NIH Office of Dietary Supplements: Minimum Criteria for Assessment of Dietary Supplement Ingredient Integrity ***(Adapted from NCCAM Guidance on Natural Product Integrity)***

- Name of the product (brand name, chemical or taxonomic nomenclature – e.g., genus, species, strain, as applicable.
- Identify the manufacturer or distributor (if any) by name and address and contact information.
- State the constituent(s) to which the product is standardized.
- Characterize the supplement composition (ingredient content and quantity), if applicable. Obtain a Certificate of Analysis (COA) from the manufacturer to show compliance to their specifications for content.
- Provide documentation that demonstrates stability of ingredients for at least the duration of the study and explain how the product will be monitored for stability throughout the project period.
- Provide description of placebo or vehicle control.
- Provide documentation that demonstrates reproducibility of product characteristics, especially if more than one batch is used in the study.
- Assure that the product is free of impurities (accidental or deliberate), e.g., pesticides, drugs, microbes, or metals.
- If the product is administered via a vehicle other than a tablet/capsule, assure that the characteristics remain stable and bioavailable (e.g., probiotic added to porridge, EGCG added to rat food).
- For placebo, verify that the product matches the test agent on sensory characteristics, that the sensory characteristics are stable, and that the product contains no bioactives.
- Provide justification for the proposed doses/concentrations and dosing schedule.
- In general, assure that the investigator will be able to appropriately describe the intervention in results papers as described in Gagnier et al. (see below).

Reference Resources

- Gagnier JJ, Boon H., Rochon P et al. Reporting Randomized, Controlled Trials of Herbal Interventions: An Elaborated CONSORT Statement. *Annals of Internal Medicine*, 2006;144:364-367.

- Hildreth J, Hrabeta-Robinson E, Applequist W, Betz J, Miller J. Standard operating procedure for the collection and preparation of voucher plant specimens for use in the nutraceutical industry. *Anal Bioanal Chem*. 2007;389:13-17.

- NCCAM website for detailed information:
  Assessing product integrity:
  http://nccam.nih.gov/research/policies/naturalproduct.htm