Report to Community
AOAC INTERNATIONAL Stakeholder Panel on Dietary Supplements
Working Group Sessions – Saturday, September 17, 2016

1. Free Amino Acids

Chair: Garrett Zielinski, Covance Laboratories

Identification and quantitation of alpha amino acids for label claim verification

Applicability: For finished product verification of label claims in complex products and may not be applicatable for purity of ingredients.

Probably using pre or post column derivitization HPLC

Different SMPR: Method probably not appropriate for purity of ingredients / raw materials which would identify impurities and perhaps, what they are.

Developed performance criteria for 04 – 10% and >10% for individual components.

Exclusivity table: Norvaline, sarcosin, carnatine, citrulline, onithine, slenenomethionine, GABA, selenocystine, 5HTP, creatine

Ingredient table: Cysteine and Cysine

Not intended to separate L and DL optical isomers

2. Ginger

Chair: Anton Bzhelyansky, USP

Proposed Fitness for Purpose

- The method must quantitate the 'pungent principles' derived from the rhizome of ginger, *Zingiber officinale* Roscoe [Fam. Zingiberaceae].
- The method must quantitate, at a minimum, [6]-, [8]- and [10]-gingerols, and [6]-shogaols.
- The method should preferably quantitate [8]- and [10]-shogaols, as well as [6]-, [8]- and [10]-paradols, [6]- and [10]-gingerdiols, [6]-, [8]- and [10]-gingerdiones, and zingerone.
- Individual constituents should be quantifiable within the range of 0.01% - 50% by weight in powdered ginger rhizome, ginger rhizome dry and soft extracts, and ginger-containing finished products, including capsules and tablets, in the presence of common excipients.
- The ability to address softgels and tinctures is advantageous, yet optional.

Applicability:

- Make method general to all ginger family *Zingiberaciae*.

- Not a method for identification / authentication
- The method must quantitate, at a minimum, [6]-, [8]- and [10]-gingerols, and [6]- [8]- and [10] shogaols.

Performance table and matrices tables completed.
Will ask stakeholders if there is any language they would like under "Intended Use".

An important discussion on the methods of validation for these natural material components as there are no blank matrices and spiking will not demonstrate extractability
…so the question is, what are the validation recommendations?

3. Vitamins K1 and K2,
Chair: Inger Reidun, Kappa Bio

Method: Vitamin K1 and K2 in dietary supplements and ingredients

- Applicability: Individually separate and quantify cis and trans forms of vitamin K1 (phylloquinone) and vitamin K2, trans MK4 and trans MK7 in dietary ingredients and dietary supplements as listed in Table X.

- Discussion on need to separate MK6 from MK7
- Discussion on necessity to test both coated and non-coated formulations.
- Ranges for both raw materials and formulations added.

- Table of Matrices.
  …Dietary ingredients: Powders, oils, extracts, encapsulated
  …Supplements: powders, tablets, gummies, oils, liquids, capsules, softgel capsules, tinctures

- USP Reference materials available: MK7, K1, MK4 from Sigma
  NIST to be provided also