



National Animal Supplement Council



Preferred Supplier Analytical Laboratory Data Sheet (ALDS)

NASC established a **Preferred Supplier Program** for companies who wish to provide products and services to NASC member companies, including raw materials (ingredients), contract manufacturing (dosage form products and feed supplements), analytical laboratory services and other services such as insurance, business consulting, legal expertise, etc.

The goal of the program is to prequalify vendors so that NASC members may accept and use products or services from Preferred Suppliers without additional vendor qualification procedures required under NASC cGMPs.

There are four categories of **NASC Preferred Suppliers**: Raw Material Suppliers, Contract Manufacturers, Analytical Laboratories and Service Providers.

The qualification procedure includes providing information to NASC on the scope of company operations, quality compliance program certifications, statements and additional documentation specific to the type of supplier, e.g., data sheets for each ingredient a Raw Material Supplier would like to qualify and include in the program.

Preferred Supplier Analytical Laboratory Data Sheet

All Analytical Laboratories must provide the information requested in this form as part of the qualification procedure for acceptance as a Preferred Supplier by NASC. Any fields not applicable to your company should be completed by entering N/A.

Please return copies of the requested certifications and the completed form electronically to Bill Bookout at b.bookout@nasc.cc or mail to:

NASC
PO Box 2568
Valley Center, CA 92082

Contact Bill Bookout at the NASC office (760-751-3360) with any questions about the **Preferred Supplier Program**.



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SECTION 1. ANALYTICAL LABORATORY INFORMATION

GENERAL LABORATORY INFORMATION (COMPANY):	Alkemist Labs
MAILING ADDRESS:	1260 Logan Ave, B2
CITY, STATE, ZIP:	Costa Mesa, CA 92626
SHIPPING ADDRESS FOR SAMPLES:	1260 Logan Ave, B2
CITY, STATE, ZIP:	Costa Mesa, CA 92626
WEB SITE:	Alkemist.com
YEARS LABORATORY WAS ESTABLISHED:	1997

SECTION 2. GENERAL LABORATORY QUESTIONS

LIST THE PRODUCTS & SERVICES OFFERED BY YOUR LAB:	Botanical Testing, Microscopy, HPTLC, HPTLC Fingerprint, HPLC/UPLC, GC, UV VIS, Wet Chemistry
NAME OF INDIVIDUAL FILLING OUT FORM:	Andrea Soler-My
NUMBER OF EMPLOYEES:	31
LIST OF INDUSTRIES YOUR LAB NORMALLY PROVIDES TESTING SERVICES FOR:	Herbal Supplement
DOES YOUR LAB DEAL WITH RAW MATERIALS OR FINISHED PRODUCTS:	Both



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SECTION 3. LABORATORY EQUIPMENT AND EVIDENCE OF COMPLIANCE

IS LAB ISO CERTIFIED YES / NO:	YES	
IS YOUR LAB CERTIFIED BY ANY OTHER ORGANIZATIONS:	NO	
FDA REGISTRATION NUMBER:	3006523238	
SPECIFY MOST RECENT LABORATORY INSPECTIONS BY STATE, FEDERAL OR FOREIGN AGENCIES:	N/A	
DATE AND RESULTS OF INSPECTION:	N/A	
DATE	INSPECTION AGENCY	RESULTS OF INSPECTION
HOW OFTEN IS YOUR LAB AUDITED / INSPECTED:		
ATTACH CERTIFICATION DOCUMENTS:	ISO 17025:2005	



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SECTION 4. LABORATORY QUALITY ASSURANCE POLICIES

<p>DOES YOUR LAB PARTICIPATE IN ANY PROFICIENTLY TESTING PROGRAMS OR COLLABORATIVE STUDIES LIKE AOAC:</p>	<p>Alkemist Labs participates in NIST proficiency testing as well as internal proficiency testing.</p>
<p>DESCRIBE YOUR QA POLICIES FOR THE FOLLOWING AREAS OR ATTACH CURRENT GLP/SOP DOCUMENTS IF AVAILABLE:</p>	
<p>PLEASE BRIEFLY EXPLAIN:</p>	
<p>INSTRUMENT / STANDARDS CALIBRATION:</p>	<p>Equipment requiring calibration is labeled to indicate the calibration status, including the date when last calibrated and the date due for recalibration. Alkemist Labs maintains an equipment log that contains the equipment calibration status.</p>
<p>INSTRUMENT QUALIFICATION:</p>	<p>All critical instrumentation used to generate cGMP results are IQ/OQ/PQ by the manufacturer upon receipt. IQ is performed by the manufacturer upon installation. Annual PM and OQ are performed by the manufacturer annually and are under service and maintenance contracts. PQ is performed once during the calendar month after the monthly internal preventative maintenance for each instrument in use. A performance qualification is also performed before a system is placed back in service after PM/OQ.</p>
<p>EMPLOYEE QUALIFICATION:</p>	<p>All chemists have, at minimum, a BS/BA in chemistry or a related field.</p>
<p>EMPLOYEE TRAINING:</p>	<p>Training is provided to meet the requirements of 21 CFR Part 111 and ISO 17025:2005. All training completed by Alkemist Labs employees is documented and filed in the employee training files. Employees receive immediate and recurring training through multiple circumstances: a new hire orientation, an ongoing development plan, upon suggestion by supervisor/quality and following the review/updating of procedures</p>
<p>DOCUMENT CONTROL:</p>	<p>The quality system documents include those required for the generation of laboratory data. All documents/test methods issued to personnel in the laboratory as part of the quality system are reviewed and approved for use by a subject matter expert prior to issuance (reviewed by personnel knowledgeable in the documented activity and then approved by management and quality). All changes are documented and records maintained by quality.</p>
<p>PLANNED AND UNPLANNED DEVIATIONS FROM ESTABLISHED</p>	<p>Planned and unplanned deviations from established SOPs are transcribed onto a deviation form. All pertinent details of the</p>



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METHODS AND SOPs:	purpose, intent, and assessment of impact of planned deviations are documented. For unplanned deviations it is necessary to determine the background of the deviation and to determine the root cause of the deviation. If deemed necessary, a CAPA investigation and resultant action will be performed.
RECORD RETENTION:	All records associated with the laboratory, testing, training and quality are retained for 7 years. MSDS/SDS are kept indefinitely. Records are kept in such a way that they are readily available for inspection.
APPROVAL OF TEST DATA:	All laboratory data undergo a two-step review process for acceptance of results. First reviewer is an intradepartmental colleague of equivalent competency or greater followed with a review by department management.
RETEST POLICY:	Retests are performed when appropriate upon OOS result or client request.
TRACEABILITY	Data is traceable to the data transcriber through their unique signature or initials which are associated with document or notebook annotations. Employees are required to sign a master signature document for record and the master signature log can be used to identify and trace signatures to the individual. References to any external documents, notebooks, or other external information will be provided to link information sources.
CLIENT NOTIFICATION OF QC PROBLEMS / TEST RESULTS:	An electronic Certificate of Analysis in PDF file format is e-mailed to the customer as per the SSF.

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SECTION 5 SUPPORTING DOCUMENTATION

ATTACH ANY APPLICABLE "STATEMENTS" OR EXAMPLES FOR YOUR LAB

<u>EXAMPLES:</u>	<u>ATTACHED: YES / NO / N-A</u>
• SAMPLE OF FINAL TEST RESULTS REPORTING DOCUMENT:	Yes
• SAMPLE SUBMISSION FORM:	Yes
• LAB PERSONNEL EDUCATION & TRAINING STATEMENT:	N/A
• AUDIT CERTIFICATIONS:	Yes – ISO 17025:2005
• FACILITY INSPECTION DOCUMENTS:	N/A
• EQUIPMENT AND CAPABILITIES LIST:	Yes


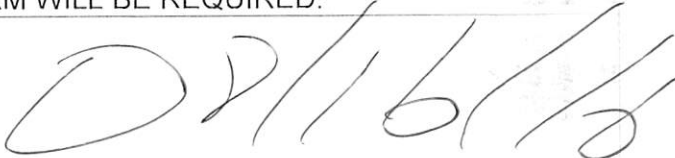
SECTION 6. ADDITIONAL INFORMATION

ADDITIONAL COMMENTS / INFORMATION:

SECTION 7. CONTACT INFORMATION

CONTACT NAME:	Elan Sudberg
TITLE:	CEO
OFFICE PHONE:	714-754-4372 x 210
OTHER PHONE:	714-402-7199
E-MAIL:	elan@alkemist.com

BY SIGNING BELOW, I CERTIFY THAT THE INFORMATION GIVEN BY ME TO THE NATIONAL ANIMAL SUPPLEMENT COUNCIL (NASC), INC. IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE. I UNDERSTAND THAT IF THE INFORMATION PROVIDED IS NOT THOROUGH AND COMPLETE, NASC WILL REJECT THE FORM AND RESUBMISSION OF THE FORM WILL BE REQUIRED.

	
SIGNATURE	DATE