

GRAS Notice (GRN) No. 556

<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm>

ORIGINAL SUBMISSION

1570

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November 24, 2014

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 EXTRACTS

Dear Dr. Antonia Mattia:

On behalf of Hunan Huacheng Biotech, Inc.[®] (HBI), we are submitting for FDA review a GRAS notification for Luo Han Guo 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.
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Agent for HBI

enclosure

Greenfruit™ MV 40;
Greenfruit™ MV 50;
Greenfruit™ MV 55; and
Greenfruit™ MV 90.

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 12.5 - 90% mogroside V. These products are similar to the products described in GRNs 301 and 359 for which FDA has issued “no question” letters.

Luo Han Guo, or *Siraitia grosvenori* (Swingle) fruit, a traditional Chinese medicine and edible fruit. The primary components of crude Luo Han Guo 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 (Lee, 1975). 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(1-2)]-[beta-D-glucopyranosyl (1 -6)]-beta-Dglucopyranoside):
CAS # 88901-36-4. Molecular Formula: C₆₀H₁₀₂O₂₉; 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

HBI's Luo Han Guo Extract Powders are manufactured in a principle similar to that described in FCC. However, HBI's manufacturing process employs more purification processes to produce highly purified products (HBI vs. FCC: up to 90-92% vs. 30% mogroside V) under cGMP.

1. Select the good Luo Han Guo fruit and saccharify the fruit at room temperature for 15 to 30 days.
2. Select the fruit which has more than 80% yellow surface area. Then mechanically press and crush the fruit.
3. Extract for 60 minutes at 70°C with deionized water three times. Gather all the extract solutions. Divide the solution into 2 portions. Use one portion in step 4, where it will undergo further purification and concentrate the other portion to 15-20% solid content with a vacuum drier. This produces the first product, 3% Mogroside V powder.
4. Heat the solution from step 3 to 100°C, then cool it down. Centrifuge the solution by disc centrifuge to precipitate protein. Filter the supernatant through ceramic membrane to remove the large molecules of pectin.

5. Pass the supernatant through a D101 resin (divinyl benzene copolymer) column, where it is desorbed by 60% ethanol. Collect the desorption solution.
6. Recycle the ethanol from the desorption solution, and then divide the solution into 2 portions. Use one portion in step 7, where it will undergo further purification. Concentrate the other portion to 15-20% solid content with a vacuum system and dried it with a vacuum drier. This produces the second product, 26-33% Mogroside V powder.
7. Pass the solution from step 6 through LSA700 resin column which adsorbs the colored melanoidin compounds and other compounds in the solution. Collect the decolorized solution and then filter the solution through a nanofiltration membrane for desalination.
8. Concentrate the solution to 15-20% solid content by vacuum system and dried it with a vacuum drier. This is the third product, 48-60% Mogroside V powder. Divide the powder into 2 portions. Use one portion in step 9 and the other one will undergo further purification and vacuum drying to the fourth product, 90-92% Mogroside V powder.
9. The process produces 4 products with varying mogroside V concentrations: 1) 3%, 2) 26-33%, 3) 48-60%, and 4) 90-92%. By blending different proportions of the products, one can produce the specified content of Mogroside V (e.g., 12.5%, 20%, 25%, 30%, 40%, 50%, 55% and 90% Mogroside V powder).

The food grade ethanol used in the purification process complies with FCC's 8th Edition specifications. The ion exchange resins and adsorption polymeric resins used in the manufacturing process comply with 21 CFR 173.25.

D.3. Specifications

As shown in Tables 1-1 - 1-8, HBI has established the specifications for the minimum mogroside content as well as the maximum microbiological and heavy metal levels for its Luo Han Guo extracts. The HBI's specifications on heavy metals are more conservative than FCC's (HBI vs. FCC: Arsenic, <0.2 vs. <0.5 ppm; lead, <0.5 vs <1 ppm; Cadmium, <0.15 vs. <1 ppm) The two specifications are comparable for ash and moisture.

Table 1-1. Specifications for Luo Han Guo Extract 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, 17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06

Cadmium(Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury(Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia.

Table 1-2. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-3. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-4. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-5. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury(Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-6. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010

<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	<100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-7. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15ppm	AOAC 2006.03
Lead (Pb)	< 0.5ppm	AOAC 2006.03
Mercury (Hg)	< 0.1ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 1-8. Specifications for Luo Han Guo Extract 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)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

E. Applicable Conditions for Use of the Notified Substance

E.1. Current Regulatory Status

The US FDA has issued ‘no question’ letters on 2 GRAS notifications related to food uses of Luo Han Guo concentrates (GRN 301, FDA, 2010; GRN 359, FDA, 2011). In GRN 301 (FDA, 2010), the subject of notification was a clarified concentrate derived from Luo Han Guo (*S. grosvenori* [Swingle]) which was sold as PureLo[®] brand Luo Han Guo fruit concentrate 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 tabletop sweetener.

In GRN 359 (FDA, 2011), the subject of this GRAS notification was *S. grosvenori* (Swingle) (Luo Han Guo) fruit extracts containing 25, 45, or 55 % mogroside V. The powdered extracts is marketed under the trade name Go-Luo[™] by Guilin Layn Natural Ingredients (Guangxi, China). The powdered extracts were intended to be used as a tabletop sweetener and as a general purpose sweetener and flavor modifier in conventional foods.

In these GRAS notices, toxicity-related studies on Luo Han Guo extract concentrate from the literature were presented which support the safety in use of Luo Han Guo extract concentrate. The FDA did not question the acceptability and suitability of these studies to establish the safety of Luo Han Guo extracts for the proposed food uses. The FDA did not have questions on summary of safety concluding that Luo Han Guo concentrate intake up to 2.5 mg mogroside V per person per day is safe. The safety and related information in the above mentioned GRAS Notices is hereby incorporated by reference into this independent GRAS determination.

In June, 2014, GLG Life Tech Corporation submitted a GRAS notice (GRN 522) of Luo Han Guo fruit extract powder for use as a general purpose non-nutritive sweetener in various foods other than in infant formulas and in meat and poultry products. Extracts are similar to the extracts 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 addition, 2 New Dietary Ingredient (NDI) notifications were accepted by FDA for use of Luo Han Guo as dietary supplement (FDA, 1996, 1999).

E.2. Intended Use Levels and Food Categories

Luo Han Guo extracts, containing mogroside V as the principal sweetening component, are intended to 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. The intended use will be as a non-nutritive sweetener as defined in 21 CFR 170.3(o)(19). Luo Han Guo extracts are intended for use in the same foods and at levels proportional to those for mogroside specified in GRNs 301, 359, and 522.

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

Using the methodology presented in GRN 301 and Renwick (2008), the EDI of the HBI's Luo Han Guo extracts have been calculated. The EDIs for high consumers of Luo Han Guo extracts ranged from up to 2.41 mg/kg BW/day (product containing 90% mogroside V) 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 for mogroside V are less than 2.2 mg/kg BW/day.

Since HBI's Luo Han Guo extracts will replace other Luo Han Guo products in the marketplace, an increase in the cumulative intake is not expected. In addition, each concentration will be used alone for each application, thus, cumulative exposure is not expected. As described in Renwick (2008) as well as in GRNs 301 and 359, the EDIs for Luo Han Guo extract products represent extremely optimistic estimates of the potential intake.

E.4. Basis for the GRAS Determination

Numerous human and animal studies have reported benefits of Luo Han Guo extracts with varying concentrations of mogroside V with no major adverse effects. The HBI 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 Luo Han Guo extracts. This GRAS determination is based on the data and information generally available and consented opinion about the safety of Luo Han Guo extracts. The literature indicates that Luo Han Guo 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 extracts as well as appropriate corroborative data.

1. HBI's Luo Han Guo extracts (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 Luo Han Guo extracts comply reliably with the established food-grade product specifications and meet all applicable purity standards and FCC standards for impurities.

3. HBI's Luo Han Guo 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 and 522. Due to the characteristic intense sweet flavor of the fruit and its derivatives, use is expected to be self-limiting.
4. The exposure estimates (EDI) under the untended use are estimated to be up to 2.2 mg mogroside V/kg BW/day for high consumers. The EDIs for Luo Han Guo extracts ranged from 2.4 to 12.4 mg/kg BW/day in high consumers, depending on the concentration of mogroside V. These levels are far below the reference dose safe for human exposure. In addition, subchronic studies reported that NOAELs for Luo Han Guo 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 (Huntingdon Life Sciences, 2010).
5. The EDI estimates are based on the assumption that HBI's Luo Han Guo extracts will replace currently marketed Luo Han Guo extracts. Thus, an increase in the cumulative intake is not expected. In addition, the EDIs presented in this notice are highly optimistic estimates.
6. In the previous GRAS notices (GRN 301 and GRN 359) to the FDA, the safety of Luo Han Guo extracts has been established in toxicological studies in animals, mutagenicity studies, and is further supported by clinical studies in human (Xu et al., 2005a, 2005b). The FDA responses to GRAS notifications on Luo Han Guo extracts indicate that the FDA is satisfied with the safety-in-use of the Luo Han Guo extracts, as long as consumption is 2.5 mg mogroside V/kg BW/day. The Furthermore, historical consumption of Luo Han Guo extracts support the safety of Luo Han Guo extracts. Additional animal studies published subsequent to the FDA GRAS notices continue to support safety of Luo Han Guo extracts as a food ingredient.

Pursuant to 21 CFR 170.30(b), HBI's[®] Luo Han Guo 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 Extracts as a component of food. Expert Panel members, Susan S. Cho, Ph.D., Robert L. Martin, Ph.D., Madhusudan Soni, 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 extracts, produced consistent with current Good Manufacturing Practice (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 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 located at 6309 Morning Dew Ct., Clarksville, MD 21029, USA.

G. Basis of GRAS determination: Through scientific procedures.

References

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FDA. 2010. Agency Response Letter GRAS Notice No. GRN 000301. CFSAN/Office of Food Additive Safety.

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EXPERT PANEL STATEMENT
DETERMINATION OF THE GENERALLY RECOGNIZED
AS SAFE (GRAS) STATUS OF
LUO HAN GUO EXTRACTS
AS A FOOD INGREDIENT

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Luo Han Guo Extracts

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1. INTRODUCTION

The undersigned, an independent panel of recognized experts (herein after 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 Huacheng Biotech, Inc.[®] (HBI), to determine the Generally Recognized As Safe (GRAS) status of its Luo Han Guo extracts (powder) as a 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 extracts was conducted and made available to the Expert Panel members. The Expert Panel members independently and critically evaluated materials submitted by HBI 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 extract powders, (2) Estimate exposure under the intended condition of use, (3) Document the literature pertaining to the safety of Luo Han Guo extracts, and (4) Assemble an independent panel of recognized experts (hereinafter referred to as the Expert Panel). The data and information summarized in this dossier demonstrate that the intended use of Luo Han Guo extracts, 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. Common or Trade Name:

The common or usual names of the Luo Han Guo extract 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 subjects of this safety evaluation are identified as Luo Han Guo extracts (powder form) as produced and sold by Hunan Huacheng Biotech, Inc. (HBI) under the trade names:

Greenfruit[™] MV 12.5;
Greenfruit[™] MV 20;
Greenfruit[™] MV 25;
Greenfruit[™] MV 30;
Greenfruit[™] MV 40;
Greenfruit[™] MV 50;
Greenfruit[™] MV 55 and
Greenfruit[™] MV 90.

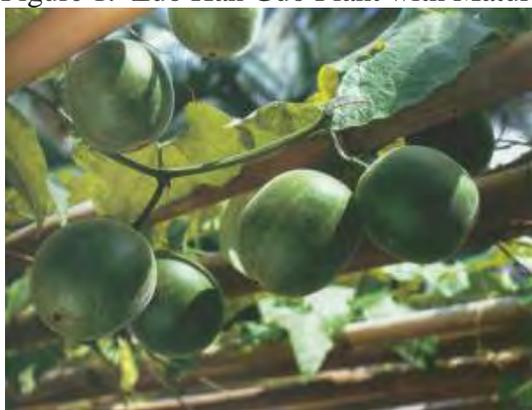
The subject extracts are mixtures of components found in the Luo Han Guo fruit. Extracts are similar to those described in GRN 301 (up to 30% mogroside V), GRN 359 (up to 55% mogroside V), and GRN 522 (up to 60% mogroside V). This GRAS document discusses extract

products containing 12.5 - 90% mogroside V. These products are similar to the products described in GRNs 301 and 359 for which FDA has issued “no question” letters.

II.B. Background

Luo Han Guo, or *Siraitia grosvenori* (Swingle) fruit, a traditional Chinese medicine and edible fruit, is a member of the genus *Siraitia*. It is also a member of the subfamily Cucurbitaceae, which includes cucumbers, melons, watermelons, squashes, gourds, and other commercially important species (Pawar et al., 2013). Figure 1 shows Luo Han Guo plant with mature fruits.

Figure 1. Luo Han Guo Plant with Mature Fruits.



Extracts from ripe Luo Han Guo are intensely sweet. It is a natural sweet food and contains glycosides 200-300 times sweeter than sucrose (Tsang and Ng, 2001), but lower calories. It can therefore be used as a substitute sugar. The fruit has an extremely long history of use in south China as a sweetener and as a household remedy for colds, sore throats, and minor stomach and intestinal troubles (Hussain et al., 1990; Pawar et al., 2013).

The primary components of crude Luo Han Guo 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 (Lee, 1975). In particular, mogroside V is the major sweetness component of the fruit. The key structural feature necessary for sweetness of the mogrosides is the presence of a β -hydroxyl group at C-11 of the aglycone. Mogroside V, the most abundant sweet constituent, was found in whole fruits at levels 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; Song et al., 2006, 2007; Wang et al., 2014).

Powdered concentrates of Luo Han Guo or *S. grosvenori* fruit extracts have been introduced for use in the US as a tabletop sweetener of foods. The overall sweetness of the typical concentrate has been estimated to be approximately 80-400 times that of sucrose depending upon the concentration of mogroside V. This GRAS document discusses extract products containing 12.5 - 90% mogroside V. Table 1 shows the sweetness intensity of Luo Han Guo products when tested against the water solution of 10% sucrose. It is commonly accepted that the sweetness

intensity of Luo Han Guo extracts is proportional to the level of mogrosides present in it. However, it also depends on the level 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 extracts, the amounts added to food products from any of the HBI's eight extracts will be self-limiting.

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

Product	Sweetness intensity
Greenfruit™ MV 12.5	80
Greenfruit™ MV 25	160
Greenfruit™ MV 30	180
Greenfruit™ MV 40	220
Greenfruit™ MV 50	250
Greenfruit™ MV 55	265
Greenfruit™ MV 90	410

II.C. Chemistry, Physico-chemical Properties, and Structure

Luo Han Guo or *S. grosvenori* extract is a mixture of compounds naturally occurring in the Luo Han Guo 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(1-2)]-[beta-D-glucopyranosyl (1 -6)]-beta-Dglucopyranoside):

CAS # 88901-36-4; Molecular Formula: C₆₀H₁₀₂O₂₉; 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.

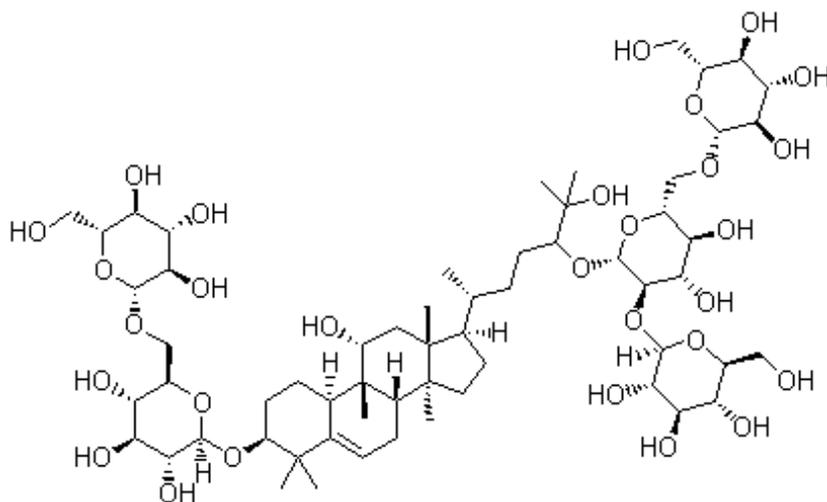


Figure 2. Chemical structure of mogroside V.

Table 2 shows a typical compositional analysis of Luo Han Guo extracts (12.5%, 30%, 55% and 90%). The other Luo Han Guo extracts show similar profiles proportional to the percent of the extract. Impurity levels (such as arsenic, cadmium, and lead) of HBI's Luo Han Guo extracts are well below those specified by Food Chemical Codex (FCC) (Table 2).

Table 2. Typical Nutritional Composition for Greenfruits™ Products

Component	Mogroside V concentration of Greenfruits™				FCC specifications
	MV 12.5	MV 30	MV 55	MV 90	
Mogroside V, %	>12.5	>30.0	>55.0	>90.0	>30.0
Protein, %	36.3	28.4	7.3	1.6	NA
Ash, %	2.3	1.6	1.25	0.45	<5.0
Sodium, mg/kg	1,450	1,120	480	172	NA
Potassium, mg/kg	173	133	136	49	NA
Calcium, mg/kg	125	165	126	138	NA
Arsenic, ppm	<0.2	<0.2	<0.2	<0.2	<0.5
Cadmium, ppm	<0.15	<0.15	<0.15	<0.15	<1
Lead, ppm	<0.5	<0.5	<0.5	<0.5	<1
Total fat, %	<0.1	<0.1	<0.1	<0.1	NA
Saturated fat, %	<0.1	<0.1	<0.1	<0.1	NA
Mono-unsaturated fat, %	<0.1	<0.1	<0.1	<0.1	NA
Moisture, %	3.7	2.7	2.13	0.85	<6.0
Dietary Fiber, %	4.2	2.3	0.5	0.31	NA
Carbohydrate, % (by calculation)	53.4	65.0	88.9	96.8	NA
Energy, kJ/g (by calculation)	14.9	14.9	15.4	15.7	NA

NA=not available.

II.D. Manufacturing Process of Luo Han Guo Extract Powders

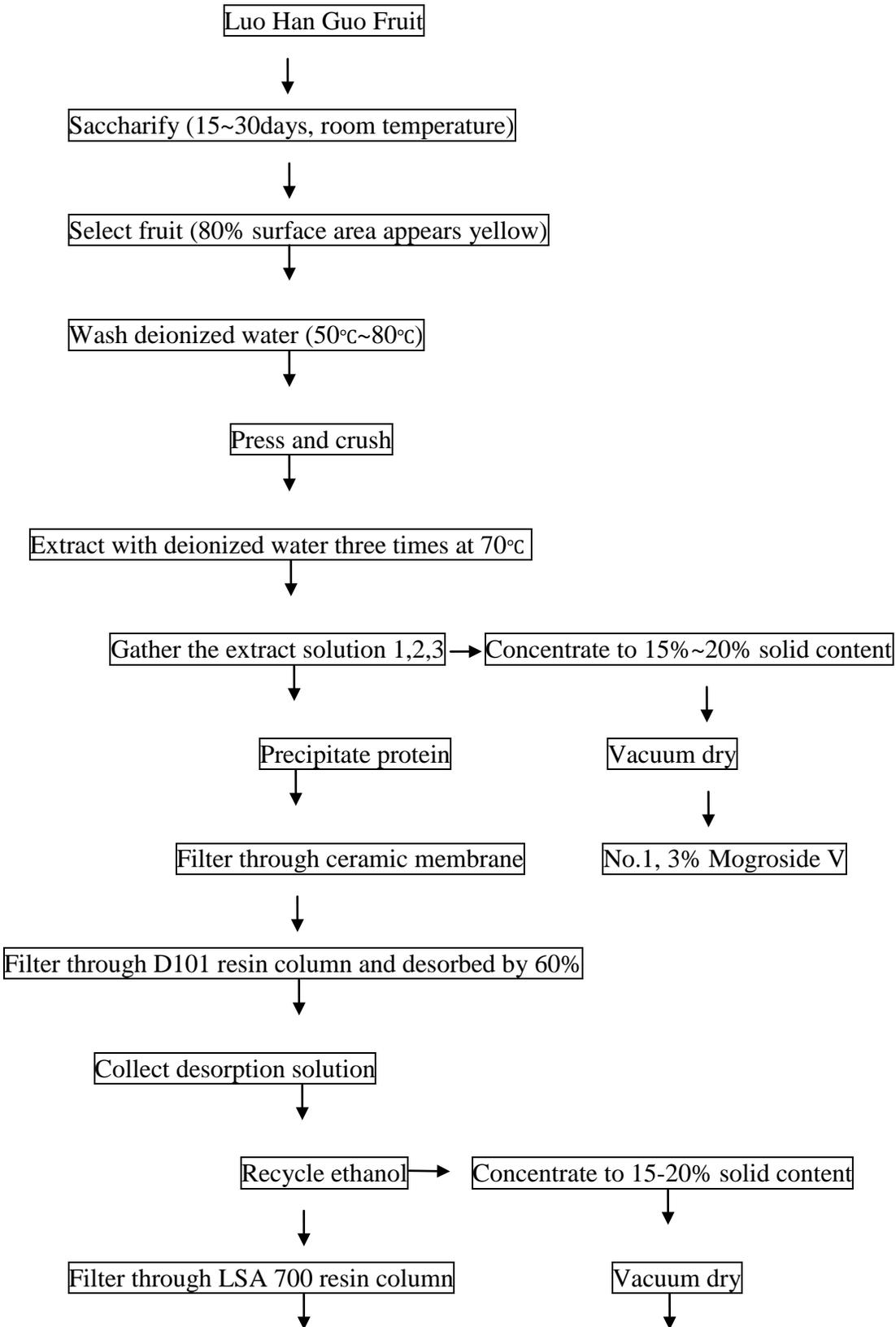
HBI's Luo Han Guo Extract Powders are manufactured in a principle similar to that described in FCC. However, HBI's manufacturing process employs more purification processes to produce highly purified products (HBI vs. FCC: up to 90-92% mogroside V vs. 30% mogroside V) under cGMP.

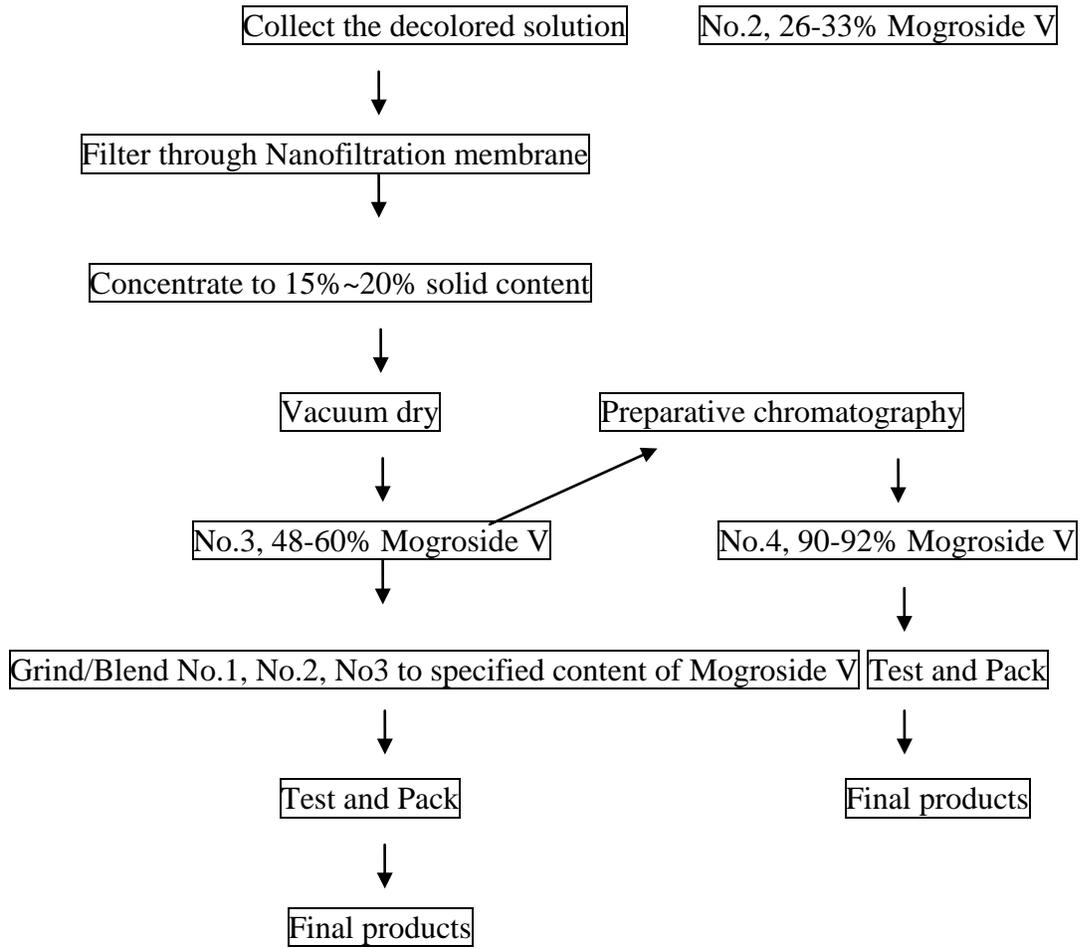
1. Select the good Luo Han Guo fruit and saccharify the fruit at room temperature for 15 to 30 days.
2. Select the fruit which has more than 80% yellow surface area. Then mechanically press and crush the fruit.
3. Extract for 60 minutes at 70°C with deionized water three times. Gather all the extract solutions. Divide the solution into 2 portions. Use one portion in step 4, where it will undergo further purification and concentrate the other portion to 15-20% solid content with a vacuum drier. This produces the first product, 3% Mogroside V powder.

4. Heat the solution from step 3 to 100°C, then cool it down. Centrifuge the solution by disc centrifuge to precipitate protein. Filter the supernatant through ceramic membrane to remove the large molecules of pectin.
5. Pass the supernatant through a D101 resin (divinyl benzene copolymer) column, where it is desorbed by 60% ethanol. Collect the desorption solution.
6. Recycle the ethanol from the desorption solution, and then divide the solution into 2 portions. Use one portion in step 7, where it will undergo further purification. Concentrate the other portion to 15-20% solid content with a vacuum system and dried it with a vacuum drier. This produces the second product, 26-33% Mogroside V powder.
7. Pass the solution from step 6 through LSA700 resin column which adsorbs the colored melanoidin compounds and other compounds in the solution. Collect the decolored solution and then filter the solution through a nanofiltration membrane for desalination.
8. Concentrate the solution to 15-20% solid content by vacuum system and dried it with a vacuum drier. This is the third product, 48-60% Mogroside V powder. Divide the powder into 2 portions. Use one portion in step 9 and the other one will undergo further purification and vacuum drying to the fourth product, 90-92% Mogroside V powder.
9. The HBI's manufacturing process produces 4 products with varying mogroside V concentrations: 1) 3%, 2) 26-33%, 3) 48-60%, and 4) 90-92%. By blending different proportions of the products, one can produce the specified content of Mogroside V (e.g., 12.5%, 20%, 25%, 30%, 40%, 50%, 55% and 90% Mogroside V powder). A flow diagram of manufacturing process is shown in Figure 2.

The food grade ethanol used in the purification process complies with FCC's 8th Edition specifications. The ion exchange resins and adsorption polymeric resins used in the manufacturing process comply with 21 CFR 173.25.

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





II. E. Specifications of HBI's Luo Han Guo Extracts

1. HBI's Specifications for Luo Han Guo Extracts

As shown in Tables 3-1 - 3-8, HBI has established the specifications for the minimum mogroside content as well as the maximum microbiological and heavy metal levels for its Luo Han Guo extracts. The HBI's specifications on heavy metals are more conservative than FCC's (HBI vs. FCC: Arsenic, <0.2 vs. <0.5 ppm; lead, <0.5 vs <1 ppm; Cadmium, <0.15 vs. <1 ppm). The two specifications are comparable for ash and moisture.

Table 3-1. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium(Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopia.

Table 3-2. Specifications for Luo Han Guo Extract 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

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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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 3-3. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010

Staphylococcus	Negative	CP 2010
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Table 3-4. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 3-5. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03

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Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 3-6. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 3-7. Specifications for Luo Han Guo Extract 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 942.05,17 th
Arsenic (As)	< 0.2ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15ppm	AOAC 2006.03
Lead (Pb)	< 0.5ppm	AOAC 2006.03
Mercury (Hg)	< 0.1ppm	AOAC 993.14
Total Plate Count	< 1,000cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

Table 3-8. Specifications for Luo Han Guo Extract 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)	< 0.2 ppm	AOAC 2013.06
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03
Lead (Pb)	< 0.5 ppm	AOAC 2006.03
Mercury (Hg)	< 0.1 ppm	AOAC 993.14
Total Plate Count	< 1,000 cfu/ml	CP 2010
<i>P. aeruginosa</i>	Absent	CP 2010
<i>S. aureus</i>	Absent	CP 2010
Salmonella	Absent	CP 2010
Yeast & Mold	< 100 cfu/g	CP 2010
<i>E. coli</i>	Negative	CP 2010
Staphylococcus	Negative	CP 2010

II.F. Food Sources of Luo Han Guo extract

Luo Han Guo, or *Siraitia grosvenori* (Swingle) fruit, a traditional Chinese edible fruit, the source of Luo Han Guo extracts.

II.G. Intended technical effects

Luo Han Guo extracts can be used as a naturally occurring high intensity sweetener.

III. INTENDED USES AND EXPOSURE ESTIMATES

III.A. Intended use

The subjects of the present GRAS determination contain 12.5, 20, 25, 30, 40, 50, 55, or 90% mogroside V. Luo Han Guo extracts, containing mogroside V as the principal sweetening component, are intended to be used as a table-top sweetener and as a general purpose non-nutritive sweetener and 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). 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 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)).

Luo Han Guo extracts are intended for use in the same foods and at levels proportional to those for mogroside specified in GRNs 301, 359, and 522. The substance mentioned in GRN 301 has been reported to contain approximately 30% mogroside V.

III.B. Estimated Dietary Intakes (EDI) Under the Intended Use

Using the methodology presented in GRN 301 and Renwick (2008), the EDI of the HBI's Luo Han Guo extracts have been calculated (Tables 4-1 - 4-8). This method used published data on dietary exposures to approved intense sweeteners to predict the maximum likely intake of high intensity sweeteners (Renwick, 2008). 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 intake of this novel intense sweetener is then calculated by dividing the estimated sucrose equivalent intakes by the relative sweetness of a Luo Han Guo extract at specific concentration of mogroside V.

In GRN 301, the estimated 90th percentile intake of Luo Han Guo concentrate (30% mogroside V) was determined as 6.8-9.9 mg/kg BW/day for an extract 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, the sweetness of Luo Han Guo concentrate 25% mogroside V) was found to be 160 times sweeter than sugar. The differences in the relative sweetness of the products resulted from the refinement of the manufacturing process of Luo Han Guo concentrates. The sweetness of HBI's Luo Han Guo extract concentrates is similar to those described in GRN 359.

The EDIs for high consumers of Luo Han Guo extracts ranged from up to 2.41 mg/kg BW/day (product containing 90% mogroside V) to 12.4 mg/kg BW/day (product containing 12.5% mogroside V) (Tables 4-1 - 4-8). 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 (Tables 4-1 - 4-8). All predicted EDIs are less than 2.2 mg/kg BW/day, which is equivalent to less than 175 mg per a 70 kg adult. Each concentration will be used independently of the others for each application, thus, cumulative exposure is not expected.

Since HBI's Luo Han Guo extracts will replace other Luo Han Guo products in the marketplace, an increase in cumulative intake is not expected. As described in Renwick (2008) as well as in GRNs 301 and 359, the EDIs for Luo Han Guo extract products represent extremely optimistic estimates of the potential intake for the following reasons: 1) the calculations are based on the assumption that Luo Han Guo extract products will capture the entire high intensity sweetener market (the presence of multiple sweeteners is likely to significantly reduce the intakes of individual compounds compared with the data presented in the present GRAS assessment) and 2) the assumptions made in many of the studies, such as the use of food groups rather than individual food items and brands, and the use of maximum permitted use levels. Indeed, the market share of Luo Han Guo extract products is very low in the intense-sweetener market.

Table 4-1. Current Daily Intake of Sugar Equivalents and EDIs of Luo Han Guo extract with 12.5% mogroside (Greenfruit™ MV 12.5 - sweetness intensity 80)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day) ^a		Intake of HBI-MV 12.5 (mg/kg BW/day) ^b		Intake of mogroside V (mg/kg) ^c	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	3.18	8.44	0.40	1.05
Diabetic Adults	280	897	3.50	11.22	0.44	1.40
Healthy Children	425	990	5.32	12.38	0.67	1.55
Diabetic Children	672	908	8.40	11.36	1.05	1.42

^a See Renwick, 2008. ^b To replace all intense sweeteners; adapted from GRN 301.

^c Calculated based on the minimum of 12.5% mogroside in Luo Han Guo extract.

Table 4-2. Current Daily Intake of Sugar Equivalents and EDI of Luo Han Guo Extract with 20% Mogroside (Greenfruit™ MV20 - sweetness intensity 128)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day) ^a		Intake of HBI-MV 20 (mg/kg BW/day) ^b		Intake of mogroside V (mg/kg) ^c	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	2.12	5.27	0.40	1.05
Diabetic Adults	280	897	2.18	7.00	0.44	1.40
Healthy Children	425	990	3.32	7.73	0.67	1.55
Diabetic Children	672	908	5.25	7.09	1.05	1.42

^a See Renwick, 2008. ^b To replace all intense sweeteners; adapted from GRN 301.

^c Calculated based on the minimum of 20% mogroside in Luo Han Guo extract.

Table 4-3. Current Daily Intake of Sugar Equivalents and EDI of Luo Han Guo Extract with 25% Mogroside (Greenfruit™ MV25- -sweetness intensity 160)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day) ^a		Intake of HBI-MV 25 (mg/kg BW/day) ^b		Intake of mogroside V (mg/kg) ^c	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	1.59	4.22	0.40	1.05
Diabetic Adults	280	897	1.75	5.61	0.44	1.40
Healthy Children	425	990	2.66	6.19	0.67	1.55
Diabetic Children	672	908	4.20	5.68	1.05	1.42

^a See Renwick, 2008. ^b To replace all intense sweeteners; adapted from GRN 301.

^c Calculated based on the minimum of 25% mogroside in Luo Han Guo extract.

Table 4-4. Current Daily Intake of Sugar Equivalents and EDI of Luo Han Guo Extract with 30% Mogroside (Greenfruit™ MV30 - sweetness intensity 180)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day) ^a		Intake of HBI-MV 30 (mg/kg BW/day) ^b		Intake of mogroside V (mg/kg) ^c	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	1.42	3.75	0.43	1.13
Diabetic Adults	280	897	1.56	4.98	0.47	1.50
Healthy Children	425	990	2.36	5.50	0.71	1.65
Diabetic Children	672	908	3.73	5.04	1.12	1.51

^a See Renwick, 2008. ^b To replace all intense sweeteners; adapted from GRN 301.

^c Calculated based on the minimum of 30% mogroside in Luo Han Guo extract.

Table 4-5. Current Daily Intake of Sugar Equivalents and EDI of Luo Han Guo Extract with 40% Mogroside (Greenfruit™ MV40 - sweetness intensity 220)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day) ^a		Intake of HBI-MV 40 (mg/kg BW/day) ^b		Intake of mogroside V (mg/kg) ^c	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	1.16	3.06	0.46	1.23
Diabetic Adults	280	897	1.27	4.08	0.51	1.63
Healthy Children	425	990	1.93	4.5	0.77	1.80
Diabetic Children	672	908	3.05	4.13	1.22	1.65

^a See Renwick, 2008. ^b To replace all intense sweeteners; adapted from GRN 301.

^c Calculated based on the minimum of 40% mogroside in Luo Han Guo extract.

Table 4-6. Current Daily Intake of Sugar Equivalents and EDI of Luo Han Guo Extract with 50% Mogroside (Greenfruit™ MV 50 -sweetness intensity 250)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day) ^a		Intake of HBI-MV 50 (mg/kg BW/day) ^b		Intake of mogroside V (mg/kg) ^c	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	1.02	2.70	0.51	1.35
Diabetic Adults	280	897	1.12	3.59	0.56	1.79
Healthy Children	425	990	1.70	3.96	0.85	1.98
Diabetic Children	672	908	2.69	3.63	1.34	1.82

^a See Renwick, 2008.

^b To replace all intense sweeteners; adapted from GRN 301.

^c Calculated based on the minimum of 50% mogroside in Luo Han Guo extract.

Table 4-7. Current Daily Intake of Sugar Equivalents and EDI of Luo Han Guo Extract with 55% Mogroside (Greenfruit™ MV 55 - sweetness intensity 265)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day) ^a		Intake of HBI-MV 55 (mg/kg BW/day) ^b		Intake of mogroside V (mg/kg) ^c	
	LOW	HIGH	LOW	HIGH	LOW	HIGH
Healthy Population	255	675	0.96	2.55	0.53	1.40
Diabetic Adults	280	897	1.06	3.38	0.58	1.86
Healthy Children	425	990	1.60	3.73	0.88	2.05
Diabetic Children	672	908	2.53	3.42	1.39	1.88

^a See Renwick, 2008. ^b To replace all intense sweeteners; adapted from GRN 301.

^c Calculated based on the minimum of 55% mogroside in Luo Han Guo extract.

Table 4-8. Current Daily Intake of Sugar Equivalents and EDI of Luo Han Guo Extract with 90% Mogroside (Greenfruit™ MV 90 - sweetness intensity 410)

POPULATION GROUP	Intakes of sweetener (g sucrose/kg BW/day) ^a		Intake of HBI-MV 55 (mg/kg BW/day) ^b		Intake of mogroside V (mg/kg) ^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 To replace all intense sweeteners; adapted from GRN 301.

^c Calculated based on the minimum of 90% mogroside in Luo Han Guo extract.

IV. BASIS FOR GRAS DETERMINATION

IV.A. Current regulatory status

USA

The FDA has issued ‘no question’ letters on 2 GRAS notifications related to food uses of Luo Han Guo concentrates (GRN 301, FDA, 2010; GRN 359, FDA, 2011). In GRN 301 (FDA, 2010), the subject of notification was a clarified concentrate derived from Luo Han Guo (*S. grosvenori* [Swingle]) which was sold as PureLo[®] brand Luo Han Guo fruit concentrate 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 359 (FDA, 2011), the subject of this GRAS notification was *S. grosvenori* (Swingle) (Luo Han Guo) fruit extracts containing 25, 45, or 55 % mogroside V. The powdered extracts are 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.

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In these GRAS notices, toxicity-related studies on Luo Han Guo extract concentrate from the literature were presented which support the safety in use of Luo Han Guo extracts. The FDA did not question the acceptability and suitability of these studies to establish the safety of Luo Han Guo extract concentrate for the proposed food uses. The FDA did not have questions on summary of safety concluding that Luo Han Guo concentrate intake up to 2.5 mg mogroside V/person/day is safe. The safety and related information in the above mentioned GRAS Notices is hereby incorporated by reference into this independent GRAS determination. The pertinent information is available as indicated below:

GRN 301:

<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm269350>.

GRN 359: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-foods-gen/documents/document/ucm270531.pdf>.

In June, 2014, GLG Life Tech Corporation submitted a GRAS notice (GRN 522) of Luo Han Guo fruit extract powder for use as a general purpose non-nutritive sweetener in various foods other than in infant formulas and in meat and poultry products. Extracts are similar to the extracts 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. This notice is pending as FDA is currently reviewing the submission:

http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=522&sort=GRN_No&order=DESC&startrow=1&type=basic&search=522.

In addition, 2 New Dietary Ingredient (NDI) notifications were accepted by FDA for use of Luo Han Guo as dietary supplement (FDA, 1996, 1999).

Joint FAO/WHO Food Standards Programme

At the 43rd session of the Codex Committee on Food Standards, Joint FAO/WHO Food Standards Programme, held in Xiamen, China (March 14–18, 2011), the Calorie Control Council (Atlanta, GA, USA), requested that the Codex Committee on Food Additives include on the “Priority List of Food Additives Proposed for Evaluation by JECFA” the intense sweetener known as monk fruit extract/Luo Han Guo *S. grosvenori* (Swingle) (FAO/WHO, 2012). The Calorie Control Council identified the extract for evaluation as the cucurbitane glycosides known as mogrosides, specifically mogrosides II, III, IV, VI, and VI, with mogroside V as the major constituent, constituting over 30 % of the product and as the component primarily responsible for the sweetness of Luo Han Guo. Subsequently in March 2012, monk fruit extract/Luo Han Guo/*S. grosvenorii* (Swingle) fruit was included on the priority list for the 44th session of the Codex Committee on Food Additives, JECFA 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 extract on the priority list of substances proposed for evaluation, as proposed by the US, with data availability projected for December 2014 (FAO, 2014).

Health Canada

On March 14, 2013, Health Canada proposed adding monk fruit extract 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 extract 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).

IV.B. Review of safety data

As noted above, the FDA has issued 'no question' letters on two GRAS Notices related to food uses of Luo Han Guo extracts. As the Luo Han Guo extracts in this GRAS determination are similar in specifications compared to the other Luo Han Guo 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 concentrates in this GRAS determination. Therefore, this notice incorporates by reference the safety and metabolism studies discussed in GRNs 301 and 359. Additionally, this notice discusses additional animal studies that have been published since the FDA's last reviews of 2011. The subject of present GRAS assessment is Luo Han Guo extracts (powder form).

IV.B.1. Metabolism of Luo Han Guo extracts

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 powder in solution (SG-gly, 117 mg/ml). 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.

IV.B.2. Mutagenicity and Genotoxicity studies

In the previous GRAS notices to the FDA, the safety of extracts from Luo Han Guo (*Siraitia grosvenori*) has been established in mutagenicity and genotoxicity studies. Since the last review of 2011, no new mutagenicity studies have been published. Thus, this GRAS notice summarizes the studies already reviewed in previous GRAS notices.

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 extract for its ability to cause point mutation in *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100 as well as in *Escherichia coli* strain WP2uvrA. Five concentrations separated by approximately half-log₁₀ 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 extract did not exhibit any cytotoxic or mutagenic potential.

IV.B.3. Animal toxicity studies

Since the FDA's last completed review of 2011, no new animal toxicity studies have been published. Thus, this GRAS notice summarizes the studies already reviewed in previous GRAS notices. The notified substance in this notice is Luo Han Guo 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 extracts. Results of animal toxicity studies are summarized in Table 5.

Overall, studies found that LD₅₀ for aqueous extract of *S. grosvenori* fruit and mogrosides are over 10 g/kg BW in mice (Lee, 1975). A compound which has a LD₅₀ value of over 5 g/kg BW in rodents is classified as 'practically nontoxic', and the compound with a LD₅₀ value of over 15 g/kg BW as 'relatively harmless' (Altug, 2003). Luo Han Guo extracts and mogrosides belong to the group with the lowest toxicity rating.

A subacute study in rats found that the NOAELs for Luo Han Guo 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 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 in male and female rats, respectively (Huntingdon Life Science, 2010).

IV.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 extract was administered to male albino mice (10 mice/group) at doses up to 15 g extract/kg BW for 1 week. Although the mice transiently exhibited mild sedation and diarrhea at a dose of 15 g/kg BW, they appeared normal within 30-60 minutes. No mortalities were observed. The author reported the LD₅₀ of Luo Han Guo extract to be in excess of 10 g/kg BW in mice.

In an acute toxicity in mice conducted by Makapugay et al. (1985), mogroside V isolated from a water-soluble Luo Han Guo extract resulted in no mortality at doses up to 2 g/kg BW. The authors reported the LD₅₀ to be greater than 2 g/kg BW and that the extract was not mutagenic.

Hussain and colleagues (1990) performed acute toxicity experiments of a Luo Han Guo extract in male Swiss-Webster mice, ages 4-6 weeks. A single oral administration of Luo Han Guo 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 extract at doses up to 2 g/kg BW did not reveal changes in body weights or signs of toxicity. The LD₅₀ was greater than 2 g/kg BW, the highest dose tested.

IV.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 not cause any adverse effects found when measuring clinical observations, body weight, food consumption, hematology, blood chemistry, urinalysis, gross necropsy, organ weight, and 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: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 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 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. The NOAEL for mogroside V could be 2,310 mg/kg BW/day in males and 2,244 mg/kg BW/day in females.

IV.B.3.3. Subchronic Toxicity Studies

Jin et al. (2007) tested the toxicity of *Siraitia grosvenori* 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% *S. grosvenori* extract for 13 weeks. No deaths were observed and there were no changes of note in general appearance, body weight, food and water consumption, hematological and serum biochemical parameters, organ weight, and histopathological findings between control and test groups. The NOAEL of *S. grosvenori* extract in Wistar Hannover rats was found to be 5% of diet, or 2,520 mg/kg/day in males and 3,200 mg/kg BW/day in females.

To test the safety of Luo Han Guo powder 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. Administration of Luo Han Guo extract powder containing 30% mogroside V did not cause any adverse effects found when measuring clinical observations, body weight, food consumption, hematology, blood chemistry, urinalysis, gross necropsy, organ weight, and histopathology. The NOAEL was found to be 3,000 mg/kg BW/day for Luo Han Guo powder extract or 900 mg/kg BW/day for mogroside V.

Hirose (1999) administered a Luo Han Guo extract containing 30% mogroside V to rats in the form of 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 extract at concentrations of 0%, 0.25%, 0.5%, 1.0% and 2.0% for 90 days. The amounts of water ingested and the 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

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intake, weights or internal organs, biochemical serum values (serum total protein, albumin, A/G ratio, bonded nitrogen, creatinine, inositol, phosphoric acid, alkaline phosphatase, GOT, and GPT, total cholesterol, and total glycerin), 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 extract 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 powder extract 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 or serum chemistry findings, nor were there any histopathological observations in any tissue samples or organs. Therefore, the NOAEL for Luo Han Guo extract powder was considered to be a dietary concentration of 5%, the highest dose tested. This dose corresponded to approximately 3,120 mg/kg BW/day and 3,750 mg/kg BW/day in male and female rats, respectively. Corresponding NOAELs for mogroside V are 1,717 and 2,062 mg/kg BW/day in male and female rats, respectively.

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Table 5. Summary of animal toxicity studies of Luo Han Guo

Species	Dose	Duration	NOAEL	Reference
Mice	Up to 2 g/kg BW Luo Han Guo extract	Single dose	LD ₅₀ >2 g/kg BW Luo Han Guo 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 extract	Single dose	LD ₅₀ >10 g/kg BW Luo Han Guo extract	Lee, 1975
Subacute toxicity				
6 Dogs (3M+3F)	Luo Han Guo extract powder (30% mogroside V) at 0 or 3,000 mg/kg/day	28 days	3,000 mg/kg/day of Luo Han Guo 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 extract powder 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 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., 2007
Subchronic toxicity				
80 young adult Wistar Hannover rats	<i>S. grosvenori</i> extract at 0, 0.04, 0.2, 1, or 5% of diet.	13 weeks	<i>S. grosvenori</i> extract – M: 2,520 mg/kg BW/day F: 3,200 mg/kg BW/day	Jin et al., 2006
12 dogs	Luo Han Guo 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 extract powder; or 900 mg/kg BW/day of mogroside V	Qin et al. 2006
100 rats	Luo Han Guo 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 extract in water	Hirose, 1999
160 rats	0, 1.25, 2.5, or 5% Luo Han Guo powder extract containing 55% mogroside V	90 days	Luo Han Guo powder : 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, 2010

M=male; F=female.

IV.B.4. Animal Efficacy Studies

Three animal efficacy studies published since 2011 reported no adverse effects of mogrosides.

Di et al. (2011) assessed the anti-inflammatory properties of mogrosides in murine macrophage RAW 264.7 cells and a murine ear edema model. Results showed that mogrosides at a concentration as high as 500 μ M did not have any adverse effect on RAW 264.7 cell growth after 24 hours of treatment. Mogrosides were shown to inhibit inflammation induced by lipopolysaccharides (LPS) in RAW 264.7 cells by down-regulating the expression of inflammatory genes nitric oxide synthase (iNOS), cyclooxygenase (COX-2), and interleukin (IL)-6 and up-regulating some inflammation protective genes, such as polymerase family, member 1 (PARP1), BCL2-like 1 (BCL2L1), transformation-related protein 53, p53 (TRP53), mitogen-activated protein kinase 9 (MAPK9), and peroxisome proliferator activator receptor δ (PPAR δ). Similarly, in the murine ear edema model, 12-O-tetradecanoylphorbol-13-acetate-induced inflammation was inhibited by mogrosides by down-regulating COX-2 and IL-6 and up-regulating PARP1, BCL2L1, TRP53, MAPK9, and PPAR δ gene expression.

Shi et al. (2014) reported protective effects and mechanisms of mogroside V on LPS-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 LPS (10 μ g in 50 μ l). After 12 h, airway inflammation in the acute lung injury (ALI) model was determined by the wet/dry weight ratio, myeloperoxidase (MPO) activity of lung tissue, leukocyte recruitment and cytokine levels in the bronchoalveolar lavage fluid (BALF). 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 inhibited airway inflammation induced by LPS 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 MPO activity, and inflammatory cell counts, interleukin-1 β (IL-1 β , 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 BALF. Additionally, mogroside V treatment reduced the activation of cyclooxygenase 2 (COX-2), iNOS, and the nuclear factor (NF)- κ B. The authors suggest that mogroside V has the potential to protect against LPS-induced airway inflammation in a model of ALI.

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.

IV.B.4. Human Clinical Studies

Two unpublished clinical studies (Xu et al., 2005a and 2005b) with Luo Han Guo extract 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 level 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 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 concentrate had no effect on blood glucose. No adverse effects of Luo Han Guo extracts were reported.

Luo Han Guo Extracts

Xu et al. (2005b) used a similar cross-over design to assess the effect of Luo Han Guo 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 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 to see no significant changes in 5 liver enzymes, alkaline phosphatase (ALP), gamma-glutamyl transpeptidase (GGT), alanine aminotransferase (ALT), aspartate aminotransferase (AST), and lactate dehydrogenase (LDH). No adverse effects of Luo Han Guo extracts were reported.

Table 6. Summary of Human Studies Showing No Adverse Effects of Luo Han Guo Extracts

Subjects	Daily dose	Duration	Measurement	Reference
5 healthy men and 5 healthy women aged 19-25 years	Day1-200 mg/kg BW of Luo Han Guo concentrate; Day 4-3000 mg/kg bw	2 doses; cross over design	No significant effects on fasting glucose conc. observed up to 3 h after each dose	Xu et al., 2005a
Six healthy males aged 19-25 years	Day1-200 mg/kg BW of Luo Han Guo concentrate; Day 4-water	Single dose; cross over design	5 liver enzymes	Xu et al., 2005b

V. SAFETY DETERMINATION

Numerous human and animal studies have reported benefits of Lou Han Guo extracts with varying concentrations of mogroside V with no major adverse effects. HBI 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 extracts. This GRAS determination is based on the data and information generally available and consented opinion about the safety of Luo Han Guo extracts. The literature indicates that Luo Han Guo 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 extracts as well as appropriate corroborative data.

1. HBI's Luo Han Guo powder extracts (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 Luo Han Guo powder extracts comply reliably with the established food-grade product specifications and meet all applicable purity standards.
3. HBI's Luo Han Guo 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, and 522. Due to the characteristic intense sweet flavor of the fruit and its derivatives, use is expected to be self-limiting.
4. The exposure estimates (EDI) under the untended use are estimated to be up to 2.2 mg mogroside V/kg BW/day for high consumers. The EDIs for Luo Han Guo extracts ranged from 2.4 to 12.4 mg/kg BW/day, depending upon the concentration of mogroside V in each Luo Han Guo 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 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 HBI's Luo Han Guo extracts will replace currently marketed Luo Han Guo extracts. 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 and GRN 359) to the FDA, the safety of Luo Han Guo extracts has been established in toxicological studies in animals, mutagenicity studies, and is further supported by clinical studies in human. The FDA responses to GRAS notifications on Luo Han Guo extracts indicate that the FDA is satisfied with the safety-in-use of the Luo Han Guo extracts, as long as consumption is 2.5 mg mogroside V/kg BW/day. The Furthermore, historical consumption of Luo Han Guo extracts support the safety of Luo Han Guo extracts.
7. Additional animal studies published subsequent to the FDA GRAS notices continue to support safety of Luo Han Guo extracts as a food ingredient.

VI. CONCLUSIONS AND GENERAL RECOGNITION OF THE SAFETY OF LUO HAN FRUIT EXTRACT CONCENTRATE (POWDER)

The intended use of Luo Han Guo extract concentrates (powder) has been determined to be safe through scientific procedures as set forth in 21 CFR 170.3(b), thus satisfying the so-called “technical” element of the 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 Huacheng Biotech, Inc. (HBI), we, the undersigned expert panel members, Susan S. Cho, Ph.D., Robert L. Martin, Ph.D., Madhusudan Soni, Ph.D. have independently evaluated the materials summarized in the Luo Han Guo extracts Generally Recognized as Safe (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 extract concentrates, produced consistent with cGMP and meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concludes that these uses of Luo Han Guo extract concentrates are 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.
NutraSource, Inc.

Date

Robert L. Martin, Ph.D.

Date

Madhusudan Soni, Ph.D.
Soni & Associates Inc.

Date

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(b) (6)

Susan Cho, Ph.D.
NutraSource, Inc.

Nov. 21, 2014

Date

(b) (6)

Robert L. Martin, Ph.D.

Nov. 20, 2014

Date

(b) (6)

Madhusudan Soni, Ph.D.
Soni & Associates Inc.

November 20, 2014

Date

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APPENDIX A. CERTIFICATES OF ANALYSIS

Certificate of Analyses of Luo Han Guo Extract 12.5% Mogroside V Lot No.LHG-140523

Product Name:Luo Han Guo Extract 12.5% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:May.23,2014; Testing Date:May.24,2014 Expire Date:May.22,2016; Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 12.5%	HPLC	12.86%
Identification	Positive	TLC	Conforms
Color	Yellow	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	3.43%
Ash	< 5.0%	AOAC 942.05,17 th	2.67%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.08 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.18 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.06 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	230
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	36
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)

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Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 12.5% Mogroside V
 Lot No.LHG-140608

Product Name:Luo Han Guo Extract 12.5% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jun.08,2014 Testing Date:Jun.08,2014 Expire Date:Jun.07,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 12.5%	HPLC	12.93%
Identification	Positive	TLC	Conforms
Color	Yellow	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	98%
Method of Extraction	Water	/	Conforms
solubility	Fully soluble in water	NLS 02.65.00	Conforms
Moisture Content	< 5.0%	GB/T 5009.3-2010	3.52%
Ash	< 5.0%	AOAC 942.05,17 th	2.48%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.11 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.04 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.17 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.06 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	180
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	42
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: [REDACTED]

QC [REDACTED]

QA: [REDACTED]

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 12.5% Mogroside V
 Lot No.LHG-140616

Product Name:Luo Han Guo Extract 12.5% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jun.16,2014 Testing Date:Jun.17,2014 Expire Date:Jun.15,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 12.5%	HPLC	13.24%
Identification	Positive	TLC	Conforms
Color	Yellow	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	99%
Method of Extraction	Water	/	Conforms
solubility	Fully soluble in water	NLS 02.65.00	Conforms
Moisture Content	< 5.0%	GB/T 5009.3-2010	3.65%
Ash	< 5.0%	AOAC 942.05,17 th	2.51%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.12 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.13 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.08 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	120
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	36
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: [Redacted]

QC [Redacted]

QA: [Redacted]

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 20% Mogroside V
 Lot No.LHG-140702

Product Name:Luo Han Guo Extract 20% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jul.02,2014 Testing Date:Jul.03,2014 Expire Date:Jul.01,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 20%	HPLC	20.65%
Identification	Positive	TLC	Conforms
Color	Yellow	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	3.28%
Ash	< 5.0%	AOAC 942.05,17 th	2.29%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.14 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.02 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.16 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.07 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	230
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	47
E.Coli	Negative	CP 2010	Negative
Staphylococcus	Negative	CP 2010	Negative
GB/T=Recommended Chinese National Standard CP 2010=Chinese Pharmacopoeia 2010 3. cfu=Colony Forming Units			

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

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 20% Mogroside V
 Lot No.LHG-140713

Product Name:Luo Han Guo Extract 20% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jul.13,2014 Testing Date:Jul.14,2014 Expire Date:Jul.12,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 20%	HPLC	20.58%
Identification	Positive	TLC	Conforms
Color	Yellow	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	98%
Method of Extraction	Water	/	Conforms
solubility	Fully soluble in water	NLS 02.65.00	Conforms
Moisture Content	< 5.0%	GB/T 5009.3-2010	3.43%
Ash	< 5.0%	AOAC 942.05,17 th	2.17%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.12 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.16 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.09 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	280
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	41
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 20% Mogroside V
 Lot No.LHG-140726

Product Name:Luo Han Guo Extract 20% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jul.26,2014 Testing Date:Jul.27,2014 Expire Date:Jul.25,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 20%	HPLC	20.73%
Identification	Positive	TLC	Conforms
Color	Yellow	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	3.35%
Ash	< 5.0%	AOAC 942.05,17 th	2.33%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.10 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.04 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.15 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.08 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	235
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	52
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 25% Mogroside V
 Lot No.LHG-140708

Product Name:Luo Han Guo Extract 25% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jul.08,2014 Testing Date:Jul.09,2014 Expire Date:Jul.07,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 25%	HPLC	25.54%
Identification	Positive	TLC	Conforms
Color	Yellow	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	99%
Method of Extraction	Water	/	Conforms
solubility	Fully soluble in water	NLS 02.65.00	Conforms
Moisture Content	< 5.0%	GB/T 5009.3-2010	3.36%
Ash	< 5.0%	AOAC 942.05,17 th	2.13%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.13 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.02 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.18 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.09 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	160
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	34
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 25% Mogroside V
 Lot No.LHG-140717

Product Name:Luo Han Guo Extract 25% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jul.17,2014 Testing Date:Jul.18,2014 Expire Date:Jul.16,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 25%	HPLC	25.61%
Identification	Positive	TLC	Conforms
Color	Yellow	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	3.22%
Ash	< 5.0%	AOAC 942.05,17 th	2.19%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.08 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.01 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.21 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.08 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	180
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	36
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			

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

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 25% Mogroside V
 Lot No.LHG-140802

Product Name:Luo Han Guo Extract 25% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Aug.02,2014 Testing Date:Aug.03,2014 Expire Date:Aug.01,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 25%	HPLC	25.83%
Identification	Positive	TLC	Conforms
Color	Yellow	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	3.27%
Ash	< 5.0%	AOAC 942.05,17 th	2.26%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.11 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.17 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.07 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	205
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	36
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 30% Mogroside V
 Lot No.LHG-140715

Product Name:Luo Han Guo Extract 30% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jul.15,2014 Testing Date:Jul.16,2014 Expire Date:Jul.14,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 30%	HPLC	30.68%
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	99%
Method of Extraction	Water	/	Conforms
solubility	Fully soluble in water	NLS 02.65.00	Conforms
Moisture Content	< 5.0%	GB/T 5009.3-2010	3.25%
Ash	< 5.0%	AOAC 942.05,17 th	2.27%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.07 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.18 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.06 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	210
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	43
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 30% Mogroside V
 Lot No.LHG-140728

Product Name:Luo Han Guo Extract 30% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jul.28,2014 Testing Date:Jul.29,2014 Expire Date:Jul.27,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 30%	HPLC	30.56%
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	3.46%
Ash	< 5.0%	AOAC 942.05,17 th	2.15%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.13 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.04 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.12 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.08 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	215
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	37
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 30% Mogroside V
 Lot No.LHG-140809

Product Name:Luo Han Guo Extract 30% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Aug.09,2014 Testing Date:Aug.10,2014 Expire Date:Aug.08,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 30%	HPLC	30.74%
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	99%
Method of Extraction	Water	/	Conforms
solubility	Fully soluble in water	NLS 02.65.00	Conforms
Moisture Content	< 5.0%	GB/T 5009.3-2010	3.51%
Ash	< 5.0%	AOAC 942.05,17 th	2.19%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.09 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.02 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.16 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.07 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	165
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	42
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 40% Mogroside V
 Lot No.LHG-140813

Product Name:Luo Han Guo Extract 40% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Aug.13,2014 Testing Date:Aug.14,2014 Expire Date:Aug.12,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 40%	HPLC	40.83%
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	2.87%
Ash	< 5.0%	AOAC 942.05,17 th	1.96%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.08 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.17 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.08 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	220
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	36
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 40% Mogroside V
 Lot No.LHG-140820

Product Name:Luo Han Guo Extract 40% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Aug.20,2014 Testing Date:Aug.21,2014 Expire Date:Aug.19,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 40%	HPLC	40.51%
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	99%
Method of Extraction	Water	/	Conforms
solubility	Fully soluble in water	NLS 02.65.00	Conforms
Moisture Content	< 5.0%	GB/T 5009.3-2010	2.75%
Ash	< 5.0%	AOAC 942.05,17 th	1.82%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.14 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.02 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.13 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.08 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	230
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	31
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 40% Mogroside V
 Lot No.LHG-140828

Product Name:Luo Han Guo Extract 40% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Aug.28,2014 Testing Date:Aug.29,2014 Expire Date:Aug.27,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 40%	HPLC	40.46%
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	2.93%
Ash	< 5.0%	AOAC 942.05,17 th	1.85%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.11 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.02 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.18 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.09 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	175
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	38
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 50% Mogroside V
 Lot No.LHG-140817

Product Name:Luo Han Guo Extract 50% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Aug.17,2014 Testing Date:Aug.18,2014 Expire Date:Aug.16,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 50%	HPLC	51.14%
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	2.73%
Ash	< 5.0%	AOAC 942.05,17 th	1.93%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.15 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.16 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.06 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	175
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	42
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 50% Mogroside V
 Lot No.LHG-140825

Product Name:Luo Han Guo Extract 50% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Aug.25,2014 Testing Date:Aug.26,2014 Expire Date:Aug.24,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 50%	HPLC	50.81%
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	2.66%
Ash	< 5.0%	AOAC 942.05,17 th	1.79%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.13 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.02 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.13 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.07 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	210
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	36
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 50% Mogroside V
 Lot No.LHG-140912

Product Name:Luo Han Guo Extract 50% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Sep.12,2014 Testing Date:Sep.13,2014 Expire Date:Sep.11,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 50%	HPLC	50.93%
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	2.58%
Ash	< 5.0%	AOAC 942.05,17 th	1.86%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.08ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.18ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.05ppm
Total Plate Count	< 1000 cfu/ml Max	CP 2010	220
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g Max	CP 2010	45
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: (6)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 55% Mogroside V
 Lot No.LHG-140614

Product Name:Luo Han Guo Extract 55% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jun.14,2014 Testing Date:Jun.15,2014 Expire Date:Jun.13,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 55%	HPLC	55.73%
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	2.27%
Ash	< 5.0%	AOAC 942.05,17 th	1.68%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.12 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.17 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.06 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	230
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	39
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 55% Mogroside V
 Lot No.LHG-140723

Product Name:Luo Han Guo Extract 55% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jul.23,2014 Testing Date:Jul.24,2014 Expire Date:Jul.22,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 55%	HPLC	55.62%
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	2.32%
Ash	< 5.0%	AOAC 942.05,17 th	1.57%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.13 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.17 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.07 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	170
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	28
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 55% Mogroside V
 Lot No.LHG-140808

Product Name:Luo Han Guo Extract 55% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Aug.08,2014 Testing Date:Aug.09,2014 Expire Date:Aug.07,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 55%	HPLC	55.96%
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	2.16%
Ash	< 5.0%	AOAC 942.05,17 th	1.71%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.08 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.17 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.08 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	185
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	31
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 90% Mogroside V
 Lot No.LHG-140614

Product Name:Luo Han Guo Extract 90% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Jun.14,2014 Testing Date:Jun.15,2014 Expire Date:Jun.13,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 90%	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 942.05,17 th	1.24%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.11 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.04 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.15 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.06 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	160
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 90% Mogroside V
 Lot No.LHG-140723

Product Name:Luo Han Guo Extract 90% Mogroside V			
Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey			
Manufacture Date:Jul.23,2014			
Testing Date:Jul.24,2014			
Expire Date:Jul.22,2016			
Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 90%	HPLC	91.26%
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	1.73%
Ash	< 5.0%	AOAC 942.05,17 th	1.16%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.13 ppm
Cadmium (Cd)	< 0.05 ppm	AOAC 2006.03	0.03 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.17 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.08ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	195
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	31
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)

Luo Han Guo Extracts

Certificate of Analyses of Luo Han Guo Extract 90% Mogroside V
 Lot No.LHG-140808

Product Name:Luo Han Guo Extract 90% Mogroside V Latin Name:Siraitia grosvenorii (Swingle) C. Jeffrey Manufacture Date:Aug.08,2014 Testing Date:Aug.09,2014 Expire Date:Aug.07,2016 Shelf Life:2 Years			
Analysis Item	Specification	Analytical method	Actual value
Mogroside V	≥ 90%	HPLC	90.75%
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	1.78%
Ash	< 5.0%	AOAC 942.05,17 th	1.29%
Arsenic (As)	< 0.2 ppm	AOAC 2013.06	0.08 ppm
Cadmium (Cd)	< 0.15 ppm	AOAC 2006.03	0.04 ppm
Lead (Pb)	< 0.5 ppm	AOAC 2006.03	0.22 ppm
Mercury (Hg)	< 0.1 ppm	AOAC 993.14	0.05 ppm
Total Plate Count	< 1000 cfu/ml	CP 2010	150
P.aeruginosa	Absent	CP 2010	Absent
S. aureus	Absent	CP 2010	Absent
Salmonella	Absent	CP 2010	Absent
Yeast & Mold	< 100 cfu/g	CP 2010	39
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)

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