

# Alkemists Pharmaceuticals, Inc.

## *Random Testing Program*

**Alkemists Labs**

*"The Plant Authentication Experts"*



# Overview

Founded in 1997 by Dr. Sidney Sudberg

Leading contract testing lab providing routine and non-routine analytical solutions to raw material suppliers and manufacturers throughout the Natural Products Industry

Market segments supported:

- Dietary Supplements/Nutraceuticals
- Natural/Organic Foods
- Functional Foods
- Natural Personal Care/Cosmeceuticals



# Accreditations & Alliances

## Accreditations

- AHPA Member
- ISO-17025 (completion date: March 2009)
- FDA Registrant

## Strategic Alliances

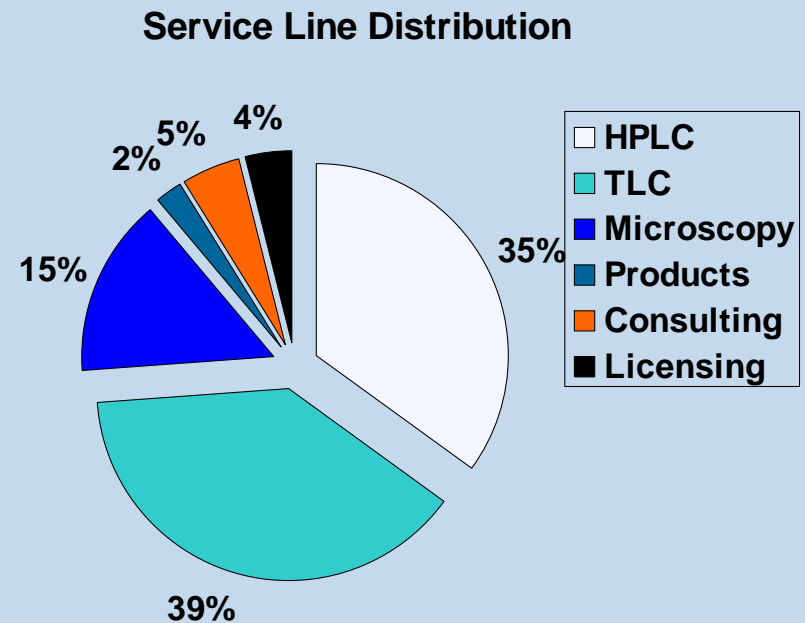
- Paragon
- Synergy
- Roex
- Naturex
- Strategic Sourcing



# Offerings

## Expertise

- Botanical Identification and Plant Authentication
- Microscopy/Macroscopy
- HPLC (High Pressure Liquid Chromatography)
- HP-TLC (Thin Layer Chromatography)
- Botanical Investigation and Finished Product De-formulation services



# Random Testing

## Assurance of Quality

- Random testing of finished products allows Clients to gain real-time unbiased “consumer” efficacy data

## Accountability for Partners

- Random testing assures a Client that all their vendors are complying with Product Quality guidelines set forth and reinforces those business relationships over time

## Quantifiable Increases in Brand Value

- Random testing is a highly versatile and valuable marketing tool a Client can leverage to drive Brand Recognition and Value to Consumers



# The RT Program

## The Random Testing Program

- 12 Month Term
- Testing: 1 batch (5 -10 Samples) per Month per Product line
  - Separate from testing of other products or ingredients
- Turn-around time: 10-15 Business Days
- Analytical Data is owned by Client and publishable
- Final Report is submitted to Client at end of Term
  - Certificate of Analysis is submitted to Client upon completion of testing for each batch of samples
- Logo Licensing options:
  - AP Logo
  - AP Certification



# Real Value

## Value Survey Conducted

- 12 Active Clients
- Prepared Product Satisfaction Surveys for their consumers
- Results:
  - End consumers responded with an overall 88% satisfaction rating in product quality when learning of the random testing program
  - End consumers felt testing to ensure product safety and quality is very important though not well promoted by most brands
  - Clients reported increases in revenue 15-40% within first 6 months of starting the Random Testing Program
  - 3 Clients reported the Random Testing Program uncovered inconsistencies between two or more manufacturers/ingredient suppliers leading to stricter controls for Product Quality



# Client Snapshot

## Have Varying Needs

- Needs vary greatly depending on product type, timing, in-house resources and size of company
- AP works with large and small companies – can provide critical consultancy on optimal testing practices and needs

## Typical Services Sought

- Botanical Identification/Authentication needs
- Product/Ingredient evaluation (for sourcing support) and equivalency determination between lots
- Investigative concerns of adulterations/contamination
- De-formulating finished products
- Maintaining quality of starting materials or intermediates as part of their Manufacturing Quality Controls/Systems
- Contract research to develop and/or validate methodologies and define Control Parameters that can be transferred back in-house for future use by the Client independently



# Regulations

## Identity Testing Requirements

- All ingredients must be identified
- TLC & Microscopy at a minimum
- Microscopy to pick up the chemically inert ingredients that have other non-detectable attributes
- TLC give full chemical spectrum fingerprint



# Assuring Quality

*HP-TLC in combination with Microscopy allow for ~80% assurance* in confirming sample identity and quality.

*HP-TLC with Microscopy and HPLC allow for >99% assurance* in confirming sample identity, quality and/or adulteration.

Extraction and Analytical Methods utilized are from a variety of published and private sources:

- AOAC
- USP/NF, BP, JP and other pharmacopeia sources
- Proprietary methods (Client or AP)



# Capabilities

## Total Processing Capabilities

- Samples analyzed per week: 600-700
- Turn-around times: ~7-15 business days
- Ad-hoc development work: 3 days (min) to 2 weeks (avg)
- Number of proprietary methods: ~1100
- Custom Botanical/Sample Database



