




## TECHNICAL DATA PACKAGE

### *HAWTHORN EXTRACT 1,8%*

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## PRODUCT SPECIFICATION SHEET

IDENTIFICATION			
NAME	HAWTHORN EXTRACT 1,8%		
BOTANICAL NAME	<i>Crataegus monogyna jacq. (Lindm) and/or Crataegus laevigata (Poir.) DC.</i>		
PLANT PART(S) USED	Leaf and Flowers		
SHELF LIFE	3 Years / 36 Months		
SOLVENT USED	Ethanol and Water		
EXTRACTION RATIO	3-5:1		
COUNTRY OF ORIGIN OF PRODUCT	Spain		
COUNTRY OF ORIGIN OF BIOMASS	Europe		
EXCIPIENTS	Maltodextrin AND Silicon dioxide		
PHYSICAL & CHEMICAL ANALYSIS			
PARAMETER	SPECIFICATION		METHODS
1 APPEARANCE	Light Brown or greenish brown powder		Visual
2 TASTE & ODOUR	Organoleptic		Characteristic
3 IDENTIFICATION	Complies SST monograph "1865"		HPTLC Eur.Ph current ed 2.8.25
4 TOTAL ASH	NMT 20,0%		USP <561>
5 LOSS ON DRYING	NMT 5,0% (m/m)		USP <731>
6 DENSITY	BULK DENSITY	NLT 0,30g/ml	USP <616>
	TAPPED DENSITY	NLT 0,40g/ml	USP <616>
7 PARTICLE SIZE (Mesh)	NLT 95% (w/w) through 80 mesh		USP <786>
8 ASSAY	Vitexin-2"-Rhamnoside (dry basis)	NLT 1,8%	HPLC
MICROBIOLOGICAL CONTROL			
PARAMETER	SPECIFICATION		METHODS
TOTAL AEROBIC MICROBIAL COUNT (TAMC)	NMT 10000 CFU/g		USP <61>
TOTAL COMBINED YEASTS & MOULDS COUNT (TYMC)	NMT 100 CFU/g		USP <61>
E. COLI	Absent/g		USP <62>
SALMONELLA	Absent/25g		USP <62>
BILE TOLERANT GRAM-NEGATIVE BACTERIA	NMT 100 CFU/g		USP <62>
STAPHYLOCOCCUS AUREUS	Absent/g		Eur.Ph. current ed. 2.6.13
CONTAMINANTS			
PARAMETER	SPECIFICATION		METHODS
HEAVY METALS	LEAD (Pb)	NMT 1,0ppm	I.C.P. – MS – Raw material
	CADMIUM (Cd)	NMT 0,5ppm	I.C.P. – MS – Raw material
	MERCURY (Hg)	NMT 1,5ppm	I.C.P. – MS – Raw material
	ARSENIC (As)	NMT 1,5ppm	I.C.P. – MS – Raw material
AFLATOXINS	B1	NMT 2,0 ppb	Eur.Ph. current ed.2.8.18- Raw material
	B1+B2+G1+G2	NMT 4,0 ppb	Eur.Ph. current ed.2.8.18- Raw material
PESTICIDES	Raw material acc. To USP <561>		GC- MS/ LC-MS
BENZOPYRENE	NMT 10,0ppb		GC-MS
4-PAH's	NMT 50,0ppb		GC-MS
RESIDUAL SOLVENTS	NMT 5000ppm		GC (Acc.CHMP/ ICH/ 82260/2006 guideline)
<b>STORAGE CONDITIONS:</b> IN TIGHTLY SEALED CONTAINER IN A DRY PLACE IN CLOSED ORIGINAL CONTAINER.			
<b>MANUFACTURING SITE:</b> THIS MATERIAL HAS BEEN CUSTOM MADE AND PROCESSED AT POLÍGONO INDUSTRIAL DE BUÑUEL, CALLE B, Nº5, CP 31540 BUÑUEL (NAVARRA), SPAIN. TO MEET SUANFARMA SPECIFICACIONES			
			José Manuel Crespo Quality Head - Nutra Division-  SUANFARMA

## ALLERGEN STATEMENT

We, Suanfarma, hereby declare the absence or presence of each allergen or intolerance according to the major Food Allergens specified in the US Federal Law of Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and EU Directive 2003/89/CE amending EU Directive 2000/13/CE in the table below for **HAWTHORN EXTRACT 1,8%**:

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES as per Annex II of FIC regulation	Direct incorporation as a base raw material or in derivative form (including the carriers, the additives, and the processing aids)		Presence on the production line		Presence in the productions workshop		Presence on the production factory	
	Yes (precise nature)	No	Yes (precise nature)	No	Yes (precise nature)	No	Yes (precise nature)	No
Cereals containing gluten (1) and products thereof		X		X		X		X
Crustaceans and products thereof		X		X		X		X
Eggs and products thereof		X		X		X		X
Fish and products thereof		X		X		X		X
Peanuts and products thereof		X		X		X		X
Soybeans and products thereof		X	X (Soy Isoflavones extract)		X (Soy Isoflavones extract)		X (Soy Isoflavones extract)	
Milk and products thereof (including lactose)		X		X		X		X
Nuts (2) and products thereof		X		X		X		X
Celery and products thereof		X		X		X		X
Mustard and products thereof		X		X		X		X
Sesame seeds and product thereof		X		X		X		X
Suphur dioxide and sulphites at concentrations of more than 10mg/kg or 10mg/l expressed as SO <sub>2</sub>		X		X		X		X
Lupin and products thereof		X		X		X		X
Mollusc and products thereof		X		X		X		X

**NOTES TO THE TABLE:**

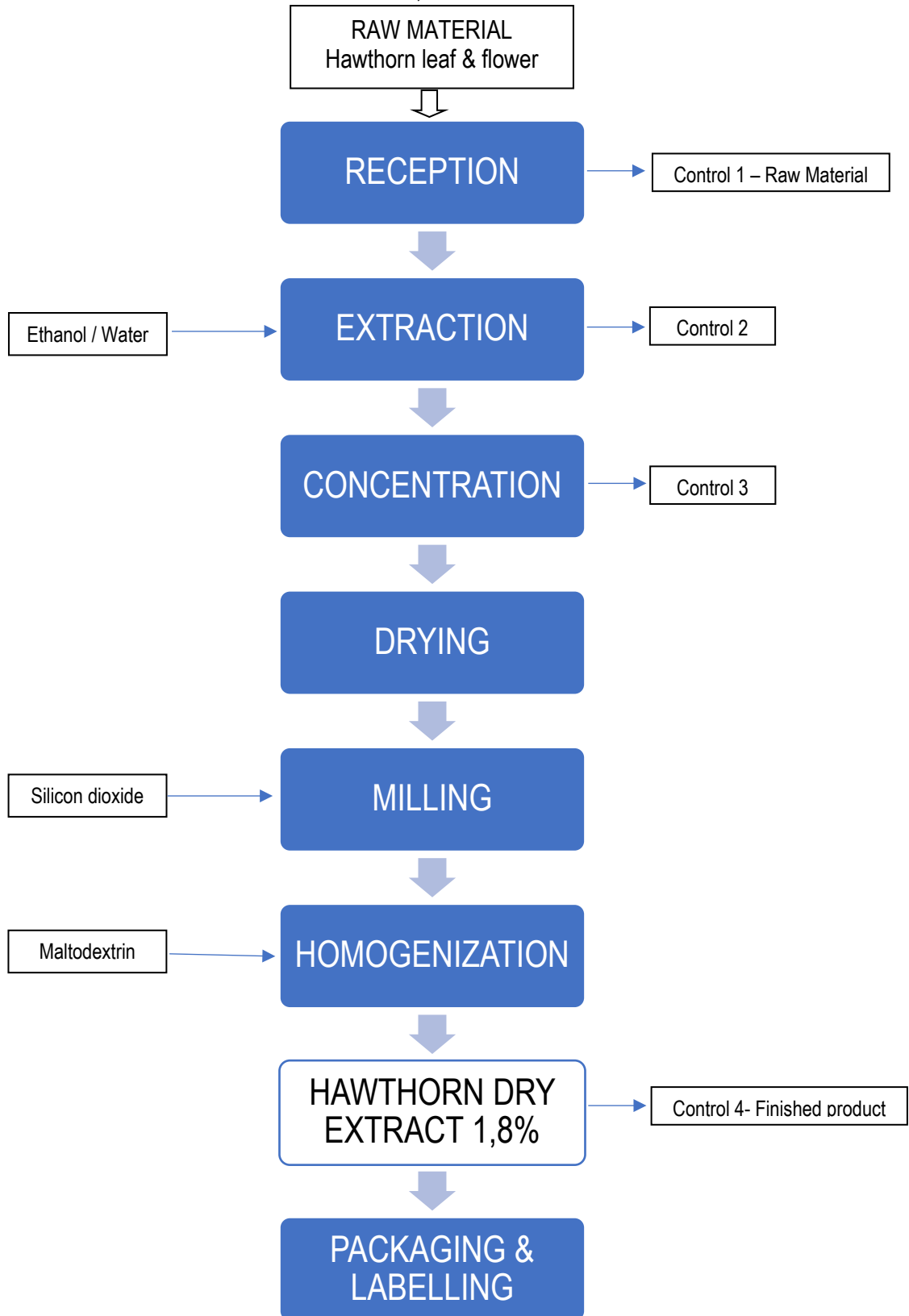
- (1) Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof, except:
  - a. Wheat based glucose syrups including dextrose.
  - b. Wheat based maltodextrin.
  - c. Glucose syrups based on barley.
  - d. Cereals used for making alcoholic distillates including ethyl alcohol of agriculture origin.
- (2) Namely, almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Junglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin.



José Manuel Crespo  
Quality Head – Nutra Division  
SUANFARMA

MANUFACTURING PROCESS FLOW CHART

Product Name: HAWTHORN EXTRACT 1,8%



SAFETY DATA SHEET  
(According to Regulation 453/2010)

**SECTION 1: PRODUCT & COMPANY IDENTIFICATION**

- 1.1 Product Identifier:**  
 Product Name: HAWTHORN EXTRACT 1,8%  
 Botanical Name: *Crataegus monogyna jacq. (Lindm) and/or Crataegus laevigata (Poir.) DC*
- 1.2 Supplier details:**  
 Supplier Name: Suanfarma, Inc.  
 17-09 Zink Place, Unit 7, Fair Lawn,  
 NJ 07410, USA  
 Phone: +1-201-343-1188  
 Fax: +1-201-343-1102  
 E-mail: adminus@suanfarma.com
- 1.3 Emergency number:**  
 CHEMTREC (24hr Access) 800-424-9300  
 International CHEMTREC, call: +1-703-527-3887
- 1.4 Use of the substance or the mixture:** Pharmaceutical, food supplements, and cosmetic industry.

**SECTION 2: HAZARD(S) IDENTIFICATION**

- 2.1 Classification**  
None, if it is used as the intended purpose.
- 2.2 Labelling**  
None, if it is used as the intended purpose.
- 2.3 Other hazards**  
None, if it is used as the intended purpose.

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1 Component**

Substance	Crataegus Leaf and Flower extract	Maltodextrin	Silicon dioxide
CAS	90045-52-6	9050-36-6	112945-53-5 7631-86-9
EINECS Number	289-914-0	232-940-4	231-545-4

SAFETY DATA SHEET  
(According to Regulation 453/2010)**SECTION 4: PRECAUTIONS FOR SAFE HANDLING AND USE****4.1 First aid measures:**

General advice	In case of adverse health effects seek medical advice.
If inhaled	After prolonged or massive inhalation of the powder, remove from the exposure to fresh air. Get medical attention for any breathing difficulty.
In case of skin contact	Rinse with running water.
In case of eye contact	Rinse immediately with plenty of running water (for 10 minutes). Get medical attention, it is necessary.
If swallowed	After massive ingestion, rinse the mouth. Drink 1-2 glasses of water, and get medical attention, it is necessary.

**4.2 Most important symptoms and effects (acute and delayed):**

No data available.

**4.3 Indication of any immediate medical attention and special treatment needed:**

No data available.

**SECTION 5: FIRE AND EXPLOSION HAZARD DATA**

Suitable extinguishing media:	Water spray jet. Extinguishing powder.
Special hazards:	Carbon monoxide may be formed during combustion.
Special protective equipment for fire fighters:	Wear self- contained breathing apparatus.

**SECTION 6: ACCIDENTAL RELEASE MEASURE**

Personal precautions:	Avoid dust formation.
Environmental precautions:	Do not allow to enter into surface water or drains. Do not allow to enter into soil/ subsoil.
For emergency personnel:	See section 8.
Methods and material for containment and cleaning up:	Remove mechanically

**SECTION 7: HANDLING AND STORAGE**

Precautions for safe handling:	Minimize dust formation and accumulation. Use adequate ventilation. Avoid open flames and sources of ignition.
Storage Conditions:	Store in a tightly sealed container. Store in a cool, dry well-ventilated place in closed original container at recommended temperature <30°C and away from heat and direct sun light.
Specific end-use:	Pharmaceutical, food supplements and cosmetic industry.

SAFETY DATA SHEET  
(According to Regulation 453/2010)**SECTION 8: EXPOSURE CONTROLS & PERSONAL PROTECTION**

## Monitoring:

Monitoring procedures: Use methods described in European standards.  
Concentrations of hazardous substances in the workplace should be monitored in accordance with the acknowledged tests methods. Mode, method, type, frequency of testing and measurement of harmful factors in the working environment should meet the requirements of local / regional / national laws.

## Exposure controls:

Exposure controls: Mandatory general regulation on occupational health.  
Do not allow to exceed the normative concentration of hazardous constituents in the workplace.  
After work, wash and clean the surface of the body and clothing. Do not eat, drink, smoke or take drugs at work. Wash hands and face before break and after working with the product.

## Eye protection

Wear safety glasses.

## Face protection

Usually not required.

## Hand protection

Wear protective gloves.

## Respiratory protection

Use precaution to avoid inhalation. In absence of suitable containment facilities, a dust mask should be worn when handling small quantities of material. For larger quantities, a dust respirator is recommended.

## Thermal protection

Not required.

## General protection:

Immediately remove soiled or soaked clothing. Wash hands before work breaks and after finishing work. Do not eat, drink, or smoke while working.

SAFETY DATA SHEET  
(According to Regulation 453/2010)

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.**

Physical state:	Solid
Appearance:	Powder
Odor:	Characteristic
Color:	Brown
pH:	N.A.
Boiling point:	N.A.
Melting point:	N.A.
Flash point:	N.A.
Evaporation rate:	N.A.
Flammable limits:	N.A.
Self-flaming:	N.A.
Explosion limits:	N.A.
Combustion properties:	N.A.
Vapor pressure:	N.A.
Refractive Index:	N.A.
Density:	Not specified.
Solubility:	N.A.
Sharing coefficient:	N.A.
Viscosity	N.A.
Loss on drying	NMT 5%

**SECTION 10: STABILITY AND REACTIVITY DATA**

Chemical stability:	No data available.
Reactivity:	This product presents no significant reactivity hazard.
Conditions to avoid:	Avoid temperatures over 30°C, open flames and sources of ignition. Keep away from heat and direct sun light.
Materials to avoid:	No data available.
Hazardous decomposition products:	Carbon monoxide may be formed during combustion.
Possibility of hazardous reactions:	This product presents no significant reactivity hazard.



SAFETY DATA SHEET  
(According to Regulation 453/2010)

**SECTION 11: HEALTH HAZARDOUS**

Information on toxicological effects	
General toxicological information	No data available

**SECTION 12: ECOLOGICAL INFORMATION**

Toxicity:	No data available.
Persistence and degradability:	No data available.
Bio accumulative potential:	No data available.
Mobility in soil:	No data available.
PBT and vPvB assessment:	No data available.
Other adverse effects:	No data available.

**SECTION 13: DISPOSAL CONSIDERATIONS**

Product	Collection and delivery to recycling enterprise or other official elimination institution.
Contaminated packing:	Disposal must be made according to official regulations.

**SECTION 14: TRANSPORT INFORMATION**

UN number:	Not applicable.
UN proper shipping name:	Not applicable.
Transport hazards class:	Not applicable.
Packing group:	Not applicable.
Environmental hazards:	Does not meet classification as hazardous for environment.
Special precautions for users:	Not hazardous according to RID/ADR, GGVS/GGVE, ADNOR, IMDG, ICAO-TI/IATA-DGR.
Transport in bulk (Annex II of Marpol):	Not applicable.
Transport in bulk (IBC Code):	Not applicable.

SAFETY DATA SHEET  
(According to Regulation 453/2010)**SECTION 15: REGULATORY INFORMATION**

Safety, health, and environmental regulations/legislation specific for the substance  
EU Regulations:

- Contains no substances with annex XVII restrictions.
- Contains no substances on the REACH Candidate list.
- Contains no REACH Annex XIV substances.

Chemical safety assessment

A chemical safety assessment has not been carried out for the mixture.

**SECTION 16: OTHER INFORMATION**

The information contained herein is based on the current state of knowledge and describes the product from the standpoint of appropriate precautions for use, handling, transport, and storage. There is no guarantee of product properties.

This information above is believed to be accurate and represents the best information currently available to us.

The user is responsible for verifying the data on the present MSDS and determining whether the product is suitable for your particular purpose and assume all risk of use, handling, and disposal of waste.

This information relates only to the product and does not relate to the combinations that can be made from this or processes that can be included.

## ADDITIONAL INFORMATION

We, SUANFARMA, hereby declare that HAWTHORN EXTRACT 1,8% is manufactured in accordance with the following guidelines:

- Botanical source: *Crataegus monogyna jacq. (Lindm) and/or Crataegus laevigata (Poir.)*
- The above material is manufactured in Spain.
- The biomass used is from Europe.
- No animal derived products have been used in the manufacture of the above material. The product does not enter in contact with animal derived material. For these reasons this material is free from components which can cause Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform encephalopathy (TSE).
- The above material has not been genetically modified or exposed to genetically modified organisms during the production process and is therefore GMO free (according to EU Regulation 1829/2003/CE & 1830/2003/CE).
- The above material complies with the pesticide limits set forth by USP <561>.
- Only the following organic solvents are used in the manufacturing process: Ethanol/Water
- The above material complies with California Proposition 65 Compliance and is safe for human consumption.
- The above material and its constituents are naturally free of products containing gluten.
- The above material is suitable for vegetarian and vegan consumption.
- This material has not been tested on animals.
- The above material does not contain any ingredient specified in EU Directive 2003/89/CE amending EU Directive 2000/13/CE: wheat, rye, barley, oat, spelt, kamut, crustacean, egg, fish, peanut, soybean, milk, nuts (almonds, hazelnuts, walnuts, cashew, pecan nuts, Brazil nuts, pistachio nuts, macadamia), celery, mustard, sesame seeds, lupin, molluscs and products made thereof.
- The above material has not been submitted to any irradiation process.
- The above material is latex free.
- The above material does not contain lactose and it is not used lactose material during process.
- The above material is free of substances classified as Carcinogenic, Mutagenic and toxic for reproduction categories under the scope of European Regulation N° 1223/2009 and the scope of European Regulation N°1272/2008)
- The above material and its raw material have not been treated with ethylene oxide (ETO) or any other chemical sterilization agent.
- At no point in the process is the above material is manufactured, handled, or comes in contact with sewage sludge, as defined in 7 CFR 205.105(g).
- The above material neither contains nor comes in contact with banned substances listed by NSF, NFL, and WADA.
- The above material has the GRAS status: 21 CFR 172.510
- The above material is Kosher certified.
- The above material meets the dictates of the Sharia, although it is NOT Halal certified.

The HAWTHORN EXTRACT 1,8% is composed by the following:

- 50%-80% Native Extract Hawthorn
- 20%-50% Maltodextrin

Typical nutritional data for the above material are as follows:

PARAMETER	RESULT	UNITS
Energy	47	kCal/100g
Protein	< 15	g/100g
Fat	< 6	g/100g
Carbohydrates	< 90	g/100g



José M. Crespo  
Quality Head – Nutra Division  
SUANFARMA

Certificate Issued To:  
**Suan Farma, Inc.**  
17-09 Zink Place, Unit 7  
Fair Lawn, NJ 07410-2018  
USA

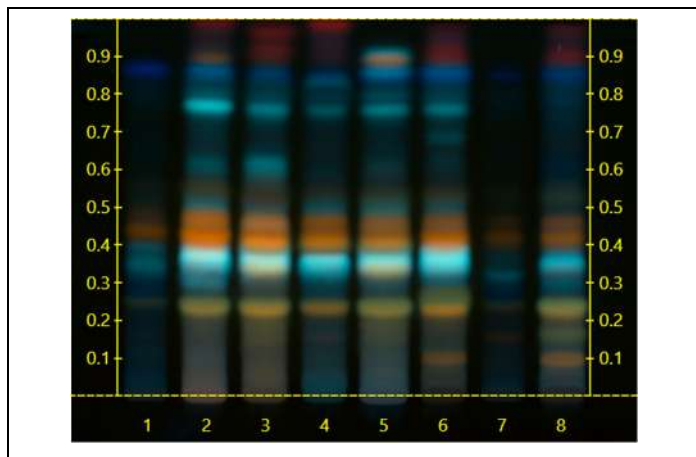


Exclusive Distribution by:  
**SUANFARMA**  
SUANFARMA  
17-09 Zink Place - Unit 7  
Fair Lawn, NJ 07410, USA  
Tel. +1-201-343-1188  
www.suanfarmausa.com

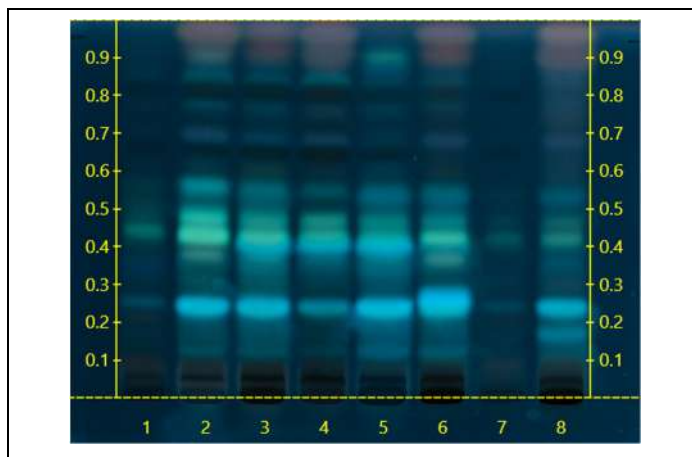
Work performed at:  
**Alkemist Labs**  
12661 Hoover Street  
Garden Grove, CA 92841  
714-754-HERB (4372)  
714-668-9972 (FAX)  
Sales@Alkemist.com  
www.Alkemist.com

**Certificate of Analysis: Hawthorn Extract 1,8% (032/2022)**  
High Performance Thin-Layer Chromatography with Photo-Documentation

1



2



Company Name: Suan Farma, Inc.  
Title: Hawthorn Extract 1,8%  
Plant Part: herb (leaf, flower)  
Sample Received: 04/13/22  
Sample Packaging: Foil Pouch  
Form of Botanical: powdered extract  
Appearance: Silver package, white label  
Lot Number: (032/2022) → Lane 3(5µl)  
Sample: 22103CAJ\_1  
Latin Name: *Crataegus monogyna* Jacq. [Rosaceae]  
Reference Sample: Lane 1(5µl) (B31113HBR2) *Crataegus monogyna* (fruit); Lane 2(5µl) (B19710AP1) *Crataegus monogyna* (herb (leaf, flower)); Lane 6(5µl) (JO14109MRH1) *Crataegus laevigata* / *Crataegus oxyacantha* (herb (leaf, flower, stem)); Lane 7(5µl) (20267PFK) *Crataegus laevigata* / *Crataegus oxyacantha* (fruit); Lane 8(5µl) (K18910AMAX) *Crataegus pinnatifida* (leaf); held at Alkemist Labs, Garden Grove, CA.  
Analyst: A.Ung, J.Mares, K.Chopra, K.Montoya, K.Tran, M.Levine, N.Carson, N.Hoang, N.Afendikova, P.Hoang, S. Kabbaj, S.Sudberg, T.Louis 174780  
Sample Preparation: 0.3g+3mL 70% grain Ethanol, sonicate/heat at 50° C for 30 min.  
Stationary Phase: Silica gel 60, HPTLC plates  
Mobile Phase: ethyl acetate: Acetic acid: Formic Acid: Water [10/0.9/0.9/2]  
Detection: (1) Natural Product + Polyethylene Glycol, 366nm (Reich, E., 2007)  
(2) 10% Sulfuric, 100°C, 2min, 366nm (Reich, E., 2007)  
Reference Source: BTM-715-0015  
IDT-SOP-72-01

**Comments & Conclusions:** Lane 3 is the test sample Hawthorn Extract 1,8% (032/2022) Lanes 1, 2, 6, 7, 8 are the reference samples used for comparison. This test sample, Hawthorn Extract 1,8% (032/2022) is consistent with the chromatographic profile of the reference samples of *Crataegus* sp., used above. **This test sample Hawthorn Extract 1,8% (032/2022) has characteristics of *Crataegus* sp., herb (leaf, flower).**

**NOTE:** The above conclusion may be a function of the natural variance found in botanicals &/or the extraction process used to create specific extracts. The growing and drying conditions, age, seasonal variations, geographic location, extraction solvents, etc. all play a role in the phytochemical fingerprint of botanicals as well as their extracts; hence, chromatographic variations are expected.

Examined, Reviewed & Authorized by: Khanh N Tran, HPTLC, R&D Supervisor, Alkemist Labs

Report Date: 04/19/22

ISO/IEC 17025



Note: Any unidentified lanes in the above chromatograms are confidential and may represent internal studies or other test samples not related to 032/2022. This report applies to the sample investigated and is not necessarily indicative of the quality or condition of apparently identical or similar products. This report is for the exclusive use of the party who requested the report and not for public dissemination or use by third parties, including for promotional purposes, without the prior written permission of Alkemist Labs, Inc. This report provides technical results for a specific sample and the report shall not be altered, modified, supplemented or abstracted in any manner. Any violation of these conditions renders the report and its results void. © 2022 Alkemist Labs, Inc. All Rights Reserved

# Nutri Analytical Testing Laboratories

1440 S State College Blvd., Suite 4G, Anaheim CA 92806

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Website: [www.nutrianalytical.com](http://www.nutrianalytical.com)

## Laboratory Report

### Suan Farma

17-09 Zinc Place, Unit 6&7

Fair Lawn, NJ 07410, USA

Email: josecrespo@suanfarma.com

Attn: Jose Crespo

Received Date: 05/10/2022

Report Date: 05/20/2022

Client Sample Description: Hawthorn Extract 1.8% Lot #032/2022

Test ID #: 202205019-3

Analyses	Claim	Result
Vitexin-2''-Rhamnoside	≥ 1.8%	1.90%

Method: UHPLC

Nutri Analytical Testing Laboratories



Lab. Manager: Ling Zhang