# Natural health products good manufacturing practices pre-inspection package:

## Checklist for manufacturers


Health Canada Santé Canada

Canada

**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.

Également disponible en français sous le titre :
Trousse de préinspection des bonnes pratiques de fabrication des produits de santé naturels : Liste de vérification pour les fabricants

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Publication date: April 2026



ISBN: 978-0-660-99150-4
Pub.: H164-421/1-2026E-PDF

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 manufactured at the site
- ☐ Product specifications are approved by the quality assurance person (QAP)
- ☐ 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 production, non-production, quarantine areas and so on
- ☐ SOPs and associated records for:
  - ☐ prevention of contamination and cross-contamination of natural health products (NHPs)

- ☐ storage conditions of raw materials, and in-process and finished products
- ☐ pest control
- ☐ janitorial duty schedule and cleaning completion
- ☐ ventilation inspection and maintenance (as applicable)
- ☐ water quality testing
- ☐ facility inspection and maintenance

## Equipment (section 46)

- ☐ 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
- ☐ SOPs for the operation of equipment

## 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, production and storage areas and equipment, such as:

- storage and protection of equipment after cleaning
- procedures for destroying and disposing of waste materials and debris
- cleaning and sanitizing agents to be used
- 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)

- SOPs and associated records for:
  - transporting, receiving, handling, storing and distributing raw materials or finished products
  - all aspects of the production run
  - specifications, certificates of analysis (CoA) and release records for all raw materials (medicinal and non-medicinal ingredients)
  - product disposition, return and disposal
  - OOS results, including investigations into root causes and resulting corrective and preventive actions
  - product complaints and resulting action
  - water sample testing demonstrating that water used in manufacturing is of acceptable quality
- Master production documents and batch records
- 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 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 raw materials, and in-process and finished products
  - ☐ finished product release
  - ☐ 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 manufacture NHPs
- ☐ Approved finished product specifications
- ☐ Approved finished product release records

## Stability period (section 52)

- 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
  - acceptable test methods and acceptance criteria used

## Records (section 53) and record maintenance (section 58)

- List of all NHPs manufactured at the site
- A copy of the sanitation program in use by the site
- SOPs for the maintenance of records by manufacturers, 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

- Records demonstrating that each lot or batch of the NHP was manufactured in accordance with the requirements of Part 3 of the regulations
- 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
- Master production documents
- Raw material specifications
- Finished product specifications
- Records containing sufficient information to enable a recall, which includes product distribution records
- CoA for all raw materials (medicinal and non-medicinal ingredients)
- CoA for the finished product
- 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

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

- SOPs and associated records for:
  - manufacturing processes
  - environmental control of particulate and microbial contamination

- clean room entry and exit process for personnel and materials
- clean room maintenance
- laminar flow maintenance
- product sterilization
- in-process and finished product testing
- QAP and product support staff qualifications and specialized training in microbiology (applies only to staff supervising the sterile manufacturing)

- Detailed floor plan showing movement of personnel and materials during sterile production
- Product-specific process validation for all critical steps of the manufacturing process, re-qualification and controls of the sterilization process
- 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)

- □ Lists 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)