




TECHNICAL DATA PACKAGE

MULLEIN EXTRACT 4:1

Product Specification Sheet	1
Allergen Statement	2
Manufacturing Process Flow Chart	3
Safety Data Sheet	4
Additional information	9

PRODUCT SPECIFICATION SHEET

IDENTIFICATION			
NAME	MULLEIN EXTRACT 4:1		
BOTANICAL NAME	<i>Verbascum thapsus L.</i>		
PLANT PART(S) USED	Leaves		
SHELF LIFE	3 Years / 36 Months		
SOLVENT USED	Ethanol / Water		
EXTRACTION RATIO	4:1		
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	Ochre coloured powder	Visual
2	ODOUR AND TASTE	Characteristic	Organoleptic
3	IDENTIFICATION	Complies	Eur. Ph. "1853"- Identification C
4	TOTAL ASH	NMT 20,0% (w/ w)	USP <561>
5	LOSS ON DRYING	NMT 5,0% (w/ w)	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 180µm	USP <786>
8	ASSAY	FLAVONOIDS EXPRESSED AS RUTOSIDE	NLT 0,50%
			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 GRAM NEGATIVE BACTERIA	NMT 100 CFU/g	USP <62>
CONTAMINANTS			
PARAMETER		SPECIFICATION	METHODS
HEAVY METALS	LEAD (Pb)	NMT 3,0 ppm	Raw material- I.C.P.-MS
	CADMIUM (Cd)	NMT 1,0 ppm	Raw material- I.C.P.-MS
	MERCURY (Hg)	NMT 0,1 ppm	Raw material- I.C.P.-MS
	ARSENIC (As)	NMT 2,0 ppm	Raw material- I.C.P.-MS
AFLATOXINS	B1	NMT 2,0 ppb	Raw material- Eur.Ph. ed.2.8.18
	B1+B2+G1+G2	NMT 4,0 ppb	Raw material- Eur.Ph. ed.2.8.18
BENZOPYRENE		NMT 10,0 ppb	GC- MS
4 PAH's		NMT 50,0 ppb	GC- MS
PESTICIDES		USP<561>	GC-MS / LC-MS
RESIDUAL SOLVENTS	ETHANOL	NMT5000ppm	GC (Acc. CHMP/ICH/82260/2006 guidelines)
STORAGE CONDITIONS: KEEP CONTAINER TIGHTLY SEALED AND STORE IN A DRY PLACE IN CLOSED ORIGINAL CONTAINER.			
MANUFACTURING SITE: THIS MATERIAL HAS BEEN CUSTOM MADE AND PROCESSED AT POLÍGONO INDUSTRIAL DE BUÑUEL CALLE B, nº5 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 **MULLEIN EXTRACT 4:1**:

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) There is no risk of cross- contamination		X (Soy Isoflavones Extract) There is no risk of cross- contamination		X (Soy Isoflavones Extract) There is no risk of cross- contamination	
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 ₂		X		X		X		X
Lupin and products thereof		X		X		X		X
Mollusc and products thereof		X		X		X		X

NOTES TO THE TABLE:

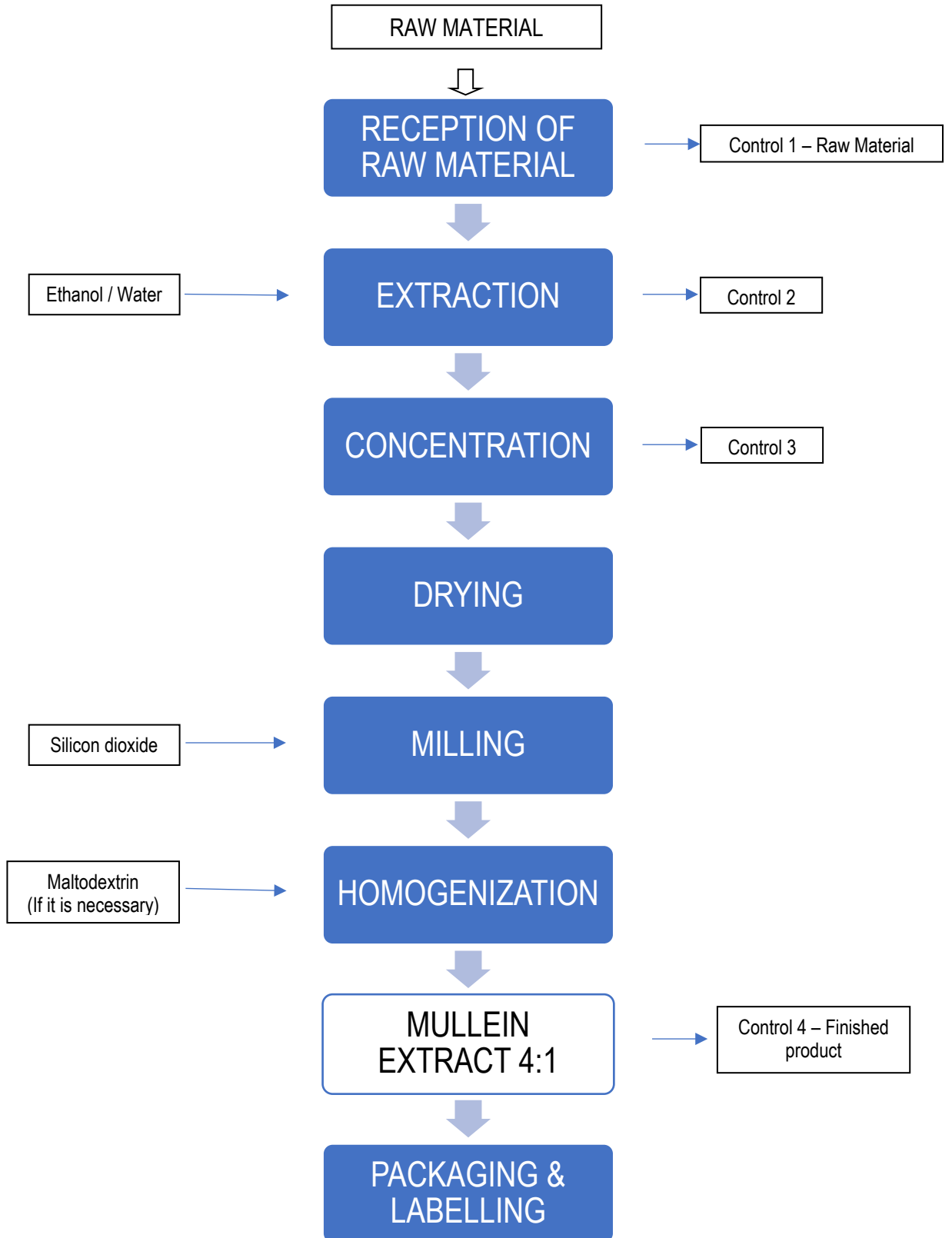
- (1) Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof, except:
 - a. Wheat based glucose syrups including dextrose.
 - b. Wheat based maltodextrin.
 - c. Glucose syrups based on barley.
 - d. Cereals used for making alcoholic 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: MULLEIN EXTRACT 4:1



SAFETY DATA SHEET
(According to Regulation 453/2010)

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

1.1 Product Identifier:

Product Name: MULLEIN EXTRACT 4:1
Botanical Name: *Verbascum thapsus L.*

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

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	Verbascum Thapsus L	Maltodextrin	Silicon dioxide
CAS	---	9050-36-6	112945-53-5 7631-86-9
EINECS Number	---	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 non-emergency personnel:	Access to non-emergency personnel to the area of accident should be restricted until completion of disposal of the product.
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.

SAFETY DATA SHEET
(According to Regulation 453/2010)

SECTION 8: EXPOSURE CONTROLS & PERSONAL PROTECTION

Monitoring:	
Monitoring procedures:	Use methods described in European standards.
Exposure controls:	Ensure good ventilation/ suction at the workplace.
Eye protection	Wear safety glasses.
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.
Hand protection	Wear protective gloves.
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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

Physical state:	Solid
Appearance:	Powder
Odor:	Characteristic
Colour:	Ochre
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.

SAFETY DATA SHEET
(According to Regulation 453/2010)**SECTION 15: REGULATORY INFORMATION****Labeling according to directives 67/548/CEE and 1999/45/CE**

Symbol of danger: None

Product name: MULLEIN LEAF DRY EXTRACT 4:1

R-phrases: None

S-phrases: None

Labeling according to Regulation No 1272/2008

Pictogram: None

Product name: MULLEIN LEAF DRY EXTRACT 4:1

Hazard statement: None

Precautionary statements: None

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 MULLEIN EXTRACT 4:1 is manufactured in accordance with the following guidelines:

- Botanical source: *Verbascum thapsus L.*
- 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 & 1830/2003).
- 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.
- The above material complies with California Proposition 65 Compliance and is safe for human consumption.
- The above material complies with Aflatoxins limits fixed by USP.
- The above material and its constituents are naturally free of products containing gluten.
- The above material is free from Melamine and PCB's.
- 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 irradiated per 7 CFR 205.105(1) requirements with understanding that "irradiation" shall be defined as outlined in 21 CFR 179.26.
- 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 NFL, and WADA.
- The above material is Kosher certified.
- The above material meets the dictates of the Sharia, although it is NOT Halal certified.

The MULLEIN EXTRACT 4:1 is composed by the following:

- 50%-80% Native Extract
- 20%-50% Maltodextrin (Characteristics: Corn, Food grade, Geographical origin: Europe)
- 0%-2% Silicon Dioxide (Characteristics: Food grade, Geographical origin: Europe)

Typical nutritional data for the above material are as follows:

PARAMETER	RESULT	UNITS
Energy	45	kCal/100g
Protein	< 15	g/100g
Fat	< 6	g/100g
Carbohydrates	< 85	g/100g



José M. Crespo
Quality Head – Nutra Division
SUANFARMA

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

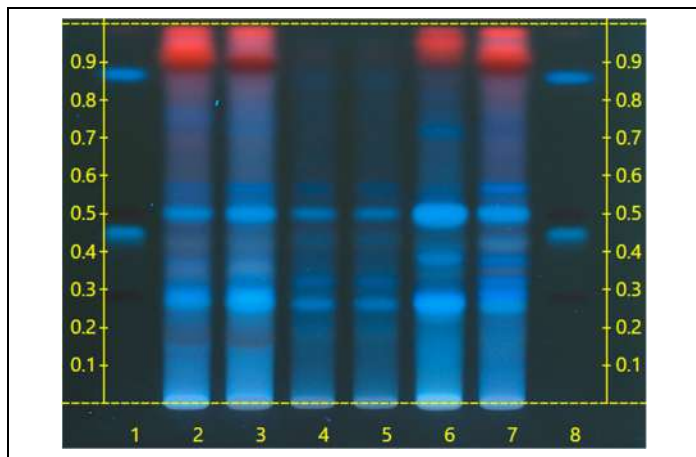


Exclusive Distribution by:
SUANFARMA
SUANFARMA
17-09 Zink Place - Unit 7
Fair Lawn, NJ 07410, USA
Tel. +1-201-343-1188
www.suanfarmausa.com

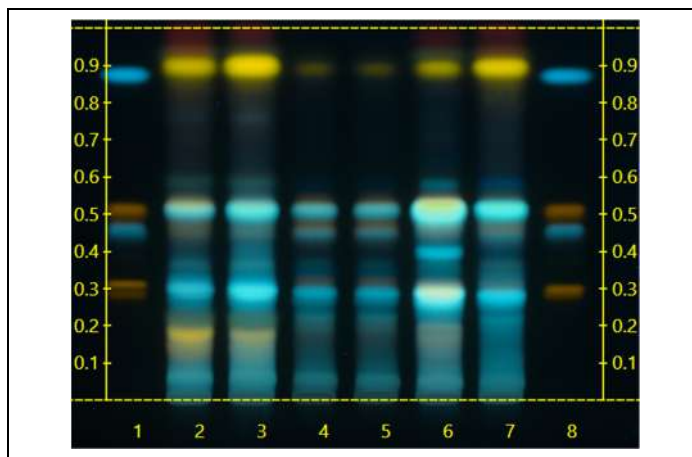
Work performed at:
Alkemist Labs
12661 Hoover Street
Garden Grove, CA 92841
714-754-HERB (4372)
714-668-9972 (FAX)
Sales@Alkemist.com
www.Alkemist.com

Certificate of Analysis: MULLEIN EXTRACT 4:1 (054/2022)
High Performance Thin-Layer Chromatography with Photo-Documentation

1



2



Company Name: SUANFARMA, Inc.
Title: MULLEIN EXTRACT 4:1
Plant Part: leaf
Sample Received: 05/26/22
Sample Packaging: Foil Pouch
Form of Botanical: powder
Appearance: Fine Powder
Source Location: Select Botanical
Lot Number: (054/2022) → Lanes 4(5µl), 5(5µl)
Sample: 22146HKF_1
Latin Name: *Verbascum thapsus* L. [Scrophulariaceae]
Reference Sample: Lane 2(5µl) (YC16505BH), Lane 3(5µl) (YC17403CHR) *Verbascum thapsus* (leaf); Lane 6(5µl) (YC21617AHP2) *Verbascum thapsus* (flower); Lane 7(5µl) (AEA20008BSI2) *Verbascum phlomoides* (herb (leaf, flower, stem)); held at Alkemist Labs, Garden Grove, CA.
Analyst: J.Mares, K.Chopra, K.Montoya, K.Tran, M.Levine, N.Carson, N.Hoang, N.Afendikova, P.Hoang, S. Kabbaj, S.Sudberg, T.Louis, D.Robinson 177195
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: Methyl Ethyl Ketone: Formic Acid: Water [5/3/1/1]
Detection: (1) UV 366 nm
(2) Natural Product + Polyethylene Glycol, 366nm (Reich, E., 2007)
Reference Standard: Lane 7(5µl) Rutin (00018440-002694, CHR), Hyperoside (113083026, SigAl), Chlorogenic Acid (00003450-550, CHR), Caffeic acid (00003024-DQB, CHR), Methanol (0000277265, VWR)
Reference Source: HPTLC Association
IDT-SOP-72-01

Comments & Conclusions: Lanes 4, 5 are the test sample MULLEIN EXTRACT 4:1 (054/2022) Lanes 2, 3, 6, 7 are the reference samples used for comparison. This test sample, MULLEIN EXTRACT 4:1 (054/2022) is consistent with the chromatographic profile of the reference samples of *Verbascum* sp., used above. **This test sample MULLEIN EXTRACT 4:1 (054/2022) has characteristics of *Verbascum* sp., leaf.**

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: Syhem W Kabbaj, HPTLC Production Supervisor, Alkemist Labs

Report Date: 06/02/22



Note: Any unidentified lanes in the above chromatograms are confidential and may represent internal studies or other test samples not related to 054/2022. 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

Tel: 714-398-8166 Email: info@nutrianalytical.com

Website: 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: 06/21/2022

Report Date: 07/13/2022

Client Sample Description: Mullein Extract 4:1 Lot #054/2022

Test ID #: 202206035-3

Analyses	Claim	Result
Total Flavonoids (as Rutosides)	>0.5%	0.679%

Method: UHPLC

Nutri Analytical Testing Laboratories



Lab. Manager: Ling Zhang