Risk Prevention & Verification of Ingredients

Considerations for Testing Ingredients in a Challenging Supply Chain

Presented by:

Eurofins SF Analytical Laboratories, Inc.

New Berlin, WI

March 2nd, 2022

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Overview

- Introduction
- Understanding risk in your supply chain and why it is important to update and reconsider your current approach
- Verify your ingredients with testing to mitigate risks
- Considerations when choosing a lab provider

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Speakers

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About Us

- New Berlin, WI
- Founded in 1900
  - Problem solving & Investigation-based analysis since early 1970's.
- "The lab to call when you don't know who to call."

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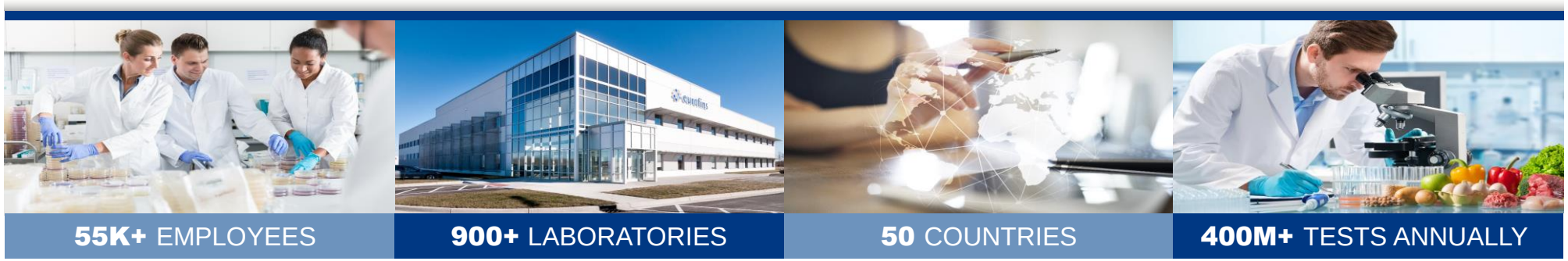
Part of the Greater Eurofins Network of ISO 17025 Laboratories.



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RAFFLE ALERT!

- Attendees today will be placed in a drawing for a $25 gift card!
- 5 Lucky winners will be selected and notified within 3 business days of our presentation.

Thank you for attending!

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Risks in your Supply Chain

- Whenever you purchases ingredients which ultimately fulfill a product branded as your own, you inherent the risk!
- What does this mean?
  - It is your job to assess those risks and develop a program to mitigate them.
- This isn’t new? Why are we talking about this?
  - Our world is changing rapidly….

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Identifying and Assessing Risk

- Risk is unavoidable, has always existed and is ever evolving due to a number of factors
  - Pandemic, climate change, regulatory updates, evolving consumer demands.
  - Leads to shortages of labor and supplies ➔ More Risk…
- To start, identify your hazards.
- Three main types:
  - Physical (foreign materials – plastics, glass, etc.)
  - Chemical (allergens, heavy metals, etc.)
  - Biological (*Salmonella, Listeria monocytogenes,* etc.)

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What are the Risks? What Could Happen?

- Food Fraud and Adulteration
  - Unknown materials, presence of pathogens, undeclared allergens, colorants, drugs, and other ingredients.
- Poor Quality
  - Insufficient purity, high levels of contamination
- Packaging Failures
  - Spoilage and loss of product
- Product Rejections, Recalls, & Quarantines
- Harm to Consumers
  - Foodborne illness, physical harm from hard objects, reactions to adulterated ingredients, etc.
- Legal Action
  - i.e. Prop 65
- Negative News
  - Social media and other media outlets

Loss of your business and trust in your brand.

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Regulatory Drivers: Why Do We Care?

- Requirement under: Food Safety Modernization Act (FSMA), which requires that the Identify, Purity, and Safety .
  - 21 CFR part 111 for Dietary Supplement Ingredients
  - 21 CFR part 210/211 for OTC, Pharma, Excipients
- Generally states that one must verify the quality of the ingredients in terms of
  - Identity, Purity, Strength, and Composition
  - Establish limits of contaminants (i.e. heavy metals, residual solvents).
- Increase quality, product performance, control over supply chain, confirm product label claims, enabling increased market share, improving your “bottom line”.
- Critical to bolster product and brand stewardship including your Company’s reputation.
- It’s “The Right Thing to Do”.

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Economically-Motivated Food Fraud

- What Products are Targeted?
  - Anything where a products functionality can be reproduced by a cheaper means.
- What You See
  - Artificial colorants used in spices and oleoresins.
  - Claiming “Organic”, but using conventionally sourced ingredients.
  - Undisclosed contaminants like antibiotics
  - Dilution with similar cheaper materials
  - And many more.

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Food Fraud Example

- Background
  - 15 year est. Pet Food Company
- Problem
  - Consistent suppliers utilized for fortification raw materials, however supplier short on raw material (Taurine).
  - Supplier found alternate source, manufacturer not notified and therefore no qualification performed on new materials for contaminants.
- Result
  - FDA audit found melamine
  - Adulteration
  - Recall lost 4K lb of product & multiple SKUs

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What to Do?

- It is not about removing risk, but managing, reducing, and potentially preventing through a robust Quality Management System.
- What preventative tools and procedures do you have in place to assess and prevent risk to your ingredients?

Verifying your suppliers routinely and strategically through proper change management is a key component to managing risk.

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Verify Through Testing!

- What is Chemical & Ingredient Verification Testing?
  - Testing to ensure/verify that raw materials meet the specifications they are intended to meet (CoA or compendia).
- Why is it performed? Confirms:
  - Quality & Safety
  - Typically, identity, purity, physical testing characteristics (such as pH)
  - Contaminants and impurities
  - Release

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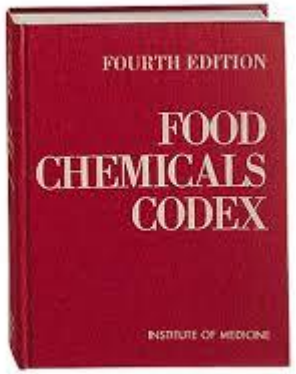
Ingredient Verification Testing

- Typically Two Types of Testing:
  - Compendial (i.e. “standard” methods) – according to a recognized method
    - USP/NF, FCC, EP, JP, BP, ACS, AOAC
    - Dissolution
    - Stability



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SUNFLOWER LECITHIN - LIQUID NON-GMO

CERTIFICATE OF ANALYSIS

LOT: 2103001

Date of Production: March, 2021
Expiration Date: March, 2024
Allergens: Contains seeds (sunflower)

Parameter	Units	Limits Min	Limits Max	Results	Method
Viscosity @ 25 degrees C			140	102	Internal Method
Gardner color	Solution 10%	11		11+	AOCS Ja 9-87
Moisture	%		1.0	0.23	AOCS Ca 2c-25
Acid Value	mg KOH/g		35	22.35	AOCS Ca 5a-40
Peroxide Value	meq O2 kg		6	0.10	AOCS Cd 8b-90
Phosphatides (as acetone insoluble)	%	60		61.79	AOCS Ja 4-46
Hexane Insoluble	%		0.3	0.21	AOCS Ja 3-87
Microbiological Analysis					
Total Plate count	cfu/g		3000	65	USP_61
Yeasts & Molds	cfu/g		300	<10	USP_61
E. Coli	(NMP/g)			Absent	USP_62
Enterobacteriaceae	cfu/g			Absent	USP_62
Salmonellas	25g			Negative in 25g	USP_62

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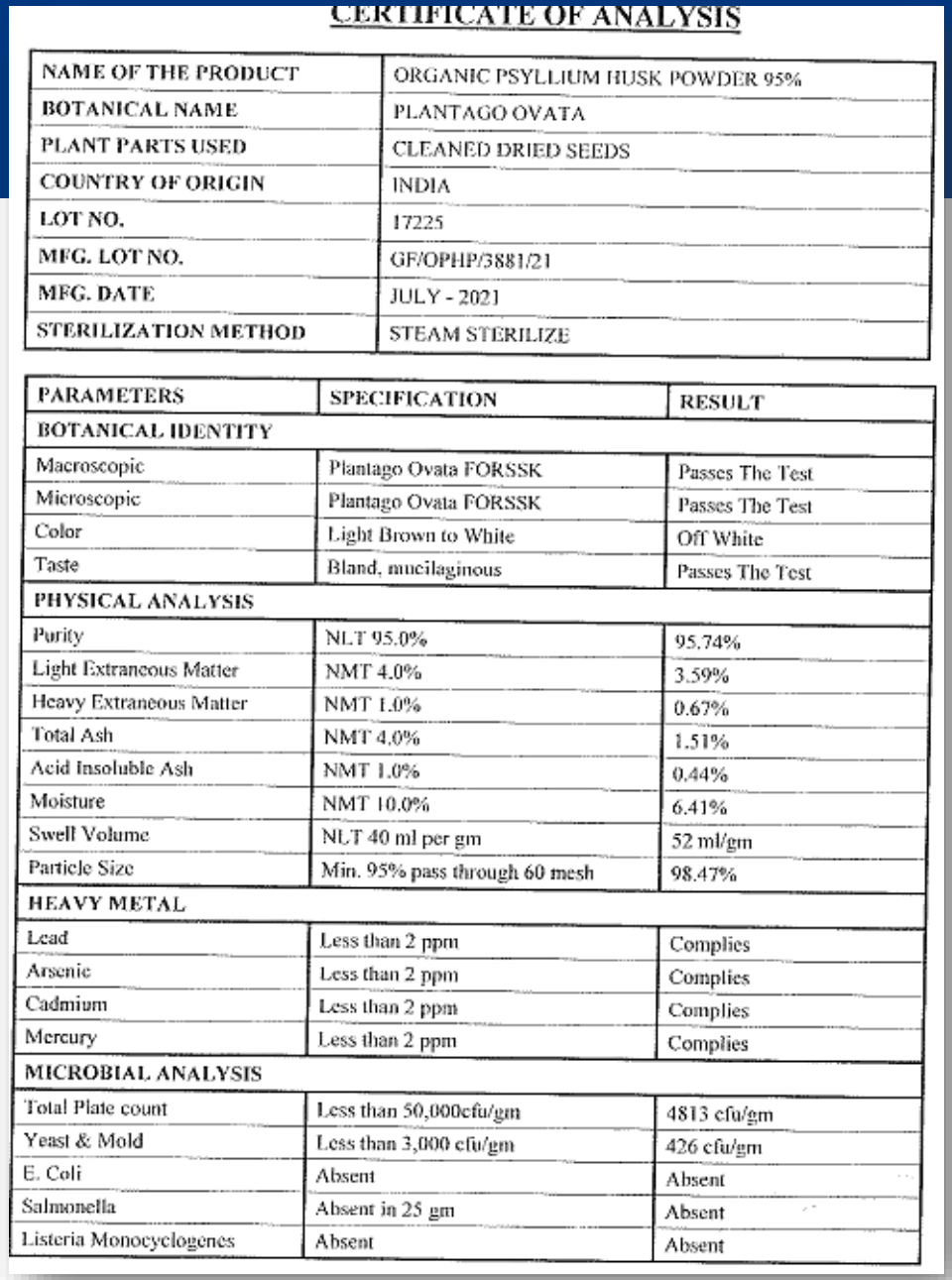
Ingredient Verification Testing

- Non-Compendial – according to a client, industry, or custom developed method
  - Method validations, verifications, transfers
  - Foreign Material ID/contaminants
  - Investigative problem solving
  - Often used for new novel ingredients



CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT	ORGANIC PSYLLIUM HUSK POWDER 95%
BOTANICAL NAME	PLANTAGO OVATA
PLANT PARTS USED	CLEANED DRIED SEEDS
COUNTRY OF ORIGIN	INDIA
LOT NO.	17225
MFG. LOT NO.	GF/OPHP/3881/21
MFG. DATE	JULY - 2021
STERILIZATION METHOD	STEAM STERILIZE

PARAMETERS	SPECIFICATION	RESULT
BOTANICAL IDENTITY		
Macroscopic	Plantago Ovata FORSSK	Passes The Test
Microscopic	Plantago Ovata FORSSK	Passes The Test
Color	Light Brown to White	Off White
Taste	Bland, mucilaginous	Passes The Test
PHYSICAL ANALYSIS		
Purity	NLT 95.0%	95.74%
Light Extraneous Matter	NMT 4.0%	3.59%
Heavy Extraneous Matter	NMT 1.0%	0.67%
Total Ash	NMT 4.0%	1.51%
Acid Insoluble Ash	NMT 1.0%	0.44%
Moisture	NMT 10.0%	6.41%
Swell Volume	NLT 40 ml per gm	52 ml/gm
Particle Size	Min. 95% pass through 60 mesh	98.47%
HEAVY METAL		
Lead	Less than 2 ppm	Complies
Arsenic	Less than 2 ppm	Complies
Cadmium	Less than 2 ppm	Complies
Mercury	Less than 2 ppm	Complies
MICROBIAL ANALYSIS		
Total Plate count	Less than 50,000cfu/gm	4813 cfu/gm
Yeast & Mold	Less than 3,000 cfu/gm	426 cfu/gm
E. Coli	Absent	Absent
Salmonella	Absent in 25 gm	Absent
Listeria Monocyclogenes	Absent	Absent

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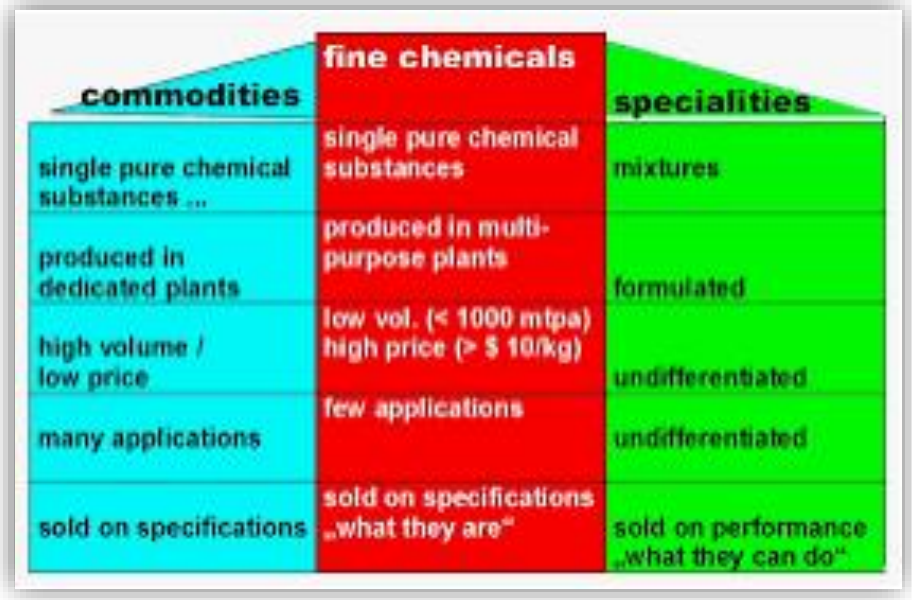
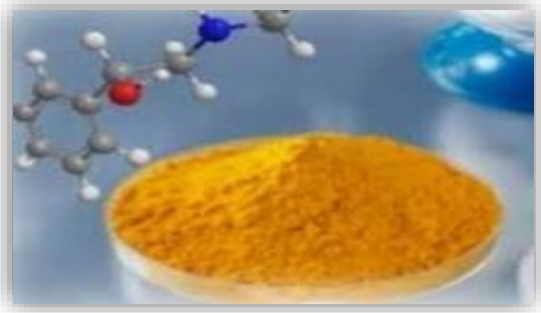
Ingredient Verification Testing





- What is Testing Performed on?
  - Raw Material Ingredients, may include APIs and excipients
  - Premises
  - Finished Products (supplement blends)
  - Personal Care Products (esp. Cosmetics)
  - OTCs (Over The Counter products)
  - Food & Beverage Ingredients
- Who does it?
  - Ingredient/supplement manufacturers
  - Chemical manufacturers and distributors
  - Pharmaceutical companies
  - Co-packers, distributers
  - Ingredient exporters and imports

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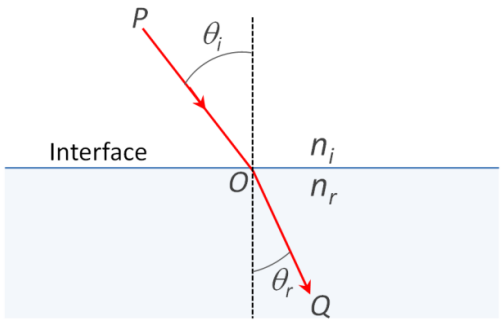
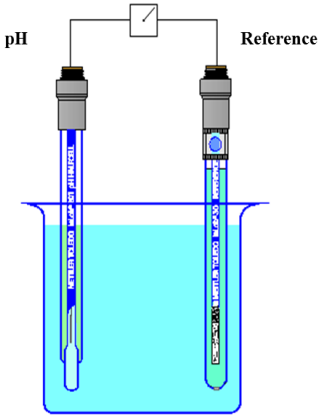
Common Tests Performed

- Loss on drying (LOD)
- Residue on ignition (ROI)
- Color
- Sulfated Ash
- Water determination (Karl Fischer)
- Minerals
- Heavy metals
- Clarity of solution
- pH, conductivity
- Specific rotation
- Identification
- Assay/Strength
- Related compounds
- Allergens
- Microbiology



- Reducing substances
- Peroxides
- Appearance of solution
- Viscosity
- Aldehydes
- Melting point
- Residue on evaporation
- Reducing sugars
- Sulfur dioxide
- Insoluble substances
- Acid-insoluble substances
- Limit of specific contaminants
- Residual Solvents
- Pesticide Residues
- Microscopic Residue
- Many, Many, More……



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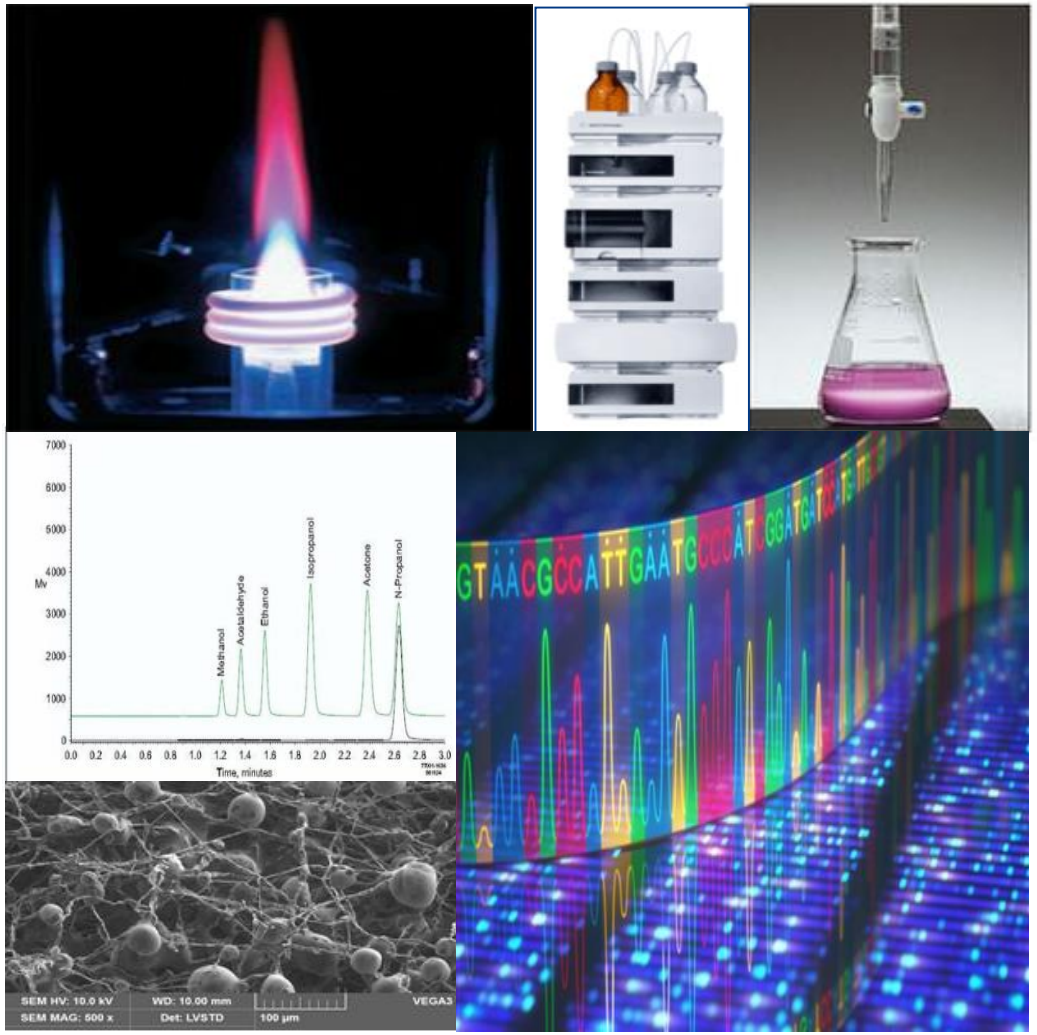
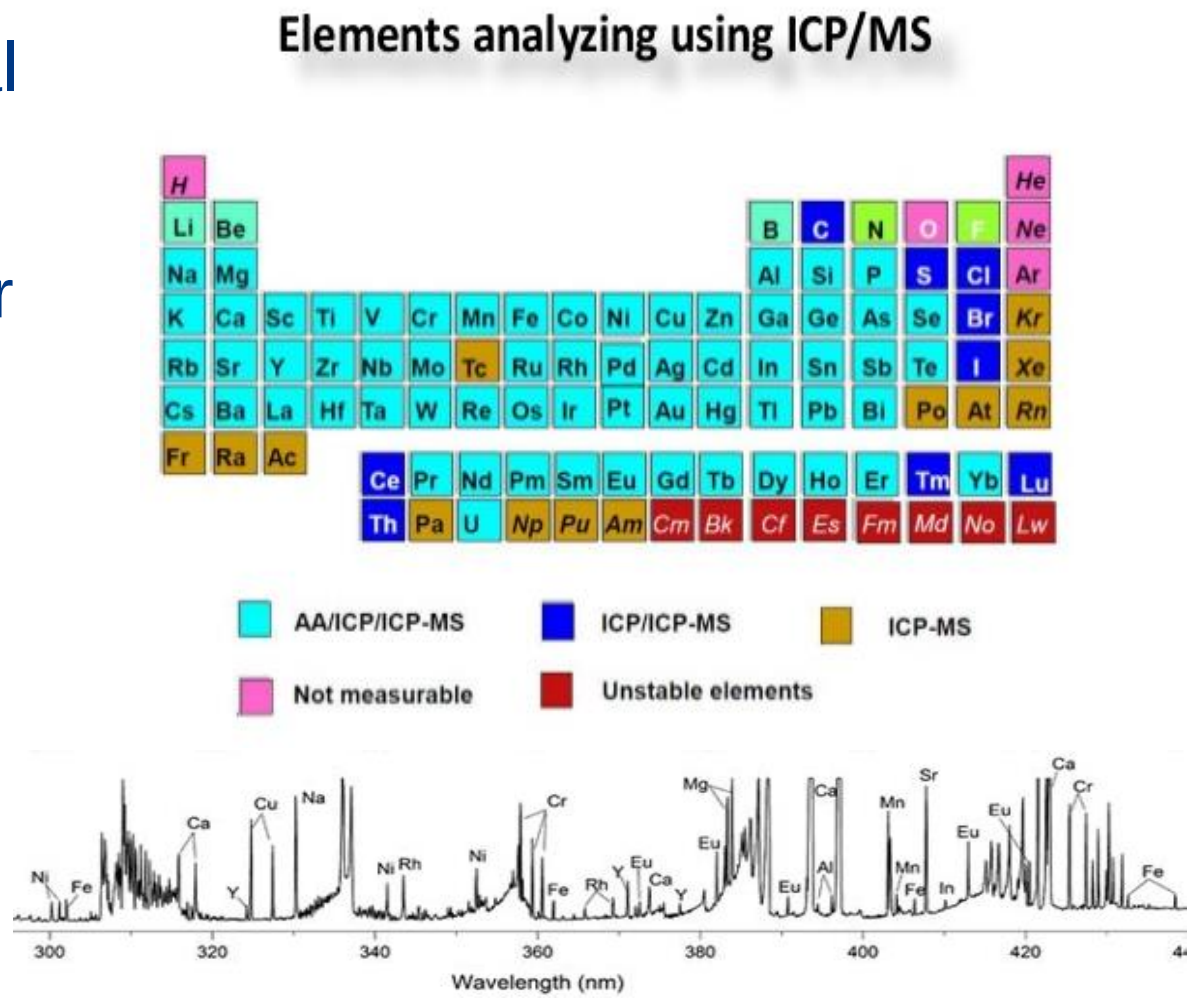
A World of Techniques

- Titration: Potentiometric, Karl Fischer, Colorimetric, Oxidation/Reduction (redox)
- Gas Chromatography (GC)
- Mass Spectrometry (MS)
- Liquid Chromatography (HPLC)
- Ultraviolet/Visible Spectrum (UV-Vis)
- Fluorescence
- Enzyme-Linked Immunosorbent Assay (ELISA)
- Real-Time PCR (RT-PCR)
- Scanning Electron Microscopy (SEM)
- And Many Others!



A World of Techniques

- Inductively Couple Plasma with Mass Spec and/or ICP-OES (optical emission spectroscopy)
- Energy Dispersion Xray Analysis EDXA (also called EDS) – useful for semi-quant screening
- Colorimetry (Discreet Analysis also Titrations)
- Ion Selective Electrode
- FAAS, GFAAS
- Ion Chromatography
- Combustion Analysis (CHN) (LECO®)



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Considerations for Selecting a Testing Partner

Your testing laboratory is your partner and key to your success.

Help support you to bring safe and high quality products to market!

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Important Factors

- Accreditations, Certifications, Licenses
  - ISO 107025, cGMP/GLP, DEA, USDA, etc.
  - Ask who accredited and which methods are accredited.
  - What quality standards does that lab meet?

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Important Factors

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  - Ask who accredited and which methods are accredited.
  - What quality standards does that lab meet?
- Technical & Regulatory Expertise
  - Support for problem solving and answering those tough questions when issues arise (and they will arise).
  - Do they understand your product matrix and its unique challenges?
  - Do they run scientifically valid methods providing accurate and defensible data?
  - Can they help you when an OOS arises?
  - Do you have access to speak with technical scientists?

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Important Factors

- Responsive Customer Support
  - Having access to a team who provides timely feedback is essential.
  - Do they provide helpful and timely feedback?
  - Are they a solution-driven team?
  - Do they provide local support or time zone friendly support?
  - Can they provide last minute rush services?
  - Is the lab an extension of your quality assurance, quality control, offer product support, bolster your confidence in your brand?
  - IF the Answer is NO, you may have the Wrong Partner

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  - Are they a solution-driven team?
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  - Can they provide last minute rush services?
- Comprehensive Solutions
  - The more labs you use, the more relationships you have to manage.
  - Do they offer a comprehensive portfolio of services and project-based solutions?
  - Do they offer a comprehensive list of methods?

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Key Takeaways

- Above all, visit and audit regularly!
- Risk is unfortunately inevitable and ever evolving.
- Verify not just your ingredients and suppliers, but also your laboratory testing partners.

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Thank You!

Questions?

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