Certification Program
Policies & Operational Procedures

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The International Aloe Science Council

8630 Fenton Street, Suite 918 • Silver Spring, MD 20910
Phone: (301) 588-1171 • Fax: (301) 588-1174
E-mail: info@iasc.org • www.iasc.org

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The IASC Certification Program: Background information

Formed in 1981, the IASC is the international trade association dedicated to serving the needs of the aloe industry. The Certification Program was created in the early 1980's in order to ensure companies provide an accurate representation of the true amount of aloe in their aloe products.

Building on a testing concept designed by member companies, the IASC developed the certification program to allow aloe growers, processors and manufacturers to submit their facilities and products to an audit program and series of rigorous tests which, if passed, would authorize them to display the IASC Seal of Certification on their products and marketing materials. This will enable program participants to distinguish themselves as having aloe content of the highest quality and purity.

Program Policies & Procedures

Standard Operating Procedures (SOPs)
The program consists of the certification of facilities that produce and manufacture aloe vera products, as well as the raw materials and finished products sold to consumers. The program offers recertification for facilities on a 3-year basis, and products/raw materials annually. The facets of the program are thoroughly outlined in the Certification Program Standard Operating Procedures (SOP's) contained in this documentation, and those considering participation are encouraged to familiarize themselves with its content and other applicable policies required for participation in the program.

Policies – Revisions & Discrepancies/Grievances
Any and all revisions to the SOPs or policies associated with the program are subject to approval by the Board of Directors or Executive Committee. Any proposed revision must also first be reviewed by the IASC Certification Committee prior to submission to the Board of Directors for approval. Any and all revisions must be based on relevant, factual evidence and maintain or improve the overall integrity and quality of the program.

Discrepancies or grievances of any kind should initially be reported to the Program Coordinator and/or Executive Director, who will attempt to mediate a resolution. If no resolution can be agreed upon, the matter will be handled according to the Code Enforcement rules as set forth in the IASC Code of Ethics & Business Conduct.

Products or raw materials currently certified within the program, and which fail to meet the standards for certification via random sampling due to deliberate adulteration, will immediately forfeit their rights of usage of the seal and be required to remove the seal from those products, materials, and other marketing or related literature within (30) days and be listed on the IASC website as no longer certified.

The program policies and procedures may be updated at any time, with or without notice. Participants agree to comply with any revisions, additions, or other modifications as of the date they are instituted.

Eligibility
The program is open to all members of the aloe industry including raw materials suppliers (including actual aloe vera plants, processed materials, etc.), manufacturers of finished products, contract manufacturers, resellers, and distributors. Procedures for potential applicants are outlined in the program SOPs and staff is available to assist with any questions.

Code of Ethics & Business Conduct
Program participants, by signing and returning the application, agree to uphold the IASC Code of Ethics & Business Conduct, which consists of a collection of trade recommendations, guidelines and industry best practices. In participants' voluntary endorsement of these meaningful guidelines, they support the promotion of industry self-regulation.

Rights of Usage
Companies participating in the program are authorized and granted the right to display and use the IASC seal, logo, and/or trademarked content and language in any and all marketing materials for the product(s) which that entity is directly engaged in selling, and that have passed the certification program criteria. These rights are not transferable to any other entity for which a business provides aloe vera raw materials, or manufacturers alternative or duplicate products. Companies may not indicate or imply in any manner that certification granted for a product(s) or facility applies to any other product(s) or facility not currently certified by the program, or that a company itself is certified beyond the components of the program (IE: a facility producing finished aloe vera products may be certified, but can not imply or intone that the entire company or its other, non-certified offerings are as well). Only the entity directly participating in the certification program is authorized or granted the rights to use the IASC seal, logo, language, and/or trademarked content without the express permission of the IASC. No company authorized to display and use the IASC seal is authorized to transfer the right to use the certification, certification certificate or in any other way authorize any third party to imply that it is a participant in the IASC program or are selling products certified under the program. Failure to comply with the rights of usage may result in legal action and de-certification.

Cancellation/Non-Renewal & Removal of The Seal/Language/Trademarked Terms
Those companies that choose to terminate participation in the program via non-renewal, non-payment or direct cancellation must remove or cease to display the certification program seal, logo, and/or trademarked terms from all marketing materials, including website(s), packaging, labels, and literature, immediately as of the day of termination. Products and facilities terminating participation in the program will be listed on the IASC website.

IASC Certification Program – Operational Procedures

1.1 FACILITY CERTIFICATION

Companies with manufacturing operations, whether contract or otherwise, are encouraged to obtain IASC Facility Certification. Those companies who utilize contract manufacturers should also encourage their manufacturing partners to become certified in order to defray associated costs, as this will eliminate travel and associated fees, such as an auditor's travel to the facility each time a new product is to be certified. Facility recertification must be completed every 3-years.

Once a facility is certified, individual products manufactured there do not require an on-site inspection by an IASC authorized auditor. Companies utilizing certified facilities are still required to pay all established fees [see section 1.5 – Fee Structure] for individual product certification, and submit the necessary samples, labels, literature, etc., associated with individual product certification. However, as noted prior, auditor travel and related expenses are eliminated.

Facility certification can be obtained in two ways: Via correspondence (available to facilities that maintain current, IASC approved 3rd party certifications as well as meeting all other applicable requirements) or by on-site inspection performed by an authorized IASC auditor.

1.1.1 CORRESPONDENCE AUDIT

Facilities already having completed at least one on-site audit conducted by an IASC auditor, and who have obtained one of the following IASC approved 3rd party certifications listed below, may apply for a facility certification via correspondence[1]. Applicants eligible and applying for this audit will pay a one (1)

[1] Subject to review and approval by the Certification Program Coordinator. Criteria for approval includes auditor feedback from on-site review and other information.

day auditor fee to have the application submitted and materials reviewed. Documents submitted must be translated into English or a translator must be provided upon request. Correspondence audits must be completed within three (3) months from the initial start date of the inspection. Applicants not completing the process within three (3) months must re-apply and pay all applicable fees again.

IASC Accepted 3rd Party Certifications (rev. 10/09)[2]:

1) United States cGMP

1.1.2 PROCEDURES

An application for facility certification can be downloaded from the IASC website (www.iasc.org) or requested via e-mail (rysasi@iasc.org). Complete and submit the application by fax (301-588-1174) or email (rysasi@iasc.org) along with the associated facility certification fees.

The application is reviewed by the IASC Certification Program Coordinator who will contact the applicant to confirm receipt of the application and fees and request any additional information. Once all information has been collected, it will be forwarded to an auditor for review.

Upon completion of the audit, the auditor creates a detailed report and provides a recommendation that is sent back to the IASC Certification Program Coordinator. The Coordinator receives the auditor's report, redacts the company information, and sends it to the Certification Program Chair for final review. Any questions are submitted to the auditor via the program coordinator until a decision is reached.

If the facility passes, a certificate is sent to the company along with a letter of approval. The company/facility name is added to the list of currently approved facilities on the IASC website and to the certification program application http://www.iasc.org/complete.htm

Those companies that are not approved will be given an explanation as to what discrepancies have caused them to fail the audit and allow them to work with the auditor to implement all necessary corrective measures until they come into compliance with the certification program requirements.

1.1.3 ON-SITE INSPECTION

New program participants and facilities that do not meet the requirements for an audit via correspondence may apply for an on-site inspection to be completed by an IASC auditor. These inspections are conducted by contracted, professional auditors who travel to different manufacturing facilities for the IASC and who audit the guidelines, standards and parameters established by the IASC certification program.

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[2] Other 3rd party certifications may be reviewed by the Certification Committee for recommendation to and approval by the Board of Directors. Unless listed here, no other 3rd party certifications are accepted. To submit a 3rd party certification for acceptance, please send all information, including any general information, audit parameters and a completed audit (all documents must be translated into English) to the Executive Director of IASC for further consideration (info@iasc.org). Parties submitting certifications for consideration will be notified within sixty (60) days of the status of any such request.

1.1.4 PROCEDURES

An application for facility certification can be downloaded from the IASC website (www.iasc.org) or requested via e-mail. Complete and submit it via fax (301.588.1174) or email (rysasi@IASC.org) along with the appropriate fees for certification [click here for fee schedule].

The program coordinator will work with the applicant and an auditor to schedule the auditor's travel to the facility, purchase airline tickets if necessary, and request local accommodation and transportation information for the auditor during the on-site facility inspection. At this time, the applicant is invoiced for the additional fees associated with the certification. International applicants will also receive a final invoice, which will be sent after the auditor returns, and will include any miscellaneous travel expenses. No certifications will be issued until payment of all program costs and expenses is received by the IASC.

A list of required documents the auditor will need to review during the on-site visit are delivered via email to the applicant and are expected to be prepared by the applicant and available in advance of the on-site audit. For International applicants, an English translator will need to be available during the on-site audit for both written and verbal communication if no English-speaking personnel are available.

After the on-site inspection, the auditor sends a report to the program coordinator. If there are any requested changes or if any additional information is required to complete the audit an interim report will be generated pending issuance of a final report. The coordinator redacts any company information and sends the report to the Certification Program Chair for approval.

The Chair reviews the materials and sends his decision to the coordinator via email. In the event the Chair needs additional information, the coordinator will work with the auditor to obtain it.

Upon approval, a certificate and approval letter is generated and sent to the successful applicant confirming facility certification. The facility name is added to the list of certified facilities on the IASC website as well as the certification program application.

1.2 AUDIT REQUIREMENTS

See Appendix I, Appendix II and Appendix III for detailed information

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1.3 PRODUCT CERTIFICATION

There are three different methods for obtaining IASC certification for products: On-site inspection, certification of products that are manufactured at a certified facility, and products that are currently certified but sold under different labels (duplicate labels).

The first method involves an on-site inspection by an IASC auditor. The auditor will observe the manufacturing process for a given products production run from start to finish. For tablets and capsules, if these processes are completed at a separate facility, the auditor will be required to also travel to and observe those facility processes as well.

The second is for products manufactured at a facility that has already been certified. For these products, applicants need to verify their products are manufactured at a certified facility and submit the completed application along with the certification fees, documents and samples outlined in the procedures below.

The third method of certification is for products that are currently certified but are sold under different labels, termed "duplicate labels"– meaning those products that are manufactured for different labeling, but maintain the same exact formulation (preservatives can differ).

1.3.1 PROCEDURES

On-Site Inspection

An application for product certification can be downloaded from the IASC website (www.iasc.org) or requested via e-mail. Complete and submit the application to rysasi@IASC.org along with the associated certification fees (bank transfers are accepted and an additional $35 USD surcharge to cover transfer fees applies. Please contact the Program Coordinator for transfer information). The Coordinator reviews the application and works with the applicant to obtain any additional information, if needed.

The program coordinator will also work with the auditor and applicant to schedule the on-site audit. Typically, these are scheduled approximately 2-4weeks in advance and primarily on weekends. Once travel arrangements have been secured, applicants will be sent an invoice for the auditors travel expenses. Full payment must be received prior to the on-site audit. A separate invoice will be sent to cover any additional, miscellaneous expenses incurred by the auditor after the on-site audit is completed. No certifications will be issued until payment of all program costs and expenses is received by the IASC.

The auditor will view the manufacturing process of each product to be certified, pull samples of the finished products (if applicable), aloe vera raw material used, labels, any literature that will display the IASC certification seal or name, specification sheets, and certificate of analysis for aloe vera raw material used. These items are returned to the IASC program coordinator for testing and approval.

The program coordinator will redact any company information and send the samples to the lab for testing. Submitted materials are reviewed by the program coordinator for compliance with the program's standards. The labels, specification sheets, certificate of analysis and literature are sent, after redacting company information, to the Certification Chair for review on an as-needed basis, such as should there be a question about a particular product label or other submitted materials.

If the products pass both the NMR analysis and the label/literature review, certification is completed by sending a certificate and approval letter. The certified products are also added to the certified products list on the IASC website. Samples are retained for 3-years.

For products that do not initially pass the certification analysis or otherwise meet program standards, the aloe vera raw material will be subject to retesting and new samples will be requested. Any retesting costs will be paid by the applicant and no certification will be issued until payment is received in full. Any product that fails to meet the certification program standards after 2 separate submissions will be subject to a 3 month waiting period before being able to reapply. Applicants will also be required to conduct an out of specification (OOS) investigation, submitting a full report to the IASC for further consideration and determination of any other necessary actions (e.g. on-site inspection by IASC auditor, collection of samples, etc.).

Products manufactured at a Certified Facility

For those individual products that are manufactured at a facility that is currently IASC certified, applicants need only complete and submit the following:

1. Application/Fees

2. List of samples & formulas

The program coordinator will redact any company information and send the samples to the lab for testing. Lab reports and submitted materials are reviewed by the program coordinator for compliance with the program's standards. The labels, specification sheets, certificate of analysis and literature are sent, after redacting company information, to the Certification Chair for review on an as-needed basis, such as should there be a question about a particular product label or other submitted materials.

If the products pass both the NMR analysis and the label/literature review, certification is completed by sending a certificate and approval letter. The certified products are also added to the certified products list on the IASC website. Samples are retained for 3-years.

For products that do not initially pass the certification analysis or otherwise meet program standards, the aloe vera raw material will be subject to retesting and new samples will be requested. Any retesting costs will be paid by the applicant and no certification will be issued until payment is received in full. Any product that fails to meet the certification program standards after 2 separate submissions will be subject to a 3 month waiting period before being able to reapply. Applicants will also be required to conduct an out of specification (OOS) investigation, submitting a full report to the IASC for further consideration and determination of any other necessary actions (e.g. on-site inspection by IASC auditor, collection of samples, etc.).

Currently certified products sold under a different label (Duplicate Labels)
For those individual products that are manufactured and sold under a duplicate label, applicants need only complete and submit the following:

1. Application/Fees

2. List of samples, labels, etc. (NO FORMULAS NEEDED)

The program coordinator will redact any company information and send the samples to the lab for testing. Lab reports and submitted materials are reviewed by the program coordinator for compliance with the program's standards. The labels, specification sheets, certificate of analysis and literature are sent, after redacting company information, to the Certification Chair for review on an as-needed basis, such as should there be a question about a particular product label or other submitted materials.

If the products pass both the NMR analysis and the label/literature review, certification is completed by sending a certificate and approval letter. The certified products are also added to the certified products list on the IASC website. Samples are retained for 3-years.

For products that do not initially pass the certification analysis or otherwise meet program standards, the aloe vera raw material will be subject to retesting and new samples will be requested. Any retesting costs will be paid by the applicant and no certification will be issued until payment is received in full. Any product that fails to meet the certification program standards after 2 separate submissions will be subject to a 3 month waiting period before being able to reapply. Applicants will also be required to conduct an out of specification (OOS) investigation, submitting a full report to the IASC for further consideration and determination of any other necessary actions (e.g. on-site inspection by IASC auditor, collection of samples, etc.).

1.3.2 RECEIVING SAMPLES

Companies requesting product certification are required to submit the following samples and documents:

- 4 small (2-4 oz) samples of each of the finished products to be certified, clearly labeled
- 4 small (2-4 oz) samples of each of the aloe vera raw materials used in each product clearly labeled with product name, lot number and date of manufacture
- Certificate of Analysis for each lot number of the aloe vera raw materials used in each product
- Specification sheet for each of the aloe vera raw materials used in each product
- 1 finished product of each of the products to be certified in its original container with product label affixed
- 1 Original label for each product to be certified - not affixed to the container
- Any literature currently or to be used to display the IASC certification seal

Upon receipt of the samples, the program coordinator will record the name of the product (listed on the product label), lot numbers, manufacturer name, describe loose labels received, specification sheets, etc. The date samples are received is marked on each sample bottle.

The program coordinator confirms receipt of all the samples requested by checking against the application. Some companies only manufacture products during certain times of the year, so all products may not be received at the same time. If all samples are not received, the program coordinator will contact the applicant to find out when they will be sending them (it could be months later).

If additional samples are received and are not on the application – applicants will be contacted and advised they must certify them as new and need to remit payment and another application for those products before the certification process will begin.

1.3.3 PREPARING SAMPLES TO BE SENT TO THE LAB

The coordinator will determine which samples are to be sent to the lab and prepare 2 samples of each product to be sent for testing. One lab will perform the NMR analysis, and the extra sample will be sent to another independent laboratory for aloin testing.

For aloe vera raw material

- The coordinator will send whatever was sent by the applicant - **no products will be sent that contain any added thickeners! These will not go through the NMR process**

For aloe Inner-leaf

- The coordinator will send whatever was sent by the applicant - send complete and intact

For finished products

- Liquids only (no creams, lotions, shampoos, tablets)
- Capsules – If the capsule only contains aloe vera powder, the raw material may be sent in lieu of the capsules
- Creams, lotions, hair care products, etc. – the aloe vera raw material/s used are sent (and all lot numbers used in that product)

The coordinator will print 2 labels for each product to be sent: Labels are printed with an assigned IASC# from the analysis request form and Sample ID, such as A,B,C, etc.

The coordinator fills out an analysis request form:

- Fill in date
- Change the IASC #
- List samples as A, B, C, etc.
- Description for finished products: ___% of __X (85% of a 1X)
    - If unknown, 1X will be used and the product will be tested "as is"
- Specify Inner-leaf (IL/Gel) or entire Leaf (Filtered Whole Leaf - FWL)

The coordinator prints out 1 copy of the analysis request form.

At the bottom of this form (IASC's copy only) –as much information as possible is transferred from the product label, such as product name, lot or batch number, date of manufacture, etc. If the product label can be removed, it will be peeled and stuck on the form.

EXAMPLE:

Sample A
Name of product
Product code
Lot #
Batch #
DOM

The coordinator will print out 2 copies - one for the customer's file and one for the "black book" for that particular year. This book contains the analysis request form, NMR analysis reply from the lab, and a copy of approved or not approved NMR analysis for the current year's certifications.

After the analysis request form is completed, the coordinator removes sample labels on the bottles and replaces them with the IASC # and Sample id label. Samples are boxed up along with the analysis request form(s) and prepared for shipping. A commercial invoice is filled out and included with the airway bill when ready to ship.

1.3.4 RECEIPT OF NMR & Aloin Analysis

NMR & aloin analysis results are received via email, and reviewed for compliance with program standards.

The coordinator will make a copy of the analysis reports and graph for the applicant file and one for the "black book" and file them appropriately.

1.4 ANNUAL RECERTIFICATION & RANDOM SAMPLING PROGRAM

All certified products and raw materials must renew certification annually, based on the date of application. In order to ensure the continued sanctity and overall integrity of the certification program, products certified by the IASC are selected for randomized testing on a monthly basis. While all program participants pay for annual recertification, not all products may be tested annually. Submission of payment for recertification indicates continued acceptance of all program requirements, policies and rules.

Random Sampling Program – Finished Products

Finished products selected for random sampling will be purchased off-the-shelf, via the internet, via direct sale, or via other appropriate means, by the Program Coordinator and submitted for testing. Those companies who utilize contract manufacturing services will have provided product samples that will be submitted for testing. Companies will be informed if chosen for random sampling and invoiced for product(s) and any applicable shipping charges as well as associated lab fees. Payment must be received prior to the submission for testing.

Random Sampling Program – Raw Materials

Raw materials selected for random sampling will be purchased via the internet, directly from the manufacturer or supplier, or via other appropriate means (in the smallest quantity available/possible) and submitted for testing. Companies will be informed if chosen for random sampling and invoiced for product(s) purchased afterwards, including any applicable shipping charges. Payment must be received prior to the submission for testing.

An invoice is sent to each active participant sixty (60) days prior to the annual recertification date with a request for the following items needed for recertification:

- Payment in full
- 1 Original label for each product to be recertified - not affixed to the container
- Any literature currently displaying the IASC certification seal
- Copy of formula for each product subject to renewal (Non-Disclosure Agreements (NDAs) can be signed/filed by IASC staff and no confidential or proprietary information will be shared with any other IASC member)

The following items are only applicable to those companies utilizing contract manufacturers:

- 4 small (2-4 oz) samples of each of the finished products to be recertified, clearly labeled
- 4 small (2-4 oz) samples of each of the aloe vera raw materials used in each product clearly labeled with product name, lot number and date of manufacture
- Certificate of Analysis for each lot number of the aloe vera raw materials used in each product
- Specification sheet for each of the aloe vera raw materials used in each product
- 1 finished product of each of the products to be recertified in its original container with product label affixed

If payment is not received within thirty (30) days prior to the annual recertification date, a letter of intent to decertify the product(s) will be sent, and manufacturers are required to remove the IASC seal from any product(s) and marketing materials that are no longer certified. Products unable to remove the seal (engrained onto the label) must cover or otherwise visibly remove the seal. These products or materials will be added to the decertified list on the IASC website.

Those products chosen for random testing will have samples sent to the lab per Product Certification (section 1.5.3), and then procedures for receipt of NMR analysis (section 1.5.4). Payment must be received from program participants prior to sending any samples for testing. Samples received will be kept and stored for 3 years.

Random Sampling Program – Failures
In the event of a product failing analysis under the random sampling program, the following actions will be taken:

- A sample of the same product that was originally tested is sent for analysis. The company is billed for the second analysis.
- If the product fails a second time, IASC counsel is notified, and together with staff a determination is made regarding any further actions (additional testing, etc.), and if none, staff contacts the company to inform them of the results and gives them 14 days to conduct an investigation and report back the results and any proposed corrective action.
- The company is subsequently informed that a subset of the Executive Committee (at least 3 members) in the form of a formal review panel, to be chosen by staff, will be provided with all information to date.
- The panel will review all information and determine if any additional analysis or research can and should be conducted. If no further options are considered viable, the review panel, in the event of decertification, will instruct IASC counsel to prepare and staff to deliver a formal communication to the company that includes:
    - A copy of the analysis and the results of any further investigation
    - Demand that the seal and any seal language be removed from the company website, any/all other marketing, and the product in question within 30 days.

    Notification that the IASC will be issuing a press release regarding the decertification of the product, as well as posting of the product on the IASC's webpage, "No Longer Certified".

1.4.1 CORPORATE CONTACTS

Companies participating in the program are responsible for providing a primary contact for all IASC certification program communications. The contact information provided must be kept current and updated at least annually by the participating company. Businesses that utilize a 3rd party to coordinate their certification are also required to provide and maintain a current corporate (in-house) contact.

1.5 FEE STRUCTURE (all fees in $USD)

The following fee structure is effective July 1, 2016.

	Member	Non-Member
Facility Certification	$1500	$2000
1st Product	$1050	$1650
Additional products (certified with initial 1st product)	$525 ea.	$825 ea.
Additional products (certified after initial products)	$1050	$1650
Annual Product Recertification	$800	$1100
Additional Annual Product Re-certifications (same time)	$525 ea.	$825 ea.
Auditor Fee (per day, including travel days)	$500/day	$500/day
Airfare, Transportation, Meals & Accommodations	At Cost	At Cost
Mileage allowance	Current IRS Rate	Current IRS Rate
Raw Material Supplier or Manufacturing Facility Change	$400	$800
Fee To Certify Same Formula w/ Different Labels	$420	$660
Laboratory Fees	$300	$300

Annual monitoring and random sampling of all certified products and facilities will be conducted at the discretion of the IASC Certification Committee. Should a product not pass certification, or if revalidation is required, a second on-site audit of the manufacturing facility may be scheduled at the expense of the company requesting certification including any airfare or other travel fees, auditor's fee, meals, lodging and lab fees. This random review ensures that participants of the program maintain the highest levels of product integrity and compliance.

APPENDIX I - FACILITY CERTIFICATION REQUIREMENTS

Written procedures for the following areas must be provided for facility certification

I. Personnel

A. Training
   1. Equipment
   2. Sanitation
   3. Hygiene

B. Provisions for health conditions to be reported and employee evaluated

II. Maintenance of building

A. Pest control plan
B. In-house inspection plan for pest-free environment
C. Housekeeping and cleaning of floors and walls
D. Exterior inspection of grounds for debris and trash

III. Receiving Aloe Vera from Field

A. Storage
B. Pre-processing steps

IV. Equipment Cleaning and Sterilization

A. Written procedures posted
B. Training
C. Daily records of cleaning
D. Type of material used in construction of tanks, pumps, valves, chambers, etc. (e.g. stainless steel, etc.)

V. Processing (from cleaning to HTST), excluding proprietary procedures

VI. Processing during membranes separation, excluding proprietary procedures

VII. Receiving

A. Quality Assurance of Raw Materials used in production
B. Quality Assurance of Containers and Closures used in production

VIII. Rejecting

A. Raw materials
B. Containers and closures
C. In process materials
D. Finished goods
E. Failure Reports

IX. Quality Control Procedures

A. Laboratory
   1. Physical tests
   2. Microbiological testing
   3. Random sampling during production
   4. Analysis of finished products

B. Production
   1. Testing for sanitation of equipment
   2. Personal protection controls

C. Storage – Raw materials, containers and closures
   1. Ensuring raw materials are evaluated and preserved in a sanitary condition
   2. Ensuring containers and closures are evaluated and preserved in a sanitary condition

D. Storage – Finished Product
   1. Quarantine procedures
   2. How stored – protected from heat and cold

X. Labels

1. Checking for accuracy when received
2. Control of labels from receipt to completion of finished goods.

XI. Record keeping

1. Batch reports
2. Lab records
3. Filing records
4. Storage records
5. Shipping records

XII. Recall of products found to be out of specification

XIII. Stability testing to assure shelf life through expiration date

XIV. Challenge testing of preservative system

XV. List of all test methods used at any phase of production

XVI. Producing a Certificate of Analysis on each batch

APPENDIX II - FACILITY & PRODUCT AUDIT REQUIREMENTS

IASC Auditor Questionnaire[3]

Personnel

1. Are all employees adequately trained in their particular job responsibilities and are appropriate records of the training kept according to applicable regulations?
2. Are all necessary employees trained in the appropriate Good Manufacturing Practices (GMP) or other applicable regulations, and is training recurring and documented appropriately?
3. Are adequate washing facilities available for production employees and are they appropriately located and/or available as to prevent microbial contamination of finished products?
4. Do employee hygiene and cleanliness standards exist and are they suitable and emphasized adequately?
5. Are there appropriate, written Standard Operating Procedures (SOPs) in place for training of employees and for preventing microbial contamination?
6. Are all applicable records kept according to any/all applicable regulations? (Documentation may include job descriptions, annual and job related training, training and other SOPs and annual performance reviews).

Facility & Grounds

1. Are the manufacturing facility, grounds, and related items (such as water supply) adequate and/or fit for purpose and kept/maintained suitably clean to produce certifiable products?
2. Is the water supply treated/tested/monitored adequately to meet requirements as a food ingredient (if applicable)?
3. Does the applicant have an adequate pest control program in place?
4. Does the applicant qualify the use of any cleaning components, pesticides, or sanitizing agents (such as an approved chemicals list for equipment vs. janitorial vs. pest control)?
5. Are there appropriate, written SOPs in place for the maintenance of the facility, grounds and pest control? (Documentation may include schedules, reports, log books, service or maintenance contracts and records, drawings or diagrams of the physical plant, material approval forms and training records)

Equipment & Utensils

1. Is all equipment cleaning, maintenance and use recorded on cleaning and use logs or other appropriate record keeping materials?

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[3] This questionnaire may or may not reflect all questions that will be asked by an auditor during an inspection, nor may an auditor ask all questions on this questionnaire during an inspection. Companies selling materials or products for use as drugs will be inspected under 21 CFR 210 & 211. Companies selling materials or products as or for use in food will be inspected under 21 CFR 110. Companies selling materials or products for use in dietary supplements will be inspected under 21 CFR 111.

2. Do the cleaning and use logs or other appropriate record keeping materials include date, time, product and batch number of each batch produced or maintenance performed?
3. Are the cleaning and use logs or other appropriate record keeping materials signed and dated by the person performing the operation and by a second person verifying the operation?
4. Is there an approved chemicals list maintained and used/monitored effectively?
5. Is all automated, mechanical and electronic equipment inspected and calibrated regularly/appropriately?
6. Are appropriate, written Standard Operating Procedures (SOPs) established for all applicable equipment cleaning & sanitation aspects of the business?
7. Are appropriate, written SOPs established for the calibration of all instruments and controls? (Documentation may include log books, calibration and service schedules, maintenance and cleaning logs and schedules, cleaning and sanitizing schedules and log books).

Production & Process Control System

1. Are procedures for the production process or system, including process controls for all stages of manufacturing, packaging, labeling and warehousing which ensure the quality of dietary supplements and in accordance with established specifications, in place and adequately monitored?
2. Are procedures established for quality control, including specifications for any material component or process where a control is necessary?
3. Are specifications for components for material identity established, including limits for contamination, in-process specifications for any manufacturing or processing intermediate or steps to ensure quality (where necessary), and limits for contamination that may adulterate a finished batch of dietary supplements?
4. Are procedures established for testing to ensure that specifications for materials, components and finished products are met and for the management of non-conforming materials or product?
5. Are procedures established for taking samples for testing and retaining reserve samples that are representative?
6. Are written SOPs defining responsibility for review of testing and approval or rejection of materials, deviations from standard procedures and reprocessing established? (Documentation may include SOPs for production processes and steps, accomplishing process controls, labeling, labeling and component issuance and control, warehousing and First-in Oldest Expiration-out procedures and log books. Quality documentation may include testing and inspection SOPs, specifications for raw materials, components intermediated and finished products, documentation of all testing , log books, and approval and release documents)

Quality Control

1. Are procedures establishing quality control responsibilities and activities for materials review, disposition procedures and criteria and procedures for testing, specifications, controls, approval, rejection or reprocessing of materials or products established and monitored appropriately?

2. Is adequate space dedicated for the purposes of Quality Assurance/Quality Control?
3. Are adequate QA/QC personnel employed or contracted and present?
4. Does the QA/QC personnel report or have any reporting responsibility to the Production Department?
5. Does the QC/QA department review and approve procedures and documentation, forms, records and log books?
6. Are all raw materials subject to release by QA/QC prior to use in production?
7. Does the QC/QA department monitor and audit processes, department and vendors?
8. Does the QC/QA department have established procedures for testing, specifications, reports, controls and deviations?
9. Does the QC/QA department perform and maintain appropriate sampling criteria and approval or rejection of materials and products based on established criteria?
10. Are there established procedures for the Review and disposition of returned goods?
11. Are there established procedures for Investigation and review of customer complaints?

Receiving Operations – Components, Packaging & Labeling

1. Are procedures for the management of components, packaging containers, labels and product labeling, the use of unique tracking numbers for each lot in each shipment of packaging and labeling components for inventory management and control established and adequately monitored?
2. Are procedures established for the visual examination of the invoice, manifest or packing slip for accuracy?
3. Are there procedures established with criteria for visual inspection of all immediate product containers, components and labeling
4. Are there procedures established for the inspection of shipping containers for visible damage
5. Are there procedures established for review of receiving documents, and quarantining of shipments?
6. Are there procedures established for sampling of components, review of specifications, inspection and /or testing of components by the quality department for approval or rejection?
7. Are there procedures established for the quarantine, sampling and examination of labeling with representative samples and approval or rejection as well as adequate storage that protects against damage and prevents mix-ups?

Master Manufacturing Record

1. Does the applicant have written master manufacturing records for each unique dietary supplement formula and batch size that include the following information (applicable to dietary supplement manufacturers only)?

   Batch records must

   - identify specific steps in the manufacturing process
   - identify control points necessary to ensure product quality specifications
   - include
     a) all components for use in manufacturing
     b) weights or measures for use in manufacturing

c) all ingredients appearing in the supplement facts label
d) any intentional overages
e) theoretical yield
f) manufacturing control points
g) verification of all weights and measures
h) special notation or precautions
i) all packaging components
j) written instructions
k) quality specifications
l) procedures for sampling
m) corrective actions if specifications are not met

Batch Record

1. Are Batch Production Records prepared each time a product is manufactured and includes all elements listed in 21 CFR 111.260, including:
   i) Are lot numbers of all raw materials used recorded on a batch record?
   ii) Are appropriate records kept of who weighed and who verified the weighing of raw materials?
   iii) Do batch records include adequate instruction for each step of the operation?
   iv) Do the batch records identify who performed and who verified each step of the operation?
   v) Do the batch records include each piece of equipment used in each step of the operation?
   vi) Are batch records issued in an appropriate manner?

Laboratory Operations

1. Are written procedures established for laboratory operations, including testing and examination to determine if product specifications are met detailing criteria for establishing specifications? (Documentation should include evidence that all tests are "fit for purpose", the initial of individuals performing the tests, documentation for all laboratory tests and all test results)

Manufacturing Operations

1. Are written procedures established for all steps in the manufacturing process which include procedures and real time documentation of all process which prevent contamination, specifications to be met or steps to protect product purity and quality, all manufacturing and processing steps, cleaning and sanitizing, temperature, time or other process controls, mechanical measures such as screens, filters, traps or magnets or metal detector and segregation of products? (Procedures should include the holding, quarantine of in-process and finished products for quality testing and review)

Packaging & Labeling Operations

1. Are written procedures established for the review for accuracy of labels and labeling, the security, control and accuracy of label issuance and inventory accountability or 100% product inspection? (There should be written procedures for packaging operations and packaging records must document cleaning and sanitizing, assignment of lot or control numbers, packaging and labeling, accountability for components and product, quality inspection and approval or rejection and any repackaging or relabeling processes)

Holding & Distribution

1. Are written procedures established for the holding and distribution of components, labeling, supplements, and in-process material, and are they under suitable environmental controls and conditions that prevent mix-ups, contamination, or deterioration and provide adequate security and SOPs for the management of reserve samples after collection? (Written SOPs should be established for distribution of finished products and for the retention of distribution records)

Product Returns & Complaints

1. **Product Returns** - Are written procedures established for documenting the receipt, quarantine, and holding of returned supplements for quality review, quality testing and disposition for release, re-processing or destruction? (Documentation should include evaluation by quality and the results of any testing and disposition)

2. **Product Complaints -** Are written procedures established for the review of written and other customer complaints by a qualified person to determine if a supplement fails to meet any of the established specifications or other requirements?

   Procedures for handling product complaints should include:

   i) An investigation of the complaint
   ii) Review by quality control and review by a qualified person for findings and follow up actions.

   Documentation for handling product complaints should include:

   i) A written investigation of the complaint
   ii) Review by a qualified person for findings and follow up actions
   iii) a written record of the complaint
   iv) name of the person or persons performing the review
   v) the name , description, lot or control number of the product
   vi) the date of the complaint

vii) the nature of the complaint

viii) any reply and findings of the investigation

Record Keeping

1. Is documentation kept for at least one year past the shelf life of a product (or two years in the event shelf-life statements are not utilized), and are all documents available to FDA inspectors?

Other Considerations

1. Is the aloe vera raw material purchased from an IASC-Certified supplier?
2. Does the applicant have a stability program that is used to determine appropriate storage conditions and expiration or shelf-life dates (if shelf-life dating is established)? During any stability testing, does the applicant use the same container-closure system as that is which products are marketed?
3. Does the applicant have an adequate adverse event reporting system in place, if applicable?

APPENDIX III – PRODUCT CERTIFICATION CRITERIA

For a company's products to successfully pass the IASC Certification Program, the following criteria must be met:

1. The source of Aloe raw materials must be certified by the IASC.

2. Finished products must contain at least 15% aloe vera. Qualification of aloe vera content is performed by NMR analysis (see below for complete list of constituents analyzed and reported).

3. A complete review of finished product labels and/or artwork and literature (such as specification sheets or sales flyers) used in reference to the aloe product(s). All product labels, artwork and literature must be submitted to the IASC certification program coordinator. Any changes to product labels, artwork or literature must be submitted prior to being used. This information will be reviewed as it applies to use of the IASC Seal of Certification and in no way implies conformity with or acceptance by any state or federal governmental laws or agencies. The following label & terminology criteria must be met:

a. Aloe vera must be properly identified on labels per the IASC labeling guidance and definitions.
b. If the term polysaccharide is to be used, refer to the Mucopolysaccharide-Polysaccharide Position Statement from the IASC. If a polysaccharide count is used, a laboratory report must be included with your method of analysis for verification purposes.
c. The acronym MPS, if used, must be followed with the following words in parenthesis (Methanol Precipitable Solids). Refer to the Polysaccharide Position Statement for more information.
d. The term "cold processed", or any equivalent term, shall only be used if it can be proven that the product is in fact cold processed or equivalent. This means "without heat" from the raw material through the finished product production. Adequate substantiation must be provided (Non-Disclosure Agreements can be signed by IASC staff and auditors).
e. Statements or other claims regarding Aloe vera must be substantiated. For example, the statement "organically grown" must be supported by the organic seal or certification from an authorized agency verifying organic certification.
f. Product label formats and claims as well as product literature must comply with applicable United States laws and regulations. If the product is only sold in jurisdictions other than the United States, the applicant may instead demonstrate that the product label and literature comply with the laws and regulations of the jurisdiction(s) in which the product is sold. Members can contact the IASC office for more information.

4. Manufacturing records for the product(s) to be certified must be reviewed by the auditor during an on-site visit.
5. Samples of aloe vera raw material will be taken or requested for analysis.
6. Production samples of finished products will be taken for analysis from the production line.
7. The auditor will observe the manufacturing process of a standard production run. The minimum batch size for certification is 55 gallons of product for liquids and 10 gallons for others.

In addition:

A physical review by an IASC auditor of the following must be conducted:
The formulation used in the manufacturing of the product, the manufacturing procedures used to make the product, the packaging, warehousing, storage, and inventory records concerning the products to be certified. The auditor will conduct an on-site visual inspection of an actual production and filling

operation used in reference to the aloe vera products. The inspector will collect samples of the aloe vera raw materials used to manufacture the product as well as finished product taken off of the production line. The samples will be sent to the lab for analysis.

Analytical Standards

Products undergoing certification must meet all of the parameters for aloe vera content as defined by the IASC. The table below outlines the constituents and adulterants that will be analyzed and reported in order to pass certification. Analysis is conducted using a cross-lab validated NMR methodology, unless otherwise noted:

Constituent Name	**Qualification or Quantification**
Beta 1,4 acetylated Polymannan (aka "acemannan" or "aloeverose")	Finished Products: Present Raw Materials: ≥ 5% by dry weight
Isocitrate (Whole Leaf Marker)	Raw Materials: ≤ 5% for inner leaf by dry weight. (Anything above this level will be considered a whole leaf ingredient).
Solids & Ash Content	Raw Materials Solids Content: ≥ 0.46% solids in single strength inner leaf juice (therefore, a 10x should have at least 4.6%) Raw Materials Ash content: ≤ 40%
Glucose	Present
Possible Adulterants	
Maltodextrin	Declared: Must be listed on label and analysis must meet label claims Undeclared: Will be considered an adulterant
Other Substances	
Aloin	10ppm or less aloin in 0.5% aloe vera solids solution for products for oral consumption – Analysis by HPLC or other fit for purpose methodology approved by the IASC

Process NMR Associates, LLC

87A Sand Pit Rd, Danbury, CT 06810 USA
Tel: (203) 744-5905 Fax: (203) 743-9297 Web: http://www.process-nmr.com

Date: February 14, 2012

To: Devon Powell
Rosie Ysasi
IASC

From: John Edwards
Process NMR Associates, LLC

Re: ^{1}H NMR Testing of Aloe Vera Sample IASC12-PNA1731 - Sample A

Materials and Method:

Chemicals used as reference and calibration items.
Nicotinic Acid Amide 99.5+% - Fluka - (CAS - 98-92-0, Lot & Filling code: 450113/1 11204240)

Chemicals used in the study:
Deuterium Oxide 99.9%D – 0.75 ml Ampoules - Norell Inc, NJ, USA (NMR Solvent)

Instrument used in study:
Varian Unity-300 NMR spectrometer operating at 7.05T, and a Varian 5mm broad-band probe.

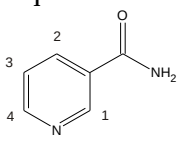
NMR Spectroscopy:
A ^{1}H NMR spectrum was acquired at a spectrometer frequency of 299.943 MHz, a spectral window of 9 kHz was acquired with a 30 degree pulse angle, a 2 s relaxation delay and an acquisition time of 3.6 s collecting 64000 data points. 128 transients were accumulated.

A measured amount of sample (approx 50-100 mg) was added to 0.75 ml of D_2O along with a measured amount of the standard material (Nicotinic Acid Amide) (approx 10-20 mg). Actual weights are recorded below.

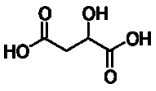
Actual Weights of Sample and Standard:
Standard: 6.2 mg
Sample: 34.0 mg

Molar ratios of individual components are calculated against the molar intensity of an accurately weighed standard (nicotinamide). From the molar intensities the wt% of each component can be calculated.

^{1}H NMR spectroscopy observes signals from all protons in the sample simultaneously. Aloe vera components, preservatives, and degradation products yield peaks at specific chemical shifts which can be integrated and quantified. Observations are made on the following peaks:

Nicotinamide:  1) 8.85 ppm, 2) 8.2 ppm (coincides with formic acid), 3) 7.55 ppm, 4) 8.65 ppm

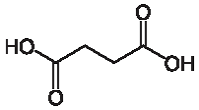
Glucose - C1 proton for α conformation at 5.2 ppm and C1 proton for β conformation at 4.6 ppm

Malic Acid -  CH at 4.35 ppm (multiplet), CH_2 at 2.4-2.8 ppm (multiplet)

Acemannan - CH_3 resonances of acemannan acetylation - fingerprint distribution of methyl resonances from 2.0-2.2 ppm

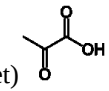
Lactic Acid CH_3 Peak at 1.33 ppm (doublet) 

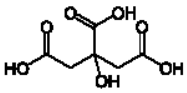
Acetic Acid - CH_3 peak at 1.92 ppm (singlet)

Succinic Acid - 2 x CH_2 peak at 2.5 ppm (singlet) 

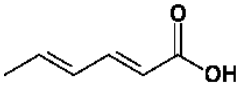
Formic Acid - Aldehyde Resonance at 8.2 ppm (singlet) 

Ethanol - CH_3 peak at 1.18 ppm (triplet)

Pyruvic Acid - CH_3 peak at 2.35 ppm (singlet) 

Citric Acid - 2 x CH_2 resonances at 2.4 to 3.0 ppm (multilet) 

Benzoate - ortho-protons (2H) give peaks at 7.8 ppm. 

Sorbate - CH_3 peak is observed at 1.77 ppm (doublet)  olefin protons observed at 5.7, 6.15, &7 ppm.

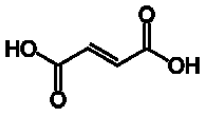
Fumaric Acid - CH peak at 6.55 ppm (singlet) 

Figure 1 shows an annotated ^{1}H NMR spectrum of an Aloe Vera Concentrate Juice with the various resonances identified.

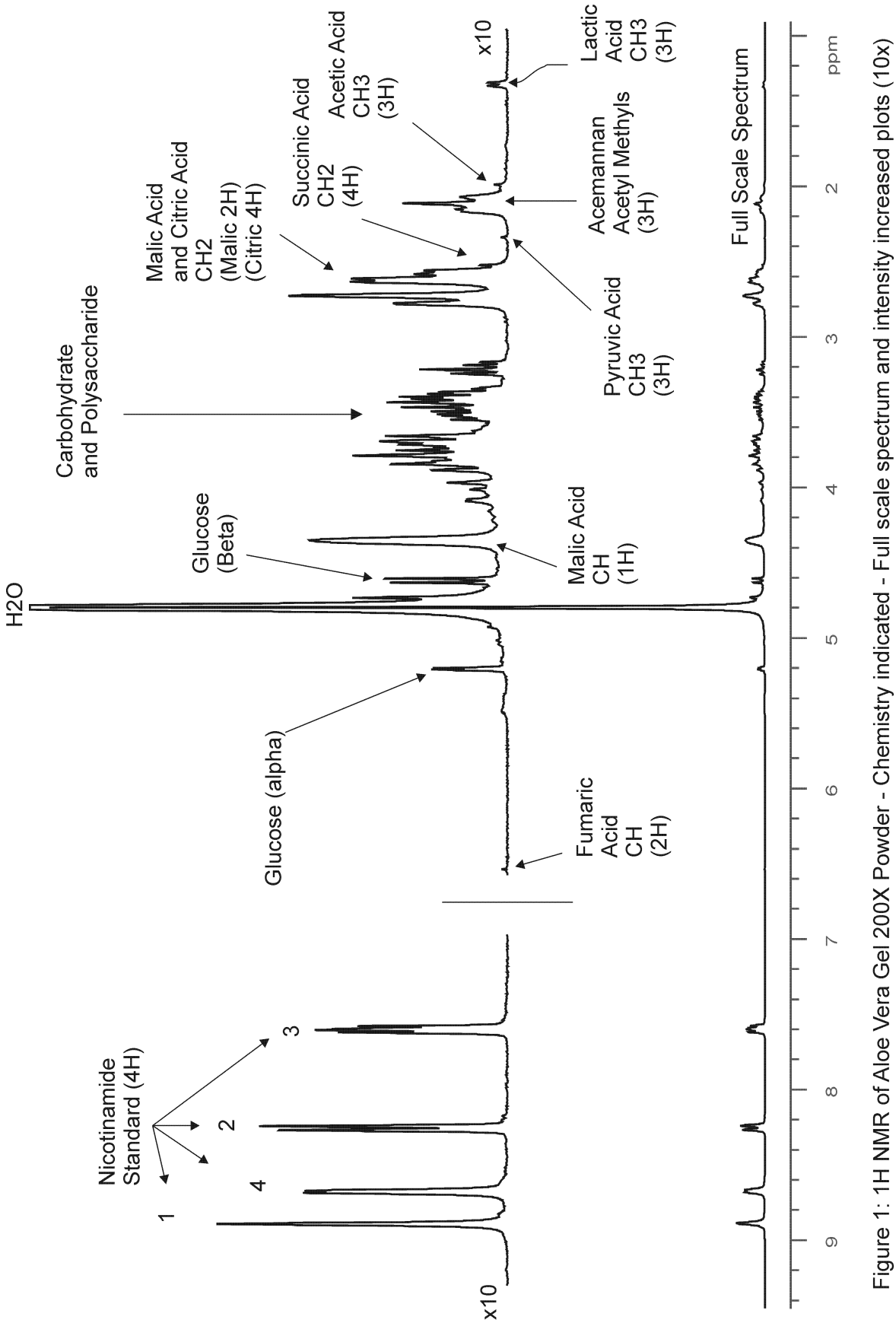


Figure 1: 1H NMR of Aloe Vera Gel 200X Powder - Chemistry indicated - Full scale spectrum and intensity increased plots (10x)

Results and Discussion: Aloe Vera Sample IASC12-PNA1731 - Sample A

A) ID and Quantification of Fresh Aloe Vera Components - consists of three main components:

1) Acemannan (2.1-2.3 ppm (CH_3)), 2) Glucose (C1 - α at 5.2 and C1 - β at 4.6 ppm, 1:2 ratio, respectively) and 3) Malic Acid (2.4 - 2.8 (CH_2) and 4.35 ppm (CH)).
All are detectable by ^{1}H NMR. These components indicate quality material.
Acemannan, Glucose, and Malic Acid are observed in this sample. These components indicate the presence of Aloe Vera.

B) NMR can also detect components that are due to degradation of the Aloe Vera. These degradation products are:

Lactic Acid (1.4 ppm) – indicative of bacterial (lactobacillus) degradation. Observed

Succinic (2.6 ppm) and Fumaric Acid (6.5 ppm) – Produced by enzymatic degradation caused by Aloe Vera's own enzyme system. Succinic Acid Observed

Acetic Acid (1.94 ppm) and Formic Acid (8.4 ppm) – indicative of hydrolysis of acemannan, and the thermal degradation of glucose during storage. Acetic Acid Observed

NMR can readily detect the presence of preservatives such as citric acid (2.6-3.0 ppm), Potassium Sorbate (1.72 ppm) and sodium benzoate (7.4 and 7.8 ppm). Preservatives Not Observed.

Finally NMR can be used to detect adulteration of the Aloe Vera product by polysaccharides such as Maltodextrine. Maltodextrin - Not observed.

Fermentation Products can be Observed – Ethanol - Not observed

Iso-Citric Acid is used to identify the presence of Whole Leaf Marker (WLM) which indicates use of whole leaf in the production of the aloe product. - WLM - Not Observed

Unusual Impurities – None Observed

Conclusion: Acemannan is not observed.

Table I contains the results of the ^{1}H NMR analysis. The following pages contain annotated spectra for your information (Figures 2 and 3).

Sincerely,

John C. Edwards

John C. Edwards, Ph.D.
Manager, Process and Analytical NMR Services
E-mail: john@process-nmr.com

Table I
Chemical Composition of Aloe Vera Sample IASC12-PNA1731 - Sample A

IASC12-PNA1731 - Sample A	
Component	Wt%
Acemannan Wt%	11.09
Glucose Wt% *	51.65
Malic Acid Wt% *	21.18
Lactic Acid	4.04
Citric Acid	0.83
Pyruvic Acid	0.16
Sorbate	0.00
Benzoate	0.00
Acetoin	0.00
2,3-butandiol	0.00
WLM	Not Observed
Acetic Acid	0.07
Succinic Acid	0.13
Formic Acid	0.00
Fumaric Acid	0.00
Ethanol	0.00
2-Propanol	0.00
Maltodextrin	0.00

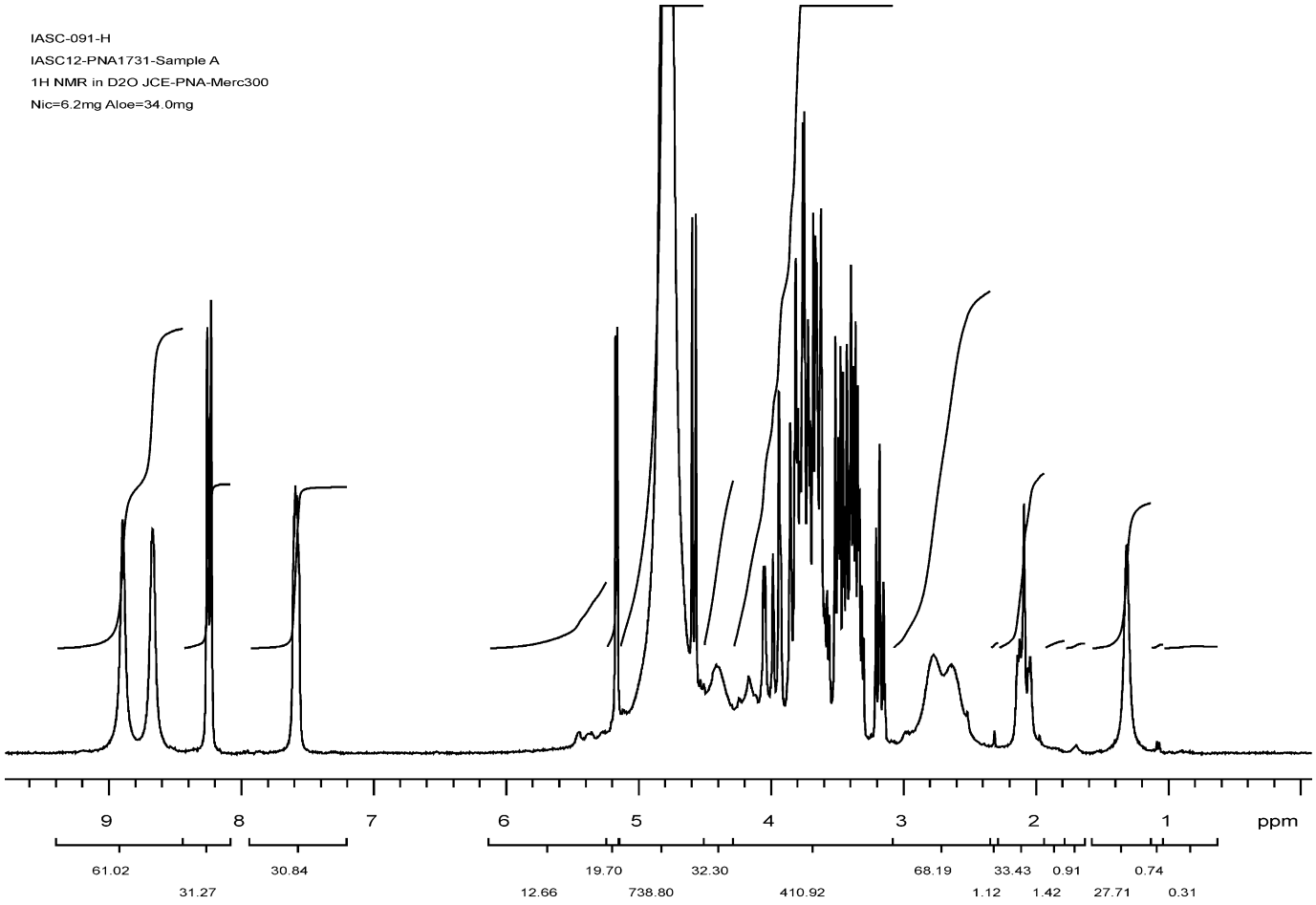

IASC-091-H
IASC12-PNA1731-Sample A
1H NMR in D2O JCE-PNA-Merc300
Nic=6.2mg Aloe=34.0mg
9
8
7
6
5
4
3
2
1
ppm
61.02
31.27
30.84
12.66
19.70
738.80
32.30
410.92
68.19
1.12
33.43
1.42
0.91
27.71
0.74
0.31

Figure 2

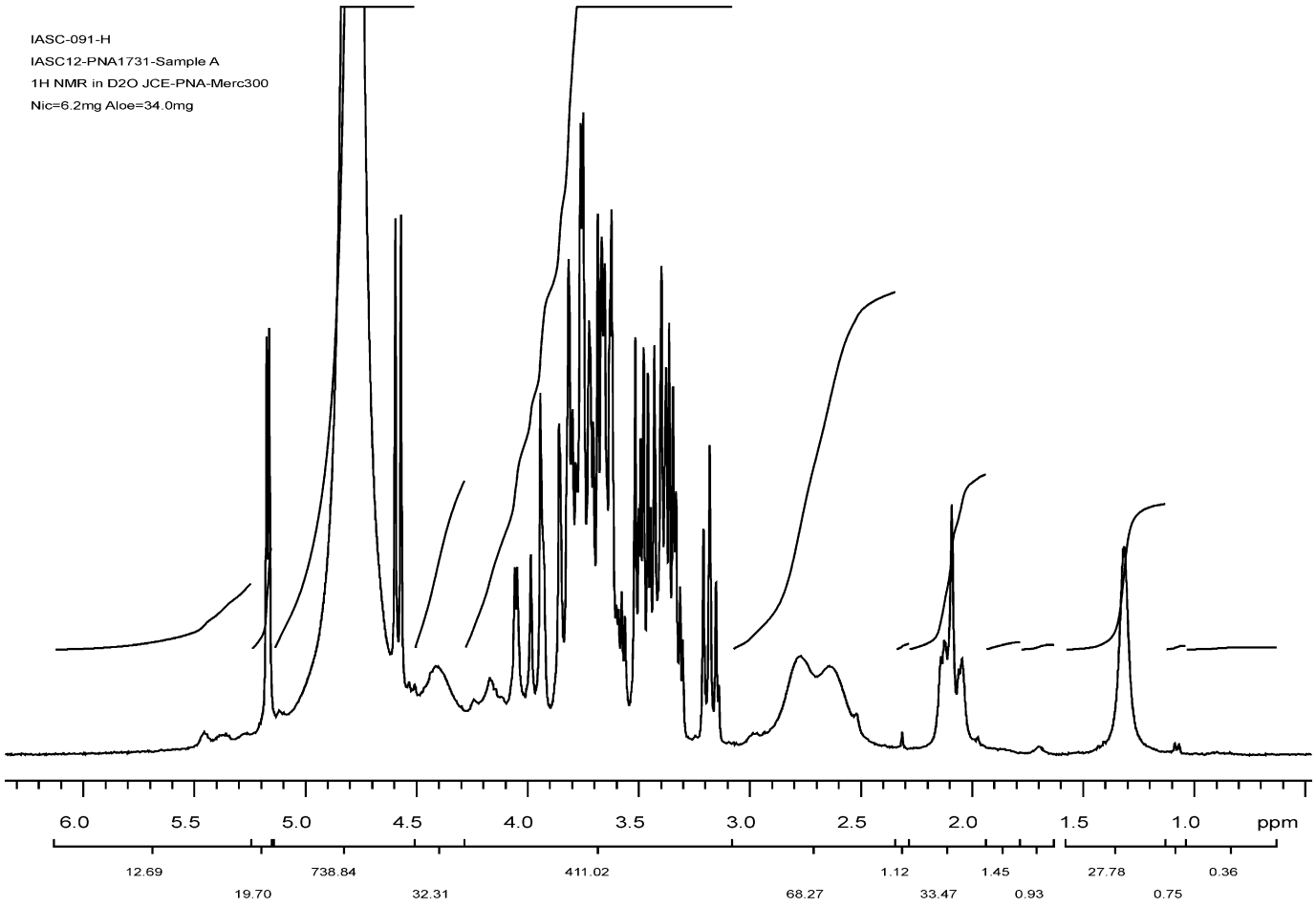

IASC-091-H
IASC12-PNA1731-Sample A
1H NMR in D2O JCE-PNA-Merc300
Nic=6.2mg Aloe=34.0mg
6.0
5.5
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
ppm
12.69
19.70
738.84
32.31
411.02
68.27
1.12
33.47
1.45
0.93
27.78
0.75
0.36

Figure 3

THE INTERNATIONAL ALOE SCIENCE COUNCIL

IASC Labeling Guidance
Adopted March 9, 2009

This guidance is required for members selling products manufactured for sale in the United States. It is recommended for products manufactured for sale worldwide.

IASC members label products containing aloe vera according to the following:

1) Terms used in the marketing and labeling of aloe vera products comply with the definitions identified in the IASC document "Definitions of Terms Commonly Used in Aloe Industry", in so far as those terms are included in the document.
2) All products (dietary supplements, conventional foods), when using *Aloe vera* (L.) Burm. f. as an ingredient, are labeled using the Standard Common Name (SCN): aloe vera
    a) The Latin binomial may be utilized after the SCN if desired
        i) Example: aloe vera [plant part] (*Aloe vera*)
        ii) Example: aloe vera [plant part] (*Aloe vera* (L.) Burm. f.)
    b) A synonymous Latin binomial may be utilized after the SCN if desired
        i) Example: aloe vera [plant part] (*Aloe barbadensis = A. vera*)
3) Identify the plant part
    a) Plant part – Leaf
        i) If the leaf in its entirety is used as the primary or starting ingredient the label identifies the plant part as "leaf". Use of this term also indicates the ingredient was subjected to processing or treatment(s) to reduce or remove the anthraquinone content.
            (1) Example: "aloe vera leaf"
    b) Plant part – Inner leaf
        i) If only the inner leaf is used as the primary or starting ingredient, the label identifies the plant part as "inner leaf".
            (1) Example: "aloe vera inner leaf"
    c) Plant part – Aloe latex
        i) If the aloe latex is used as an ingredient, the label identifies the plant part as "Aloe latex".
4) Products are not marketed or labeled as "whole leaf" unless:
    a) The use of additional and accurate descriptive language is included
        i) Example: Aloe vera de-colorized whole leaf or De-colorized whole leaf
        ii) Example: Aloe vera active charcoal filtered whole leaf or charcoal filtered whole leaf
        iii) Example: Aloe vera filtered whole leaf or filtered whole leaf
    b) Notwithstanding paragraph 4a above, the IASC strongly recommends that members refrain from marketing or labeling products with the term, "whole leaf", with or without the use of additional

descriptive language. The recommended term for use is “aloe vera leaf – gel/juice/capsules, etc.”

5) Conventional foods/beverages are labeled with a Nutrition Facts table compliant with 21CFR 101.9 and dietary supplements are labeled with a Supplement Facts table in compliance with 21CFR 101.36.
6) Products in liquid form declare the following on labels:
   a) If the beverage is represented to contain aloe vera juice, the percentage of juice is declared by the words "Contains _ percent (or %) aloe vera juice" or "_ percent (or %) juice," or a similar phrase, with the blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the juice (e.g., "Contains 50 percent aloe vera juice" or "100 percent juice").
   b) If the beverage contains less than 1 percent of aloe vera juice, declare the total percentage of juice as "less than 1 percent aloe vera juice" or "less than 1 percent juice".
   c) If the beverage contains 100 percent aloe vera juice and also contains non-juice ingredients that do not result in a diminution of the juice soluble solids or, in the case of expressed juice, in a change in the volume, when the 100 percent aloe vera juice declaration appears on a panel of the label that does not also bear the ingredient statement, it must be accompanied by the phrase "with added ___," the blank filled in with a term such as "ingredient(s)," "preservative," or "sweetener," as appropriate (e.g., "100% aloe vera juice with added sweetener"), except that when the presence of the non-juice ingredient(s) is declared as a part of the statement of identity of the product, this phrase need not accompany the 100 percent juice declaration.
   d) If the product in liquid form is or contains reconstituted aloe vera, the label:
      i) Declares the percentage of aloe vera
      ii) States that it has been “reconstituted” or is “from concentrate”
      iii) Declares water, or other liquids used to reconstitute, as ingredient(s)
7) Concentrated aloe vera ingredients and products:
   a) Are labeled in a manner that is truthful and not misleading
   b) Accurately declare the quantitative concentration level derived from:
      i) Example: via calculation of solids (200lbs x .5% solids = 1 lb. : reconstitute with 199lbs water = 200X concentrate) ;or
      ii) Example: Liquid volume – water volume = concentration ; or
      iii) Other accurate calculations

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Definition of Terms Commonly Used in the Aloe Industry

Term	Definition
Grind	Biomaterial from entire leaf is ground up into a mash
Cold Pressed	Biomass is claimed to be pressed and treated without any heat. It is recommended that this term not be adopted and removed from use as it is believed to be misleading. Unless a company can provide information on substantiation for this process.
Enzyme Treated	Entire leaf biomass is ground into a slurry, enzymes are added to assist in breaking down the fiber into a liquid. The enzymes are then neutralized/deactivated.
Non Enzyme Treated	Biomass is processed into a liquid without the use of enzymes
Filtered	Biomass is mechanically forced thru a filtering device (screen; sieve; membrane, etc.) to remove soluble material
Activated Charcoal Filtered	A form of filtration using activated charcoal; utilized primarily to remove anthraquinones
De-colorized	A process, usually by filtration with activated charcoal, that makes the liquid aloe mass clear
De-carmelized	Same as De-colorized
HTST (Pasteurization)	High Temperature Short Time process utilized to reduce microbial counts.
Low Heat Process	A process to concentrate or powder material
Evaporative Concentrate	The process of removing water from the biomass so the material is more concentrated
Evaporative Concentrate Vacuum	The process of using a vacuum environment to remove water from the Biomass so the material is more concentrated
Preserved	Use of chemical components to maintain freshness. Individual ingredients used as preservatives must be designated as such on labels for raw materials and finished products
Non-Preserved	Raw material and finished product does not contain preservatives
Organic Certified	Product or raw material that complies with USDA or country of origin certification requirements
Spray-dried	The liquid concentrated aloe is mechanically processed to force evaporation of water and convert it into a powdered form
Freeze-dried	The liquid concentrated aloe is frozen in a vacuum state to remove water and convert it into a powdered form
Reflective Dried	The liquid concentrated aloe is placed on mylar over high heat to remove water and convert it into a powdered form
Granulated/Powdered	Powder that has been processed to a specific screen size/dried Aloe vera.
Reconstituted from Concentrate	A liquid aloe vera concentrate that is diluted with water

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Term	Definition
Reconstituted from Powder	Aloe vera powder that is liquefied by adding water
Hand Fillet	Aloe leaves that have the outer rind of the leaf removed manually to leave only the inner leaf
Machine Fillet	Aloe leaves that have the outer rind of the leaf removed by mechanical means to leave only the inner leaf
Alcohol Precipitated	Alcohol is used to remove water and isolate the solids of the inner leaf
Squeezed Fillet	A process that via mechanical pressure extracts the inner leaf without manually or mechanically removing the rind first
Inner leaf	Plant part used to describe the clear, central parenchymatous tissues of the aloe leaf
Aloe Latex	Brown, yellow-brown, or occasionally red exudate found in between the rind and inner leaf. Also called "sap", it contains several constituents, but most notably anthraquinones
Anthraquinone	An organic compound primarily found in the aloe latex whose structure serves as a basic building block for a number of naturally occurring plant pigments. The substance is commonly utilized for laxative purposes
Juice	Liquid product derived from *Aloe vera* leaf
Gel	Liquid product typically derived from the inner leaf that may contain pulp, and may or may not have added thickening agents (which must be identified on the label)
Leaf	The part of the *Aloe vera* plant utilized in commerce where processing is begun without stripping off of the rind
"Whole leaf"	Historically used to describe products derived from the entire leaf that were filtered/purified. However, usage of this terminology without adequate additional descriptors is not recommended in order to avoid misbranding concerns and is considered technically inaccurate otherwise. This terminology is now seen on products or in reference to raw material where the entire leaf is used as a starting ingredient to create aloe vera juice. The IASC now recognizes this terminology to be accurate only if no purification, filtration or other treatment (enzyme, etc.) is conducted on the ingredient beyond removal of any insoluble material[1]
Purified/Filtered "whole leaf"	Terminology used on products or raw material where the entire leaf is used as a starting ingredient and where some sort of purification or filtration is utilized (and may also be treated with enzymes, etc.) to remove or substantially reduce unwanted material and substances from the resulting juice or powder, such as the rind and aloe latex. Other terms such as "charcoal filtered" or "treated" may also be seen in use as descriptors[2]

[1, 2] *See IASC Labeling Guidance – Section 4

Rev. 4/5/10

IASC Position Statement on Polysaccharides

By Ivan E. Danhof, Ph.D. M.D.

Aloe polysaccharides consist of linear (unbranched) chains of beta-1-4-linked glucose and mannose molecules: owing to the presence of these two simple hexose sugars, they are also called glucomannans, and because there is considerably more mannose than glucose present, they are also sometimes called polymannans.

These linear chains range in size from a few molecules to several thousand molecules. By convention the lower limit is usually taken as a molecular weight of about 1,000 daltons for the material to qualify as a polysaccharide.

Different molecular-sized fractions may possess different physical characteristics as well as widely differing potential biological activities. Whatever the length of the chain or the physical characteristics, they are all properly designated aloe polysaccharides.

The use of the term - mucopolysaccharides - has been widely misunderstood. It should be restricted to designate long-chain polysaccharides in which the linear molecules are chemically linked forming a colloidal system. When these linkages between these long molecules have been formed, the physical characteristics of the aqueous solution assume an increased viscosity with gel-like characteristics and, instead of being a clear solution, assume a degree of opacification.

As the chain lengths, the glucose to mannose ratios, the degree of colloidal chemical linkages are only very rarely determined owing to the sophisticated methodology required and the high cost of such evaluations, the term - mucopolysaccarides - should be actively discouraged and phased out in product descriptions as being without any cogent meaning or significance because in a given product these colloidally-linked molecular species are not determined.

Upon standing, an aloe liquid with the physical characteristics of increased viscosity and opacification will undergo spontaneous loss of both of these characteristics as the chemical linkages between the long chains become severed. The remaining clear solution, now possessing water-like consistency, still contains the long chain molecules or polysaccharides, but none would now qualify as mucopolysaccharides.

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