
Natural health products good manufacturing practices pre-inspection package:

Checklist for importers



Regulatory Operations
and Enforcement

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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Trousse de préinspection des bonnes pratiques de fabrication des produits de santé naturels : Liste de vérification pour les importateurs

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Regulatory Operations and Enforcement

Specifications (section 44)

- Standard operating procedures (SOPs) and associated records for finished product testing and specifications, including an assessment of the following:
 - raw materials against specifications, if applicable
 - finished products against specifications, including a description of:
 - how finished product specifications are tested or controlled (for example, testing is product-specific, frequency of testing)
 - how to handle out-of-specification (OOS) results
- Product specifications for all products imported
- Product specifications are approved by the quality assurance person (QAP)
- Certificate of analysis (CoA) for each lot of product that demonstrates the product meets its specifications according to requirements outlined in the [Quality of natural health products guide](#)
- Evidence that products are tested according to their finished product specifications, including testing methods and acceptance criteria as outlined in the [Quality of natural health products guide](#) and as outlined in the [Good manufacturing practices guide for natural health products \(GUI-0158\)](#) if the following are used:
 - reduced testing (microbial contaminants)
 - exemption to product testing before release (chemical contaminants)
 - rotational testing (medicinal ingredients)
 - quantification by input
- Finished product specification change control log
- Evidence that testing is done at a laboratory that adheres to good laboratory practices (GLP) or other comparable quality standards (for example, the International Organization for Standardization (ISO))

Premises (section 45)

- A detailed floor plan showing, for example, the warehouse, including quarantine area, release area and retain samples room
- SOPs and associated records for:
 - prevention of contamination and cross-contamination of natural health products (NHPs)
 - storage conditions of bulk and finished products
 - pest control
 - janitorial duty schedule and cleaning completion
 - ventilation inspection and maintenance (as applicable)
 - facility inspection and maintenance

Equipment (section 46, if applicable)

- SOPs for the operation of equipment, such as temperature and humidity monitoring devices
- Preventive maintenance schedule or program for equipment, which includes identification of equipment and instructions on how to maintain it
- Equipment usage, cleaning and maintenance logs
- Calibration program and records for equipment that requires it, including proof of the calibration standard or reference being used

Personnel (section 47)

- SOPs for the appropriate education, training or work experience for all personnel
- List of qualified QAP designate(s)
- Records of completed training relating to assigned duties and responsibilities (for example good manufacturing practices (GMP) training) of personnel
- Employee training schedule or attendance records that demonstrate initial and on-going relevant training
- Job descriptions that outline roles and responsibilities of positions
- Résumé or curriculum vitae that show the person meets their job description

Sanitation program (section 48)

- SOPs and associated records for a sanitation program that includes information on cleaning of premises and storage areas, where applicable, such as:
 - procedures for destroying and disposing of waste materials and debris
 - cleaning and sanitizing agents to be used, if applicable
 - cleaning frequencies
 - facility cleaning schedule
 - cleaning completion
- SOPs and associated records for a health and hygiene program that includes:
 - personnel hygiene training
 - guidance related to personal hygiene

Operations (section 49, if applicable)

- SOPs and associated records for:
 - transporting, receiving, handling, storing and distributing bulk or finished products
 - specifications, CoAs and release records for all raw materials (medicinal and non-medicinal ingredients) and packaging material
 - product disposition, return and disposal
 - out-of-specification results, including investigations into root causes and resulting corrective and preventive actions
 - product complaints and resulting action
- Master production documents, master labels and batch records, certificates of manufacture or batch certificates (when applicable)
- Quality agreements with contractors (for example, manufacturers, packagers, labellers, warehouses, test labs, wholesalers, quality assurance consultants) and suppliers
- List of all contract manufacturers, packagers and labellers used domestically and in foreign countries, as applicable

Operations (section 50)

- SOPs and associated records for recalling a NHP and recall reporting
- Each lot of raw material and released bulk or finished product has distinct identification for traceability (for example, lot number)
- Distribution records for all products
- Signed quality agreement outlining recall responsibilities

Quality assurance (section 51)

- Organizational chart showing independence of QAP's function
- Identification of the QAP and delegate (where applicable)
- QAP's and delegate's (where applicable) résumé, including education
- QAP's training record demonstrating ongoing and relevant training
- SOPs and associated records for:
 - QAP job description that outlines roles and responsibilities, required training, experience and technical knowledge
 - approval of bulk or finished products
 - investigation and resolution/corrective actions for complaints, deviations, OOS test results, and returned, rejected and expired products
 - disposition, distribution and disposal of products
 - review and approval of methods, procedures and systems used to import and store NHPs
- Approved finished product specifications
- Approved finished product release records

Stability period (section 52, if applicable)

- SOPs and associated records for stability data, testing or determining expiry date, including a:
 - description of testing procedures and schedule
 - direction on storage of samples at recommended conditions
 - direction on actions to be taken if a product fails stability, stability failure investigations and recalls

- establishing and extending product expiry dates
- description of how product shelf life is re-evaluated when significant changes are made to:
 - formulation
 - manufacturing process
 - packaging that may affect a product's stability
- Laboratory results demonstrating that every product meets its specifications at expiry, including:
 - corresponding testing results for each time point as indicated in the stability testing protocol
 - acceptance test methods and acceptance criteria used

Records (section 56) and record maintenance (section 58)

- List of all NHPs handled at the site
- A copy of the sanitation program in use by the importer
- Records demonstrating that each lot or batch of the NHP was manufactured, packaged and labelled in accordance with the requirements of Part 3 of the regulations
- Master production documents
- Records containing sufficient information to enable a recall
- Finished product specifications
- CoA for the finished product
- Access to the following records, if requested:
 - batch records (when quantification by input is used)
 - results of packaging material testing and raw material testing (when quantification by input is used)
 - specifications of raw materials and packaging materials
- Stability data for each product

- Relevant records are maintained for a period of 1 year following the expiry date of the NHP to which that record relates
- Relevant SOPs for the maintenance of records by importers, including the following:
 - change control
 - record control and retention
 - control of electronic records
 - use of electronic signatures
 - good documentation practices
 - document translation
 - review and approval of GMP documents
 - SOP creation and maintenance
- When an electronic document management system is in place:
 - information that supports the suitability and reliability of the system
 - documentation that outlines the development and maintenance of the system
- When electronic signatures are in use:
 - documentation detailing the development and maintenance of the electronic signature identification system
 - they must be tested and evaluated for security, validity and reliability

Sterile natural health products (section 59) and ophthalmic use (section 60)

- Maintain copies of the:
 - product-specific process validation for all critical steps of the manufacturing and packaging process (as applicable), re-qualification and controls of the sterilization processes
 - in process and finished product testing results
 - product sterilization record
 - records of environmental control of particulate and microbial

- contamination
- QAP and product support staff qualifications and specialized training in microbiology (applies only to staff supervising the sterile manufacturing)
- clean room maintenance records
- laminar flow maintenance records
- Have access to copies of complete protocols and related studies for all validation activities
- For more information, refer to [Annex 1 to the Good manufacturing practices guide – Manufacture of sterile drugs \(GUI-0119\)](#)

Lot or batch samples (section 61)

- SOPs and associated records for:
 - sampling protocol
 - sample retention
 - store samples in the environmental conditions listed on the label
 - samples should be stored for 1 year after the product has expired
 - samples should be stored in the same container closure system as the finished product
- Retain an adequate number of samples of each lot of a finished product, to permit complete duplicate testing according to the specifications and product licence

Recall reporting (section 62)

- SOPs and associated records for:
 - how to recall an NHP
 - information you need to provide to Health Canada when there is a recall (including contact information for the appropriate Health Canada regional office)
- List of all previous recalls and reasons for the recalls
- Recall report or records if a recall took place, including:

- documentation of all recall information
- product distribution records
- documentation of recalled product's final disposition
- Mock recall report (if no actual recall is conducted)