



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 <i>Food and Drugs Act</i> ; and | Yes | No |
| (e) tested according to C.01.065 of the <i>Food and Drugs Act</i> .       | 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