Protected when completed

Supplementary Quality Assurance Report (SQAR) Form for Homeopathic Medicines (HM)

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 HM	Sterile HM
Manufacturing	☐	☐
Packaging	☐	☐
Labelling	☐	☐

7. b) Contract manufacturer Yes ◯ No ◯

8. Dosage Form(s):

Tablet ☐ Pellet ☐ Liquid ☐ Lotion ☐ Powder ☐ Granule ☐ Syrup ☐

Other (specify)

9. Method of Preparation Reference:

Homeopathic Pharmacopeia of the United States (HPUS) ☐

Homöopathisches ArzneiBuch (HAB) or German Homeopathic Pharmacopoeia (GHP) ☐

French Pharmacopoeia (PhF) ☐

European Pharmacopoeia (Ph.Eur.) ☐

Encyclopedia of Homeopathic Pharmacopoeia (EHP) ☐

C. Quality Assurance Person(s) (QAP)

10. a) Name of Quality Assurance Person who completed the SQAR 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 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 Supplementary Quality Assurance Report

Places

Premises

[Section 45 of the Regulations and Appendix 1 of the Good Manufacturing Practices guidance document]

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

(a)	preparing in rooms or workstations that have appropriate environmental controls;	Yes ◯ No ◯
(b)	distinct separation from products which are volatile or have permeating odours;	Yes ◯ No ◯
(c)	isolating toxic or infectious raw materials from other materials;	Yes ◯ No ◯
(d)	handling of raw materials in segregated areas with appropriate environmental controls suitable for each material.	Yes ◯ No ◯

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

If yes, describe the potential source(s) of contamination and how they are controlled and monitored.

If no, provide a rationale.

Equipment
[Section 46 of the Regulations and Appendix 1 of the Good Manufacturing Practices guidance document]

(2) Equipment and utensils are used exclusively for homeopathic preparations. Yes ◯ No ◯

List SOP (titles and numbers) related to question 2.

If yes, describe the potential source(s) of contamination and how they are controlled and monitored.

If no, provide a rationale.

People

Personnel
[Section 47 of the Regulations, and Appendix 1 of the Good Manufacturing Practices Guidance Document]

(3) Individuals involved in manufacturing, packaging, and labelling have appropriate education, training or experience, demonstrated by:

(a) training specific to the attenuation and/or trituration of homeopathic medicines; Yes ◯ No ◯

(b) restricting the entry of untrained or unnecessary personnel in processing areas designated for attenuation and trituration. Yes ◯ No ◯

Supporting documentation related to education, training and/or work experience will be made available upon request. Yes ◯ No ◯

List SOP (titles and numbers) related to question 3.

Processes

Sanitation Program

[Section 48 of the Regulations and Appendix 1 of the Good Manufacturing Practices Guidance Document]

(4) Manufacturers, packagers, and labellers must ensure that the sanitation program does not contaminate the homeopathic product with chemicals or particulate matter by having:

(a) cleaning requirements for all processing areas, with emphasis on areas designated for attenuation and trituration; Yes ◯ No ◯

(b) methods to ensure cleaning products do not contaminate product; and Yes ◯ No ◯

(c) adequate methods to ensure there is no cross contamination of products. Yes ◯ No ◯

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

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

Operations

[Section 49 of the Regulations and Appendix 1 of the Good Manufacturing Practices guidance document]

(5) Homeopathic medicines are made according to the preparation methods in the homeopathic pharmacopoeias:

(a) raw materials that are toxic or potentially infectious must be labelled and handled according to their safety status; Yes ◯ No ◯

(b) critical production processes are controlled (such as labelling equipment, containers, and raw materials used during in-process stages). Yes ◯ No ◯

(c) The master formula includes special precautions that may be relevant to the particular classification of preparation (e.g. nosodes). Yes ◯ No ◯

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

Provide a copy of a completed mother tincture or medicating potency batch record.

Product

Specifications

[Section 44 of the Regulations, Appendix 1 of the Good Manufacturing Practices guidance document and the Evidence for Homeopathic Medicines guidance document]

(6) All homeopathic products are prepared in accordance with specifications that include the methods outlines in one of the homeopathic pharmacopoeias:

(a) the identity of the raw materials are verified prior to use in manufacturing; Yes ◯ No ◯

(b) procedures are in place and followed in the manufacture of mother tinctures. Yes ◯ No ◯

Product specifications and associated certificates of analysis will be made available upon request for all products manufactured, packaged, and/or labelled. Yes ◯ No ◯

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

Provide a copy of the SOP and one template related to raw material specifications.

Stability

[Section 52 of the Regulations and Appendix 1 of the Good Manufacturing Practices guidance document]

(7) With respect to stability, every manufacturer has:

(a) developed and maintains SOP that ensure the stability of the homeopathic medicines; Yes ◯ No ◯

(b) records of purity testing; Yes ◯ No ◯

(c) packaging and labelling materials that are confirmed to maintain integrity and do not contaminate the product during its established shelf life. Yes ◯ No ◯

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

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