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NSF International Standard for Dietary Supplements — Dietary supplements

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5.3.4 Natural toxins

Botanicals listed in annex A shall not contain aristolochic acid (limit of detection = 0.5 µg/gm).

5.3.5 Known adulterants

Products shall be evaluated to ensure they do not contain known adulterants including, but not limited to, the following:

- *Eleutherococcus senticosus* shall not contain *Periploca sepium* root.
- *Plantago lanceolata* shall not contain *Digitalis lanata* leaf.
- *Scutellaria lateriflora* shall not contain *Teucrium chamaedrys*.
- *Stephania tetrandia* shall not contain *Aristolochia fangchi*.

5.3.6. Food Allergen Claims

Raw materials and finished products which claim the absence of specific allergens shall be evaluated in accordance with 7.5 and/or 8. Raw materials and finished products shall not contain specific proteins or other analyte(s) associated with the allergen at levels above the method detection limits.

5.3.7 Genetically Modified Organism (non-GMO) Claims

Claims that the product contains no genetically modified organisms (no GMO) shall be verified in accordance with 7.5 and/or 8.

5.3.68 Other product claims

Claims that the product is free of a particular contaminant or substance shall be verified in accordance with 7.4 and/or 8.

5.4 Disintegration

Supplements shall be verified as meeting the requirements for disintegration when tested using the methods described in USP 25-NF 20. The minimum exposure time to immersion fluids shall not be less than 60 min. Chewables and liquid extracts are exempt from disintegration testing requirements.

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7.4 Test methods for chemical contaminants

Testing shall be performed based on USFDA's Method for Determination of Aristolochic Acid in Traditional Chinese Medicines and Dietary Supplements.

The most appropriate method shall be used to confirm claims for the product under evaluation. The source of these methods may include AOAC International, USP, EPA, FDA, AHP, European, German, Japanese monographs, INA, industry standards, etc. The use of any new method shall require that a validation be performed which includes an evaluation of specificity, linearity, reproducibility, spike recovery and method detection limit. More rigorous validation could follow according to the guidelines of ICH, FDA, CEN, GLP, AOAC, as appropriate.

Unless manufacturers have controls in place to assess the rancidity of oil ingredients, the following testing shall be performed. The Peroxide Value of the oil shall be tested according to AOAC Method 965.33 (which is equivalent to AOCS

8-53). The p-Anisidine Value of the oil shall be tested by AOCS Cd 18-90.⁷ The Totox Number will be calculated as the sum of the p-Anisidine Value and two times the Peroxide Value.

7.5 Test methods for food allergens

7.5.1 Gluten

Testing shall be performed based on the RIDASCREEN Gliadin Enzyme Immunoassay for the quantitative analysis of gliadins and corresponding prolamines (Manufactured by r-Biopharm). The typical detection level for the testing of raw ingredients and finished products is 20 ppm or less.

7.5.2 Soy

Testing shall be performed based on the End-Point Polymerase Chain Reaction (PCR) method (licensed technology by Genetic ID) or equivalent. The typical detection level for testing, using this semi-quantitative method for raw ingredients and finished products, is 1.5 ng/g of DNA.

7.5.3 Milk

Testing shall be performed based on the Veratox Total Milk Allergen Immunoassay for the quantitative analysis of milk proteins (Manufactured by Neogen). The typical detection level for the testing of raw ingredients and finished products is 2.5 ppm.

7.5.4 Other food allergens

The most appropriate method shall be used to confirm claims for the product under evaluation. The source of these methods may include AOAC International, USP, EPA, FDA, AHP, European, German, Japanese pharmacopoeial monographs, INA, industry standards, etc. The use of any new method shall require that a validation be performed which includes an evaluation of specificity, linearity, reproducibility, spike recovery and method detection limit. More rigorous validation could follow according to the guidelines of ICH, FDA, CEN, GLP, AOAC, as appropriate.

7.6 Test method for genetically modified organisms

Testing shall be performed based on the End-Point Polymerase Chain Reaction (PCR) method (licensed technology by Genetic ID) or equivalent. The typical detection level for testing, using this semi-quantitative method for raw ingredients and finished products, is 0.01% GMO DNA.

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