

Quick NOTES

NHP Good Manufacturing Practices

FEBRUARY 2009
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OVERVIEW

- The Natural Health Product (NHPs) regulations require that any site engaged in manufacturing, packaging, labelling, importing and distributing natural health products intended for sale in Canada comply with Canadian Good Manufacturing Practices (GMPs) for NHPs.
- It is the responsibility of the importer to ensure that any foreign or domestic sites on their site licence comply with the Canadian GMPs.

Refer to the *Good Manufacturing Practices Guidance Document*:
<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf-eng.php>

WHO DOES THIS APPLY TO

- Importers, packagers, labellers, manufacturers, distributors
- Warehouse/storage facilities

WHAT'S NEW

- The *Good Manufacturing Practices Guidance Document* has been in place since August 2006.

KEY POINTS

Places

- Premises must be clean and orderly, with surfaces that allow for effective cleaning and are designed to prevent contamination of the NHP.
- Equipment surfaces must allow for effective cleaning, must function in accordance with intended use and be designed to prevent contamination of the NHP.

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People

- Personnel must be qualified by education, training or experience to perform their respective functions.
- Quality Assurance is responsible to release each product for sale, release raw materials and packaging components for use, approve all operational procedures, master formulae and specifications, review all returns prior to resale and investigate each complaint.

Processes

- Sanitation program includes documented procedures for the effective cleaning of the premises, equipment, handling of substances and the health and hygienic behaviour of personnel.
- Operation includes systems for:
 - Review and release of all raw materials and packaging materials
 - Water that is potable and meets the *Guidelines for Canadian Drinking Water Quality*
 - Complete batch records for each batch allowing for traceability
 - Each finished package is identified with a lot number and expiry date
 - Labels are secured and controlled
 - Quality agreements are in place with contractors

Products

- Specifications are available for every product and include purity, quantity, identity of medicinal ingredients, potency and test methods.

See the *Site Licence Guidance Document* at:
http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/sl-gd-drle_e.html

Refer to the *Guidelines for Canadian Drinking Water Quality*:
http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/guidelines_sixth-rec-eng.php

- Every lot must be tested for conformance with its finished product specifications.

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- Importers may follow a reduced testing program in which:
 - The first lot of each product is fully tested.
 - For each subsequent lot:
 - A Certificate of Analysis (C of A) with actual test results is reviewed,
 - The lot is positively identified upon receipt, and
 - Transportation and storage conditions do not adversely impact the product.
 - Full confirmatory testing is conducted on at least one lot per year per dosage form, per supplier.
 - Stability results demonstrate that the product will meet specifications under the recommended storage conditions.
 - Samples are retained under the recommended storage conditions for one year past the expiration date of the product. There is sufficient sample available to perform complete testing of the product.
 - Records must be retained for one year past the expiration date of the product to which they refer.
 - Recall procedure is documented and effective.
 - Sterile NHPs must be manufactured and packaged in a separate enclosed area under the supervision of a trained person using scientifically proven methods to ensure sterility.

FAQ

1. Do I need to test each lot of product?

Yes. Every lot of product must be assessed for compliance with the specifications prior to release. Importers may apply a reduced testing program that relies on the test results from their supplier provided that a certificate of analysis is submitted with each lot received.

2. Do I need to test all my actives?

Yes. All medicinal ingredients must be tested for content. In some circumstances, quantification by input is considered acceptable.

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3. When do I need to comply?

The Natural Health Products Regulations came into force on January 1, 2004 and apply to all natural health products as of this date.

4. Will I be inspected?

Yes. Health Canada will be implementing a program of routine inspections of NHP site licence holders. This may commence in 2009 or 2010.

5. Do I need to validate?

No, however, the guidelines do require that equipment functions in accordance with intended use. There is no expressed requirement for equipment qualification or process validation.

It is required that cleaning is effective but there is no expressed requirement for cleaning validation.

Analytical procedures are required to be accurate and consistent, compendial methods are acceptable.

If records are maintained electronically they must be backed up, printable and accessible one year after expiry. Electronic signatures are allowed if the system has been tested for security, validity and reliability.

6. What kind of stability program is required for each product?

There must be data from real time or accelerated studies available on the product or a similar formulation to support the initial determination of the expiry date. Following this, real time studies to expiration should be conducted on the product. There is no requirement at this time for on-going studies once the expiration date has been confirmed, unless there are significant changes to the formulation, process or package.

7. Do I need to perform heavy metals testing on every batch?

Yes. Heavy metals testing need to be performed on every batch unless it is controlled at the raw material level. This justification needs to be presented in the Product Licence Application.

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Contact NHP Compliance
with your questions about Natural Health Products.
Phone Graham Mills toll-free at 1-877-877-5152,
extension 210, or email him at g mills@qualityandcompliance.com.

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