FREQUENCY	ACUTE DOSING
Granules (small pellets, pilules) (Oral)	Adults and children ≥ 12 years	1 whole unit dose (tube or container)	Once daily	10-20 granules 2-3 times daily
	Children 1-11 years*			
	Infants 0-11 months*			
Globules (regular and	Adults and children ≥ 12 years	3-5 globules	2-3 times daily	Every 15-60 min. (up to 12 times/day) or until

DOSAGE FORM	SUB-POPULATION	AMOUNT	FREQUENCY	ACUTE DOSING
large pellets)	Children 1-11 years*			improvement of symptoms. Then resume general dosing.
	Infants 0-11 months*			
Tablets	Adults and children ≥ 12 years	1-4 tablets	1-4 times per day	Every 15-60 min. (up to 12 times/day) or until improvement of symptoms. Then resume general dosing.
	Children 6-11 years	1-3 tablets	1-4 times per day	
	Children 1-5 years*	½ - 3 tablets	1-3 times per day	
	Infants 0-11 months*	½ - 3 tablets	1-2 times per day	
Oral Drops	Adults and children ≥ 12 years	10-30 drops	1-3 times per day	Every 15-60 min. (up to 12 times/day) or until improvement of symptoms. Then resume general dosing.
	Children 6-11 years	5-15 drops		
	Children 1-5 years	5-10 drops		
	Infants 0-11 months	1-5 drops		
Liquid (Oral drinkable vials)	Adults and children ≥ 12 years	1 ampoule	1-3 times per day	Up to three times per day
	Children 6-11 years	2/3 ampoule		
	Children 1-5 years	½ ampoule		
	Infants 0-11 months	1/3 ampoule		
Oral solution (Unit dose)	Adults and children ≥ 12 years	Unit oral dose	1-3 times per day	Give one unit dose upon onset of symptoms. Repeat two more times at 15-minute intervals. Repeat process up to 9 times per day if symptoms reappear.
	Children 1-11 years			
	Infants 0-11 months			
Oral Syrup	Adults and children ≥ 12 years	1-2 tsp	Every 4 to 6 hours	Not applicable
	Children 1-11 years	½ -1 tsp	1-3 times per day	
	Infants 0-11 months	½ tsp	1-3 times per day	
Cream/Ointment	Adults and children	Cover affected area	Use as needed	Not applicable

DOSAGE FORM	SUB-POPULATION	AMOUNT	FREQUENCY	ACUTE DOSING
Nasal spray	Adults and children ≥ 12 years	1-2 sprays/ nostril	3-5 times per day	Not applicable
	Children 1-11 years	1 spray/ nostril	4 times per day	
	Infants 0-11 months	1 spray/ nostril	4 times per day	
Eye Drops	Adults and children ≥ 12 years	2-3 drops	3 times per day	1 drop in the affected eye every 15 minutes for a maximum of 3 hours.
	Children 1-11 years	1-2 drops	3 times per day	
	Children 0-11 months	1 drop	2 times per day	
Ear Drops	Adults and children ≥ 12 years	1 complete vial	3 times per day	Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosage.
	Children 1-11 years	3-4 drops		
	Infants 0-11 months	2-3 drops		
Suppositories	Adults and children ≥ 12 years	1 suppository	1-4 times per day	Maximum 5 per day
	Children 6-11 years		1-3 times per day	Maximum 4 per day
	Children 1-5 years		1-2 times per day	Maximum 3 per day
	Infants 0-11 months		1-2 times per day	Maximum 2 per day

* Dissolve dose in a small amount of water before administration to infants and children 0-2 years old.

Product licence applicants may recommend a dose amount and frequency not outlined above providing the recommendation is accompanied by an adequate rationale.

Risk Information

Cautions and Warnings, Contraindications and Known Adverse Reactions

Risk information regarding cautions, warnings and contraindications is mandatory where safety concerns have been noted. It is the responsibility of the applicant to declare any known risk information associated with the use of their product.

Homeopathic medicines with a non-specific recommended use or purpose must include a risk statement to the effect of: “Consult a health care practitioner if symptoms persist or worsen,” The wording “Or to be used as directed by a health care practitioner” as a direction for use is not

adequate to meet the above requirement and, in this case, applicants will be required to also add the statement “Consult a health care practitioner if symptoms persist or worsen.”

Homeopathic medicines with a specific recommended use or purpose must either provide risk information appropriate to the proposed claim *or* a statement to the effect of “Consult a health care practitioner if symptoms persist or worsen.”

Examples of additional risk information would be:

- “Do not use during pregnancy or breast feeding.”
- “Keep this and all medications out of the reach of children.”

8.0 EVIDENCE REQUIREMENTS FOR HOMEOPATHIC MEDICINES

8.1 Types of Evidence

The NHPD recognizes different levels of evidence, ranging from traditional use to randomized, placebo-controlled, double-blind clinical trials. The table below outlines different levels of evidence as presented in the document entitled *Evidence for the Safety and Efficacy of Finished Natural Health Products.* Any or all types of evidence found in Table 4 may be submitted to support the recommended conditions of use (claim, dose, route of administration, etc).

Table 4: Levels of Evidence

Level	Type of Evidence
I	Well-designed systematic reviews and meta-analyses of randomized controlled trials or other clinical trials, OR At least one well-designed randomized controlled trial (preferably multi-centred)
II	Well-designed clinical trials without randomization and/or control groups
III	Well-designed descriptive and observational studies, such as correlational studies, cohort studies and case-control studies
IV	Peer-reviewed published articles, conclusions of other reputable regulatory agencies, previous marketing experience, expert opinion reports, textbooks, homeopathic *materia medica*, homeopathic pharmacopoeias, homeopathic provings, homeopathic repertories
V	References to a traditional use

The NHPD encourages the use of level I-III evidence where it exists. Scientific evidence from Levels I-III may be used to support novel conditions of use which are not supported by homeopathic provings or references such as the homeopathic *materia medica*. Homeopathic *materia medica* and homeopathic provings are the most commonly available evidence, and are accepted as Level IV evidence.

Some of the types of evidence listed above, particularly in levels I-III, are available from database sources such as PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi). Applicants may refer to *Evidence for the Safety and Efficacy of Finished Natural Health Products* for general guidance on how to conduct a literature search for such evidence when using a database such as PubMed.

8.2 Evidence to Support a Specific Recommended Use or Purpose

Sufficient evidence must be provided to demonstrate a clear rationale for the inclusion of each medicinal ingredient in the homeopathic medicine. For a homeopathic medicine with a specific recommended use or purpose (claim), evidence must link each medicinal ingredient to the symptom(s) of the claim it is intended to address. It is not necessary to link each medicinal ingredient to every symptom included in the claim. For example, if the claim is “For the fever, pain and irritability associated with teething”, evidence might demonstrate that ingredient A treats fever and pain, ingredient B also helps reduce fever and ingredient C treats irritability.

See **Appendix 1** for a list of sample references for homeopathic medicines.

8.3 How to Include Evidence with the Product Licence Application

The Product Licence Application must include photocopies of the references for **each** medicinal ingredient. These photocopies must include:

- the text that makes reference to the recommended use or purpose. It is the responsibility of the product licence applicant to underline (not highlight) the exact information being referenced in order to ensure clarity after photocopying; Applications containing evidence that is not underlined may take longer to assess than those where relevant sections have been clearly marked;
- the authorship;
- the edition;
- the year and the place of publication; and
- the title page.

9.0 QUALITY

Finished homeopathic medicines must meet the quality requirements outlined in the accepted homeopathic pharmacopoeias, as they are amended from time to time, as well as the quality requirements specified by the NHPD. This chapter provides an overview of the NHPD's quality requirements. For additional information on quality requirements for homeopathic medicines, please refer to **Appendix 8** of this document or the document entitled *Evidence for the Quality of Finished Natural Health Products* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq_e.html).

Good manufacturing practices (GMPs) must be followed during the manufacturing, packaging, labelling, importing, distributing and storing of homeopathic medicines. The requirements for GMPs outlined in Part 3 of the Regulations and the *Good Manufacturing Practices Guidance Document* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf_e.html) apply to all homeopathic medicines.

Homeopathic medicines being compounded by practitioners for patient use are not subject to the requirements of the Regulations. For more information, please see the Natural Health Product (NHP) Compounding Policy at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/policy_compound-politique_compose_e.html.

9.1 Overview of Quality Specifications for Homeopathic Medicines

The quality requirements for homeopathic medicines include specifications for the following:

- identity (physical and chemical); and
- purity (microbial and chemical).

Applicants are required to provide the specification details at the raw material and/or at the finished product stage as outlined below.

9.2 Identity of Finished Homeopathic Medicines

Identity testing of medicinal ingredients must be conducted as outlined in the referenced accepted homeopathic pharmacopoeia (HAB and the HPUS monographs published September 2004 and later) unless the medicinal ingredients are pharmacopoeial grade as per Schedule B of the *Food and Drugs Act* (e.g. United States Pharmacopeia). Identity testing is required for all types of medicinal ingredients (mineral, chemical, zoological, botanical and nosodes). Testing of the medicinal ingredients must be done at the raw material stage.

Further information on identity testing can be found in the document entitled *Evidence for the Quality of Finished Natural Health Products* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq_e.html).

9.3 Purity of Finished Homeopathic Medicines

For complete information on purity testing for homeopathic medicines, please refer to the document entitled *Evidence for the Quality of Finished Natural Health Products* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq_e.html).

9.3.1 Microbial Testing

Homeopathic medicines must be tested for microbiological contaminants at the finished product stage, as outlined in **Appendix 8**. Methods outlined in the *Homöopathisches ArzneiBuch* and the *Pharmacopée française* are also accepted because they are based on the *European Pharmacopoeia*.

Because nosodes are, by nature, prone to microbial contamination, the NHPD requires assurance of their sterility at the raw material stage. The sterilization technique used in the preparation of the homeopathic medicine must comply with the sterility requirements in the HPUS.

Microbial Testing of Solid Dosage Forms

Microbial testing is required for solid dosage forms of homeopathic medicines on a lot-by-lot basis. It may be possible to change to periodic or skip sub-lot testing (testing lots at predetermined intervals) only when it can be proven (e.g. through historical data) that the production lots consistently meet the acceptance criteria. Skip sub-lot testing requirements will be decided upon on a case-by-case basis. For more information, please refer to the *Good Manufacturing Practices Guidance Document*.

Microbial Testing of Liquid Dosage Forms

Microbial testing of liquid dosage forms is not required when the finished product is in a solvent containing at least 50% ethanol. When ethanol is not present, or the ethanol content is less than 50%, microbial testing is required on a lot-by-lot basis. However, as with solid dosage forms, it may be possible to change to periodic or skip sub-lot testing when it can be proven (e.g. through historical data) that the production lots consistently meet the acceptance criteria. Skip sub-lot testing requirements will be decided upon on a case-by-case basis. For more information, please refer to the *Good Manufacturing Practices Guidance Document*.

9.3.2 Chemical Contaminant Testing

Each medicinal ingredient used in the product must also be tested for the chemical contaminants at the raw material stage, as outlined in **Appendix 8**. Chemical contaminant testing at the raw material stage is not required for homeopathic potencies of 1 CH (2X) or higher because at this dilution level, under normal circumstances, any contaminants will be sufficiently diluted to fall within safety parameters.

9.3.3 Additional Purity Testing Information

If an applicant wishes to use a testing method not outlined by the NHPD or in the accepted homeopathic pharmacopoeias, the testing method will be evaluated on a case-by-case basis.

If an applicant does not test the medicinal ingredients for the microbiological and chemical contaminants, then a scientific rationale must be provided in order to justify the test exemption. For example, the NHPD may grant a test exemption for certain minerals and synthetic duplicates that do not support the growth of bacteria.

Please note that all products for topical use must be tested for microbial contamination. Topical products need not be tested for heavy metals if a) they are more dilute than mother tincture (1X and above) and b) contain pharmaceutical grade non-medicinal ingredients (e.g. *United States Pharmacopeia* grade).

9.4 Quality of Nasal and Ophthalmic Homeopathic Medicines

The storage and sterilization procedures for homeopathic medicines with nasal and ophthalmic routes of administration must follow the quality specifications as outlined in the most current edition of *Homeopathic Pharmacopeia of the United States* or the *European Pharmacopoeia*.

10.0 LABELLING

10.1 Submission of Label Text

The Regulations require that a printed version of the proposed label text for the homeopathic medicine be submitted with the Product Licence Application. Advertising information and graphics are not required.

10.2 Labelling Requirements Specific to Homeopathic Medicines

The following chart outlines statements that must appear on homeopathic medicines.

Table 5: Labelling requirements for homeopathic medicines.

	Homeopathic Medicines with a Non-Specific Claim	**Homeopathic Medicines with a Specific Claim**
Identification of Medicine Type	One of the following must appear on the label: "homeopathic medicine", "homeopathic remedy", "homeopathic drug", "homeopathic preparation".	
Statement of Recommendation for Use or Purpose	No recommended use or purpose, whether explicit or implicit, is permitted on the label.	Label must state the recommended use or purpose in specific, current, unambiguous terms.
Statement of Risk Information	Label must make a statement to the effect of : a) "Consult a health care practitioner if symptoms persist or worsen."	Risk information must be appropriate to proposed claim. In the absence of other risk statements, the label must include a statement to the effect of: "Consult a health care practitioner if symptoms persist or worsen."

Source Information

While complete source information must appear on the Product Licence Application (PLA) form, an applicant may choose to write the information as it appears on the PLA form on the label, OR to provide source information to consumers through a Web site as an extension of the label. If this alternative is chosen, the label is required to include the term "source:" or "source information:", followed by either the NHPD Web site (www.hc-sc.gc.ca/dhp-mps/prodnatur/index_e.html) OR a company or association Web site which provides a link to the NHPD Web site. A database listing proper and common names of homeopathic medicines as well as complete source information, as found in the accepted homeopathic pharmacopeias, will be published on the NHPD Web site in the near future.

10.3 Labels for Small Packages

The NHPD recognizes that small packages, such as those used by some homeopathic medicine manufacturers, may not have an area large enough for the inner labelling requirements. Therefore, separate small package labelling requirements have been developed. Please see the *Labelling* guidance document for information specific to small package labelling.

Refer to **Appendix 9** for a checklist of requirements for inner labels, outer labels and small package labels. Refer to the *Product Licensing Guidance Document* for detailed explanations of each label requirement listed.

10.4 Labelling of Nasal, Ophthalmic and Otic Homeopathic Medicines

Labelling of homeopathic medicines for nasal or ophthalmic use must follow the specifications outlined in the most current edition of the *Homeopathic Pharmacopeia of the United States* (HPUS) or the *European Pharmacopoeia*.

HPUS ophthalmic solution specifications include:

- a label stating the preservatives used, if applicable; or
- for multiple-dose containers, a warning stating that the preparation should not be used more than 30 days after the seal is broken (these multiple-dose containers should not exceed 15 mL).

HPUS nasal solution specifications include:

- a label stating all preservatives, isotonicity, viscosity and stabilization agents.

Ear drops must be labelled with a statement to the effect of “Consult a health care practitioner if you have a fever, ear pain, changes in hearing and/or discharge from the ear.”

GLOSSARY OF TERMS

Allersode: Homeopathic preparations of antigens, (substances which, under suitable conditions, can induce the formation of antibodies). Antigens include toxins, ferments, precipitinogens, agglutinogens, opsonogens, lysogens, venins, agglutinins, complements, opsonins, amboceptors, precipitins and most native proteins.

CFU: Colony forming units (Absent refers to < 10 CFU per g or per mL)

Chemical name: Any unambiguous chemical name provided by an authoritative reference such as the *Merck Index*, the *United States Pharmacopeia Dictionary*, etc., or a name determined using the *International Union of Pure and Applied Chemistry* (IUPAC) nomenclature system.

Combination (multiple-ingredient) homeopathic medicine: A homeopathic medicine manufactured from two or more medicinal ingredients.

Dilution level: See Homeopathic Potency.

Drug Identification Number (DIN): The identification number located on the label of prescription and over-the-counter drug products that have been evaluated by the Therapeutic Products Directorate (TPD) and approved for sale in Canada.

DIN-HM: Stands for DIN-Homeopathic Medicine and is the product licence number located on the label of homeopathic medicines that have been evaluated by the NHPD and approved for sale in Canada.

Efficacy: The extent to which a specific intervention, procedure, regimen or service produces a beneficial result under ideal conditions. In other words, it is the ability for a NHP to produce the desired health outcome, when it is used according to the Recommended Conditions of Use, under ideal conditions.

Expiry date: The earlier of:

- the date, expressed at minimum as a year and month, up to and including which a NHP maintains its purity and physical characteristics and its medicinal ingredients maintain their quantity per dosage unit and their potency; and
- the date, expressed at minimum as a year and month, after which the manufacturer recommends that the NHP should not be used.

Homeopathic medicine: Medicines that are manufactured only from those substances or sources referenced as monographs in the *Homeopathic Pharmacopeia of the United States* (HPUS), the *Homöopathisches ArzneiBuch* (HAB), the *Pharmacopée française* (PhF), the *European Pharmacopoeia* (Ph.Eur.) or the *Encyclopedia of Homeopathic Pharmacopoeia* (EHP), as they are amended from time to time, and that are prepared in accordance with these pharmacopoeias.

Homeopathic potency: The strength or quantity of a homeopathic medicine. Also called homeopathic attenuation, the potency refers to the number of times the original substance has been diluted and succussed according to a method described in one of the accepted homeopathic

pharmacopoeia. Homeopathic potency is written as a number associated with one of the following letters or combinations of letters: X, D, C, CH, K, CK, M, MK, LM or Q. Examples: *Arnica montana* 6X, *Chamomilla* 30 CH.

HPLC: High-performance liquid chromatography

Indication for use: A specific symptom or set of symptoms that the medicine is intended to treat. This term is replaced by the expression “recommended use or purpose”, as stated in the Regulations and other guidance documents.

Isode: Homeopathic preparations of botanical, zoological or chemical substances, including drugs, excipients or binders, which have been ingested or otherwise absorbed by the body and are believed to have produced a disease or disorder which interferes with homeostasis. They are sometimes referred to as Detoxodes.

Label: Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package.

Lot: A quantity of any NHP in dosage form, a raw material or a packaging material, homogeneous within specified limits, constituting all or part of a single batch and identified by a distinctive lot number which appears on the label of the finished product.

Lot number: Any combination of letters, figures, or both, by which a NHP can be traced in manufacture and identified in distribution.

Monograph (Homeopathic): A monograph is a written description in a pharmacopoeia of an individual homeopathic medicinal ingredient. The description includes, but is not limited to, information about the ingredient name, name synonym, description of the substance, preparation and homeopathic potency for various purposes.

Natural health product (NHP): A substance set out in Schedule 1 of the Regulations or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state or its symptoms in humans;
- restoring or correcting organic functions in humans; or
- modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a NHP does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Schedule 1 - Included Natural Health Product Substances

1. A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2. An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3. Any of the following vitamins: biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B_6 , vitamin B_{12}, vitamin C, vitamin D, vitamin E
4. An amino acid
5. An essential fatty acid
6. A synthetic duplicate of a substance described in any of items 2 to 5
7. A mineral
8. A probiotic

Schedule 2 – Excluded Natural Health Product Substances

1. A substance set out in Schedule C to the *Food and Drugs Act*.
2. A substance set out in Schedule D to the *Food and Drugs Act*, except for the following:
   (a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and
   (b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
3. A substance regulated under the *Tobacco Act*
4. A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*
5. A substance that is administered by puncturing the dermis.
6. An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic.

Natural Product Number (NPN): Precedes the product licence number on the label of most NHPs that have been evaluated by the NHPD and approved for sale in Canada. See also DIN-HM.

Nosode: Homeopathic preparations of: pathological organs or tissues; causative agents such as bacteria, fungi, ova, parasites, virus particles and yeast; disease products; excretions or secretions.

Potency: The amount per dosage unit of the standardized components that further characterizes the quantity of the ingredient. For example:

- quantity: 500mg *Echinacea purpurea* extract
- potency: 0.4% echinosides

For homeopathic medicines, please see definition above for Homeopathic Potency.

Product Number: An eight (8)-digit numerical code assigned to each NHP approved under the Regulations, (e.g. DIN-HM 80000001, NPN 80000002)

Quantity: Refers to the amount of medicinal ingredient(s) per dosage unit. A statement of quantity is required for all products as it represents the amount of medicinal ingredient in the product. For homeopathic medicines, quantity is the homeopathic potency (see definition above).

Recommended conditions of use: Refers to information about a NHP that enables consumers to make an informed choice regarding its use. It includes the following elements:

- recommended use or purpose;
- dosage form;
- recommended route of administration;
- recommended dose;
- recommended duration of use, if any; and
- risk information, including any cautions, warnings, contraindications or known adverse reactions associated with its use.

Safety: The ability of a NHP to produce a beneficial health outcome, outweighing the risk associated with using it, in humans, according to the recommended conditions of use.

Sarcode: Homeopathic preparations of wholesome organs, tissues, or metabolic factors obtained from healthy specimens.

Self-care: Activities individuals undertake for the prevention, treatment and symptomatic relief of diseases, injuries or chronic conditions that individuals can recognize and manage on their own behalf, either independently or with participation from a health care practitioner.

Single-ingredient homeopathic medicine: A homeopathic medicine with only one medicinal ingredient.

Source material: For homeopathic medicines, source material is the starting substance of medicinal value used to manufacture a homeopathic medicine.

APPENDIX 1: EXAMPLES OF REFERENCES FOR HOMEOPATHIC MEDICINES WITH A SPECIFIC RECOMMENDED USE OR PURPOSE

The following list of reference texts is intended as a guide only and is not intended to be all inclusive. The NHPD does not specifically endorse any of the references listed. While references outside of this collection may also provide valuable information, the use of references intended for use by the general public is not encouraged.

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APPENDIX 2: SAMPLE OF A COMPLETED PRODUCT LICENCE APPLICATION FORM FOR A HOMEOPATHIC MEDICINE WITH A NON-SPECIFIC RECOMMENDED USE OR PURPOSE

Health Canada / Santé Canada	**PRODUCT LICENCE APPLICATION FORM** **Natural Health Products Directorate**	**Protected when completed**

HEALTH CANADA USE ONLY		3. Date/Time of Receipt
1. Submission Number	2. File Number	

Please refer to the Guide for instructions on how to complete this application.

PART 1 – APPLICANT AND CONTACT INFORMATION

A. – APPLICANT OR LICENSEE (This is the product licence holder)

4. Applicant/Company Name* VANCOUVER HOMEOPATHICS			5. Company Code (If known) 12345
6. Address: Street/Suite/PO Box* 123 MONTREAL ST.			
7. City – Town* VANCOUVER	9. Province – State* B.C.	8. Country* CANADA	10. Postal/ZIP Code* A1B 2C3

B. – SENIOR OFFICIAL (This is the name of the principal contact person for the applicant/company)

11. Name □ Mr. **X** Ms. □ Dr.		12. Title CEO	13. Language preferred: **X** English □ French
Surname*__ARCHAMBAULT___Given Name*_____ MARIE_____			
14. Company Name (* if different from Applicant/Licensee)			**15. Address same as "A" X**
16. Street/Suite/PO Box*			
17. City – Town*	19. Province – State*	18. Country*	20. Postal/Zip Code*

21. Telephone No.* (111) 123-4567	Ext. 8	22. Fax No. (111) 234-5678	23. E-mail marie@VH.com

C. – CONTACT FOR THIS APPLICATION (This is the contact person for product-specific questions)

24. Contact same as "B" □		26. Title Regulatory Affairs Officer	27. Language preferred: **X** English □ French
25. Name **X** Mr. □ Ms. □ Dr.			
Surname**__WANG_____ Given Name*___STEVEN_____			
28. Company Name (*if different from Applicant/Licensee)			**29. Address same as "A" X**
30. Street/Suite/PO Box*			
31. City – Town*	33. Province – State*	32. Country*	34. Postal/Zip Code*

35. Telephone No.* (111) 123-4567	Ext. 20	36. Fax No. (111) 234-5678	37. E-mail steven@VH.com

Attach separate sheets (same format) if necessary. Number of pages attached: _____

D. – REPRESENTATIVE IN CANADA (Only required where Address in "A" is not in Canada)

38. Contact same as "C" □		40. Title	41. Language preferred: □ English □ French
39. Name □ Mr. □ Ms. □ Dr.			
Surname*_____ Given Name*_____			
42. Company Name (* if different from Applicant/Licensee)			**43. Address same as "C"** □
44. Street/Suite/PO Box*			
45. City – Town*	47. Province – State*	46. Country* **Canada**	48. Postal/Zip Code*

49. Telephone No.*	Ext.	50. Fax No.	51. E-mail

E. – CONTACT TO WHOM THE PRODUCT LICENCE IS TO BE SENT:	**52. As Above: B: X C:□ D: □** (check only one box) Not Applicable:□ Name:_____

AUSSI DISPONIBLE EN FRANÇAIS

Copy this form as necessary

VERSION 2.0 * - denotes Mandatory, ** - if yes complete Animal Tissue Form Page 1 of 6

PART 2 – SUBMISSION TYPE

A. – PRODUCT LICENCE APPLICATION

53. Indicate the type of application (*select one only)
□ Compendial □ Traditional claim □ Non-traditional claim **X** Homeopathic □ TPD Category IV/Labelling Standard
□ Homeopathic DIN (DIN#_____) □ Transitional DIN (DIN#_____)

54. Is this formulation hypothetical? □ Yes **X** No

55. NPN/DIN-HM #_____ (* - required for Section **B**. **C, and D**. only).

B. – MONOGRAPH REVISIONS AFFECTING AN EXISTING PRODUCT LICENCE

56. □ Yes, revisions to the published NHPD Compendial Monograph affect the NPN above.
NHPD Compendial Monograph:_____ Date: _____

C. – PRODUCT LICENCE – AMENDMENT

57. Indicate the affected change to the NPN/DIN-HM above. (select one or more)

□ Potency
□ Source material of any of its medicinal ingredients
□ Addition or substitution of a non-medicinal ingredient not on the NHPD List of Acceptable non-medicinal ingredients
□ Specification
□ Deletion or modification of risk information on any labels
□ Recommended dose
□ Change to Animal Tissue Form(s)
□ Recommended use/purpose
□ Change to or from synthetically manufactured
□ Recommended duration of use
□ Change to manufacturing information

D. – PRODUCT LICENCE – NOTIFICATION

58. Indicate the type of change(s) that have been made to the NPN/DIN-HM above. (select one or more)

□ Addition or substitution of any of its proposed non-medicinal ingredient other than those originally authorized for the product.
□ Change to the common name of any of its medicinal ingredients
□ Addition of risk info on any of its labels
□ Change to the name, address, telephone number, fax number, and/or electronic mail address of the manufacturer, packager, labeller, importer, and distributor.
□ Sale under a brand name other than the one(s) originally authorized for the product license
□ Change to the proper name of any of its medicinal ingredients
□ Change to the name, address, telephone number, fax number, and/or electronic mail address of the applicant or Canadian representative.
□ Change to a Site Licence number for a Canadian manufacturer, packager, labeller, or importer.
□ Addition of a site associated with the product.

E. – SUBMISSION CONTENT

59. Type of supporting documents, by volume: check type that is applicable and indicate the volume in which the document is submitted.

			Volume #
Number of Volumes: ____1_____	□ Animal tissue form(s)	#: _____	_____
X Product licence application form	□ Designated Party Authorization form:		_____
□ Additional pages for Product Information	**X** Label Text	#: _____	_____
□ Additional pages for Site Information	□ TPD Label Text (Transitional DIN or Homeopathic DIN)	#: _____	_____
□ Evidence Summary Report:	**X** Quality Summary Report:		_____
□ Safety Summary Report:	**X** Other, Claim Evidence:		HAB monographs

F. – REFERENCE SUBMISSION (if applicable)

60. Other submission that contains the evidence to support the safety, efficacy and/or quality of this particular submission.

Company #: _____ File #: _____ Submission #: _____ NPN/DIN-HM #: _____
Contains information to support: □ Safety □ Efficacy □ Quality Letter of access(es) enclosed: □ Yes □ Not Applicable

Company #: _____ File #: _____ Submission #: _____ NPN/DIN-HM #: _____
Contains information to support: □ Safety □ Efficacy □ Quality Letter of access(es) enclosed: □ Yes □ Not Applicable

Company #: _____ File #: _____ Submission #: _____ NPN/DIN-HM #: _____
Contains information to support: □ Safety □ Efficacy □ Quality Letter of access(es) enclosed: □ Yes □ Not Applicable

G. – NHPD MASTER FILE (if applicable)

61. Master file that contains the evidence to support the safety, efficacy and/or quality of this particular submission.

Master File #: _____ Letter of access enclosed: □ Yes □ Not Applicable
Contains information to support: □ Safety only □ Efficacy only □ Quality only □ Complete submission
Attach separate sheets (same format) if necessary. Number of pages attached: _____

Copy this form as necessary
* - denotes Mandatory
** - if yes complete Animal Tissue Form

PART 3 – SITE INFORMATION

62. Company Name VANCOUVER HOMEOPATHICS			63. X Manufacturer SL# 22222 X Packager SL# 22222 X Labeller SL# 22222 X Importer SL# 22222 X Distributor
64. Number, Street – Suite – PO Box 123 MONTREAL ST.			
65. City VANCOUVER			
66. Province – State B.C.	67. Country CANADA	68. Postal Code – Zip Code A1B 2C3	
62. Company Name			63. ☐ Manufacturer SL# ___________ ☐ Packager SL# ___________ ☐ Labeller SL# ___________ ☐ Importer SL# ___________ ☐ Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country	68. Postal Code – Zip Code	
62. Company Name			63. ☐ Manufacturer SL# ___________ ☐ Packager SL# ___________ ☐ Labeller SL# ___________ ☐ Importer SL# ___________ ☐ Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country	68. Postal Code – Zip Code	
62. Company Name			63. ☐ Manufacturer SL# ___________ ☐ Packager SL# ___________ ☐ Labeller SL# ___________ ☐ Importer SL# ___________ ☐ Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country	68. Postal Code – Zip Code	
62. Company Name			63. ☐ Manufacturer SL# ___________ ☐ Packager SL# ___________ ☐ Labeller SL# ___________ ☐ Importer SL# ___________ ☐ Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country	68. Postal Code – Zip Code	
69. Attach separate sheets (same format) if necessary. Number of pages attached: __________			

Copy this form as necessary
* - denotes Mandatory
** - if yes complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

70. Primary Brand Name* ARNICA D6

71. If necessary, attach a separate sheet with other brand names. Number of pages attached: _____

A. – MEDICINAL INGREDIENT(S)

72. Ingredient No.	73. Standard or Grade	74. NHPD Compendial Monograph		75. Proper Name*	76. Common Name	77. Quantity per Dosage Unit*	78. Synthetic*		79. Animal Tissue**	
		Name	Date				Yes	No	Yes	No
1.	HAB			*Arnica montana*	*Arnica montana*	D6		X		X
2.										
3.										
4.										
5.										
6.										
7.										
8.										
9.										
10.										
11.										
12.										

80. Ingredient No.	81. Potency (if applicable)		84. Source Information* (if more than one enter on new line)	85. Extract (if applicable)				90. Method of preparation
				86. Ratio	87. Quantity Crude Equivalent	Original Material		
	82. Amount	83. Constituent				88. Fresh	89. Dry	
1.	2 mL	of D6 dilution	Whole plant					HAB method 3c
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								

91. Attach separate sheets (same format) if necessary. Number of pages attached: _____

Copy this form as necessary
* - denotes Mandatory
** - if yes complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

B. – NON-MEDICINAL INGREDIENT(S)

92. Ingredient No.	93. Proper Name	94. Common Name*	95. Purpose*	96. Animal Tissue Used**	
				Yes	No
1.		Ethanol	Solvent		X
2.		Distilled Water	Solvent		X
3.					
4.					
5.					
6.					
7.					
8,					
9.					
10.					
11.					
12.					

97. Ingredient No.	98. Standard or Grade	99. Quantity	100. Source Information (if more than one enter on new line)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8,			
9.			
10.			
11.			
12.			

C. – INGREDIENT(S) USED IN PROCESSING

101. "Was animal tissue used in the **processing** of this product, although not present in the final product?" ** ☐ Yes **X** No

Copy this form as necessary
* - denotes Mandatory
** - if yes complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

D. – RECOMMENDED CONDITIONS OF USE

102. Recommended Use or Purpose*

HOMEOPATHIC MEDICINE

103. Dosage Form (one only)*	104. Sterile*	105. Route of Administration*
LIQUID	□ Yes **X** No	ORAL

106. Duration of Use (if any)

Recommended Dose (repeat for each sub-population group)

107. Sub-population group*	108. Amount to be taken at one time:		111. Frequency	112. Directions of Use
	109. No. of Dosage Units* (e.g. 1, 2, etc.)	110. Dosage Unit* (e.g. capsule, tsp, etc.)		
ADULT	10	DROPS	THREE TIMES A DAY	IN A GLASS OF WATER OR AS DIRECTED BY A HEALTH CARE PRACTITIONER

Risk Information

113. Cautions and Warnings*

CONSULT A HEALTH CARE PRACTITIONER IF SYMPTOMS PERSIST OR WORSEN.

114. Contraindications*

115. Known Adverse Reactions*

ATTESTATION

"I attest that the natural health product that is the subject of this product license application will be manufactured, packaged, labelled, distributed and stored:

a) If the natural health product is imported, in accordance with the 'Good Manufacturing Practices' requirements as set out in Part 3 of the Natural Health Products Regulations or in accordance with requirements that are equivalent to those set out in Part 3, or

b) If the natural health product is not imported, in accordance with the 'Good Manufacturing Practices' requirements set out in Part 3 of the Natural Health Products Regulations.

I, the undersigned, certify that the information and material included in this product licence application is accurate and complete".**

116. Name of Authorized Senior Official[1] (print)*	117. Signature*	118. Date*
MARIE ARCHAMBAULT		2 0 0 6 0 9 2 1

If the signing official is a third party acting on behalf of the Senior Official of the applicant company designated in Part 1 of the application, a designated Party Authorization form must be signed by the Senior Official and filed with the complete application.

Copy this form as necessary

* - denotes Mandatory

** - if yes complete Animal Tissue Form

APPENDIX 3: SAMPLE OF A COMPLETED PRODUCT LICENCE APPLICATION FORM FOR A HOMEOPATHIC MEDICINE WITH A SPECIFIC RECOMMENDED USE OR PURPOSE

Health Canada Santé Canada

PRODUCT LICENCE APPLICATION FORM
Natural Health Products Directorate

Protected when completed

HEALTH CANADA USE ONLY		3. Date/Time of Receipt
1. Submission Number	2. File Number	

Please refer to the Guide for instructions on how to complete this application.

PART 1 – APPLICANT AND CONTACT INFORMATION

A. – APPLICANT OR LICENSEE (This is the product licence holder)

4. Applicant/Company Name* VANCOUVER HOMEOPATHICS			5. Company Code (If known) 12345
6. Address: Street/Suite/PO Box* 123 MONTREAL ST.			
7. City – Town* VANCOUVER	9. Province – State* B.C.	8. Country* CANADA	10. Postal/ZIP Code* A1B 2C3

B. – SENIOR OFFICIAL (This is the name of the principal contact person for the applicant/company)

11. Name □ Mr. **X** Ms. □ Dr. Surname*____ARCHAMBAULT___Given Name*____MARIE _____		12. Title CEO	13. Language preferred: **X** English □ French
14. Company Name (* if different from Applicant/Licensee)			**15. Address same as "A" X**
16. Street/Suite/PO Box*			
17. City – Town*	19. Province – State*	18. Country*	20. Postal/Zip Code*

21. Telephone No.* (111) 123-4567	Ext. 8	22. Fax No. (111) 234-5678	23. E-mail marie@VH.com

C. – CONTACT FOR THIS APPLICATION (This is the contact person for product-specific questions)

24. Contact same as "B" □		26. Title Regulatory Affairs Officer	27. Language preferred: **X** English □ French
25. Name **X** Mr. □ Ms. □ Dr. Surname**__WANG_____ Given Name*___STEVEN_____			
28. Company Name (*if different from Applicant/Licensee)			**29. Address same as "A" X**
30. Street/Suite/PO Box*			
31. City – Town*	33. Province – State*	32. Country*	34. Postal/Zip Code*

35. Telephone No.* (111) 123-4567	Ext. 20	36. Fax No. (111) 234-5678	37. E-mail steven@VH.com

Attach separate sheets (same format) if necessary. Number of pages attached: _____

D. – REPRESENTATIVE IN CANADA (Only required where Address in "A" is not in Canada)

38. Contact same as "C" □		40. Title	41. Language preferred: □ English □ French
39. Name □ Mr. □ Ms. □ Dr. Surname*_____ Given Name*_____			
42. Company Name (* if different from Applicant/Licensee)			**43. Address same as "C"** □
44. Street/Suite/PO Box*			
45. City – Town*	47. Province – State*	46. Country* **Canada**	48. Postal/Zip Code*

49. Telephone No.*	Ext.	50. Fax No.	51. E-mail

E. – CONTACT TO WHOM THE PRODUCT LICENCE IS TO BE SENT:	**52. As Above: B: X C:□ D: □** (check only one box) Not Applicable:□ Name:_____

Copy this form as necessary
*- denotes mandatory
** - if yes, complete Animal Tissue Form

PART 2 – SUBMISSION TYPE

A. – PRODUCT LICENCE APPLICATION

53. Indicate the type of application (*select one only)
□ Compendial □ Traditional claim □ Non-traditional claim **X** Homeopathic □ TPD Category IV/Labelling Standard
□ Homeopathic DIN (DIN#_____) □ Transitional DIN (DIN#_____)

54. Is this formulation hypothetical? □ Yes **X** No

55. NPN/DIN-HM #_____ (* - required for Section **B**. **C, and D**. only).

B. – MONOGRAPH REVISIONS AFFECTING AN EXISTING PRODUCT LICENCE

56. □ Yes, revisions to the published NHPD Compendial Monograph affect the NPN above.
NHPD Compendial Monograph:_____ Date: _____

C. – PRODUCT LICENCE – AMENDMENT

57. Indicate the affected change to the NPN/DIN-HM above. (select one or more)

□ Potency
□ Source material of any of its medicinal ingredients
□ Addition or substitution of a non-medicinal ingredient not on the NHPD List of Acceptable non-medicinal ingredients
□ Specification
□ Deletion or modification of risk information on any labels
□ Recommended dose
□ Change to Animal Tissue Form(s)
□ Recommended use/purpose
□ Change to or from synthetically manufactured
□ Recommended duration of use
□ Change to manufacturing information

D. – PRODUCT LICENCE – NOTIFICATION

58. Indicate the type of change(s) that have been made to the NPN/DIN-HM above. (select one or more)

□ Addition or substitution of any of its proposed non-medicinal ingredient other than those originally authorized for the product.
□ Change to the common name of any of its medicinal ingredients
□ Addition of risk info on any of its labels
□ Change to the name, address, telephone number, fax number, and/or electronic mail address of the manufacturer, packager, labeller, importer, and distributor.
□ Sale under a brand name other than the one(s) originally authorized for the product license
□ Change to the proper name of any of its medicinal ingredients
□ Change to the name, address, telephone number, fax number, and/or electronic mail address of the applicant or Canadian representative.
□ Change to a Site Licence number for a Canadian manufacturer, packager, labeller, or importer.
□ Addition of a site associated with the product.

E. – SUBMISSION CONTENT

59. Type of supporting documents, by volume: check type that is applicable and indicate the volume in which the document is submitted.

			Volume #
Number of Volumes: ____1_____	**X** Animal tissue form(s)	#: ___2_____	_____
X Product licence application form	□ Designated Party Authorization form:		_____
□ Additional pages for Product Information	**X** Label Text	#: _____	_____
□ Additional pages for Site Information	□ TPD Label Text (Transitional DIN or Homeopathic DIN)	#: _____	_____
□ Evidence Summary Report:	**X** Quality Summary Report:		_____
□ Safety Summary Report:	**X** Other, Claim Evidence:		HPUS monographs

F. – REFERENCE SUBMISSION (if applicable)

60. Other submission that contains the evidence to support the safety, efficacy and/or quality of this particular submission.

Company #: _____ File #: _____ Submission #: _____ NPN/DIN-HM #: _____
Contains information to support: □ Safety □ Efficacy □ Quality Letter of access(es) enclosed: □ Yes □ Not Applicable

Company #: _____ File #: _____ Submission #: _____ NPN/DIN-HM #: _____
Contains information to support: □ Safety □ Efficacy □ Quality Letter of access(es) enclosed: □ Yes □ Not Applicable

Company #: _____ File #: _____ Submission #: _____ NPN/DIN-HM #: _____
Contains information to support: □ Safety □ Efficacy □ Quality Letter of access(es) enclosed: □ Yes □ Not Applicable

G. – NHPD MASTER FILE (if applicable)

61. Master file that contains the evidence to support the safety, efficacy and/or quality of this particular submission.
Master File #: _____ Letter of access enclosed: □ Yes □ Not Applicable
Contains information to support: □ Safety only □ Efficacy only □ Quality only □ Complete submission
Attach separate sheets (same format) if necessary. Number of pages attached: _____

Copy this form as necessary
*- denotes mandatory
** - if yes, complete Animal Tissue Form

PART 3 – SITE INFORMATION

62. Company Name VANCOUVER HOMEOPATHICS 64. Number, Street – Suite – PO Box 123 MONTREAL ST. 65. City VANCOUVER 66. Province – State: B.C. | 67. Country: CANADA | 68. Postal Code – Zip Code: A1B 2C3	63. X Manufacturer SL# 22222 X Packager SL# 22222 X Labeller SL# 22222 X Importer SL# 22222 X Distributor
62. Company Name 64. Number, Street – Suite – PO Box 65. City 66. Province – State | 67. Country | 68. Postal Code – Zip Code	63. ☐ Manufacturer SL# ___ ☐ Packager SL# ___ ☐ Labeller SL# ___ ☐ Importer SL# ___ ☐ Distributor
62. Company Name 64. Number, Street – Suite – PO Box 65. City 66. Province – State | 67. Country | 68. Postal Code – Zip Code	63. ☐ Manufacturer SL# ___ ☐ Packager SL# ___ ☐ Labeller SL# ___ ☐ Importer SL# ___ ☐ Distributor
62. Company Name 64. Number, Street – Suite – PO Box 65. City 66. Province – State | 67. Country | 68. Postal Code – Zip Code	63. ☐ Manufacturer SL# ___ ☐ Packager SL# ___ ☐ Labeller SL# ___ ☐ Importer SL# ___ ☐ Distributor
62. Company Name 64. Number, Street – Suite – PO Box 65. City 66. Province – State | 67. Country | 68. Postal Code – Zip Code	63. ☐ Manufacturer SL# ___ ☐ Packager SL# ___ ☐ Labeller SL# ___ ☐ Importer SL# ___ ☐ Distributor

69. Attach separate sheets (same format) if necessary. Number of pages attached: ___

Copy this form as necessary
*- denotes mandatory
** - if yes, complete Animal Tissue Form

VERSION 2.0

PART 4 – PRODUCT INFORMATION

70. Primary Brand Name* SORE THROAT RELIEF

71. If necessary, attach a separate sheet with other brand names. Number of pages attached: _____

A. – MEDICINAL INGREDIENT(S)

72. Ingredient No.	73. Standard or Grade	74. NHPD Compendial Monograph		75. Proper Name*	76. Common Name	77. Quantity per Dosage Unit*	78. Synthetic*		79. Animal Tissue**	
		Name	Date				Yes	No	Yes	No
1.	HPUS			*Atropa belladonna*	Belladonna	12X		X		X
2.	HPUS			Sulphur	Sulphur	12X		X		X
3.	HPUS			*Lachesis mutus*	*Lachesis mutus*	12X		X	X	
4.										
5.										
6.										
7.										
8.										
9.										
10.										
11.										
12.										

80. Ingredient No.	81. Potency (if applicable)		84. Source Information* (if more than one enter on new line)	85. Extract (if applicable)				90. Method of preparation
				86. Ratio	87. Quantity Crude Equivalent	Original Material		
	82. Amount	83. Constituent				88. Fresh	89. Dry	
1.			Whole plant					HPUS, class M
2.			Sulphur					HPUS, class F
3.			Venom					HPUS, class F
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								

91. Attach separate sheets (same format) if necessary. Number of pages attached: _____

Copy this form as necessary

*- denotes mandatory

** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

B. – NON-MEDICINAL INGREDIENT(S)

92. Ingredient No.	93. Proper Name	94. Common Name*	95. Purpose*	96. Animal Tissue Used**	
				Yes	No
1.		Lactose	Homeopathic triturating agent	X	
2.					
3.					
4.					
5.					
6.					
7.					
8,					
9.					
10.					
11.					
12.					

97. Ingredient No.	98. Standard or Grade	99. Quantity	100. Source Information (if more than one enter on new line)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8,			
9.			
10.			
11.			
12.			

C. – INGREDIENT(S) USED IN PROCESSING

101. "Was animal tissue used in the **processing** of this product, although not present in the final product?" ** ☐ Yes **X** No

Copy this form as necessary
*- denotes mandatory
** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

D. – RECOMMENDED CONDITIONS OF USE

102. Recommended Use or Purpose*

FOR THE RELIEF OF SYMPTOMS ASSOCIATED WITH SORE THROAT, SUCH AS PAIN, DRYNESS AND SWELLING OF GLANDS.

103. Dosage Form (one only)*	104. Sterile*	105. Route of Administration*
TABLET	□ Yes **X** No	ORAL

106. Duration of Use (if any)
5 DAYS

Recommended Dose (repeat for each sub-population group)

107. Sub-population group*	108. Amount to be taken at one time:		111. Frequency	112. Directions of Use
	109. No. of Dosage Units* (e.g. 1, 2, etc.)	110. Dosage Unit* (e.g. capsule, tsp, etc.)		
ADULT	2	TABLET	EVERY 60 MINUTES UNTIL SYMPTOMS IMPROVE. MAXIMUM 12 TABLETS DAILY.	DISSOLVE TABLETS IN MOUTH.
CHILDREN (6-11 YEARS)	1	TABLET	EVERY 60 MINUTES UNTIL SYMPTOMS IMPROVE. MAXIMUM 12 TABLETS DAILY.	DISSOLVE TABLETS IN MOUTH.

Risk Information

113. Cautions and Warnings*

CONSULT A HEALTH CARE PRACTITIONER IF SYMPTOMS WORSEN OR DO NOT IMPROVE WITHIN 5 DAYS.

114. Contraindications*

115. Known Adverse Reactions*

ATTESTATION

"I attest that the natural health product that is the subject of this product license application will be manufactured, packaged, labelled, distributed and stored:

- **c) If the natural health product is imported, in accordance with the 'Good Manufacturing Practices' requirements as set out in Part 3 of the Natural Health Products Regulations or in accordance with requirements that are equivalent to those set out in Part 3, or**
- **d) If the natural health product is not imported, in accordance with the 'Good Manufacturing Practices' requirements set out in Part 3 of the Natural Health Products Regulations.**

I, the undersigned, certify that the information and material included in this product licence application is accurate and complete".**

116. Name of Authorized Senior Official[1] (print)*	117. Signature*	118. Date*
MARIE ARCHAMBAULT		2 0 0 6 0 9 2 1

If the signing official is a third party acting on behalf of the Senior Official of the applicant company designated in Part 1 of the application, a designated Party Authorization form must be signed by the Senior Official and filed with the complete application.

Copy this form as necessary
*- denotes mandatory
** - if yes, complete Animal Tissue Form

APPENDIX 4: SAMPLE OF A COMPLETED ANIMAL TISSUE FORM

Health Canada / Santé Canada

ANIMAL TISSUE FORM
Natural Health Products Directorate
Protected when completed

FORMULAIRE POUR LES TISSUS D'ORIGINE ANIMALE
Direction des produits de santé naturels
Protégé une fois rempli

1. – Ingredient derived from animal tissue: / Ingrédient contenant un (des) dérivé(s) de tissu animal :

Name / Nom : Lactose

2. – Used as / Utilisé

☑ Ingredient / comme ingrédient OR / OU ☐ In processing of product / dans la fabrication du produit

3. – Animal species / Espèce animal :

☑ cattle / vache ☐ deer or elk / cerf ou wapiti ☐ sheep / mouton ☐ goat / chèvre
☐ pig / cochon ☐ poultry / volaille ☐ crustacean / crustacé ☐ Other / Autre

4. – Animal tissues used / Tissu animal utilisé :

☐ adipose tissue/omentum / tissu adipeux/épiploon
☐ antler velvet / velours de bois
☐ appendix / appendice
☐ bile
☐ blood/blood products / sang/produits sanguins
☐ bones (other than vertebral column) / os (autre que la colonne vertébrale)
☐ brain / cerveau
☐ colostrum
☐ dorsal root ganglia / ganglion de la racine dorsale
☐ dura mater / dure-mère
☐ enzymes
☐ eyes/corneas / yeux/cornée
☐ heart/pericardium / coeur/péricarde
☐ intestine / intestin ☐ small / petit ☐ large / grand
☐ kidney / rein
☐ lung / poumon
☐ mammary gland / glande mammaire
☐ Other / Autre

☑ milk and milk products / lait, produits laitiers
☐ muscle, skeletal / muscle, muscle squelettique
☐ ovary / ovaire
☐ pancreas / pancréas
☐ pituitary / hypophyse
☐ saliva, salivary gland / salive, glande salivaire
☐ skin/hides / peau/cuir
☐ skull / crâne
☐ spinal cord / moelle épinière
☐ spleen / rate
☐ tendons, ligaments
☐ testis / testicule
☐ thymus
☐ thyroid / glande thyroïde
☐ tonsils / amygdales
☐ trigeminal ganglia / ganglion de Gasser
☐ vertebral column / colonne vertébrale

If you checked cattle; deer or elk; sheep; or goat, in section 3 please fill in the following two sections. (5. & 6.)
Si vous avez coché vache; cerf ou wapiti; mouton; ou chèvre, dans section 3 veuillez remplir les sections ci-dessous. (section 5, 6).

5. – What is (or will be) the age of the animals used / Quel âge ont (ou auront) les animaux utilisés?

Under / Moins de : 11 Month or / ou Range from / de : _____ to / à _____

6. – Country/Countries from which the animals originated (or will originate) / De quel(s) pays proviennent (ou proviendont) ces animaux?

☐ Argentina / Argentine ☐ Brazil / Brésil ☐ United States / États-Unis ☐ Other / Autre
☐ Australia / Australie ☑ New Zealand / Nouvelle-Zélande ☐ Uruguay / Uruguay

Signing Authority / Signataire autorisé

I am aware that the above information may be used to conduct a risk-based assessment before any decision is taken with regard to the accompanying Product License application. I agree that if the company changes either the source or the type of animal sourced material used in the product prior to or after receiving final approval for a product submission, it must submit an Amendment of Product License form to the Natural Health Products Directorate of Health Canada.

Je suis conscient que l'information ci-dessus pourrait être utilisée pour procéder à une évaluation des risques avant qu'une décision ne soit prise concernant la demande de licence de mise en marché ci-jointe. Je sais que si l'entreprise change la source ou le type de matière animale utilisé dans le produit avant ou après avoir reçu l'approbation finale, elle devra présenter une demande de modification au formulaire de licence de mise en marché à la Direction des produits de santé naturels de Santé Canada.

M. Jones
Signature

Date: 2 0 0 8 0 6 1 6

Canada

APPENDIX 5: SUBSTANCES ELIGIBLE FOR A DIN-HM UNDER THE REGULATIONS

The substances listed below are found in accepted homeopathic pharmacopoeia and are covered by the Regulations. Therefore, they qualify for a DIN-HM.

Homeopathic Medicines Derived from Substances on Schedule D of the *Food and Drugs Act*[1] (Biologics)		
Anthracinum	*Elaps corallinus*	*Psorinum*
Bacillinum pulmo	*Hippozaeninum*	*Pyrogenium*
BCG	*Influenzinum*	*Sinusitisinum*
Candida albicans	*Lachesis mutus*	*Staphylococcinum*
Candida parapsilosis	*Lyssin*	*Streptococcinum*
Cenchris contortrix	*Medorrhinum*	*Syphilinum*
Colibacillinum cum natrum muriaticum	*Morbillinum*	*Tuberculinum*
Crotalus cascavella	*Naja tripudians*	*Vaccinotoxinum*
Crotalus horridus	*Pertussinum*	*Vipera berus*
Diphtherinum	*Proteus*	

Homeopathic Medicines Derived from Substances Regulated under the *Tobacco Act*[2]	
Nicotinum	*Tabacum*

Homeopathic Medicines Derived from Substances listed on Schedule F of the *Food and Drug Regulations*[3] (Prescription substances)		
Adrenocorticotrophin	Cortisone aceticum	Podophyllinum**
Ammonium bromatum	Digitalinum	Podophyllum peltatum**
Atropinum*	Digitalis purpurea	Rauwolfia serpentina
Atropinum sulphuricum*	Digitoxinum	Secale cornutum
Aurum bromatum	Hydrocotyle asiatica	Strontium bromatum
Aurum iodatum	Kali bromatum	Sulphanilamidum
Aurum metallicum	Lithium bromatum	Thyroidinum
Aurum muriaticum	Lithium carbonicum	Veratrinum
Aurum muriaticum kalinatum	Lithium muriaticum	Veratrum album
Aurum muriaticum natronatum	Natrum bromatum	Veratrum nigrum
Aurum sulphuratum	Nicotinum	Veratrum viride
Chloralum	Phenacetinum	Yohimbinum

* Permitted only in an ophthalmic preparation.
** Permitted only when sold or recommended for topical use.

[1] Please verify Schedule D by referring to http://laws.justice.gc.ca/en/F-27/240957.html#rid-240960
[2] Please verify the *Tobacco Act* by referring to http://laws.justice.gc.ca/en/T-11.5/
[3] Please verify Schedule F by referring to http://www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/pdf/e_k-schd-f.pdf

APPENDIX 6: SUBSTANCES NOT REGULATED UNDER THE REGULATIONS

These substances are found in accepted pharmacopoeia but are not regulated under the Regulations and therefore do not qualify for a DIN-HM:

Homeopathic Medicines Derived from Substances in Schedules I to V of the Controlled Drugs and Substances Act[4] (Narcotic ingredients)		
Cannabis indica	*Erythroxylon coca*	*Narceinum*
Cannabis sativa	*Morphinum*	*Narcotinum*
Cocainum	*Morphinum aceticum*	*Opium*
Cocainum muriaticum	*Morphinum muriaticum*	*Phenobarbital*
Codeinum	*Morphinum sulphuricum*	

Homeopathic Medicines Derived from Substances in Schedule C of the *Food and Drugs Act*[5] (Radiopharmaceuticals)		
Iridium metallicum	*Strontium bromatum*	*Strontium nitricum*
Radium bromatum	*Strontium carbonium*	*Uranium nitricum*

Dilution Scales	
Scale	**Designation Equivalence**
Decimal (1/10)	X = D = DH
Centesimal (1/100)	CH = C = CK = K
Millesimal (1/1000)	M = MK
Fifty Millesimal (1/50,000)	LM = Q

[4] Please verify substances on Schedules I to V by referring to http://laws.justice.gc.ca/en/C-38.8/
[5] Please verify Schedule C by referring to http://laws.justice.gc.ca/en/F-27/61279.html#rid-61397

APPENDIX 7: NON-MEDICINAL INGREDIENTS REFERENCE LIST

Committee on Food Chemicals Codex. Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. Food Chemical Codex . (4th ed). Washington (DC): National Academy Press, 1996.

Kibbe AH. *Handbook of Pharmaceutical Excipients* (3rd ed). Washington DC (US): American Pharmaceutical Association; 2000.

European Pharmacopoeia edition in force. Published under the direction of the European Directorate for the Quality of Medicines, of the Council of Europe, Strasbourg

Minister of Public Works and Government Services. *Canadian Food and Drug Regulations*. Ottawa (Canada): Government of Canada; 2001. http://www.hcsc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/e_index.html

Minister of Public Works and Government Services. *Natural Health Products Regulations of the Canadian Food and Drug Act*. Ottawa (Canada): Government of Canada; 2003. http://www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/e_index.html

Natural Health Products Directorate. *NHPD List of Accepted Non-Medicinal Ingredients.* Ottawa (Canada): Government of Canada; 2006. http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/nmi-imn_list_e.pdf

Pharmacopée française. Commission nationale de la Pharmacopée francaise, Agence française de sécurité sanitaire des produits de santé. Direction des laboratoires et des controles, Unité pharmacopée.

The British Pharmacopoeia. Published under the direction of the General Council of Medical Education and Registration of the United Kingdom, pursuant to the Acts XXI and XXII Victoria, cap. XC, 1858 and XXV and XXVI Victoria, cap. XCI, 1862.

The International Pharmacopoeia. Marketing and Dissemination World Health Organization, Geneva (Switzerland): World Health Organization.

United States Pharmacopeial Convention. *The United States Pharmacopeia*. The National Formulary. Rockville (MD): United States Pharmacopeial Convention, 2001.

APPENDIX 8: QUALITY REQUIREMENTS FOR MEDICINAL INGREDIENTS USED IN HOMEOPATHIC MEDICINES

Quality Test Requirements per Category of Homeopathic Medicines

The following chart outlines the quality tests required for different categories of homeopathic medicines.

Category of Homeopathic Medicine	**Identity Testing[6] (raw material stage)**	**Microbial contaminants (finished product stage)**	**Chemical Contaminants (raw material stage) Not required for homeopathic potencies 1 CH (2X) or higher[7]**
Mineral/ Chemical	Required	Required	Heavy metal testing (required for minerals only)
Zoological (including sarcodes)	Required	Required	Heavy metal and pesticide testing (required for all)
Botanical	Required	Required	Heavy metal and pesticide testing (required for all) Aflatoxin testing (required for ginseng/tree nuts only)
Nosode	Required	Required N.B. Sterilization technique must be stated (e.g. as per USP)	Since the minimum homeopathic potency for all nosodes is higher than 1 CH (2X), chemical contaminant testing is not required.

Examples of accepted techniques for identity testing include: HPLC fingerprinting, macroscopic and microscopic identification, and certificates of botanical origin. Other techniques can be found in the document *Evidence for the Quality of Finished Natural Health Products* that can be found at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/docs/index_e.html

[6] Identity testing is required for all medicinal ingredients according to the criteria set out in the accepted homeopathic pharmacopoeias (HAB and HPUS monographs published September 2004 and later) unless the medicinal ingredients are pharmacopoeial grade as per Schedule B of the *Food and Drugs Act* (e.g. *United States Pharmacopeia*).

[7] Heavy metal and pesticide testing is not required for homeopathic medicines at homeopathic potencies of 1 CH (2x) or higher because at this dilution level, under normal circumstances, any contaminants will be sufficiently diluted to fall within safety parameters.

Raw Material Testing

Test Parameters	Test	Method(s)	Tolerances
Identity (raw material)	Chemical fingerprinting	TLC, HPTLC or HPLC or GC, and/or spectroscopic methods	Characteristic for the item
	Appearance and Odour	Observation and Smell	Clear, colourless, etc.
Purity[8] Chemical contaminants (raw material)	Total Heavy metals (arsenic, cadmium, lead and total mercury)	Pharmacopoeial or WHO	Max. 10 ppm
	Pesticides	Pharmacopoeial or WHO	
	Mycotoxins[9]	AOAC-International (Association of Analytical Chemists)	Aflatoxins < 20 ppb

Finished Product Testing

Test Parameters	Test	Method(s)	Tolerances
Purity[10] Microbiological contaminants (finished product)	Contaminating fungus (yeast and mould)[11]	Pharmacopoeial or WHO	< 1 X 10^4 CFU/g or /mL
	Total Aerobic Count[12]	Pharmacopoeial or WHO	< 1 X 10^5 CFU/g or /mL
	Escherichia coli[13]	Pharmacopoeial or WHO	Absent
	Salmonella spp.[14]	Pharmacopoeial or WHO	Absent
	Staphylococcus aureus[15]	Pharmacopoeial or WHO	Absent
	Pseudomonas aeruginosa[16]	Pharmacopoeial or WHO	Absent

[8] Chemical contaminant testing is not required for raw materials in topical products that are a) at a homeopathic potency of 1X or above in the finished product and b) contain pharmaceutical-grade non-medicinal ingredients.
[9] These microbial tests are not required when the finished product is available in a solvent containing equal to or greater than 50% ethanol.
[10] Microbiological testing is required for all topical products.
[11,12,13,14,15,16] These microbial tests are not required when the finished product is available in a solvent containing equal to or greater than 50% ethanol.

APPENDIX 9: LABELLING CHECKLIST

Inner Label and Outer Label Requirements

Front Panel (Principal Display Panel):

- brand name;
- product number: eight-number DIN-HM
- the words “Homeopathic Medicine,” “Homeopathic Preparation,” “Homeopathic Drug” or “Homeopathic Remedy”;
- dosage form;
- the word “sterile” if the product is sterile; and
- net amount in the immediate container in terms of weight, measure or number.

Side Panel:

- name and address of the product license holder;
- name and address of the importer, if any;
- medicinal ingredients;
  - proper name, common name (if different from proper name), homeopathic potency
  - source information
- non-medicinal ingredients;
- recommended use or purpose;
- recommended route of administration, recommended dose, recommended duration of use, if any;
- risk information: cautions, warnings, known adverse reactions, contraindications;
- recommended storage conditions, if any;
- lot number; and
- expiry date.

Outer Label Only

- non-medicinal ingredients:
  - common name
- the quantity of mercury contained in the product if it contains mercury or its salts or derivatives as a non-medicinal ingredient;

Bilingual Text:

- recommended use or purpose;
- dosage form;
- recommended route of administration, recommended dose, recommended duration of use, if any;
- risk information: cautions, warnings, contraindications, known adverse reactions;
- medicinal ingredients;
  - proper name, common name (if different from proper name), homeopathic potency
  - source information
- non-medicinal ingredients;

    - common name
- storage conditions, if any.

Pressurized Container:

- signal word, primary hazard statement; and
- additional cautions.

Cautionary statements: as required.

Small Package Requirements

Outer label, if any:

- must be labelled as required in chapter 3.1 of the *Labelling Guidance Document*.

On the Inner Label:

- brand name
- product number: eight-number DIN-HM;
- the word “sterile” if the product is sterile;
- the words “Homeopathic Medicine,” “Homeopathic Preparation,” “Homeopathic Drug” or “Homeopathic Remedy”;
- the net amount in the immediate container in terms of weight, measure or number;
- proper name of each medicinal ingredient;
- recommended use or purpose;
- recommended dose;
- recommended duration of use, if any;
- lot number;
- expiry date; and
- when the package does not have an outer label, a statement that refers the purchaser or consumer to a leaflet that displays the statements, information and declarations required to be shown on the outer label.