
Natural health products good manufacturing practices pre-inspection package:

Information requested before an inspection



**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.

Également disponible en français sous le titre :
Trousse de préinspection des bonnes pratiques de fabrication des produits de santé naturels : Renseignements demandés avant une inspection

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Regulatory Operations and Enforcement

The following checklist outlines the type of information that you may be asked to provide the inspector before an inspection. Depending on the licensable activity being evaluated, you may be asked to provide other information.

- Current organizational chart, including names of persons holding positions relevant to the inspection
- List of current standard operating procedures (SOPs) including the title, version and effective date
- Site floor plan
- Nature of activities conducted at the facility
- A list (in a table) of all natural health products (NHPs) handled on-site and sourced from a supplier, indicating the following:
 - product name
 - medicinal ingredients
 - dosage form class (for example, powder, tablet, capsule, cream) and if the product is sterile
 - natural product number (NPN)
 - product licence holder (the "NPN owner")
 - for each NHP, specify the:
 - sites that manufacture, package, label, store or import it (for sites in Canada, specify if they hold a valid site licence for the applicable activities conducted on your behalf)
 - address(es) where testing takes place (provided by the foreign manufacturer or tested in Canada)
 - quantities manufactured, packaged, labelled or imported (including the lot or batch number identification)
 - labelled storage conditions
- List of where retention samples, finished products and good manufacturing practices (GMP) documents are stored

- Summary list (in a table) of complaints, deviations and out-of-specification test results
 - include product names, lot numbers, brief description of event, tracking number (if applicable) and outcome
- Confirmation that documents relevant to the inspection are in 1 of Canada's official languages