



Voice of the Natural Products Industry



La voix de l'industrie des produits naturels

BASELINE TESTING

Based on discussions with industry, this document has been refined since first presented to the NHPD in January 2009. This is a work in progress; it is anticipated that further discussions will take place and, as a result, additional modifications may happen.

Test	Possible Methods	Raw Material – Medicinal Ingredients Only (Frequency of testing)	Finished Product (Frequency of testing)	Rationale
IDENTITY	Any method that will confirm identity including physical (e.g. visual, organoleptic) and chemical methods.	Acceptance of Supplier's CofA <u>OR</u> Every lot	Every lot (To avoid product mixup and recall)	Identity confirmation required for each RM and FP.
POTENCY	Any method that will confirm potency including input.	Acceptance of Supplier's CofA <u>OR</u> Every lot	Skip lot testing For multiple ingredient products test using the "marker" with the lowest concentration in the product <u>OR</u> the least stable marker <u>OR</u> the primary ingredient <u>OR</u> rotate through active ingredients. Every batch for Input method.	One "marker" ingredient tested for multiple ingredient products. Manufacturer approves the supplier's CofA for each RM. Emphasis on manufacturing controls and in-process checks. Manufacturer conducts full testing to specifications during the SL renewal process – one lot per dosage form to a maximum of 3 lots.

Test	Possible Methods	Raw Material – Medicinal Ingredients Only (Frequency of testing)	Finished Product (Frequency of testing)	Rationale
HEAVY METALS (Applicable only to natural resourced raw materials)	Acceptable Method	Acceptance of Supplier’s CofA <u>OR</u> Every lot	Every lot	*Tested at <u>either</u> RM or FP stage Sum of results of raw material testing need to be extrapolated to finished product to ensure compliance with FP and NHPD requirements. NB If testing is conducted on the raw materials, then applicable non-medicinal ingredients must also be tested.
PCB’s (Marine products where PCBs are known to accumulate)	Acceptable Method	Acceptance of Supplier’s Cof A <u>OR</u> Every lot	Every lot	*Tested at <u>either</u> RM or FP stage
PESTICIDES (Applicable to plant based materials only)	Acceptable Method	Acceptance of Supplier’s CofA <u>OR</u> Confirmation of “organic” status	Every lot	*Tested at <u>either</u> RM or FP stage NB If testing is conducted on the raw materials, then applicable non medicinal ingredients must also be tested.

Test	Possible Methods	Raw Material – Medicinal Ingredients Only (Frequency of testing)	Finished Product (Frequency of testing)	Rationale
		<u>OR</u> Every lot		
MICRO	Acceptable Method	Acceptance of Suppliers CofA <u>OR</u> Testing of every lot of material which could support microbial growth.	No testing on FP required if product will not support microbial growth.	Test at FP stage if shown to support microbial growth.
DISINTEGRATION (Tablets & Capsules)	Acceptable Method		Skip lot testing	
DISSOLUTION (Time Release Products)	Acceptable Method		Skip lot testing One ingredient only required for multi-ingredient products.	

Test	Possible Methods	Raw Material – Medicinal Ingredients Only (Frequency of testing)	Finished Product (Frequency of testing)	Rationale
PEROXIDE/ ANISIDINE/ TOTOX	Acceptable Method	Acceptance of Supplier’s CofA <u>OR</u> Every lot	Skip lot testing	For fish and seal oils only (to be confirmed). Option of tesing at RM <u>OR</u> FP stage.
RESIDUAL SOLVENTS	Acceptable Method	No testing requried if supplier will certify that they do not use solvents in their production process. <u>OR</u> Acceptance of Supplier’s CofA <u>OR</u> Every lot		Applicable only when solvents are used in the manufacturing of the RM .

Guiding principles for baseline testing requirements:

1. Safety of products is paramount.
2. Products comply with all regulatory requirements.
3. Products comply with their approved specifications.
4. Frequency and depth of routine testing are based on risk assessment criteria.
5. Products are manufactured in NHP GMP (or equivalent) compliant facilities.
6. Canadian suppliers (manufacturers, packagers, importers, labelers) possess valid Site Licenses.
7. In accordance with subsection 43(2) of the NHP regulations, no additional GMP requirements shall be placed on importers beyond that which is required for manufacturers.