NUTRACEUTICAL PRODUCT SAFETY

SAFETY ASSESSMENT AND TESTING FOR RESIDUE CHEMICALS AND MICROBIAL

Your Regulatory and Quality Testing Service Partner

- Industry leader with global expertise from regulatory consulting to analytical testing
- Over 15 years of in-depth expertise in natural botanical ingredients in various products
- ISO-17025 and cGMP111, 210/211 complied state-of-the-art laboratory analytical capabilities

Natural nutraceutical ingredients are found in a broad range of products including dietary supplement, functional foods, and over-the-counter (OTC) health products. Under the DSHEA law, FDA requires supplement products be manufactured under cGMP to ensure identity, potency, purity and safety. Regulatory agencies of other countries have various regulations on supplement product safety. You can count on the in-depth expertise and capability of Intertek Champaign Laboratories to help ensure your regulatory compliance on product safety testing.

The Challenge

Global natural ingredient supply involves complex supply chain process often across multiple countries. Under the DSHEA law, US manufacturers must meet safety regulations for their ingredients and finished products to not be contaminated with various harmful agents and meet the potency and purity requirements. To ensure products are free from potential contaminants such as heavy metals, residue solvents, microbial and adulterants and in compliance with FDA regulations, manufacturers and distributors increasingly turn to the in-depth knowledge and analytical capability of external laboratories for support their needs.

Our Solutions

Intertek offers identity, potency, purity and safety testing based on global expertise and over 15 years of focused analytical work in natural ingredients and products in our state-of-the-art cGMP and ISO-17025 certified laboratories. We can support your analytical needs of safety tests, particularly trace level contaminant tests, throughout the entire product life cycle from ingredients to finished products.

CASE STUDY

Identification and potency verification of botanical ingredients

A well-respected contract formulation and manufacturer of natural dietary supplements changed the source of key blended ingredients. To comply with cGMP and related quality process, the manufacturer must independently verify the new ingredients meet the safety requirements on trace contaminants throughout the manufacturing process. Intertek Champaign Laboratories provided a breadth of expertise with a thorough review of the quality documents, advised the client on the tests required to comply with the regulations, and provided robust tests using a suite of techniques to deliver the results within their manufacturing timeline requirements.

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Total Quality. Assured.

CASE STUDY

Identification of unknown contaminants

To ensure herbal raw ingredients are free from natural microtoxin contamination during a lengthy and complex supply chain process, a client turned to Intertek Champaign Labs for their analytical testing. Our scientific and technical staff provided a rapid review of the quality document and supply chain history, derived a test plan, and delivered timely independent tests to enable a critical decision on the use of materials in their supplement manufacturing, thus mitigating a potential risk of the contaminated ingredients in the cGMP manufacturing regulatory compliance and product safety.

Our Services

Intertek Champaign Laboratories, an Intertek Center of Excellence in botanical chemicals analysis, offers a suite of chemical, biochemical and microbial testing supports for natural ingredients in raw ingredients and finished products to meet quality, safety and regulatory requirements. Our state-of-the-art laboratories are equipped with analytical technologies such as HPTLC, HPLC, GC/GC-MS, LC-MS/MS, ICP, FT-IR, RT-PCR, wet chemistry, biochemical and microbiological analysis for both raw ingredients and finished products by a range of analytical tests for trace contaminants and adulterants. Our laboratories can provide the analytical tests using either published (e.g., USP, AOAC) or cGMP validated methods in compliance with regulatory and client requirements.

The following are examples of the range of contaminants and adulterants that may lead to product failure or non-compliance:

- **Heavy metal contaminants** – Pb, Hg, As, Cd, Sb and others
- **Pesticides contaminants** – Chlorinated pesticides, phosphorus pesticides, nitrogenous pesticides
- **Organic solvent residues** – Class I, II, III and special solvent residues
- **Antibiotics residues** – Chlorampheniocol, Tetracycline antibiotics, Penicillin, Neomycin and related antibiotics, Streptomycine and more
- **Restricted chemicals in packaging materials** – Biophenol A, Phthalates, PAH, Ethylene oxide, Pyrrolizidines and more
- **Food allergens** – Various allergens in nuts, milk, fish, soy, wheat and egg
- **Natural microtoxins** – Aflatoxins, Ochratoxins, Deoxynivalenol, Putulin, Sterigmatocystin, Zearalenone, Hydrocyanic acid, Citrinin and more

Intertek Champaign Laboratories can help you mitigate these risks with independent testing. We provide these services with our dedicated client services team and consult with our senior scientific and technical staff when required.

The Intertek Advantage

Intertek is a leading Total Quality Assurance provider to industries worldwide. Through our network of more than 1,000 laboratories and offices and over 42,000 people in more than 100 countries, the Group is re-defining the industry with our Total Quality Assurance proposition.

We go beyond physical quality control to provide total peace of mind through our innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently, with precision, pace and passion, enabling our customers to power ahead safely.

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