

Appendix 2: Supporting GMP evidence

The Web SLA form outlines the evidence that is required to demonstrate compliance with the NHP GMPs as outlined in Part 3 of the NHPR. In summary, the application must contain the following GMP evidence:

1. Quality assurance report (QAR)

Per Section 28(f) of the NHPR, the application for a site licence requires a QAR, prepared by the quality assurance person (QAP), demonstrating compliance with Part 3 (GMP) of the NHPR. The QAP responsible for the site – who must have the training, experience and technical knowledge relating to the activities conducted and the applicable GMP requirements – must complete this report.

- One QAR is required for each site listed on the application (e.g. if the product is imported, a QAR is required for the importing site AND the manufacturing site).

2. Standard Operating Procedures (SOPs)

Each QAR requires the following SOPs:

- a) product recall;
- b) finished product testing;
- c) product release; and
- d) determination of expiry date.

Standard Operating Procedures

Appendix 4 of the [Good Manufacturing Practices Guidance Document](#) outlines expectations for SOPs.

The recall SOP must align with the [Drug and natural health products recall guide](#).

3. Records pertaining to both the site(s) and product(s)

The following records are required for each alcohol-based hand sanitizer (i.e., **product**) that is manufactured or imported by the applicant, in support of demonstrating compliance with sections 44 and 49 to 52 of the NHPR.

- a) finished product release for sale;
- b) finished product testing (i.e. certificate of analysis); and
- c) data to support the determination of the expiry date (i.e, stability data).

Note: If your company intends to solely manufacture or import alcohol-based hand sanitizers (i.e., no other NHPs), stability data is not required as part of this application. Stability data will be required at your first site licence renewal, assuming you are issued a site licence.

The following records are required for each **site** listed as part of the application:

- a) Batch record - in support of demonstrating compliance with section 44 and 49 to 51 of the NHPR, a batch record is a document prepared for each batch or lot that includes all ingredients, process details and equipment used to make the product.
- b) Storage controls - in support of demonstrating compliance with section 45(2) of the NHPR, provide records demonstrating that NHPs are stored under conditions that maintain their quality and safety (e.g. daily data logs recording temperature and/or humidity).
- c) Pest controls - in support of demonstrating compliance with section 45(1)(d and e) of the NHPR, provide records demonstrating that NHPs are manufactured, packaged, labeled and stored in premises that are maintained in a manner that prevent their contamination (e.g. contractor pest control invoice, pest activity inspection logs).
- d) Sanitation - in support of demonstrating compliance with sections 46(a) and 48 of the NHPR, provide records demonstrating that NHPs are manufactured, packaged, labeled and

stored in compliance with a sanitation program (e.g., data logs of site and equipment cleaning, including schedules and frequencies).