Protected when completed

Quality Assurance Report Form (QAR)

Please refer to the instructions on how to complete this form.

HC Use Only

Submission Number	
File Number	
Date/Time of Receipt	

General Information

A. Company/Building Information

1. Company/Building Name

2. Address (Number/Street/Suite/Direction)

3. City/Town | 4. Province/State | 5. Postal/Zip Code | 6. Country

B. Operation(s) at this Building

7. a) Indicate the activity or activities at this building by checking the appropriate box(es)

	Non-Sterile	Sterile	Homeopathic Medicine
Manufacturing	☐	☐	☐
Packaging	☐	☐	☐
Labelling	☐	☐	☐
Importing	☐	☐	☐
Storage only	☐	☐	☐

7. b) Contract manufacturer Yes ◯ No ◯

7. c) Secondary packager (labeller) Yes ◯ No ◯

7. d) Supplementary QAR form (for homeopathic medicines only) attached? Yes ◯ No ◯
**Not required for importing activities*

8. Dosage Form(s):

Capsule ☐ Tablet ☐ Pellet ☐ Liquid ☐ Lotion ☐ Solid Extract ☐ Tincture ☐ Powder ☐

Other (specify)

9. Product Type(s):

Plant, alga or fungus ☐	Non-human animal material ☐	Bacterium ☐
Extracts ☐	Isolates ☐	Enzymes ☐
Vitamins ☐	Minerals ☐	Amino acids ☐
Essential fatty acids ☐	Synthetic duplicates ☐	Probiotic ☐
Homeopathic medicines ☐	Traditional medicines ☐	

C. Quality Assurance Person(s) (QAP)

10. a) Name of Quality Assurance Person who completed the QAR for this building as per Section 28(f) of the *Natural Health Products Regulations*:

10. b) In-House ◯ Third Party ◯

11. a) Name of Quality Assurance Person who is responsible for ensuring that compliance to Section 51 of the *Natural Health Products Regulations* is met:

11. b) In-House ◯ Third Party ◯

Attestation

I attest that the building(s), practice(s), and procedure(s) used for conducting activities in our facility comply with the Good Manufacturing Practices set out in Part 3 of the *Natural Health Products Regulations* (the Regulations).

Name of Quality Assurance Person	Signature of Quality Assurance Person	Date (yyyy-mm-dd)

Detailed Quality Assurance Report

Places

Premises

[Section 45 of the Regulations and chapter 2.1.1 of the Good Manufacturing Practices guidance document]

(1) Building is designed and constructed to allow manufacturing, packaging, labelling and storage activities to be performed in a way that prevents contamination, cross-contamination and adulteration of natural health products by way of:

- (a) adequate construction and design for intended use, including adequate ventilation, filtration and airflow, appropriate plumbing size, design and construction; Yes ◯ No ◯
- (b) appropriate water supply and purity for the intended purposes (e.g. production, cleaning or utility functions); Yes ◯ No ◯
- (c) appropriate space to carry out the operations of the facility; Yes ◯ No ◯
- (d) separated production and non-production areas; Yes ◯ No ◯
- (e) clearly defined and delineated areas (e.g. receiving, quarantine, sampling); and Yes ◯ No ◯
- (f) sealed building surfaces (e.g. windows, floors, ceilings and production surfaces) made of materials that facilitate maintenance and sanitation. Yes ◯ No ◯

(2) Building is designed and maintained to prevent cross-contamination of the natural health product(s) and the entry and harbouring of insects, rodents, birds and other animals by way of:

- (a) appropriately maintained exterior grounds; Yes ◯ No ◯
- (b) maintained proper state of repair; Yes ◯ No ◯
- (c) established barriers to prevent entry of pests; and Yes ◯ No ◯
- (d) established pest control procedures, preventative and corrective. Yes ◯ No ◯

Records related to building design, maintenance and pest control (internal or contractor) will be available upon request. Yes ◯ No ◯

(3) Raw material(s) and finished product(s) are manufactured, packaged, labelled and stored under conditions that maintain quality and safety by way of:

- (a) appropriately maintained temperature and humidity regulating equipment; Yes ◯ No ◯
- (b) recording temperature, humidity and light monitoring; Yes ◯ No ◯
- (c) investigating deviations from appropriate conditions; Yes ◯ No ◯
- (d) procedures to address product affected by failed environmental conditions. Yes ◯ No ◯

Records related to environmental monitoring of production and storage areas will be available upon request. Yes ◯ No ◯

List standard operating procedure(s) (SOP) (titles and numbers) related to questions 1 to 3.

Equipment
[Section 46 of the Regulations and Chapter 2.1.2 of the Good Manufacturing Practices guidance document]

(4) Equipment is designed, constructed, arranged, operated, and maintained in a manner that:

(a) permits effective cleaning of equipment surfaces and utensils;	Yes ◯ No ◯
(b) permits intended functioning;	Yes ◯ No ◯
(c) prevents contamination of the product; and	Yes ◯ No ◯
(d) ensures maintenance and calibration in accordance with intended use.	Yes ◯ No ◯
Records related to maintenance and calibration of equipment will be available upon request.	Yes ◯ No ◯

List SOP (titles and numbers) related to question 4.

People

Personnel
[Section 47 of the Regulations and Chapter 2.2.1 of the Good Manufacturing Practices guidance document]

(5) Individuals involved in manufacturing, packaging, labelling and/ or storage activities have appropriate education, training or experience demonstrated by:

(a) documented job description; and	Yes ◯ No ◯
(b) good manufacturing practices (GMP) training related to assigned duties.	Yes ◯ No ◯
Supporting documentation related to education, training and/ or work experience will be available upon request.	Yes ◯ No ◯

List SOP (titles and numbers) related to question 5.

Quality Assurance
[Section 51 of the Regulations and Chapter 2.2.2 of the Good Manufacturing Practices guidance document]

(6) Individuals involved in manufacturing, packaging, labelling and/ or storage activities have appropriate education, training or experience demonstrated by:

(a) has a documented job description;	Yes ◯ No ◯
(b) has the appropriate training, experience and technical knowledge;	Yes ◯ No ◯
(c) approves raw, packaging and labelling materials;	Yes ◯ No ◯
(d) is responsible for methods and procedures;	Yes ◯ No ◯

(e) approves product lot or batch release for sale; Yes ◯ No ◯

(f) approves returned product prior to release for re-sale; Yes ◯ No ◯

(g) takes corrective actions to non-conformities; and Yes ◯ No ◯

(h) investigates and records complaints. Yes ◯ No ◯

Supporting documentation related to the quality assurance person responsibilities and activities will be available upon request. Yes ◯ No ◯

List SOP (titles and numbers) related to question 6.

Provide a copy of the SOP related to quality assurance product release.

Provide a copy of a completed record related to finished product release for sale.

Processes

Sanitation Program

[Section 48 of the Regulations and Chapter 2.3.1 of the Good Manufacturing Practices guidance document]

(7) The sanitation program at the site includes:

(a) procedures for effectively cleaning the premises (including production and storage areas); Yes ◯ No ◯

(b) procedures for the cleaning of equipment; Yes ◯ No ◯

(c) procedures for handling any substance used in the activity; and Yes ◯ No ◯

(d) policies and procedures related to the health and hygiene of personnel. Yes ◯ No ◯

Records related to cleaning of the facility and equipment will be available upon request. Yes ◯ No ◯

List SOP (titles and numbers) related to question 7.

Operations

[Section 49 of the Regulations and Chapter 2.3.2 of the Good Manufacturing Practices guidance document]

(8) The manufacturer, packager, labeler and/or importer:

(a) maintains appropriate standard operating procedures related to the activity; and Yes ◯ No ◯

(b) has an established inspection program for any work contracted out (e.g. contract testing laboratories, raw material suppliers, etc.). Yes ◯ No ◯

List SOP (titles and numbers) related to question 8.

Operations and Recall Reporting
[Sections 50 and 62 of the Regulations and Chapter 2.3.2 & 2.4.5 of the Good Manufacturing Practices guidance document]

(9) The manufacturer and/or importer:

(a) maintains procedures to ensure the effective recall of a product; and — Yes ◯ No ◯

(b) maintains procedures to ensure that the required information, as per section 62 of the Regulations, is submitted to the appropriate HPFBI Regional Operational Centre when a recall is initiated. — Yes ◯ No ◯

List SOP (titles and numbers) related to question 9.

Provide a copy of the SOP related to recall.

Product

Specifications
[Section 44 of the Regulations, Chapter 2.4.1 of the Good Manufacturing Practices guidance document and Chapter 1.5.3 of the Quality of Natural Health Products Guide]

(10) With respect to raw material and finished natural health product specifications:

(a) procedures are in place and followed to assess raw and/or packaging materials against written specifications; — Yes ◯ No ◯

(b) procedures are in place and followed to assess finished products against specifications for purity (microbiological and chemical contaminants); — Yes ◯ No ◯

(c) procedures are in place and followed to assess finished products for medicinal ingredient quantity and identity; — Yes ◯ No ◯

(d) procedures are in place and followed to assess finished products for potency (if applicable); — Yes ◯ No ◯

(e) procedures are in place to ensure that any change(s) in finished product specifications are reflected in the operations; and — Yes ◯ No ◯

(f) procedures are in place to ensure that every change to specifications is approved by the quality assurance person. — Yes ◯ No ◯

Product specifications and certificates of analysis will be available upon request. — Yes ◯ No ◯

If an alternate site, listed in the site licence application, is responsible for this section, please describe:

List SOP (titles and numbers) related to question 10.

Provide a copy of the SOP related to finished product specifications and testing.

Provide a copy of a completed record related to finished product testing (certificate of analysis or other finished product test record).

Stability

[Section 52 of the Regulations and Chapter 2.4.2 of the Good Manufacturing Practices guidance document]

(11) With respect to an on-going stability program, every manufacturer and/or importer has:

(a) Data demonstrating product meets specifications at expiry; Yes ◯ No ◯

(b) Data from initial accelerated or real-time stability studies from similar products; formulations to determine the expiration date; and Yes ◯ No ◯

(c) Data from real-time stability studies to support an extended expiration date. Yes ◯ No ◯

Data related to determination of expiry date will be available upon request. Yes ◯ No ◯

If an alternate site, listed in the site licence application, is responsible for this section, please describe:

List SOP (titles and numbers) related to question 11.

Provide a copy of the SOP related to determination of expiry date.

Provide a copy of a complete record of data demonstrating determination of expiry date.

Samples
[Section 61 of the Regulations and Chapter 2.4.3 of the Good Manufacturing Practices guidance document]

(12) With respect to lot or batch samples:

(a) a sample retention program is in place at the site; Yes ◯ No ◯

(b) lot or batch samples are available upon request; Yes ◯ No ◯

(c) sufficient quantities of lot or batches are maintained; and Yes ◯ No ◯

(d) samples are retained for a period of one year past the expiry date of the product. Yes ◯ No ◯

List SOP (titles and numbers) related to question 12.

Records
[Sections 53-58 of the Regulations and Chapter 2.4.4 of the Good Manufacturing Practices guidance document]

(13) Manufacturers, packagers, labelers, importers and/or distributors:

(a) maintain records as per sections 53 to 57 of the Regulations; and Yes ◯ No ◯

(b) maintain batch and lot records for a period of one year past the expiry date of the product. Yes ◯ No ◯

List SOP (titles and numbers) related to question 13.

Sterile Products
[Sections 59 and 60 of the Regulations and Chapter 2.4.6 of the Good Manufacturing Practices guidance document]

(14) All sterile (ophthalmic) products are manufactured and packaged:

(a) in a separate and enclosed area; Yes ◯ No ◯

(b) under the supervision of personnel trained in microbiology; Yes ◯ No ◯

(c) using a method scientifically proven to ensure sterility; Yes ◯ No ◯

(d) prepared according to C.01.064 of the *Food and Drugs Act*; and Yes ◯ No ◯

(e) tested according to C.01.065 of the *Food and Drugs Act*. Yes ◯ No ◯

If no, provide a rationale.

List SOP (titles and numbers) related to question 14.

Provide a copy of the SOP related to product sterilization.

Please refer to the sterile requirements for drugs for more information.

List of Products Manufactured, Packaged, Labelled, Imported, and/or Stored at the Site

Product Name	Dosage Form	Product Type	Route of Administration	Natural Product Number (NPN)	Storage Conditions Requirements