



TECHNICAL DATA PACKAGE

ASHWAGANDHA EXTRACT 1.5% HPLC

Product Specification Sheet.....1
Allergen Statement.....2
Manufacturing Process Flow Chart.....3
Safety Data Sheet.....4
Additional Information.....8

SUANFARMA

PRODUCT SPECIFICATION SHEET

REVISION 1.2020

IDENTIFICATION

NAME	ASHWAGANDHA EXTRACT 1.5% HPLC
BOTANICAL NAME	<i>Withania somnifera</i>
SYNONYMS	Ayurvedic Ginseng, Winter Cherry
PRODUCT CODE	ASE01HPLC
SHELF LIFE	36 Months
PLANT PART(S) USED	Dried Roots
EXTRACT RATIO	10 : 1
SOLVENT USED	Ethanol, Water
EXCIPIENT USED	NMT 2% Colloidal Silicon Dioxide
CARRIER USED	NMT 10% MCCP
COUNTRY OF ORIGIN	India

PHYSICAL & CHEMICAL ANALYSIS

PARAMETER	SPECIFICATION	METHODS
1. APPEARANCE	Dry powder	Visual
COLOR	Brown	Visual
ODOR	Characteristic	Organoleptic
2. IDENTIFICATION	Chromatographic profile matching with standard	HPLC
3. PARTICLE SIZE	NLT 95% through 40 mesh	In-house
4. LOSS ON DRYING	NMT 5.0% w/w	USP <921>
5. WATER SOLUBLE EXTRACTIVES	NLT 40% w/w on d/b	In-house
6. 60% ALCOHOL SOLUBLE EXTRACTIVES	NLT 60% w/w on d/b	In-house
7. ASH CONTENT	NMT 10% w/w	In-house
8. BULK DENSITY	NLT 0.3 g/mL	USP <616>
9. PH (1% w/v aqueous solution)	4 – 7	USP <791>
10. ASSAY OF WITHANOLIDES	NLT 1.5% w/w on d/b	HPLC
11. HEAVY METALS	NMT 10 ppm	USP <231>
LEAD	NMT 2 ppm	AAS
ARSENIC	NMT 2 ppm	AAS
CADMIUM	NMT 0.2 ppm	AAS
MERCURY	NMT 0.2 ppm	AAS

MICROBIOLOGY CONTROL

Total Plate Count	NMT 5,000 cfu/g	USFDA-BAM
Yeast & Mold	NMT 100 cfu/g	USFDA-BAM
Coliforms	NMT 3 org/g	AOAC
Escherichia coli	Absent/10g	USP
Salmonella	Absent/10g	USP
Staphylococcus aureus	Absent/10g	USP
Pseudomonas aeruginosa	Absent/10g	USP

STORAGE CONDITIONS: PRESERVE IN TIGHTLY-SEALED CONTAINERS UNDER COOL, DRY CONDITIONS. AVOID EXCESSIVE EXPOSURE TO SUNLIGHT.

MANUFACTURING SITE: THIS MATERIAL HAS BEEN CUSTOM MADE AND PROCESSED AT 107-109 KIADB, III PHASE INDUSTRIAL AREA, MALUR – 563160, KOLAR DISTRICT, KARNATAKA, INDIA TO MEET SUAN FARMA, INC. SPECIFICATIONS.

Juliana Chedid

 Julianna Chedid, QA/QC Assistant
 DATE PRINTED: February 28, 2020



ALLERGEN STATEMENT

We, Suan Farma, Inc., hereby declare that Ashwagandha Extract 1.5% HPLC (product code: **ASE01HPLC**) does not contain as an ingredient and is not manufactured on processing equipment that comes in contact with any of the commonly recognized allergens including, but not limited to the following:

- Peanuts (including peanut oil)
- Cashew - nut (including oil)
- Walnut (including oil)
- Hazelnut (including oil)
- Brazil walnut (including oil)
- Pecan nut (including oil)
- Macadamia nut (including oil)
- Pistachio - nut (including oil)
- Pine kernel (including oil)
- Almond (including oil)
- Celery and derived products
- Mustard and derived products
- Lupin (*lat. lupinus*) and derived products
- Sesame Seeds
- Milk and derived products
- Eggs and derived products
- Fish and derived products
- Shellfish and derived products
- Soy and derived products
- Gluten origin material
- Sulphites

Regards,

A handwritten signature in cursive script that reads "Julianna Chedid". The signature is written in black ink and is positioned above a thin horizontal line.

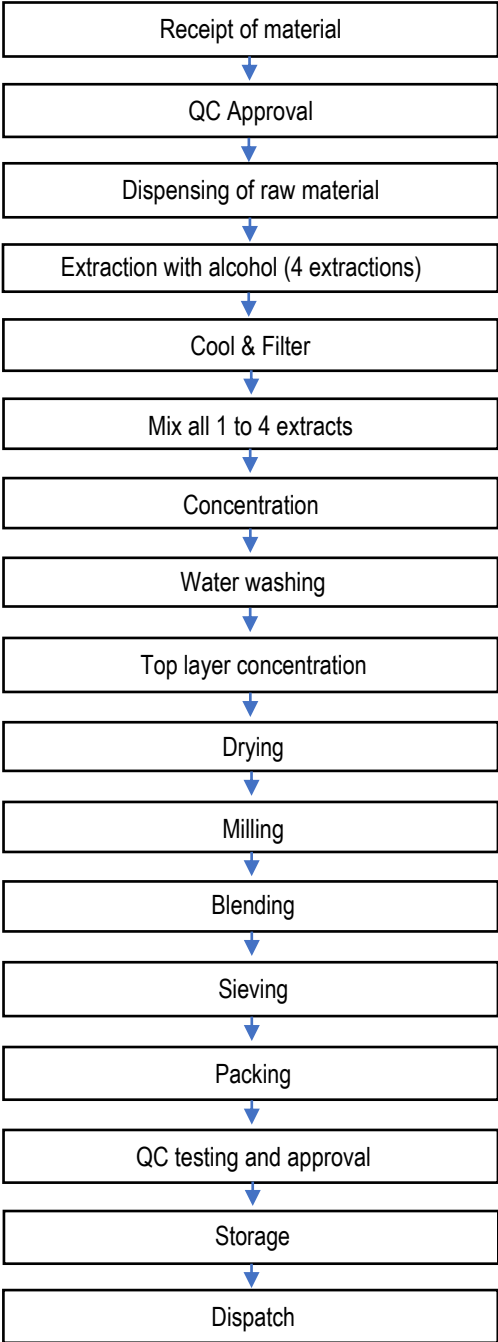
Julianna Chedid
QA/QC Assistant
February 2020



MANUFACTURING PROCESS FLOW CHART

Product Name: Ashwagandha Extract 1.5% HPLC

Product Code: ASE01HPLC



SAFETY DATA SHEET

REVISION 01.2020

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

1.1 Identification of the substance or preparation:

Product name: ASHWAGANDHA EXTRACT 1.5% HPLC
Botanical Name: *Withania somnifera*
Common Name: Ashwagandha

1.2 Supplier information:

Supplier Name: Suan Farma, Inc.
17-09 Zink Place, Unit 7 Fair Lawn, NJ 07410
Phone: 201-343-1188
FAX: 201-343-1102
E-mail: adminus@suanfarma.com

1.3 Emergency telephone number:

CHEMTREC (24-hr Access) 800-424-9300;
International CHEMTREC, call: 703-527-3887

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Routes of entry:

2.1.1 Eye contact: Mild irritation may occur
2.1.2 Skin contact: Mild irritation may occur
2.1.3 Ingestion: Not known
2.1.4 Inhalation: Irritating

2.2 Hazard statement(s): Globally harmonized



2.3 Pictograms:

2.4 Precautionary statements: Keep away from heat, sparks, open flames, hot surfaces. No smoking.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Ingredients: Powdered extract of ashwagandha root

3.2 Hazardous components: None

SECTION 4: FIRST AID MEASURES

4.1 General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.

4.2 Eyes: Flush with plenty of water or eye wash, consult a physician.

4.3 Skin: Wash off with soap and water – seek medical attention if irritation persists.

4.4 Ingestion: Seek medical advice.

4.5 Inhalation: If breathed in, move person to fresh air. Consult a physician.

SAFETY DATA SHEET

SECTION 5: FIRE FIGHTING MEASURES

5.1 Flammability of the product:	Not available
5.2 Flash points:	Not available
5.3 Flammable limits:	Not available
5.4 Products of combustion:	Not available
5.5 Fire hazard in presence of various substances:	Not available
5.6 Explosion hazards in presence of various substances:	Not available
5.7 Risks of explosion of the product in presence of mechanical impact:	Not available
5.8 Risks of explosion of the product in presence of static discharge:	Not available
5.9 Fire Fighting Media and Instructions:	Not available
5.9.1 Small Fire:	Use dry chemical powder.
5.9.2 Large Fire:	Use water spray, fog, or foam. Do not use water jet.
5.10 Special remarks on fire hazards:	Not available
5.11 Special remarks on explosion hazards:	Not available

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Small spill

Use appropriate tools to put the spilled solid in a convenient waste disposal container.

6.2 Large spill

Clean area with absorbent substrata; finish cleaning by spreading water on the contaminated surface and with soap.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions:

- | | |
|----------------------|--|
| 7.1.1 Safe handling: | Avoid contact with skin and eyes. Avoid inhalation of vapor. Wash hands thoroughly after handling. Keep away from fire and open flames. Do not overheat. |
| 7.1.2 Storage: | (Requirement for storage Areas and Containers). Store in a cool, dry location, in a sealed container. Protect from light. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Engineering controls: No special ventilation requirements

Personal protection

(Work/hygiene practice): Normal work and hygiene practices for handling non-hazardous material



- | | |
|--|--|
| 8.2 Eye: | Safety glasses should be worn. |
| 8.3 Skin/body: | Aprons, Gloves should be worn. |
| 8.4 Respiratory: | Not needed under normal conditions of use. |
| 8.5 Other: | Evaluate need based on application. |
| 8.6 Slip proof shoes may be worn where spills may occur. | |
| 8.7 Personal protection in case of large spill: | |



SAFETY DATA SHEET

Safety goggles. Apron. Vapor respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product, consult a specialist before handling this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Physical State:	Powder
9.2 Appearance:	Brown color dry powder
9.3 Odor:	Characteristic
9.4 Odor Threshold:	No data available
9.5 pH:	Not applicable
9.6 Evaporation Rate:	No data available
9.7 Melting Point:	No data available
9.8 Freezing Point:	No data available
9.9 Boiling Point:	No data available
9.10 Flash Point:	NA
9.11 Auto-ignition Temperature:	No data available
9.12 Decomposition Temperature:	No data available
9.13 Flammability (solid, gas):	No data available
9.14 Vapor Pressure:	No data available
9.15 Relative Vapor Density at 20°C:	No data available
9.16 Relative Density:	No data available
9.17 Specific Gravity:	NA
9.18 Solubility:	Soluble in water
9.19 Viscosity:	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1 Storage stability:	Stable under recommended storage conditions
10.2 Incompatibility (Materials to avoid):	Steel, aluminum, acidic or alkaline media, oxidizing agents.
10.3 Conditions to avoid:	Do not overheat. Reduce heat if product smokes.
10.4 Corrosivity:	Not available.
10.5 Hazardous decomposition product:	Avoid contact with skin and eyes. Avoid inhalation of vapor or mist.
10.6 Hazardous polymerization:	Does not occur.

SECTION 11: TOXICOLOGY INFORMATION

11.1 Toxicity in animals:	No toxicity has been reported
11.2 Chronic effects on humans:	Not available
11.3 Other toxic effects on humans:	Not available
11.4 Special remarks on chronic effects on humans:	Not available
11.5 Skin:	Mild irritation may occur
11.6 Eyes:	Mild irritation may occur
11.7 Ingestion:	Not available
11.8 Inhalation:	Irritation



SAFETY DATA SHEET

SECTION 12: ECOLOGICAL INFORMATION

12.1 Ecotoxicity: No data available
12.2 BOD 5 and COD: Not available
12.3 Biodegradation: Expected to be ultimately biodegradable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste Disposable method: Dispose of according to local, state and federal regulations.

SECTION 14: TRANSPORT INFORMATION

14.1 ADR/RID Not available
14.2 IMDG Not available
14.3 IATA Not available

SECTION 15: REGULATORY INFORMATION

15.1 Risk phrases (R): Not applicable
15.2 Safety phrases (S): Not applicable
15.3 WHMIS classification of product: Not applicable

SECTION 16: OTHER INFORMATION

Further information

This information is based upon the present state of our knowledge. This SDS had been compiled and is solely intended for this product.

Notice to reader

Employers should use this information only as a supplement to other information gathered by them and should make independent judgement of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty and any use of the product not in conformance with this Safety Data Sheet or in combination with any other product or process is the responsibility of the user.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information and we assume no liability resulting from its use, users should make their own investigations to determine the suitability of the information for their purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

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ADDITIONAL INFORMATION

We, Suan Farma, Inc., hereby declare that Ashwagandha Extract 1.5% HPLC (product code: ASE01HPLC) is manufactured in accordance with the following guidelines:

- No animal derived products have been used in the manufacture of the above extract, making this material free from components which can cause Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE).
- The above extract has not been genetically modified or exposed to genetically modified organisms during the production process and is therefore GMO free.
- Ashwagandha Extract 1.5% HPLC and its constituents are naturally free of products containing gluten (i.e., wheat, rye, barley, triticale, etc.).
- The above extract has not been irradiated per 7 CFR 205.105(f) requirements with the understanding that "irradiation" shall be defined as outlined in 21 CFR 179.26.
- The above extract has not been treated with ETO (ethylene oxide) or any other chemical sterilizing agent.
- The above extract is suitable for vegetarian and vegan consumption.
- At no point in the process is the above extract derived from, produced using, or handled with sewage sludge, as defined in 7 CFR 205.105(g).
- Ashwagandha Extract 1.5% HPLC is composed of NLT 88% dried ashwagandha root, NMT 10% MCCP, NMT 2% Colloidal silicon dioxide (anti-caking agent).
- The above extract complies with the limits set forth in USP<467> regarding solvent residues.

Regards,

Julianna Chedid

Julianna Chedid
QA/QC Assistant
February 2020