ORIGINAL SUBMISSION

NutraSource, Inc.
6309 Morning Dew Ct, Clarksville, MD 21029
(410)-531-3336 or (301) 875-6454

629

February 1, 2015

Dr. Antonia Mattia
Office of Food Additive Safety (HFS-255)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Subject: GRAS notice for LUO HAN GUO FRUIT EXTRACTS GRN 000629

Dear Dr. Antonia Mattia:

On behalf of Hunan Nutramax, Inc.®, we are submitting for FDA review a GRAS notification for Luo Han Guo fruit extracts. The attached documentation contains the specific information that addresses the safe human food uses for the subject notified substance. We believe that this determination and notification are in compliance with proposed Sec. 170.36 of Part 21 of the Code of Federal Regulations (21 CFR section 170.36) as published in the Federal Register, Vol. 62, FR 18960, April 17, 1997.

We enclose an original and two copies of this notification for your review. Please feel free to contact me if additional information or clarification is needed as you proceed with the review. We would appreciate your kind attention to this matter.

Sincerely,

(b) (6)

Susan Cho, Ph.D.
Susanscho1@yahoo.com
Agent for Hunan Nutramax, Inc.®

enclosure

GRAS EXEMPTION CLAIM FOR LUO HAN GUO FRUIT EXTRACTS (SWEETMONK™) MANUFACTURED BY HUNAN NUTRAMAX, INC.® (NUTRAMAX®)

Prepared by: NutraSource, Inc.
6309 Morning Dew Court
Clarksville, MD 21029
Tel: 410-531-3336;
Susanscho1@yahoo.com

GRAS EXEMPTION CLAIM

A. LUO HAN GUO FRUIT EXTRACTS (SweetMonk™): Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 5 170.36(1)

Hunan NutraMax Inc.® (hereinafter referred to as Nutramax) has determined that its Luo Han Guo fruit extracts (powder form) are Generally Recognized As Safe (GRAS). Consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act,* this determination is based on scientific procedures described in the following sections. Since these procedures specify the conditions of its intended use in food, the use of Nutramax's Luo Han Guo fruit extracts (SweetMonk™) is exempt from the requirement of premarket approval.

Signed
(b) (6)

2/1/2016

Susan Cho Date:
Agent for
Hunan NutraMax Inc. (Nutramax)

B. Notifier's Name and Address

Baotang Zhang
Hunan NutraMax Inc. (Nutramax)
Changhai Base, 627 Lugu Rd
Changsa High-Tech Industrial Development Zone
Changsa, Hunan, China
TEL: 0086-731-82939658
Fax: 0086-731-82938822
Email: sales@nutra-max.com

C. Name of GRAS Substance

The common name of the notified substance is Luo Han Guo fruit extracts. The subjects of the notice are Luo Han Guo (*Siraitia grosvenorii* Swingle) fruit extracts (containing ≥7.0%, ≥12.5%, ≥20.0%, ≥25.0%, ≥30.0%, ≥40.0%, ≥50.0%, ≥60.0%, ≥90.0%, and ≥95.0%).

GRAS EXEMPTION CLAIM FOR LUO HAN GUO FRUIT EXTRACTS (SWEETMONK™) MANUFACTURED BY HUNAN NUTRAMAX, INC. ® (NUTRAMAX®)

Prepared by: NutraSource, Inc.
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Signed

Susan Cho Date:
Agent for
Hunan NutraMax Inc. (Nutramax)

B. Notifier's Name and Address

Baotang Zhang
Hunan NutraMax Inc. (Nutramax)
Changhai Base, 627 Lugu Rd
Changsa High-Tech Industrial Development Zone
Changsa, Hunan, China
TEL: 0086-731-82939658
Fax: 0086-731-82938822
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Trade names are:
SweetMonk™ MV 7;
SweetMonk™ MV 12.5;
SweetMonk™ MV 20;
SweetMonk™ MV 25;
SweetMonk™ MV 30;
SweetMonk™ MV 40;
SweetMonk™ MV 50;
SweetMonk™ MV 55
SweetMonk™ MV 60;
SweetMonk™ MV 90; and
SweetMonk™ MV 95.

D. Product Description

D.1. Identity

Luo Han Guo, or *Siraitia grosvenori* (Swingle) fruit, a traditional Chinese medicine and edible fruit, is a member of the genus *Siraitia.* The subject extracts are mixtures of components found in the Luo Han Guo fruit. This GRAS document discusses extract products containing 7- 95% mogroside V. These products are similar to the products described in GRNs 301, 359, 522 and 556 for which FDA has issued "no question" letters.

The primary components of crude Luo Han Guo fruit extracts are cucurbitane glycosides (known as mogrosides, specifically mogrosides II, III, IV, V, and VI) along with flavonoids and melanoidins. Mogroside V is the major sweetness component of the fruit.

It does not have a single CAS registry number. However, some of the major sweetening component have CAS numbers as follows:
Mogroside V (mogro-3-O-[beta-D-glucopyranosyl(1-6)-beta –D-glucopyranoside]-24-O-{[beta-D-glucopyranosyl(l-2)]-[beta-D-glucopyranosyl (1 -6)]-beta-Dglucopyranoside):
CAS # 88901-36-4. Molecular Formula: $C_{60}H_{102}O_{29;}$ Molecular Weight: 1287.43.

Other mogrosides also have CAS numbers as follows: Mogroside IV: CAS #89590-95-4 and Mogroside VI: CAS #89590-98-7.

D.2. Manufacturing process

Nutramax's Luo Han Guo fruit extract powders are manufactured in a process similar to that described in previous GRNs. However, Nutramax's manufacturing process employs more purification processes to produce highly purified products (Hunan Nutramax vs. Food Chemical Codex (FCC): up to 95% mogroside V vs. 30% mogroside V) under current Good Manufacturing Process (cGMP).

The following outlines the procedures by which Nutramax processes its Luo Han Guo fruit extract powders:
1) Fresh fruit with the peel intact are selected and weighed. Mature fruits from the Luo Han Guo plant are inspected upon arrival at the processing plant. Distilled water is used for washing the fresh fruits to remove any impurities.

2) The fruit is then crushed, while preventing crushing the fruit seeds. Then the same weight of distilled water containing enzymes (pectinase) is added and the mixture is incubated at 40℃ for one day.
3) Distilled water is added; the mixture is boiled at 100 ℃; extracted three times, each time for one hour, the third extract solution is used as the solvent for first extraction of the next batch.
4) The solutions from step 3 are then combined, cooled to room temperature, and subjected to high-speed centrifugation (5000 rpm for 30 min). To produce 45%, 60%, or 95% of the content, chitosan acetic acid (0.5% in water) is added to precipitate calcium before filtering, followed by the high-speed centrifugation.
5) The centrifugal liquid is absorbed with D101 resin (a divinylbenzene copolymer, a macroporous polymeric adsorbent) to remove impurities with 20% ethanol. This is then concentrated and dried to get product 1 (2% mogroside V).
6) The resin is eluted with 50% ethanol, the eluate solution is then concentrated and dried to get product 2 (18-23% mogroside V) and product 3 (24-27% mogroside V).
7) High-speed centrifugation (5000 rpm for 30 min) is used after recovering ethanol from the eluate.
8) The mixture is then centrifuged (5000 rpm for 30 min) after macroporous D900 anion exchange resin decolorization. Then concentrated and dried to get product 4 (40% mogroside V) and product 5 (45% mogroside V).
9) The decolorizing resin liquid from step 8) is further decolorized and purified by macroporous D941 ion exchange resin, and then concentrated and dried to get product 6 (50% mogroside V) and product 7 (60% mogroside V).
10) After decolorizing, a reverse phase silica gel column chromatography (using 30% ethanol in water as a mobile phase) is used to get product 8 (90% mogroside V) and product 9 (95% mogroside V).
11) The products from steps 5-9 are then mixed with the option to specify the product.

Luo han guo fruit extracts are manufactured under cGMP using common food industry materials and processes in accordance with the applicable parts of 21 CFR, part 110 of the Code of Federal Regulations. The food grade ethanol used in the purification process complies with FCC's 8th Edition specifications. The ion exchange resins and adsorption resins used in the manufacturing process comply with 21 CFR 173.25.

D.3. Specifications

As shown in Tables 1-1 to 1-11, Nutramax has established the specifications for the minimum mogroside V content as well as the maximum microbiological and heavy metal levels for its Luo Han Guo fruit extracts. The specifications meet or exceed those specified by the Food Chemical Codex (FCC).

Table 1-1. Specifications for SweetMonk™ with 7% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥7%	HPLC
Identification	Positive	TLC
Color	Yellow	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-2. Specifications for SweetMonk™ with 12.5% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥12.5%	HPLC
Identification	Positive	TLC
Color	Yellow	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium(Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury(Hg)	≤ 0.1ppm	AOAC 993.14

Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-3. Specifications for SweetMonk™ with 20% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥20%	HPLC
Identification	Positive	TLC
Color	Yellow	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-4. Specifications for SweetMonk™ with 25% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 25%	HPLC
Identification	Positive	TLC
Color	Yellow	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008

pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-5. Specifications for SweetMonk™ with 30% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 30%	HPLC
Identification	Positive	TLC
Color	Light yellow	GB/T[1] 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010

Staphylococcus	Negative	CP 2010

Table 1-6. Specifications for SweetMonk™ with 40% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 40%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury(Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-7. Specifications for SweetMonk™ with 50% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 50%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06

Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-8. Specifications for SweetMonk™ with 55% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 55%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-9. Specifications for SweetMonk™ with 60% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 60%	HPLC
Identification	Positive	TLC

Color	White	GB/T[1] 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-10. Specifications for SweetMonk™ with 90% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 90%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010

Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-11. Specifications for SweetMonk™ with 95% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 95%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P. aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

E. Applicable Conditions for Use of the Notified Substance

E.1. Current Regulatory Status

The US FDA has issued 'no question' letters on four GRAS notifications related to food uses of Luo Han Guo fruit extracts (GRN 301, FDA, 2010; GRN 359, FDA, 2011; GRN 522, 2014; GRN 556, 2015).

In addition, two New Dietary Ingredient (NDI) notifications were accepted by FDA with no objection for use of Luo Han Guo fruit extract as dietary supplement (FDA, 1996, 1999).

E.2. Intended Use Levels and Food Categories

Luo Han Guo fruit extracts, containing mogroside V as the principal sweetening component, are intended to be used as a table-top sweetener and general purpose non-nutritive sweetener and as a flavor modifier in various foods other than in infant formulas and in meat and poultry products. The intended use will be as a non-nutritive sweetener as defined in 21 CFR 170.3(o)(19). Luo Han Guo fruit extracts are intended for use in the same foods and at levels proportional to those for mogroside V specified in GRNs 301, 359, 522 and 556.

E.3. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extract Based upon Intended Food Uses

Using the methodology presented in GRN 301 and Renwick (2008), the EDI of the Nutramax's Luo Han Guo fruit extracts have been calculated. The EDIs for high consumers of Luo Han Guo fruit extracts ranged from 1.6 mg/kg body weight (BW)/day (product containing 90-95% mogroside V) to 22 mg/kg BW/day (product containing 7% mogroside V). All predicted EDIs for mogroside V are 2.2 mg/kg BW/day or less.

Since Nutramax's Luo Han Guo fruit extracts will replace other Luo Han Guo fruit extract products in the marketplace, an increase in the cumulative intake is not expected. As described in Renwick (2008) as well as in GRNs 301, 359 and 556, the EDIs for Luo Han Guo fruit extract products represent extremely optimistic estimates of the potential intake.

E.4. Basis for the GRAS Determination

The intended use of Luo Han Guo (*Siraitia grosvenori*) fruit extracts (SweetMonk™; powder form) has been determined to be safe though scientific procedures as set forth in 21 CFR 170.3(b), thus satisfying the so-called "technical" element of the Generally Recognized as Safe (GRAS) determination. In addition, because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

<u>Safety Evaluation</u>

Numerous human and animal studies have reported benefits of Lou Han Guo fruit extracts with varying concentrations of mogroside V with no major adverse effects. The Nutramax uses a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications. There is broad-based and widely disseminated knowledge concerning the chemistry of mogroside V, a major active component of Lou Han Guo fruit extracts. This GRAS determination is based on the data and information generally available and consented opinion about the safety of Luo Han Guo fruit extracts. The literature indicates that Luo Han Guo fruit extracts offers consumers benefits without adverse effects.

The following safety evaluation fully considers the composition, intake, nutritional, microbiological, and toxicological properties of Luo Han Guo fruit extracts as well as appropriate corroborative data.

1. Nutramax's Luo Han Guo fruit extracts are manufactured under current Good Manufacturing Practices (cGMP) using common food industry materials and processes.
2. Analytical data from multiple lots indicate that the Luo Han Guo fruit extract powders comply reliably with the established food-grade product specifications and meet all applicable purity standards.
3. Nutramax's Luo Han Guo fruit extracts will be used as a table-top sweetener and general purpose non-nutritive sweetener and as a flavor modifier in various foods other than in infant formulas and in meat and poultry products. Intended use is the same as that was described in GRN 556. Due to the characteristic intense sweet flavor of the fruit and its derivatives, use is expected to be self-limiting.
4. The exposure estimates, estimated dietary intakes (EDI), under the intended use are estimated to be up to 2.2 mg mogroside V/kg BW/day for high consumers. For high consumers, the EDIs for Luo Han Guo fruit extracts ranged from 1.6 to 22 mg/kg BW/day, depending on the concentration of mogroside V in each Luo Han Guo fruit extract product. These levels are far below the reference dose safe for human exposure. In addition, subchronic studies reported that NOAELs for Luo Han Guo fruit extract were over 3,120 mg/kg BW/day and 3,750 mg/kg BW/day in male and female rats, respectively (Jin et al., 2007), and those of mogroside V were over 1,717 and 2,062 mg/kg BW/day, respectively (Huntingdon Life Science, 2009).
5. The EDI estimates are based on the assumption that Nutramax's Luo Han Guo fruit extract will replace currently marketed Luo Han Guo fruit extract. Thus, cumulative exposures are not expected. In addition, the EDIs presented in this notice are highly optimistic estimates.
6. In the previous GRAS notices (GRN 301, 359, 522 and 556) to the FDA, the safety of Luo Han Guo fruit extracts had been established in toxicological studies in animals, mutagenicity studies, and is further supported by clinical studies in humans. The FDA responses to GRAS notifications on Luo Han Guo fruit extracts indicate that the FDA is satisfied with the safety-in-use of the Luo Han Guo fruit extract, as long as consumption is less than 2.5 mg mogroside V/kg BW/day. Furthermore, historical consumption of Luo Han Guo fruit extract support the safety of Luo Han Guo fruit extract.
7. An additional animal study published subsequent to the FDA GRAS notices continue to support the safety of Luo Han Guo fruit extract as a food ingredient.

Pursuant to 21 CFR 170.30(b), Nutramax's Luo Han Guo fruit extracts (powder form) have been determined to be GRAS on the basis of scientific procedures. This determination is based on the views of experts who are qualified by scientific training and experience to evaluate the safety of Luo Han Guo fruit extracts as a food ingredient. Expert Panel members, Susan S. Cho, Ph.D., Robert L. Martin, Ph.D., George C. Fahey, Jr., Ph.D., have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that Luo Han Guo fruit extracts, produced consistent with cGMP and meeting the specifications described herein, is safe under its intended conditions of use. The Expert Panel further unanimously concludes that these uses of Luo Han Guo fruit extracts are GRAS based on scientific procedures, and that other experts qualified to assess the safety of food and food ingredients would concur with these conclusions.

F. Availability of Information
The detailed data and information that serve as a basis for this GRAS determination will be provided to the U. S. FDA upon request, or are available for the FDA's review and copying during reasonable business hours at the offices of NutraSource, Inc. located at 6309 Morning Dew Ct., Clarksville, MD 21029, USA.

G. Basis of GRAS determination: Through scientific procedures.

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EXPERT PANEL STATEMENT

OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LUO HAN GUO (*SIRAITIA GROSVENORI*) FRUIT EXTRACTS (SWEETMONK™) AS A FOOD INGREDIENT

Prepared by: NutraSource, Inc.
6309 Morning Dew Court
Clarksville, MD 21029
Tel: 410-531-3336
Susanscho1@yahoo.com

DETERMINATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF *SIRAITIA GROSVENORI* LUO HAN GUO FRUIT EXTRACTS (SWEETMONK™) AS A FOOD INGREDIENT

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1. INTRODUCTION

The undersigned, an independent panel of recognized experts (hereinafter referred to as the Expert Panel), qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, was convened by NutraSource, Inc., at the request of Hunan NutraMax, Inc.® (hereinafter referred to as Nutramax), to determine the Generally Recognized As Safe (GRAS) status of its Luo Han Guo fruit extracts (SweetMonk™) as a table-top sweetener and general purpose non-nutritive sweetener as defined in 21 CFR 170.3(o)(19) and as a flavor modifier in foods. A comprehensive search of the scientific literature for safety and toxicity information on Luo Han Guo fruit extracts was conducted and made available to the Expert Panel members. The Expert Panel members independently and critically evaluated materials submitted by Nutramax and other information deemed appropriate or necessary. Following an independent, critical evaluation, the Expert Panel unanimously agreed to the decision described herein.

The purpose of this dossier is to (1) Outline the identity and composition of Luo Han Guo fruit extracts powders, (2) Estimate exposure under the intended condition of use, (3) Document the literature pertaining to the safety of Luo Han Guo fruit extracts, and (4) Assemble an independent panel of recognized experts (referred to as the Expert Panel). The data and information summarized in this dossier demonstrate that the intended use of Luo Han Guo fruit extracts (powder form), produced using current Good Manufacturing Practices (cGMP) and meeting food-grade specifications, is GRAS, based on scientific procedures, as described herein.

II. INFORMATION ABOUT THE IDENTITY OF THE NOTIFIED SUBSTANCE

II.A. Background

Siraitia grosvenorii Swingle, commonly known as Luo Han Guo or monk fruit, is a plant native to Southern China. Luo Han Guo fruit extracts contain varying concentrations of mogrosides, which are the non-nutritive constituents of the fruit primarily responsible for the characteristic sweetness of Luo Han Guo fruit extracts (FDA, 2015a). Luo Han Guo fruit extracts, depending on the mogroside V content, are reported to be 100 to 400 times sweeter than sugar (FDA, 2015a, 2015b). They therefore can be used as a sugar substitute.

The primary components of Luo Han Guo fruit extracts are cucurbitane glycosides (known as mogrosides, specifically mogrosides II, III, IV, V, and VI) along with flavonoids and melanoidins. Mogrosides IV, V, and VI, members of the family of triterpene glycosides, are very sweet and are responsible for the sweetness of Luo Han Guo fruit extracts (Lee, 1975). In particular, mogroside V is the major sweetness component of the fruit. Mogroside V, the most abundant sweet constituent, has been found in whole fruits at concentrations of 0.8-1.3 % w/w (Makapugay et al., 1985; Pawar et al., 2013). Mogrosides are known to function as antioxidants, anti-carcinogens, and anti-inflammatory substances (Chen et al., 2007; Wang et al., 2014).

Luo Han Guo fruit extracts (in both powder and liquid forms) have been introduced for use in the U.S. as a tabletop sweetener of foods.

This GRAS document discusses extract products containing 7 - 95% mogroside V. Table 1 shows the sweetness intensity of Luo Han Guo fruit extract products when tested against a water solution of 10% sucrose. It is commonly accepted that the sweetness intensity of Luo Han Guo fruit extracts is proportional to the concentration of mogrosides present in it. However, it also depends on the concentration of mogroside V in a particular concentrate. At high concentrations of mogrosides the sweetness may slightly level off. Given the organoleptic characteristics of Luo Han Guo fruit extracts, the amounts added to food products from any of Nutramax's eleven extracts will be self-limiting.

Table 1. Sweetness Intensity of Nutramax's Luo Han Guo Fruit Extracts Relative to Sucrose

Product	Sweetness intensity
SweetMonk™ MV 7	45
SweetMonk™ MV 12.5	80
SweetMonk™ MV 20	130
SweetMonk™ MV 25	160
SweetMonk™ MV 30	180
SweetMonk™ MV 40	220
SweetMonk™ MV 50	250
SweetMonk™ MV 55	265
SweetMonk™ MV 60	275
SweetMonk™ MV 90	410
SweetMonk™ MV 95	420

III. CLAIM OF GRAS STATUS

III.A. Claim of Exemption from the Requirement for Premarket Approval Requirements Pursuant to Proposed 21 CFR § 170.36(c)(1)

SweetMonk™ (common name- *Siraitia grosvenorii* Swingle Luo Han Guo fruit extracts [hereinafter referred to as Luo Han Guo fruit extracts]) for use as a table top sweetener and non-nutritive sweetener and as a flavor modifier has been determined to be Generally Recognized As Safe (GRAS) and, therefore, is exempt from the requirement of premarket approval under the conditions of its intended use as described below. The basis for this finding is described in the following sections.

III.B. Common or Trade Name:

The common or usual names of the Luo Han Guo fruit extracts that is the subject of this GRAS evaluation include: Luo Han Guo (LHG), Lo Han Guo, Lor Hon Kor, *Siraitia grosvenori* (Swingle) fruit, Lo Han Kuo, Arhat Fruit, Fructus Momordicae, *Momordicae Grosvenorii* Fructus, monk fruit, magic fruit, and longevity fruit.

The specific substances that are the subject of this safety evaluation are identified as Luo Han Guo (*Siraitia grosvenorii* Swingle) fruit extracts (containing ≥7.0%, ≥12.5%, ≥20.0%, ≥25.0%,

≥30.0%, ≥40.0%, ≥50.0%, ≥60.0%, ≥90.0%, and ≥95.0%) as produced and sold by Nutramax under the following trade names:
SweetMonk™ MV 7;
SweetMonk™ MV 12.5;
SweetMonk™ MV 20;
SweetMonk™ MV 25;
SweetMonk™ MV 30;
SweetMonk™ MV 40;
SweetMonk™ MV 50;
SweetMonk™ MV 55
SweetMonk™ MV 60;
SweetMonk™ MV 90; and
SweetMonk™ MV 95.

The extracts are mixtures of components found in the Luo Han Guo fruit. Extracts are similar to those described in GRN 301 (up to 30% mogroside V), GRN 359 (up to 55% mogroside V), GRN 522 (up to 60% mogroside V), and GRN 556 (up to 90% mogroside V) (FDA, 2010, 2011, 2014, 2015a). This GRAS document discusses extracts products containing 7 - 95% mogroside V. These products are similar to the products described in the above mentioned GRNs for which FDA has issued "no question" letters.

III.C. Name and Address of Responsible Individual:

Baotang Zhang
Hunan NutraMax Inc. (Nutramax)
Changhai Base, 627 Lugu Rd
Changsa High-Tech Industrial Development Zone
Changsa, Hunan, China
TEL: 0086-731-82939658
Fax: 0086-731-82938822
Email: sales@nutra-max.com

III.D. Chemistry, Physicochemical Properties, and Structure

Luo Han Guo fruit extracts or *S. grosvenori* Swingle fruit extracts are mixtures of compounds naturally occurring in the Luo Han Guo fruit. The primary components are cucurbitane glycosides known as mogrosides (II-VI) that are responsible for imparting the characteristic sweet taste. Mogroside V (CAS Reg. No. 88901-36-4) is the major sweet component of Luo Han Guo fruit extracts.

Some of the major sweetening component have CAS numbers as follows:
Mogroside V (mogro-3-O-[beta-D-glucopyranosyl(1-6)-beta –D-glucopyranoside]-24-O-{[beta-D-glucopyranosyl(l-2)]-[beta-D-glucopyranosyl (1 -6)]-beta-D-glucopyranoside):

CAS # 88901-36-4; Molecular Formula: $C_{60}H_{102}O_{29;}$ Molecular Weight: 1287.43. The chemical structure of mogroside V is shown in Figure 1.

Other mogrosides also have CAS numbers as follows:
Mogroside IV: CAS #89590-95-4 and
Mogroside VI: CAS #89590-98-7.

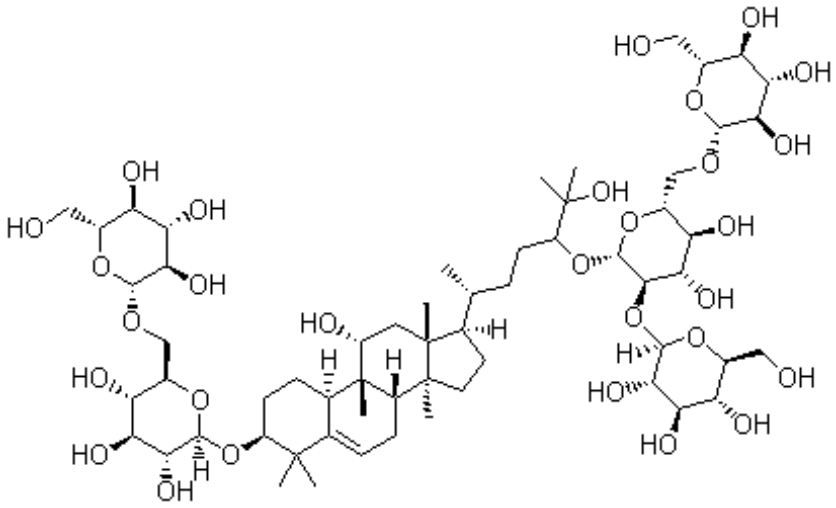


Figure 1. Chemical Structure of mogroside V.

SweetMonk™

Table 2 shows a typical compositional analysis of Nutramax's Luo Han Guo fruit extracts (7-95% mogroside V).

Table 2. Typical Compositional Analysis of Nutramax's Luo Han Guo Fruit Extracts

Component	Mogroside V concentration of SweetMonk™											FCC specif-ications
	MV 7	MV 12.5	MV 20	MV 25	MV 30	MV 40	MV 50	MV 55	MV 60	MV 90	MV 95	
Mogroside V, %	≥7.0	≥12.5	≥20.0	≥25.0	≥30.0	≥40.0	≥50.0	≥55.0	≥60.0	≥90.0	≥95.0	≥30.0
Protein, %	36.6	36.3	35.9	35.4	28.4	14.8	8.7	7.3	6.7	1.6	1.5	NA
Ash, %	2.42	2.3	2.06	1.95	1.6	1.48	1.32	1.25	1.1	0.45	0.23	<5.0
Na, mg/kg	1,450	1,410	1390	1,370	1,120	862	600	480	420	172	153	NA
K, mg/kg	191	173	158	150	133	147	127	136	107	49	32	NA
Ca, mg/kg	141	125	87.53	71.13	165	178.63	490	126	124	138	147	NA
As, ppm	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<0.5
Cd, ppm	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Pb, ppm	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Total fat, %	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	NA
SAT, %	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	NA
MUFA, %	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	NA
Moisture, %	4.1	3.7	3.15	3.02	2.7	2.58	2.27	2.13	1.73	0.85	0.72	<6.0
Dietary Fiber, %	4.5	4.2	3.8	3.0	2.3	1.61	0.56	0.5	0.54	0.31	0.25	NA
Carbohydrate, %	51.4	53.4	57.2	57.60	65.0	79.6	87.1	88.9	90.1	96.8	97.3	NA

MUFA= Mono-unsaturated fat; MV=mogroside V; SAT=saturated fat; Specifications meet or exceed those specified by Food Chemical Codex (FCC).

III.E. Manufacturing Process of Luo Han Guo Fruit Extracts

Nutramax's Luo Han Guo fruit extract powders are manufactured in a process similar to that described in previous GRNs. However, Nutramax's manufacturing process employs more purification processes to produce highly purified products (Nutramax vs. Food Chemical Codex [FCC]: up to 95% mogroside V vs. 30% mogroside V) under cGMP.

Figure 2. Luo Han Guo plant with mature fruit

The following outlines the procedures by which Nutramax processes its Luo Han Guo fruit extracts powders:

1) Fresh fruit with the peel intact are selected and weighed. Mature fruits from the Luo Han Guo plant (Figure 2) are inspected upon arrival at the processing plant. Distilled water is used for washing the fresh fruits to remove any impurities.

2) The fruit is then crushed, while preventing crushing the fruit seeds. Then the same weight of distilled water containing enzymes (pectinase) is added and the mixture is incubated at 40℃ for one day.

3) Distilled water is added; the mixture is boiled at 100 ℃; extracted three times, each time for one hour, the third extracts solution is used as the solvent for first extraction of the next batch.

4) The solutions from step 3 are then combined, cooled to room temperature, and subjected to high-speed centrifugation (4,000 rpm for approximately 30 min). To produce 45%, 60%, or 95% of the content, chitosan acetic acid (0.5% in water) is added to precipitate calcium before filtering, followed by the high-speed centrifugation.

5) The centrifugal liquid is absorbed with D101 resin (a divinylbenzene copolymer, a macroporous polymeric adsorbent) to remove impurities with 20% ethanol. This is then concentrated and dried to get product 1 (2% mogroside V).

6) The resin is eluted with 50% ethanol, the eluate solution is then concentrated and dried to get product 2 (18-23% mogroside V) and product 3 (24-27% mogroside V).

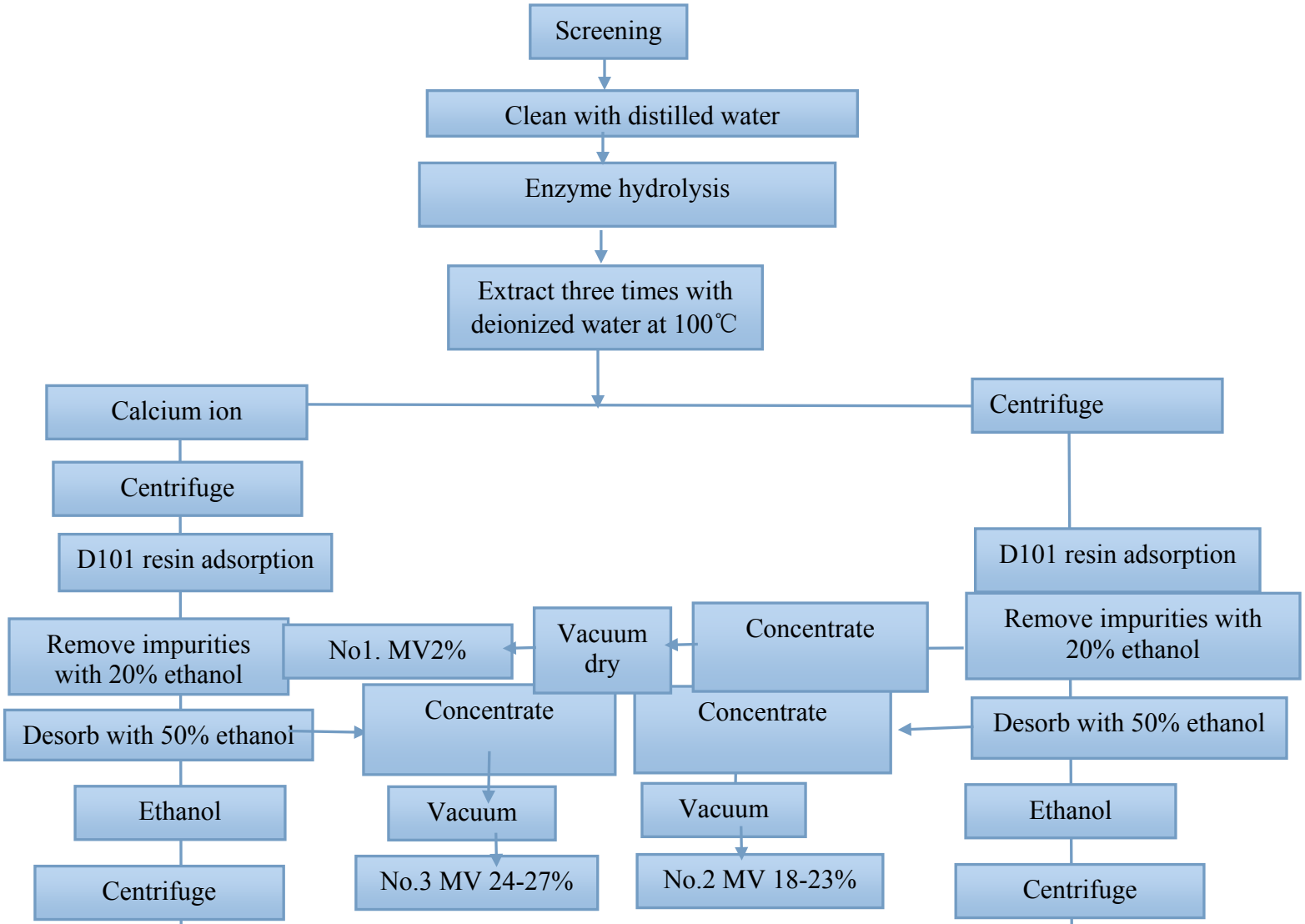
7) High-speed centrifugation (4,000 rpm for ~30 min) is used after recovering ethanol from the eluate.

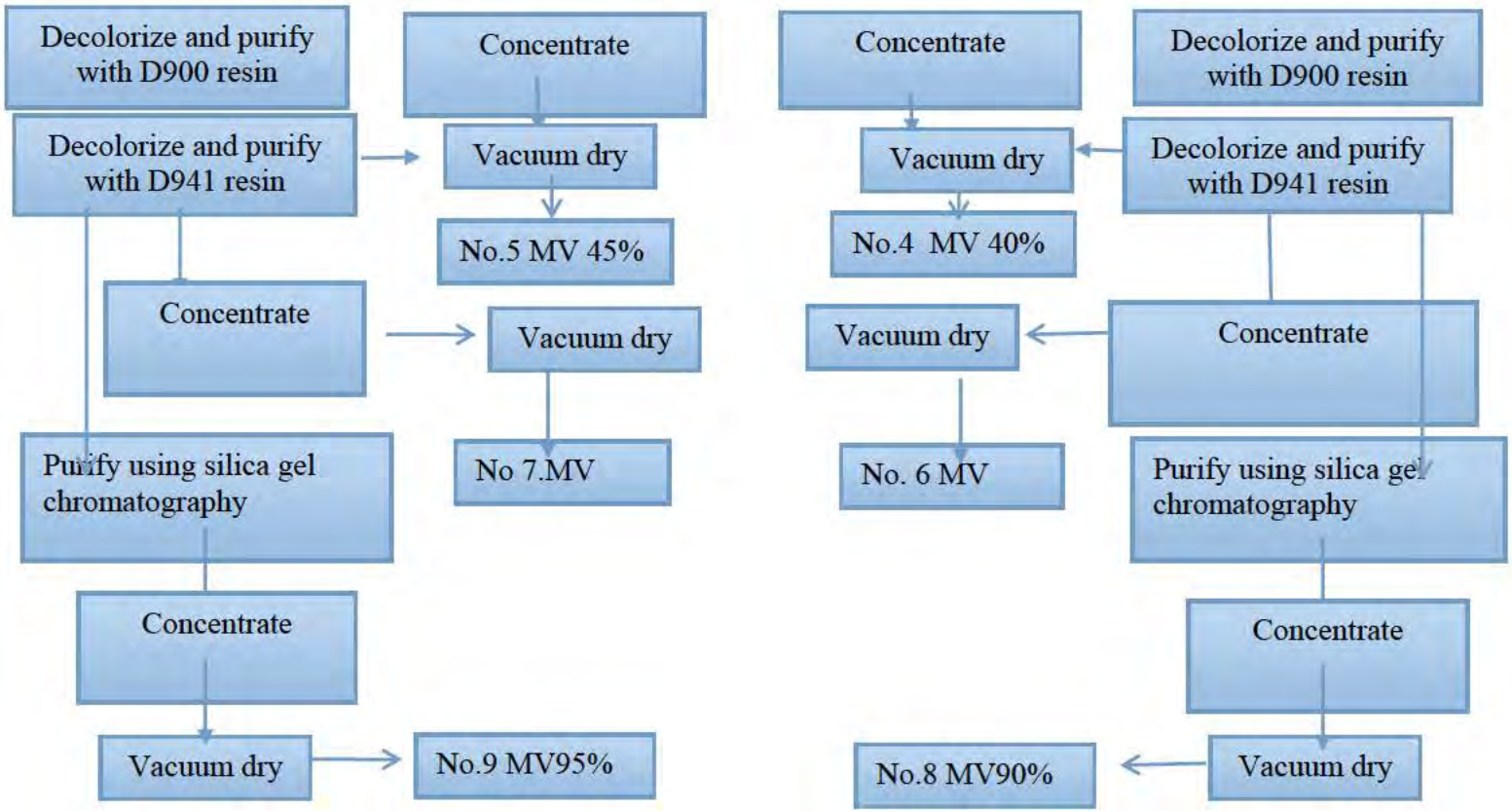
8) The mixture is then centrifuged (4,000 rpm for ~30 min) after macroporous D900 anion exchange resin decolorization. Then concentrated and dried to get product 4 (40% mogroside V) and product 5 (45% mogroside V).

9) The decolorizing resin liquid from step 8) is further decolorized and purified by macroporous D941 ion exchange resin, and then concentrated and dried to get product 6 (50% mogroside V) and product 7 (60% mogroside V).
10) After decolorizing, a reverse phase silica gel column chromatography (using 20-60% ethanol in water as a gradient mobile phase) is used to get product 8 (90% mogroside V) and product 9 (95% mogroside V).
11) The products from steps 5-9 are then mixed with the option to specify the product.

Luo Han Guo fruit extracts are manufactured under cGMP using common food industry materials and processes in accordance with the applicable parts of 21 CFR, part 110 of the Code of Federal Regulations. Nutramax uses a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications. The food grade ethanol used in the purification process complies with FCC's 8th Edition specifications. The ion exchange resins and adsorption resins used in the manufacturing process are food grade and comply with 21 CFR 173.25. A flow diagram of the manufacturing process is presented in Figure 3.

Figure 3. Manufacturing Process of Nutramax's Luo Han Guo Fruit Extracts





Mix the product of NO.1,2,3,4,5,6, 7 for the desired concentrations of Mogroside V

III. F. Specifications of Nutramax's Luo Han Guo Fruit Extracts (SweetMonk™)

As shown in Tables 3-1 to 3-11, Nutramax has established the specifications for the minimum mogroside V content as well as the maximum microbiological and heavy metal concentrations for its Luo Han Guo fruit extracts. Specifications meet or exceed those specified by the Food Chemical Codex (FCC). The subjects of the notice are Luo Han Guo (*Siraitia grosvenorii* Swingle) fruit extracts (containing ≥7.0%, ≥12.5%, ≥20.0%, ≥25.0%, ≥30.0%, ≥40.0%, ≥50.0%, ≥60.0%, ≥90.0%, and ≥95.0%).

Table 3-1. Specifications for SweetMonk™ with 7% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥7%	HPLC
Identification	Positive	TLC
Color	Yellow	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-2. Specifications for SweetMonk™ with 12.5% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥12.5%	HPLC
Identification	Positive	TLC
Color	Yellow	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\

Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium(Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury(Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-3. Specifications for SweetMonk™ with 20% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥20%	HPLC
Identification	Positive	TLC
Color	Yellow	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-4. Specifications for SweetMonk™ with 25% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 25%	HPLC
Identification	Positive	TLC
Color	Yellow	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-5. Specifications for SweetMonk™ with 30% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 30%	HPLC
Identification	Positive	TLC
Color	Light Yellow	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010

P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-6. Specifications for SweetMonk™ with 40% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 40%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury(Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-7. Specifications for SweetMonk™ with 50% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 50%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\

Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-8. Specifications for SweetMonk™ with 55% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 55%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05,17th
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-9. Specifications for SweetMonk™ with 60% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 60%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-10. Specifications for SweetMonk™ with 90% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 90%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37

Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

Table 3-11. Specifications for SweetMonk™ with 95% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 95%	HPLC
Identification	Positive	TLC
Color	White	GB/T[1] 5492-2008
Odor	Mild Fruity Characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
pH	8.0±0.5	\
Sieve Analysis	NLT 95% pass 80 mesh	80 Mesh Screen
Method of Extraction	Water	\
Solubility	Fully soluble in water	\
Moisture Content	≤ 5.0%	GB/T 5009.3-2010
Ash	≤ 5.0%	AOAC 942.05
Arsenic (As)	≤ 1 ppm	AOAC 2013.06
Cadmium (Cd)	≤ 1 ppm	AOAC 2006.03
Lead (Pb)	≤ 1 ppm	AOAC 2006.03
Mercury (Hg)	≤ 0.1ppm	AOAC 993.14
Residual Ethanol	≤ 50 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	CP 2010
P.aeruginosa	Negative	CP 2010
S. aureus	Negative	CP 2010
Salmonella	Negative	CP 2010
Yeast & Mold	≤ 100 cfu/g	CP 2010
E. coli	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia; AOAC=association of analytical communities; HPLC=high-performance liquid chromatography; TLC=thin layer chromatography; USP= United States Pharmacopeia.

IV. INTENDED USES AND EXPOSURE ESTIMATES

IV. A. Intended Technical Effects
Luo Han Guo fruit extracts can be used as a naturally occurring high intensity sweetener.

IV.B. Intended Use
The subjects of the present GRAS determination contain 7, 12.5, 20, 25, 30, 40, 50, 55, 60, 90 or 95% mogroside V. Luo Han Guo fruit extracts, containing mogroside V as the principal sweetening component, are intended to be used as a table-top sweetener, a general purpose non-nutritive sweetener, and a flavor modifier in various foods, for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. The intended use will be as a non-nutritive sweetener as defined in 21 CFR 170.3(o)(19). The intended use levels will vary by food category, but the actual levels are self-limiting due to organoleptic characteristics. The amounts of purified Luo Han Guo fruit extracts to be added to foods will not exceed the amounts reasonably required to accomplish its intended technical effect in foods as required by FDA regulation (21 CFR 182.1(b)(1)). Nutramax does not intend to use Luo Han Guo fruit extracts as a component of infant formula or in foods under the USDA's jurisdiction such as meat, poultry, and egg products.

Luo Han Guo fruit extracts are intended for use in the same foods and at levels proportional to those for mogroside V specified in GRNs 301, 359, 522 and 556.

IV.B. Estimated Dietary Intakes (EDIs) Under the Intended Use
Using the methodology presented in GRN 301 and Renwick (2008), the EDI of Nutramax's Luo Han Guo fruit extracts have been calculated (Tables 4-1 to 4-11). The amount of sucrose replaced by an intense sweetener equals the dietary exposure for that sweetener multiplied by its relative sweetness intensity compared with sucrose. The EDIs of Luo Han Guo fruit extracts are then calculated by dividing the estimated sucrose equivalent intakes by the relative sweetness of a Luo Han Guo fruit extract at specific concentrations of mogroside V.

EDIs for high consumers of Luo Han Guo fruit extracts ranged from 1.6 mg/kg body weight (BW)/day (product containing 90-95% mogroside V) to 22.0 mg/kg BW/day (product containing 7% mogroside V). The EDIs for high consumers of mogroside V for the general population, diabetic adults, healthy children, and diabetic children are up to 1.53, 2.03, 2.23, and 2.05 mg/kg BW/day, respectively. All predicted EDIs for mogroside V are less than 2.3 mg/kg BW/day, which is equivalent to less than 161 mg per 70 kg adult. Each concentration will be used independently of the others for each application; thus, cumulative exposure is not expected. Based on the totality of science and as discussed below, these intake levels are considered safe.

In this GRAS assessment, Luo Han Guo fruit extracts are intended to be used as alternatives for the currently marketed Luo Han Guo fruit extract products. Thus, the overall exposure to Luo Han Guo fruit extracts is not expected to increase as a result of the introduction of Nutramax's Luo Han Guo fruit extract products into the market. As described in Renwick (2008), as well as in GRNs 301 and 359, calculations made in this GRAS assessment likely overestimate the potential intake of Luo Han Guo fruit extracts for the following reasons; 1) there are assumptions present in many of the studies, such as the use of food groups rather than individual food items and brands, 2) calculations have assumed the use of maximum permitted use levels although all foods under the intended uses will not be used at the maximum use levels, and 3) the intense sweetener market is unlikely to be dominated by a single sweetener; the presence of multiple sweeteners is likely to reduce the intakes of individual compounds compared with the data given in this section. Indeed, the market share of Luo Han Guo fruit extract products is very low in the intense-sweetener market.

Table 4-1. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 7% Mogroside (SweetMonk™ MV 7 - sweetness intensity 45)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ 12.5 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg BW/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	5.7	15.0	0.40	1.05
Diabetic Adults	280	897	6.2	19.9	0.44	1.40
Healthy Children	425	990	9.4	22.0	0.66	1.54
Diabetic Children	672	908	14.9	20.2	1.05	1.41

a See Renwick, 2008. [b]Calculation method was adopted from GRNs 301 and 556.
c Calculated based on the minimum of 7.0% mogroside V in Luo Han Guo fruit extract. BW=body weight; MV=mogroside V.

Table 4-2. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 12.5% Mogroside (SweetMonk™ MV 12.5 - sweetness intensity 80)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ 12.5 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg BW/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	3.2	8.4	0.40	1.05
Diabetic Adults	280	897	3.5	11.2	0.44	1.40
Healthy Children	425	990	5.3	12.4	0.67	1.55
Diabetic Children	672	908	8.4	11.4	1.05	1.42

a See Renwick, 2008. [b]Calculation method was adopted from GRNs 301 and 556.
c Calculated based on the minimum of 12.5% mogroside V in Luo Han Guo fruit extract. BW=body weight; MV=mogroside V.

Table 4-3. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 20% Mogroside (SweetMonk™ MV20 - sweetness intensity 130)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ MV 20 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg BW/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	2.0	5.2	0.40	1.04
Diabetic Adults	280	897	2.2	6.9	0.43	1.38
Healthy Children	425	990	3.3	7.6	0.65	1.52
Diabetic Children	672	908	5.2	7.0	1.03	1.40

a See Renwick, 2008. [b]Calculation method was adopted from GRNs 301 and 556.
c Calculated based on the minimum of 20% mogroside V in Luo Han Guo fruit extract. BW=body weight; MV=mogroside V.

Table 4-4. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 25% Mogroside (SweetMonk™ MV25- -sweetness intensity 160)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ MV 25 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg BW/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	1.6	4.2	0.40	1.05
Diabetic Adults	280	897	1.8	5.6	0.44	1.40
Healthy Children	425	990	2.7	6.2	0.67	1.55

Diabetic Children	672	908	4.2	5.7	1.05	1.42

[a] See Renwick, 2008. [b]Calculation method was adopted from GRNs 301 and 556. [c]Calculated based on the minimum of 25% mogroside V in Luo Han Guo fruit extract. BW=body weight; MV=mogroside V.

Table 4-5. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 30% Mogroside (SweetMonk™ MV30 - sweetness intensity 180)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ MV 30 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg BW/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	1.4	3.8	0.43	1.13
Diabetic Adults	280	897	1.6	5.0	0.47	1.50
Healthy Children	425	990	2.4	5.5	0.71	1.65
Diabetic Children	672	908	3.7	5.0	1.12	1.51

[a] See Renwick, 2008. [b]Calculation method was adopted from GRNs 301 and 556.
[c] Calculated based on the minimum of 30% mogroside V in Luo Han Guo fruit extract. BW=body weight; MV=mogroside V.

Table 4-6. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 40% Mogroside (SweetMonk™ MV40 - sweetness intensity 220)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ MV 40 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg BW/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	1.2	3.1	0.46	1.23
Diabetic Adults	280	897	1.3	4.1	0.51	1.63
Healthy Children	425	990	1.9	4.5	0.77	1.80
Diabetic Children	672	908	3.0	4.1	1.22	1.65

a See Renwick, 2008. [b] Calculation method was adopted from GRNs 301 and 556.
c Calculated based on the minimum of 40% mogroside V in Luo Han Guo fruit extract. BW=body weight; MV=mogroside V.

Table 4-7. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 50% Mogroside (SweetMonk™ MV 50 - sweetness intensity 250)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ MV 50 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg BW/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	1.0	2.7	0.51	1.35
Diabetic Adults	280	897	1.1	3.6	0.56	1.79
Healthy Children	425	990	1.7	4.0	0.85	1.98
Diabetic Children	672	908	2.7	3.6	1.34	1.82

a See Renwick, 2008.
b Calculation method was adopted from GRNs 301 and 556.
c Calculated based on the minimum of 50% mogroside V in Luo Han Guo fruit extract.
BW=body weight; MV=mogroside V.

Table 4-8. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 55% Mogroside (SweetMonk™ MV 55 - sweetness intensity 265)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ MV 55 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg BW/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	1.0	2.6	0.53	1.40
Diabetic Adults	280	897	1.1	3.4	0.58	1.86
Healthy Children	425	990	1.6	3.7	0.88	2.05
Diabetic Children	672	908	2.5	3.4	1.39	1.88

[a] See Renwick, 2008. [b] Calculation method was adopted from GRNs 301 and 556.
[c] Calculated based on the minimum of 55% mogroside V in Luo Han Guo fruit extract.
BW=body weight; MV=mogroside V.

Table 4-9. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 60% Mogroside (SweetMonk™ MV 60 - sweetness intensity 275)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ MV 60 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg BW/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	0.93	2.4	0.56	1.47
Diabetic Adults	280	897	1.0	3.3	0.61	1.96
Healthy Children	425	990	1.5	3.6	0.93	2.16
Diabetic Children	672	908	2.4	3.3	1.47	1.98

[a] See Renwick, 2008. [b] Calculation method was adopted from GRNs 301 and 556.
[c] Calculated based on the minimum of 60% mogroside V in Luo Han Guo fruit extract.
BW=body weight; MV=mogroside V.

Table 4-10. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 90% Mogroside (SweetMonk™ MV 90 - sweetness intensity 410)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ MV 90 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg bw/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	0.62	1.64	0.56	1.48
Diabetic Adults	280	897	0.68	2.18	0.61	1.97
Healthy Children	425	990	1.04	2.41	0.93	2.17
Diabetic Children	672	908	1.64	2.21	1.48	1.99

[a] See Renwick, 2008. [b] Calculation method was adopted from GRNs 301 and 556.
[c] Calculated based on the minimum of 90% mogroside V in Luo Han Guo fruit extract.
BW=body weight; MV=mogroside V.

Table 4-11. Estimated Dietary Intakes (EDIs) of Luo Han Guo Fruit Extracts with 95% Mogroside (SweetMonk™ MV 95 - sweetness intensity 420)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day)[a]		EDI of SweetMonk™ MV 95 (mg/kg BW/day)[b]		EDI of mogroside V (mg/kg bw/day)[c]	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	0.61	1.6	0.58	1.53
Diabetic Adults	280	897	0.67	2.1	0.63	2.03
Healthy Children	425	990	1.0	2.4	0.96	2.23
Diabetic Children	672	908	1.6	2.2	1.52	2.05

[a] See Renwick, 2008. [b] Calculation method was adopted from GRNs 301 and 556.
[c] Calculated based on the minimum of 95% mogroside V in Luo Han Guo fruit extract.
BW=body weight; MV=mogroside V.

V. BASIS FOR GRAS DETERMINATION

V.A. Current Regulatory Status

USA

The FDA has issued 'no question' letters on four GRAS notifications related to food uses of Luo Han Guo fruit extract concentrates (GRN 301, FDA, 2010; GRN 359, FDA, 2011; GRN 522, FDA 2015a; GRN 556, FDA 2015b). The GRAS notices are summarized in Table 5.

Table 5. Summary of GRAS Notices

GRN (year of closure)	Mogroside V content, %	90th Pcercentile EDI of mogroside V	Intended use	Company
301 (2010)	30	2.97	As a sweetener and flavor enhancer in foods, excluding infant formula, meat and poultry products	BioVittoria, New Zealand
359 (2011)	25, 45, or 55	2.18	As a sweetener and flavor enhancer in foods, excluding infant formula, meat and poultry product	Guilin Layn Natural Ingredients Corp., China
522 (2014)	30, 50, or 60	2.12	As a table-top sweetener and as a sweetener in foods, excluding infant formula, meat, and poultry product	GLG Life Tech Corp., Canada
556 (2015a)	12.5, 20, 25, 30, 40, 50, 55, or 90	2.17	As a table-top sweetener and general purpose non-nutritive sweetener, and as a flavor modifier for use in foods other than infant formula and meat and poultry products	Hunan Huacheng Biotech, Inc., China
Present notice	7, 12.5, 20, 25, 30, 40, 50, 55, 60, 90, or 95	2.23	As a table top sweetener and general purpose non-nutritive sweetener and as a flavor modifier in foods, excluding infant formula, meat, and poultry products	Nutramax Inc., China

EDI=Estimated Dietary Intake. Max. EDI for mogroside V = 90th percentile intakes of mogroside V.

In GRN 301 (FDA, 2010), the subject of notification was a concentrate derived from Luo Han Guo fruit extracts (*S. grosvenori* Swingle) which was sold as PureLo® brand by BioVittoria (Hamilton, New Zealand). The primary components of the concentrate were mogrosides, with mogroside V constituting more than 30 % of the product. The powdered extracts were intended to be used as a component of sweetener blends that can be added to foods or used as tabletop sweeteners. In GRN 301, the estimated 90th percentile intake of Luo Han Guo fruit extracts (30% mogroside V) was determined as 6.8-9.9 mg/kg BW/day for an extracts 100 times sweeter than sugar and the 90th percentile EDI of the mogroside V (Luo Han Guo concentrate-30% mogroside V) was calculated as 2.04-2.97 mg/kg BW/day.

In GRN 359 (FDA, 2011), the subject of this GRAS notification was Luo Han Guo fruit extracts containing 25, 45, or 55% mogroside V. The powdered extracts were to be marketed under the trade name Go-Luo™ by Guilin Layn Natural Ingredients (Guangxi, China). The powdered extracts were intended to be used as general purpose sweeteners and flavor modifiers in various food products. In GRN 359, the sweetness of Luo Han Guo fruit extracts concentrate (25% mogroside V) was found to be 160 times sweeter than sucrose. The differences in the

relative sweetness of the products resulted from the refinement of the manufacturing process of Luo Han Guo fruit extracts. The sweetness indices of Nutramax's Luo Han Guo fruit extracts concentrates are similar to those described in GRN 339 and 556.

In June, 2014, GLG Life Tech Corporation submitted a GRAS notice (GRN 522) of Luo Han Guo fruit extract powders for use as a general purpose non-nutritive sweetener in various foods other than in infant formulas and in meat and poultry products (Date of closure: December 8, 2014; FDA 2014). Extracts are similar to those described in GRN 359 (up to 55% mogroside V) and to that described in GRN 301 (up to 30% mogroside V), but were more purified, containing up to 60% mogroside V.

In December, 2014, Hunan Huacheng Biotechnology, Inc., China, submitted a GRAS notice (GRN 556) of Luo Han Guo fruit extracts powder for use as a table-top sweetener and general purpose non-nutritive sweetener and as a flavor modifier in various foods other than in infant formulas and in meat and poultry products (date of closure: June 17, 2015; FDA, 2015a). Extracts are similar to the extracts described in GRN 301, 359, and 522, but were more purified, containing up to 90% mogroside V. In GRN 556, the EDIs for high consumers of Luo Han Guo fruit extracts were up to 12.4 mg/kg BW/day (product containing 12.5% mogroside V). The EDIs for high consumers of mogroside V for the general population, diabetic adults, healthy children, and diabetic children are up to 1.48, 1.97, 2.17, and 1.99 mg/kg BW/day, respectively. All predicted EDIs were less than 2.2 mg/kg BW/day, which is equivalent to less than 175 mg per 70 kg adult.

In this GRAS notice, extracts are similar to those described in GRN 359 (up to 55% mogroside V), GRN 301 (up to 30% mogroside V), GRN 522 (up to 60% mogroside V) and GRN 556 (up to 90% mogroside V), but are more purified, containing up to 95% mogroside V. In this GRAS notice, the EDIs of the mogroside V for high consumers are estimated to be up to 2.23 mg/kg BW/day.

The FDA did not have questions on the summary of safety concluding that Luo Han Guo fruit extracts intake up to 2.5 mg mogroside V/kg BW/day is safe. The FDA did not question the acceptability and suitability of these studies to establish the safety of Luo Han Guo fruit extract concentrates for the proposed food uses. The safety and related information in the above mentioned GRAS notices is hereby incorporated by reference to this independent GRAS determination.

The pertinent information is available as indicated below:
GRN
301: http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=301&sort=GRN_No&order=DESC&startrow=1&type=basic&search=luo%20han%20guo.

GRN 359:
http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=359&sort=GRN_No&order=DESC&startrow=1&type=basic&search=luo%20han%20guo

GRN 522:
http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=522&sort=GRN_No&order=DESC&startrow=1&type=basic&search=luo%20han%20guo.

GRN 556:
http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=556&sort=GRN_No&order=DESC&startrow=1&type=basic&search=luo%20han%20guo.

In addition, two New Dietary Ingredient (NDI) notifications were accepted by FDA with no objection for use of Luo Han Guo fruit extracts as a dietary supplement (FDA, 1996, 1999).

In 2015, the FDA issued 'Additional Information about High-Intensity Sweeteners Permitted for Use in Food in the United States' (FDA, 2015b). The agency included *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extracts (SGFE) in the high-intensity sweeteners and stated that 'High-intensity sweeteners are commonly used as sugar substitutes or sugar alternatives because they are many times sweeter than sugar but contribute only a few to no calories when added to foods. High-intensity sweeteners, like all other ingredients added to food in the United States, must be safe for consumption.' (FDA, 2015b).

Joint FAO/WHO Food Standards Programme

In March 2012, monk fruit extract/Luo Han Guo/SGFE was included on the priority list for the 44th session of the Codex Committee on Food Additives, JEFCA Standards Programme held in Hangzhou, China. The questions before the committee included those of safety assessment and establishment of specifications (FAO/WHO, 2012). In March 2014, the 46th session of the JECFA Standards Program/Codex Committee on Food Additives, maintained Luo Han Guo fruit extracts on the priority list of substances proposed for evaluation, as proposed by the U.S. (FAO/WHO, 2014).

Health Canada

On March 14, 2013, Health Canada proposed adding monk fruit extracts to the *List of Permitted Sweeteners*. Monk fruit was added to Health Canada's List of Permitted Sweeteners on December 2, 2013 as Item M.4. Monk fruit extracts or Luo Han Guo fruit extracts was authorized for use in Canada as a table-top sweetener at a maximum use level of 0.8% calculated as mogroside V (Health Canada, 2013).

V.B. Review of Safety Data

As noted above, the FDA has issued 'no question' letters on four GRAS notices related to food uses of Luo Han Guo fruit extracts. As the Luo Han Guo fruit extracts in this GRAS determination are similar in specifications compared to the other Luo Han Guo fruit extracts in the FDA GRAS notices, it is recognized that the information and data in the other GRAS notices are pertinent to the safety of the Luo Han Guo fruit extracts in this GRAS determination. Therefore, this notice incorporates by reference the safety and metabolism studies discussed in previous GRNs. Additionally, this notice discusses an additional animal study that has been published since the FDA's last reviews of 2015. The subject of the present GRAS assessment is Luo Han Guo fruit extracts (powder form).

V.B.1. Metabolism of Luo Han Guo Fruit Extracts

Since the FDA's last completed review in 2015, one animal metabolism study of mogroside V has been published. Thus, this GRAS notice includes this additional metabolism study in animals.

Murata et al. (2010) examined the metabolism of mogroside V in 10 week old Wistar rats (4-6 rats per group). The rats were given free access to a standard pellet diet and water. After 16 hours of fasting, they were orally administered 1 ml of *Siraitia grosvenori* (Swingle) glycoside (SG-gly containing 72% mogroside V, 117 mg/ml) powder in solution. After 2 hours, the contents of the small intestine and portal blood were collected. After 24 hours, feces were collected. The distributions of mogroside V and its metabolites were analyzed in the small intestine, portal blood, and whole blood after a single ingestion of SG-gly. When administered to rats, mogroside V was mostly degraded by digestive enzymes and intestinal microflora, and was excreted in the feces as mogrol (aglycone) and its mono- and diglucosides. The amount of mogrosides found in the feces was equivalent to 61% of the administered mogroside V, and no SG triterpenoids were found excreted in the urine. Most of the orally ingested mogroside V is excreted without absorption. As no SG triterpenoids were detected in whole blood, the absorbed amount of SG-gly and its metabolites was very low. Trace amounts of mogrol and its monoglucoside were found in the portal blood as sulfates and/or glucuronide conjugates.

A study by Xu et al. (2015) confirmed the previous finding (Murata et al., 2010) that most of mogroside metabolites are excreted in feces. The total peak area of mogroside V metabolites in feces was 182 times higher than that of urine suggesting that the metabolite. However, the peak area of mogroside V in feces was only approximately 0.13% of that of urine (29747017), implying that mogroside V was mainly excreted in the urine.

Taken together, it appears that most of the orally administered mogroside V is excreted without absorption.

V.B.2. Mutagenicity and Genotoxicity Studies

Since the FDA's last review in 2015, no new mutagenicity studies have been published. Thus, this GRAS notice summarizes the studies already reviewed in previous GRAS notices. In the previous GRAS notices to the FDA, the safety of Luo Han Guo fruit extracts has been established in mutagenicity and genotoxicity studies.

As described in GRN 359, an Ames test (Ames et al., 1975) was conducted at Huntingdon Life Sciences (2009a; HLS Study No. HUD0D72) to assess Luo Han Guo fruit extract for its ability to cause point mutation in *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100 as well as in *Escherichia coli* strain WP2*uvr*A. Five concentrations separated by approximately half-$\log_{10}$ intervals were tested, with a maximum of 5,000 μg of mogroside V per plate with and without S9 activation. In addition to the test article, strains were assayed with an aqueous negative control and with positive controls. No cytotoxic activity was observed at the concentrations tested. There were no substantial increases in revertant colony numbers over aqueous control counts at any concentration tested, with or without S9 mix. Under those test conditions, Luo Han Guo fruit extract did not exhibit any cytotoxic or mutagenic potential.

V.B.3. Animal Toxicity Studies

Since the FDA's last completed review of 2015, no new animal toxicity studies have been published. Thus, this GRAS notice summarizes the studies already reviewed in previous GRAS notices. The notified substances in this notice are Luo Han Guo fruit extracts at varying concentrations of mogroside V, thus, it included the safety studies of mogroside V as the basis of discussing the safety of Luo Han Guo fruit extract. Results of animal toxicity studies are summarized in Table 6.

Overall, studies found that the LD_{50} for an aqueous extract of *S. grosvenori* fruit and mogrosides are over 10 g/kg BW in mice (Lee, 1975). A compound that has a LD_{50} value over 5 g/kg BW in rodents is classified as 'practically nontoxic', and a compound with a LD_{50} value over 15 g/kg BW as 'relatively harmless' (Altug, 2003). According to this, Luo Han Guo fruit extract and mogrosides belong to the group with the lowest toxicity rating.

Table 6. Summary of Animal Toxicity Studies of Luo Han Guo Fruit Extracts

Species	Dose	Duration	NOAEL	Reference
Mice	Up to 2 g/kg BW Luo Han Guo fruit extract	Single dose	LD_{50} >2 g/kg BW Luo Han Guo fruit extract	Hussain et al., 1990;
Mice	Up to 2 g/kg BW mogroside V	Single dose	LD_{50} >2 g/kg BW mogroside V	Makapugay et al., 1985
Mice	Up to 10 g/kg BW Luo Han Guo fruit extract	Single dose	LD_{50} >10 g/kg BW Luo Han Guo fruit extract	Lee, 1975
Subacute toxicity				
6 Dogs (3M+3F)	Luo Han Guo fruit extract (30% mogroside V) at 0 or 3,000 mg/kg/day	28 days	3,000 mg/kg/day of Luo Han Guo fruit extract powder; or 900 mg/kg BW/day of mogroside V, the highest level tested	Qin et al., 2006
104 Sprague-Dawley rats	Luo Han Guo fruit extract at 0, 1, 3, or 10% of diet (containing 30% mogroside V)	4 weeks	M: 7,070 mg/kg/day F: 7,480 mg/kg/day for Luo Han Guo fruit extract powder; M: 2,310 mg /kg BW/day and F: 2,244 mg/kg BW/day for mogroside V, the highest level tested	Marone et al., 2008
Subchronic toxicity				
80 young adult Wistar Hannover rats	Luo Han Guo fruit extract at 0, 0.04, 0.2, 1, or 5% of diet.	13 weeks	Luo Han Guo fruit extract– M: 2,520 mg/kg BW/day F: 3,200 mg/kg BW/day	Jin et al., 2007
12 dogs	Luo Han Guo fruit extract powder (30% mogroside V) at 0 or 3,000 mg/kg/day	28 or 90 days	3,000 mg/kg BW/day of Luo Han Guo fruit extract powder; or 900 mg/kg BW/day of mogroside V	Qin et al. 2006
100 rats	Luo Han Guo fruit extract powder (30% mogroside V) at conc. of 0, 0.25, 0.5, 1.0, or 2.0% in water	90 days	2.0% Luo Han Guo fruit extract in water	Hirose, 1999
160 rats	0, 1.25, 2.5, or 5% Luo Han Guo fruit extract containing 55% mogroside V	90 days	Luo Han Guo fruit extract: M, 3,120 mg/kg BW/day, F- 3,750 mg/kg BW/day; Mogroside V: M- 1,717 mg/kg BW/day, F- 2,062 mg/kg BW/day	Huntingdon Life Science, 2009b

Adopted from GRN 556; M=male; F=female. BW=body weight.

A subacute study in rats found that the no observed adverse effect levels (NOAELs) for Luo Han Guo fruit extract were 7,070 mg/kg BW/day in males and 7,480 mg/kg/day in females and those for mogroside V were approximately 2,310 mg /kg BW/day in males and 2,244 mg/kg BW/day in females (Marone et al., 2008).

Subchronic studies reported that NOAELs for Luo Han Guo fruit extract were over 3,120 mg/kg BW/day and 3,750 mg/kg BW/day in male and female rats, respectively, and those of mogroside V were over 1,717 and 2,062 mg/kg BW/day in male and female rats, respectively (Huntingdon Life Science, 2009b).

V.B.3.1.Acute toxicity

The first reported acute toxicity testing of a Luo Han Guo fruit extract was conducted by Lee (1975). Luo Han Guo fruit extract was administered to male albino mice (10 mice/group) at doses up to 15 g/kg BW for 1 week. Although the mice transiently exhibited mild sedation and diarrhea at the dose of 15 g/kg BW, they appeared normal within 30-60 minutes. No mortalities were observed. The author reported the LD_{50} of Luo Han Guo fruit extract to be in excess of 10 g/kg BW in mice.

In an acute toxicity study in mice conducted by Makapugay et al. (1985), mogroside V isolated from a water-soluble Luo Han Guo fruit extract resulted in no mortality at doses up to 2 g/kg BW. The authors reported the LD_{50} to be greater than 2 g/kg BW and that the extract was not mutagenic.

Hussain et al. (1990) performed acute toxicity experiments of a Luo Han Guo fruit extract in male Swiss-Webster mice, ages 4-6 weeks. A single oral administration of Luo Han Guo fruit extract in 1% aqueous sodium carboxymethylcellulose was administered at doses of 1 or 2 g/kg BW. Animals were observed for toxicity and changes in body weight for 14 days. The authors reported that administration of Luo Han Guo fruit extract at doses up to 2 g/kg BW did not reveal changes in body weights or signs of toxicity. The LD_{50} was thus reported to be greater than 2 g/kg BW, the highest dose tested.

V.B.3.2. Subacute Toxicity

To test the safety of Luo Han Guo fruit extract powder (30% mogroside V), Qin et al. (2006) performed a 28 day oral study in dogs. Three dogs of each sex were assigned to 0 or 3,000 mg/kg BW/day. Administration of Luo Han Guo fruit extract did results in any adverse effects in measured clinical observations, body weight, food consumption, hematology, blood chemistry, urinalysis, gross necropsy, organ weight, or histopathology. The NOAEL for Luo Han Guo fruit extract powder was determined to be 3,000 mg/kg BW/day (or 900 mg /kg BW/day for mogroside V) in dogs.

Marone et al. (2008) examined the toxicity of Luo Han Guo fruit extract powder (30% mogroside V) in Hsd:Sprague Sawley (SD) rats in a 28 day study. Groups of 20 rats (10/sex/group) were fed diets containing 0, 1, 3, or 10% of Luo Han Guo fruit extract powder. Luo Han Guo fruit extract powder was well tolerated and produced no significant adverse effects. Statistically significant changes were found in clinical chemistry (decreased bilirubin, increased total protein) and relative organ weights of the liver, adrenals, ovaries, testes, and epididymides were not correlated with any histopathological findings and not considered adverse. While a few clinical and pathological findings suggested potential treatment-related effects, these findings were transient, inconsistent, non-adverse, not dose-dependent, and not supported by histopathological findings. The NOAEL was concluded to be 10.0% in the diet for Luo Han Guo fruit extract (30% mogroside V), which is equivalent to 7,070 mg/kg BW/day in males and 7,480 mg/kg BW/day in females. Based on these findings, the NOAEL for mogroside V could be 2,310 mg /kg BW/day in males and 2,244 mg/kg BW/day in females.

V.B.3.3. Subchronic Toxicity Studies

Jin et al. (2007) tested the toxicity of Luo Han Guo fruit extract (mogroside V content, not specified) with a 13-week repeated dose study performed on Wistar Hannover rats. Male and female rats were divided into five groups with eight rats each and given a diet consisting of 0%, 0.04%, 0.2%, 1%, or 5% Luo Han Guo fruit extract for 13 weeks. No deaths were observed and there were no significant changes reported in general appearance, body weight, food and water consumption, hematological and serum biochemical parameters, organ

weight, or histopathological findings between control and test groups. During the experimental period, an increasing or decreasing tendency of food and water consumption was sometimes observed in females of the 0.2–5% groups and males of the 5% group, as compared with the corresponding control group. However, these changes appeared to be attributable to the fact that some of the animals in these groups spilled food and water from the feeders and water bottles. In addition, there were no significant changes in body weight gain in these treated groups. Thus, these fluctuations are not considered to be due to the treatment of *S. grosvenori* extract. In hematological examinations, a significant increase in the ratio of stab cells and monocytes was observed in males of the 1% and 5% groups. However, the changes were very small in their fluctuation range, and there were no remarkable changes in the total count of white blood cells in any of the treated groups. Therefore, these findings were not regarded as a treatment-related change. In serum biochemical examinations, a significant increase in total cholesterol level (62.0 ± 10.9 mg/dl) was observed in females of the 5% group. However, the values were very close to the normal range of the historical background data (62.7 ± 9.4 mg/dl) of Wistar Hannover rats. In addition, the serum biochemistry showed a significant decrease in inorganic phosphate in females of the 5% group. However, the serum level of inorganic phosphate in the 5% group (4.7 ± 0.4 mg/dl) was very close to the normal range of historical data (4.6 ± 0.5 mg/dl). Therefore, these fluctuations are considered to be of no toxicological significance. The authors concluded that there were no toxic changes related to the administration of *S. grosvenori* extract in rats given 5% of diet and that the NOAEL (no-observed-adverse effect level) of this extracts in Wistar Hannover rats was estimated to be 5% (corresponding to 2,520 mg/kg/day in males and 3,200 mg/kg/day in females) or more. The authors indicated that *S. grosvenori* extract would not induce any serious toxic changes to consumers by the ingestion of this extracts via food.

To test the safety of Luo Han Guo fruit extract containing 30% mogroside V, Qin et al. (2006) performed a 90-day oral study in dogs. Three dogs of each sex were assigned to 0 or 3,000 mg/kg BW/day. The Luo Han Guo fruit extract was well tolerated and did not produce any general organ or systemic toxicity when fed via gavage to male and female dogs at a dose of 3,000 mg/kg BW/day over a period of 90 days. There were no significant effects on clinical signs or organ weights and no histological changes considered to be related to treatment. There were no consistent, adverse, or clinically relevant changes in hematology, clinical biochemistry, or urinalysis parameters at 90-day terminal time points. The authors concluded that the NOAELs were 3,000 mg/kg BW/day for Luo Han Guo fruit extracts or 900 mg/kg BW/day for mogroside V.

Hirose (1999) administered a Luo Han Guo fruit extract containing 30% mogroside V to rats in the form of a reddish brown solid paste dissolved in tap water. Five groups of ten male and ten female 6-week old rats were given access to drinking water that contained Luo Han Guo fruit extract at concentrations of 0%, 0.25%, 0.5%, 1.0%, or 2.0% for 90 days. The amount of water ingested and the body weights of the animals were recorded to calculate dose levels. No significant differences were attributable to the test material during the experiment, and no significant changes in water intake, body weights or internal organs, biochemical serum values (serum total protein, albumin, albumin/globulin ratio, bonded nitrogen, creatinine, inositol, phosphoric acid, alkaline phosphatase, aspartate transaminase, alanine transaminase, total cholesterol, and total glycerides), serum mineral content, hematology or histopathological findings were found when the test groups were compared to the control.

In GRN 359, a 90-day oral rat toxicity study of Luo Han Guo fruit extracts containing 55% mogroside V was described (Huntingdon Life Science, 2009b). Four groups each of 20 male and 20 female Crl:CD® (SD) IGS BR rats were fed either 0 (control), 1.25, 2.5, or 5% of Luo Han Guo fruit extracts containing 55% mogroside V for 90 days. No treatment-related mortality was observed and no significant differences in body weights or food consumption during the dosing and recovery periods were reported. There were no significant effects in hematology, serum chemistry findings, or histopathological observations in any tissue samples or organs. Therefore, the NOAEL for Luo Han Guo fruit extracts powder was considered to be a dietary concentration of 5% (corresponding to 3,120 mg/kg BW/day in males and 3,750 mg/kg BW/day in female rats), the highest dose tested. Corresponding NOAELs for mogroside V were determined to be 1,717 and 2,062 mg/kg BW/day in male and female rats, respectively.

V.B.4. Animal Efficacy Studies

Since the FDA's last completed review in 2015, no new animal efficacy studies have been published. Thus, this GRAS notice summarizes the studies already reviewed in previous GRAS notices.

Di et al. (2011) assessed the anti-inflammatory properties of mogrosides in a murine ear edema model. Results showed that mogrosides inhibited 12-O-tetradecanoylphorbol-13-acetate-induced inflammation by down-regulating COX-2 and IL-6 and up-regulating PARP1, BCL2l1, TRP53, MAPK9, and PPARδ gene expression.

Shi et al. (2014) reported protective effects and mechanisms of mogroside V on lipopolysaccharide-induced acute lung injury in mice. Female BALB/c mice were treated with commercial mogroside V (2.5, 5, and 10 mg/kg) for 1 h prior to intranasal injection of lipopolysaccharide (10 μg in 50 μl). After 12 h, airway inflammation in the acute lung injury model was determined by the wet/dry weight ratio, myeloperoxidase activity of lung tissue, leukocyte recruitment, and cytokine levels in the bronchoalveolar lavage fluid. Additionally, lung tissue was examined by histology and western blotting to investigate the changes in pathology and the signaling in the presence and absence of mogroside V. Mogroside V at 5 and 10 mg/kg BW inhibited airway inflammation induced by lipopolysaccharide as measured by the decrease in the histological changes (44 and 67.3% reduction in lung injury score, respectively), a 28.9 and 55.3% reduction in lung myeloperoxidase activity, and inflammatory cell counts, interleukin-1β (IL-1β, 382 and 280 pg/ml, respectively), IL-6 (378 and 232 pg/ml, respectively), and tumor necrosis factor-α (TNF-α, 12.5 and 7.8 ng/ml, respectively) levels in the bronchoalveolar lavage fluid. Additionally, mogroside V treatment reduced the activation of cyclooxygenase 2 (COX-2), iNOS, and the nuclear factor (NF)-κB. The authors suggest that mogroside V has the potential to protect against lipopolysaccharide-induced airway inflammation in a model of acute lung injury.

Wang et al. (2014) reported that cucurbitane glycosides derived from mogroside IIE, a bitter triterpenoid saponin which is the main component of unripe Luo Han Guo fruit and a precursor of mogroside V, have antioxidant activity.

V.B.5. Human Clinical Studies

Since the FDA's last completed review in 2015, no new human clinical studies have been published. Thus, this GRAS notice summarizes the studies already reviewed in previous GRAS notices (Table 7). Two unpublished clinical studies (Xu et al., 2005a and 2005b) with Luo Han Guo fruit extracts were reported in GRN 301.

Xu et al. (2005a) assessed the comparative effect of consumption of Luo Han fruit concentrate containing 30% mogroside V on blood glucose concentration in a crossover design. After fasting overnight, 5 healthy men and 5 healthy women aged 19-25 years consumed 200 mg/kg BW of the Luo Han Guo fruit extract concentrate (30% mogroside V) dissolved in water. Their blood glucose levels were tested at 0, 15, 30, 60, 120, and 180 minutes after dosing. Ingestion of Luo Han Guo fruit extract concentrate had no effect on blood glucose. No adverse effects of Luo Han Guo fruit extract were reported.

Xu et al. (2005b) used a similar crossover design to assess the effect of Luo Han Guo fruit extract concentrate containing 30% mogroside V and that of water on blood levels of liver enzymes. Six healthy males aged 19-25 years fasted overnight and then consumed 200 mg/kg BW of Luo Han Guo fruit extract concentrate dissolved in water. Three days later they consumed only water. On both days, blood samples were taken at 0, 1, 2, 3, and 6 hours after administration and no significant changes were observed in 5 liver enzymes; alkaline phosphatase, gamma-glutamyl transpeptidase, alanine aminotransferase, aspartate aminotransferase, and lactate dehydrogenase. No adverse effects of Luo Han Guo fruit extract were reported.

Table 7. Summary of Human Studies of Luo Han Guo Fruit Extracts

Subjects	Daily dose	Duration	Measurement	Reference
5 healthy men and 5 healthy women aged 19-25 years	Day 1-200 mg/kg BW of Luo Han Guo fruit extract concentrate (30% mogroside V); Day 4-3000 mg/kg BW	2 doses; crossover design	No significant effects on fasting glucose concentrations observed up to 3 h after each dose	Xu et al., 2005a
Six healthy males aged 19-25 years	Day 1-200 mg/kg BW of Luo Han Guo fruit extract concentrate (30% mogroside V); Day 4-water	Single dose; crossover design	5 liver enzymes	Xu et al., 2005b

Adopted from GRNs 556 and 301. BW=body weight.

VI. SAFETY DETERMINATION

Numerous human and animal studies have reported benefits of Luo Han Guo fruit extracts with varying concentrations of mogroside V with no major adverse effects. Nutramax uses a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications. There is broad-based and widely disseminated knowledge concerning the chemistry of mogroside V, a major active component of Lou Han Guo fruit extract. This GRAS determination is based on the data and information generally available and consented opinion about the safety of Luo Han Guo fruit extract. The literature indicates that Luo Han Guo fruit extracts offers consumers benefits without adverse effects.

The following safety evaluation fully considers the composition, intake, nutritional, microbiological, and toxicological properties of Luo Han Guo fruit extracts as well as appropriate corroborative data.

1. Nutramax's Luo Han Guo fruit extracts concentrates (powder form) are manufactured under current Good Manufacturing Practices (cGMP) using common food industry materials and processes.
2. Analytical data from multiple lots indicate that the Luo Han Guo fruit extracts powders comply reliably with the established food-grade product specifications and meet all applicable purity standards.
3. Nutramax's Luo Han Guo fruit extracts will be used as a table-top sweetener and as a general purpose non-nutritive sweetener or a flavor modifier in various foods other than in infant formulas and in meat and poultry products. Intended use is the same as that was described in GRNs 301, 359, 522 and 556. Due to the characteristic intense sweet flavor of the fruit and its derivatives, use is expected to be self-limiting.
4. The exposure estimates, estimated dietary intakes (EDI), under the intended use are estimated to be up to 2.2 mg mogroside V/kg BW/day for high consumers. The EDIs for Luo Han Guo fruit extracts ranged from 1.6 to 22 mg/kg BW/day, depending on the concentration of mogroside V in each Luo Han Guo fruit extracts product. These levels are far below the reference dose safe for human exposure. In addition, subchronic studies reported that NOAELs for Luo Han Guo fruit extracts were over 3,120 mg/kg BW/day and 3,750 mg/kg BW/day in male and female rats, respectively, and those of mogroside V were over 1,717 and 2,062 mg/kg BW/day, respectively.
5. The EDI estimates are based on the assumption that Nutramax's Luo Han Guo fruit extracts will replace currently marketed Luo Han Guo fruit extract. Thus, cumulative exposures are not expected. In addition, the EDIs presented in this notice are highly optimistic estimates.
6. In the previous GRAS notices (GRNs 301, 359, 522 and 556) to the FDA, the safety of Luo Han Guo fruit extracts had been established in toxicological studies in animals, mutagenicity studies, and is further supported by clinical studies in humans. The FDA responses to GRAS notifications on Luo Han Guo fruit extracts indicate that the FDA is satisfied with the safety-in-use of the Luo Han Guo fruit extract, as long as consumption is 2.5 mg mogroside V/kg BW/day. Furthermore, historical consumption of Luo Han Guo fruit extracts support the safety of Luo Han Guo fruit extract.
7. Additional animal studies published subsequent to the FDA GRAS notices continue to support the safety of Luo Han Guo fruit extracts as a food ingredient.

VII. CONCLUSIONS AND GENERAL RECOGNITION OF THE SAFETY OF LUO HAN GUO (*SIRAITIA GROSVENORI*) FRUIT EXTRACTS (SWEETMONK™)

The intended use of Luo Han Guo (*Siraitia grosvenori*) fruit extracts (SweetMonk™; powder form) has been determined to be safe though scientific procedures as set forth in 21 CFR 170.3(b), thus satisfying the so-called "technical" element of the Generally Recognized as Safe (GRAS) determination. In addition, because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

On behalf of Hunan NutraMax Inc., (Nutramax), we, the undersigned expert panel members, Susan S. Cho, Ph.D., Robert L. Martin, Ph.D., and George C. Fahey, Jr., Ph.D. have independently evaluated the materials summarized in the Luo Han Guo fruit extracts GRAS report. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to foods. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that Luo Han Guo fruit extracts (SweetMonk™), produced consistent with current Good Manufacturing Processes and meeting the specifications described herein, are safe under its intended conditions of use (as a table-top sweetener and general purpose non-nutritive sweetener as defined in 21 CFR 170.3(o)(19) and as a flavor modifier in foods).

The Expert Panel further unanimously concludes that the intended use of Luo Han Guo fruit extracts is GRAS based on scientific procedures, and other experts qualified to assess the safety of food and food ingredients would concur with these conclusions.

_____ _____

Susan Cho, Ph.D. Date
NutraSource, Inc., Clarksville, MD 21029

_____ _____

Robert L. Martin, Ph.D. Date

_____ _____

George C. Fahey, Jr, Ph.D. Date
Professor Emeritus, University of Illinois, Urbana, IL 61801

VII. CONCLUSIONS AND GENERAL RECOGNITION OF THE SAFETY OF LUO HAN GUO (*SIRAITIA GROSVENORI*) FRUIT EXTRACTS (SWEETMONK™)

The intended use of Luo Han Guo (*Siraitia grosvenori*) fruit extracts (SweetMonk™; powder form) has been determined to be safe though scientific procedures as set forth in 21 CFR 170.3(b), thus satisfying the so-called "technical" element of the Generally Recognized as Safe (GRAS) determination. In addition, because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

On behalf of Hunan NutraMax Inc., (Nutramax), we, the undersigned expert panel members, Susan S. Cho, Ph.D., Robert L. Martin, Ph.D., and George C. Fahey, Jr., Ph.D. have independently evaluated the materials summarized in the Luo Han Guo fruit extract GRAS report. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to foods. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that Luo Han Guo fruit extracts (SweetMonk™), produced consistent with current Good Manufacturing Processes and meeting the specifications described herein, are safe under its intended conditions of use (as a table-top sweetener and general purpose non-nutritive sweetener as defined in 21 CFR 170.3(o)(19) and as a flavor modifier in foods).

The Expert Panel further unanimously concludes that these uses of Luo Han Guo fruit extracts are GRAS based on scientific procedures, and other experts qualified to assess the safety of food and food ingredients would concur with these conclusions.

(b) (6)

2/1/2016

Susan Cho, Ph.D.
NutraSource, Inc.

Date

(b) (6)

Jan. 29, 2016

Robert L. Martin, Ph.D.

Date

(b) (6)

1/20/16

George C. Fahey, Jr, Ph.D.
Professor Emeritus, University of Illinois, Urbana, IL 61801

Date

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APPENDIX A. CERTIFICATES OF ANALYSIS

Certificate of Analyses of LUO HAN GUO FE95% Mogroside V

Lot No.LHG-150528

Product Name: LUO HAN GUO FE95% Mogroside V Latin Name:*Siraitia grosvenorii* (Swingle) C. Jeffrey Manufacture Date:May.28,2015; Testing Date:Jun.1,2015; Expire Date:May.27,2017; Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Acutal value
Mogroside V	≥ 95%	HPLC	90.83%
Identification	Positive	TLC	Conforms
Color	White	GB/T[1] 5492-2008	Conforms
Odor	Mild Fruity: Characteristic	GB/T 5492-2008	Conforms
Taste	Sweet	GB/T 5492-2008	Conforms
Sieve Analysis	> 95% pass 80 mesh	USP 37	100%
Method of Extraction	Water	/	Conforms
solubility	Fully soluble in water	NLS 02.65.00	Conforms
Moisture Content	< 5.0%	GB/T 5009.3-2010	1.85%
Ash	< 5.0%	AOAC 942.05,17th	1.24%
Arsenic (As)	< 1ppm	AOAC 2013.06	0.11ppm
Cadmium(Cd)	< 1ppm	AOAC 2006.03	0.04ppm
Lead (Pb)	< 1ppm	AOAC 2006.03	0.15ppm
Mercury(Hg)	< 0.1ppm	AOAC 993.14	0.06ppm
Residual Ethanol	< 50 ppm	USP37	3 ppm
Total Plate Count	< 1000cfu/ml	CP 2010	160
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100cfu/g	CP 2010	24
E.Coli	Negative	CP 2010	Negative
Staphylococcus	Negative	CP 2010	Negative
1. GB/T=Recommended Chinese National Standard 2. CP 2010=Chinese Pharmacopoeia 2010 3. cfu=Colony Forming Units			

Analyst (b) (6) QC (b) (6) QA (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150621	**Manufacture Date**	June 21, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	June 28, 2015
Ananlysis:	500 Kg	**Report Date**	July 1, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT7% Mogrosides	7.41%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.39%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.17%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
ExpirationDate	June 20, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150714	**Manufacture Date**	July 14, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	July21, 2015
Ananlysis:	500 Kg	**Report Date**	July24, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT7% Mogrosides	7.45%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.45%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.38%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	July 13, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150516	**Manufacture Date**	May 16, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	May 23, 2015
Ananlysis:	500 Kg	**Report Date**	May 26, 2015
Analysis Item	Specification	Result	Test Method
ve Ingredeints			
Assay	NLT7% Mogrosides	7.35%	HPLC
sical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.41%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.36%	AOAC 942.05,17th
mical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
robiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
king and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	May 15, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	LUO HAN GUO FE	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150802	**Manufacture Date**	August 2, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	August 9, 2015
Ananlysis:	500 Kg	**Report Date**	August 12, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT12.5% Mogrosides	12.64%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.35%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.14%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	August 1, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150719	**Manufacture Date**	July 19, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	July 26, 2015
Ananlysis:	500 Kg	**Report Date**	July 29, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT12.5% Mogrosides	12.67%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.16%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.05%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	July 18, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150618	**Manufacture Date**	June 18, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	June 25, 2015
Ananlysis:	500 Kg	**Report Date**	June 28, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT12.5% Mogrosides	12.62%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.37%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.25%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	June 17, 2015		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	LUO HAN GUO FE	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150709	**Manufacture Date**	July 9, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	July 16, 2015
Ananlysis:	500 Kg	**Report Date**	July 19, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT20% Mogrosides	20.52%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.48%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.15%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	July 8, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150913	**Manufacture Date**	September 13, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	September 20, 2015
Ananlysis:	500 Kg	**Report Date**	September 23, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT20% Mogrosides	20.57%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.31%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.12%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	September 12, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-151016	**Manufacture Date**	October 16, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	October 23, 2015
Ananlysis:	500 Kg	**Report Date**	October 26, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT20% Mogrosides	20.61%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.52%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.67%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	October 15, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150711	**Manufacture Date**	July 11, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	July 18, 2015
Ananlysis:	500 Kg	**Report Date**	July 21, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT25% Mogrosides	25.50%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.24%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.09%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	July 10, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150827	**Manufacture Date**	August 27, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	September 3, 2015
Ananlysis:	500 Kg	**Report Date**	September 6, 2015
Analysis Item	Specification	Result	Test Method
tive Ingredeints			
Assay	NLT25% Mogrosides	25.61%	HPLC
ysical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.14%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.05%	AOAC 942.05,17th
emical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
crobiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
cking and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	August 26, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150528	**Manufacture Date**	May 28, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	June 4, 2015
Ananlysis:	500 Kg	**Report Date**	June 7, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT25% Mogrosides	25.41%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.19%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.13%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	May 27, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150821	**Manufacture Date**	August 21, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	August 28, 2015
Ananlysis:	500 Kg	**Report Date**	August 31, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT30% Mogrosides	30.49%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	Light Yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.69%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.47%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	August 20, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150926	**Manufacture Date**	September 26, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	October 3, 2015
Ananlysis:	500 Kg	**Report Date**	October 6, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT30% Mogrosides	30.57%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	Light Yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.83%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.77%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	September 25, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150619	**Manufacture Date**	June 19, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	June 26, 2015
Ananlysis:	500 Kg	**Report Date**	June 29, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT30% Mogrosides	30.62%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	Light Yellow	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.65%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.74%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	June 18, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150819	**Manufacture Date**	August 19, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	August 26, 2015
Ananlysis:	500 Kg	**Report Date**	August 29, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT40% Mogrosides	40.36%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.12%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.08%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	August 18, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150906	**Manufacture Date**	September 6, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	September 13, 2015
Ananlysis:	500 Kg	**Report Date**	September 16, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT40% Mogrosides	40.26%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.09%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.11%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	September 5, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150925	**Manufacture Date**	September 25, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	October 2, 2015
Ananlysis:	500 Kg	**Report Date**	October 5, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT40% Mogrosides	40.41%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.23%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.01%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	September 24, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150618	**Manufacture Date**	June 18, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	June 25, 2015
Ananlysis:	500 Kg	**Report Date**	June 28, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT50% Mogrosides	50.62%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	1.98%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.12%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	June 17, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150629	**Manufacture Date**	June 29, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	July 6, 2015
Ananlysis:	500 Kg	**Report Date**	July 9, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT50% Mogrosides	50.73%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	1.89%	GB/T 5009.3-2010
Ash	NMT 5.0%	1.95%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	June 28, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150723	**Manufacture Date**	July 23, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	July 30, 2015
Ananlysis:	500 Kg	**Report Date**	August 2, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT50% Mogrosides	50.66%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.01%	GB/T 5009.3-2010
Ash	NMT 5.0%	1.95%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	July 22, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	LUO HAN GUO FE	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150528	**Manufacture Date**	May 28, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	June 4, 2015
Ananlysis:	500 Kg	**Report Date**	June 7, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT55% Mogrosides	55.63%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.17%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.10%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	May 27, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150716	**Manufacture Date**	July 16, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	July 23, 2015
Ananlysis:	500 Kg	**Report Date**	July 26, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT55% Mogrosides	55.75%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.42%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.03%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	July 15, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150823	**Manufacture Date**	August 23, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	August 30, 2015
Ananlysis:	500 Kg	**Report Date**	September 2, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT55% Mogrosides	55.86%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.02%	GB/T 5009.3-2010
Ash	NMT 5.0%	1.93%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	August 22, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150718	**Manufacture Date**	July 18, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	July 25, 2015
Ananlysis:	500 Kg	**Report Date**	July 28, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT60% Mogrosides	60.53%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	2.21%	GB/T 5009.3-2010
Ash	NMT 5.0%	2.06%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	July 17, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150823	**Manufacture Date**	August 23, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	August 30, 2015
Ananlysis:	500 Kg	**Report Date**	September 2, 2015
Analysis Item	Specification	Result	Test Method
tive Ingredeints			
Assay	NLT60% Mogrosides	60.61%	HPLC
ysical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	1.89%	GB/T 5009.3-2010
Ash	NMT 5.0%	1.83%	AOAC 942.05,17th
emical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
crobiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
cking and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	August 23, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150920	**Manufacture Date**	September 20, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	September 27, 2015
Ananlysis:	500 Kg	**Report Date**	September 30, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT60% Mogrosides	60.56%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	1.92%	GB/T 5009.3-2010
Ash	NMT 5.0%	1.85%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	September 19, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	LUO HAN GUO FE	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150617	**Manufacture Date**	June 17, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	June 24, 2015
Ananlysis:	500 Kg	**Report Date**	June 27, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT90% Mogrosides	90.76%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	1.01%	GB/T 5009.3-2010
Ash	NMT 5.0%	0.89%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	June 16, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150724	**Manufacture Date**	July 24, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	July 31, 2015
Ananlysis:	500 Kg	**Report Date**	August 3, 2015
Analysis Item	Specification	Result	Test Method
tive Ingredeints			
Assay	NLT90% Mogrosides	90.83%	HPLC
ysical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	0.98%	GB/T 5009.3-2010
Ash	NMT 5.0%	0.87%	AOAC 942.05,17th
emical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
crobiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
cking and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	July 23, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150918	**Manufacture Date**	September 18, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	September 25, 2015
Ananlysis:	500 Kg	**Report Date**	September 28, 2015
Analysis Item	Specification	Result	Test Method
tive Ingredeints			
Assay	NLT90% Mogrosides	90.75%	HPLC
ysical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	0.93%	GB/T 5009.3-2010
Ash	NMT 5.0%	0.78%	AOAC 942.05,17th
emical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
crobiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
cking and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	September 17, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150816	**Manufacture Date**	August 16, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	August 23, 2015
Ananlysis:	500 Kg	**Report Date**	August 26, 2015
Analysis Item	Specification	Result	Test Method
tive Ingredeints			
Assay	NLT95% Mogrosides	95.88%	HPLC
ysical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	0.63%	GB/T 5009.3-2010
Ash	NMT 5.0%	0.23%	AOAC 942.05,17th
emical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
crobiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
cking and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	August 15, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	LUO HAN GUO FE	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-150913	**Manufacture Date**	September 13, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	September 20, 2015
Ananlysis:	500 Kg	**Report Date**	September 23, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT95% Mogrosides	95.79%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	0.58%	GB/T 5009.3-2010
Ash	NMT 5.0%	0.25%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative in 10 g	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative in 1g	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	September 12, 2017		

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	LUO HAN GUO FE	**Country of Origin:**	P. R. China
Latin Name:	Momordica Grosvenori Swingle	**Type of extraction:**	Ethanol & Water
Batch No:	LHG-151008	**Manufacture Date**	October 8, 2015
Plant Part:	Fruit (Fresh, 100% Natural)	**Analysis Date**	October 15, 2015
Ananlysis:	500 Kg	**Report Date**	October 18, 2015
Analysis Item	Specification	Result	Test Method
Active Ingredeints			
Assay	NLT95% Mogrosides	95.86%	HPLC
Physical Control			
Identification	Positive	Conforms	TLC
Appearance	White	Conforms	GB/T 5492-2008
Odor	Characteristic	Conforms	GB/T 5492-2008
Taste	Characteristic	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	80 Mesh Screen
Solubility	Soluble in Water	Conforms	GB/T 5009.3-2010
Moisture Content	NMT 5.0%	0.61%	GB/T 5009.3-2010
Ash	NMT 5.0%	0.24%	AOAC 942.05,17th
Chemical Control			
Residual ethanol	<50 ppm	Conforms	USP 37
Mercury(Hg)	NMT 0.1ppm	Conforms	AOAC 993.14
Arsenic (As)	NMT 1ppm	Conforms	AOAC 2013.06
Cadmium(Cd)	NMT 1ppm	Conforms	AOAC 2006.03
Lead (Pb)	NMT 1ppm	Conforms	AOAC 2006.03
Microbiological Control			
Total Plate Count	1000cfu/ml Max	Conforms	CP 2010
Salmonella	Negative	Conforms	CP 2010
Yeast & Mold	100cfu/g Max	Conforms	CP 2010
E.Coli	Negative	Conforms	CP 2010
Packing and Storage			
Packing	25kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years .		
Expiration Date	October 7, 2017		

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