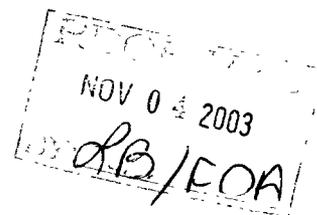


**The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance  
Towards  
Pre-market Notification for Dietary Supplement Substance in USA**

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Han Xu, M.D.  
Pharm1 Medicine Technology INC.  
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Susan Walker, M.D.,  
Division Director,  
Division of Dietary Supplements Programs,  
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820),  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration,  
5100 Paint Branch Parkway, College Park, MD 20740  
Telephone number: 301 436 - 2375



Dear FDA Officer Dr. Susan Walker - Acting Director,

**Subject: Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance towards  
75-Day Pre-market Notification for Dietary Supplement Substance in USA**

Thank you for your reading.

We are Conseco Sea buckthorn Co., Ltd.. Right now, we submit the documents about "The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance towards 75-Day Pre-market Notification for Dietary Supplement Substance in USA" to FDA, CFSAN. Please relevant Officers review the documents according to "Federal Food, Drug, and Cosmetic Act" of USA, and tell us all of your viewpoints, in order to let us finish the whole notification process of the product.

Thank you for your considering.

We are looking forward to hearing from you as soon as possible.

Sincerely yours,

*Han Xu*

Han Xu, M.D.  
Senior Researcher

86392

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Overview - The Warmhearted Brand Sea Buckthorn Rich Flavone  
Extraction Substance

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**Catalog**

My name and complete address: ..... 2

The name of the new dietary supplement: ..... 2

    The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance ..... 2

The description of the dietary supplement substance: ..... 2

    Our products abide by following P. R. China Industry Standards:..... 2

    The level of the dietary ingredients in the product:..... 3

        Dietary Ingredients: Total Sea Buckthorn Flavones  $\geq$  0.7g/100g ..... 3

    The conditions of use of the product:..... 3

    The label contents of the product:..... 3

    The history of use like as herbal extraction in P. R. China:..... 4

        Domestic Dietary Supplement Approval Certification ..... 4

        Product Name: Sea Buckthorn Rich Flavone Extraction Soft Capsule.... 4

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My signature by myself you can contact me if you have any questions..... 9

All of materials I will send an original and two copies (3 copies).

## Overview - The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance

---

### **My name and complete address:**

Han Xu, M.D.  
Pharm1 Medicine Technology INC.  
No: A-1 Fuxing Road, Haidian District, Beijing 100038, P. R. China  
**Tel:** 0086-010-63205022, **Fax:** 0086-010-63204359  
**E-mail:** [infor@pharm1.com](mailto:infor@pharm1.com) or [hanxu62@sina.com](mailto:hanxu62@sina.com)

### **The name of the new dietary supplement:**

The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance

### **The description of the dietary supplement substance:**

This is the 100% natural herbal dietary supplement substance obtained from the botanical fruits of Sea buckthorn (*Hippophae rhamnoides* L.). Like as the material substance of dietary supplement, we recommend that the product can be used as soft capsule in 0.45g/capsule, oral administration, [**Specification:** 0.45g/capsule] [**Dosage:** 4 capsules/time, 2 times/day].

Our products abide by following P. R. China Industry Standards:

Document Digest

**Green Trade Standards of Importing & Exporting Medicinal Plants & Preparations**

P. R. China Foreign Trade Industry Standards

WM2-2001

Ministry of Foreign Trade and Economic Cooperation, PRC

(Ministry of Commerce P. R. China)

2001-04-23 Published

2001-07-01 Implemented

#### **4. Limited Quantity Indexes**

4. 1. Heavy Metal and Arsenate
4. 1. 1. Total Heavy Metal  $\leq 20.0$  mg/kg
4. 1. 2. Pb  $\leq 5.0$  mg/kg
4. 1. 3. Cd  $\leq 0.3$  mg/kg
4. 1. 4. Hg  $\leq 0.2$  mg/kg
4. 1. 5. Cu  $\leq 20.0$  mg/kg

Page-2

---

Pharm1 Medicine Technology INC.

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## Overview - The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance

---

4. 1. 6. As  $\leq 2.0$  mg/kg
4. 2. Aflatoxin Content
  4. 2. 1. B1(Aflatoxin)  $\leq 5$   $\mu$  g/kg
4. 3. Pesticide Residual Quantity
  4. 3. 1. BHC  $\leq 0.1$  mg/kg
  4. 3. 2. DDT  $\leq 0.1$  mg/kg
  4. 3. 3. PCNB  $\leq 0.1$  mg/kg
  4. 3. 4. Aldrin  $\leq 0.02$  mg/kg
4. 4. Microbiology Indexes: Escherichia coli -- 0/g or 0/ml  
Staphylococcus aureus -- 0/g or 0/ml  
Pseudomonas aeruginosa -- 0/g or 0/ml

The level of the dietary ingredients in the product:

**Dietary Ingredients:** Total Sea Buckthorn Flavones  $\geq 0.7$ g/100g

The conditions of use of the product:

Like as the botanical material substance of dietary supplement, we recommend that the product can be used as soft capsule in 0.45g/capsule, oral administration, [**Specification:** 0.45g/capsule] [**Dosage:** 4 capsules/time, 2 times/day].

The label contents of the product:

**Brand Name:** Warmhearted Brand.

**Product Name:** Sea Buckthorn Rich Flavone Extraction Substance.

**Serving Size:** According to customer requirements.

**Dietary Ingredients:** Total Sea Buckthorn Flavones  $\geq 0.7$ g/100g

**Recommendation:** Like as the botanical material substance of dietary supplement, we recommend that the product can be used as soft capsule in 0.45g/capsule, oral administration, [**Specification:** 0.45g/capsule] [**Dosage:** 4 capsules/time, 2 times/day].

**Claim:** This is the 100% natural herbal dietary supplement. The statement has not been evaluated or approved by the FDA of USA. The product is not intended to diagnosis, treat, cure, or prevent any disease.

**Alert:** Keep out the children. Forbid in diabetes. Pay attention to body weight.

**Store:** Store at a cool & dry location.

**Distributor:** Pharm1 Medicine Technology INC.

No: A-1 Fuxing Road, Haidian District, Beijing 100038, P. R. China

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---

## Overview - The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance

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The history of use like as herbal extraction in P. R. China:

Document Digest

Ministry of Health P. R. China

### **Domestic Dietary Supplement Approval Certification**

**Product Name: Sea Buckthorn Rich Flavone Extraction Soft Capsule**

**Approval Date: September 5, 2000**

Approval Number: WeiShiJianZi (2000) Di 0426 Hao

Dietary Ingredient: Total Flavone 710mg/100g

Dosage: 2times/day, 4capsules/time.

Specification: 0.45g/capsule

Guarantee Period: 18 months

Storage: cool & dry.

Claim: The product cannot replace medicines or drugs.

**The product usage history as herbal extraction should be beginning from September 5, 2000 formally. Until right now, there is no adverse reaction report in P. R. China.**

The other evidences of safety:

Document Digest

Department of Nutrition & Food Hygiene

Beijing Medical University

### **CERTIFICATE OF ASSAY**

**Number of Delivery:** 981101

**Name of Sample:** Sea Buckthorn Rich Flavone Extraction

**Items of Assay:** 10-days acute toxic tests, 30-days long-term toxicity studies.

**Date of Acceptance:** November 1998.

**Date of Report:** March 1999.

**Result of Evaluation:** The test results towards Sea Buckthorn Rich Flavone Extraction show that: according to the 10-days acute toxic tests in Kunming white mice and Wistar rats, the report determines that the product LD50 is 10.0g/kgbw and belongs to non-toxicity grade in fact; according to the 30-days long-term toxicity studies, in Wistar rat results about growth & development, blood & blood biochemistry index, organ weights and tissue pathology examination, the report overalls above data and demonstrates that the Sea Buckthorn Rich Flavone Extraction causes no adverse reactions in Wistar rats.

**(This is just certificated for the delivered sample)**

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## Overview - The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance

**Sample:** Sea Buckthorn Rich Flavone Extraction Capsule, brown semi-solid.

**Experiment Animals:** healthy Kuming white mice (Approval Number YiDongZi 01-3049), healthy Wistar rats (Approval Number YiDongZi 01-3056). Supplied by Division of Laboratory Animals, Beijing Medical University.

### Methods & Results:

#### 10-days acute toxic tests towards mice:

The 50 healthy Kuming white mice, 25 male and 25 female, mouse body weight (bw) 18-22g, divided into 5 dosage groups random, the highest dosage 21.5g/kgbw, the lowest dosage 1.0g/kgbw, data separation 2.15. Fast 14 hours, injection gastric (i.g.) with the product, Sea Buckthorn Rich Flavone Extraction. Observe 10 days, record toxicity & death, and calculate LD50 values with specific data table.

#### 10-days acute toxic tests towards rats:

The 50 healthy Wistar rats, 25 male and 25 female, rat body weight (bw) 180-220g, divided into 5 dosage groups random, the highest dosage 21.5g/kgbw, the lowest dosage 1.0g/kgbw, data separation 2.15. Fast 14 hours, injection gastric (i.g.) with the product, Sea Buckthorn Rich Flavone Extraction. Observe 10 days, record toxicity & death, and calculate LD50 values with specific data table.

According to the 10-days acute toxic tests in Kunming white mice and Wistar rats, the report determines that the product LD50 is 10.0g/kgbw and belongs to non-toxicity grade in fact

**Table 1** - The Acute Toxic Tests towards Mice & Rats for Sea Buckthorn Rich Flavone Extraction

Animal	Sex	Path	LD50 (g/kgbw)
Wistar rats	Male	Oral - i.g.	10.0
	Female		10.0
Kuming mice	Male	Oral - i.g.	10.0
	Female		10.0

#### 30-days long-term toxicity studies:

Wistar rats 80, 40 male and 40 female, average body weight (bw)  $50.6 \pm 6.4$ g. Divided into 4 groups random, each group 20 rats, half male and half female. According to LD50=10.0g/kgbw, dosage groups 1/5, 1/15, 1/45LD50 and control group; fed control group ordinary food; for experiment groups, Sea Buckthorn Rich Flavone Extraction mixed into ordinary food, (according to 10% body weight for food amount/rat/day), fed 1/45LD50 group Sea Buckthorn Rich Flavone Extraction/food 2.2g/kg, fed 1/15LD50 group Sea Buckthorn Rich Flavone Extraction/food 6.7g/kg, fed 1/5LD50 group Sea Buckthorn Rich Flavone Extraction/food 20.0g/kg. Fed groups in cages individually. Freedom drink and food, fed for 30 days, and observe indexes as following:

Page-5

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## Overview - The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance

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**General observations:** record ordinary conditions and behaviors about animals, toxicity reactions and death. In 4 weeks, there are no toxicity reactions or deaths in all of animal groups.

**Body weight and food-using rate:** Table 5, balance body weight (bw) and food ingestion each week, calculate food-using rate. There is no significant difference comparison to control group about body weight (bw), net body weight (bw) rising, or food-using rate.

**Blood examinations:** Table 6, sampling animal blood at the end of experiments, assay Hb, RBC count, WBC count & classify. In female dosage groups, there are significant differences comparisons to control group about marked lower lobocyte ratio for WBC classify ( $P<0.05$ ), and marked higher lymphocyte ratio for WBC classify ( $P<0.05$ ). There is no significant difference comparison to control group about other blood indexes.

**Blood biochemistry examinations:** Table 7, sampling animal blood at the end of experiments, (before blood sampling, fasting 16 hours), separate serum, assay biochemistry indexes as following: GPT, Total Protein, Albumin, Triglyceride, Total Cholesterol, Blood Sugar, and BUN. There is no significant difference comparison to control group about all of above blood biochemistry indexes.

**Organ weights and organ-weight/body-weight ratio:** Table 8, sampling rat liver, kidney, spleen, balance weight and calculate organ-weight/body-weight ratio. There is no significant difference comparison to control group about all of above indexes.

**Tissue pathology examinations:** sampling liver, kidney, spleen, stomach & duodenum, sex gland (ovaries or testes), record macroscopic observations and tissue slides, there are no macroscopic pathological changes or tissue pathology changes in above organs.

According to the 30-days long-term toxicity studies, there are no abnormal changes about growth & development; there are no abnormal changes about blood biochemistry indexes; In female dosage groups, there are significant differences comparisons to control group about marked lower lobocyte ratio for WBC classify ( $P<0.05$ ), and marked higher lymphocyte ratio for WBC classify ( $P<0.05$ ); there are no tissue pathology changes in liver, kidney, spleen, stomach & duodenum, and sex gland (ovarium or testes).

### **Conclusions:**

According to the 10-days acute toxic tests in Kunming white mice and Wistar rats, the report determines that the product LD50 is 10.0g/kgbw and belongs to non-toxicity grade in fact; according to the 30-days long-term toxicity studies, in Wistar rat results about growth & development, blood & blood biochemistry indexes, organ weights and tissue pathology examinations, the report overalls above and demonstrates that the Sea Buckthorn Rich Flavone Extraction causes no adverse reactions in Wistar rats.

## Overview - The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance

**Table 5 - Sea Buckthorn Rich Flavone Extraction towards 30-days Rat Body Weight and Food-Using Rate (Average  $\pm$  SD)**

Sex	Group	Animal Count	Initial body weight (g)	End body weight (g)	Net bw rising (g)	Total food ingestion (g)	Food-using rate (%)
Male	Control	10	54.4 $\pm$ 6.2	199.2 $\pm$ 16.9	144.8 $\pm$ 14.5	460.9 $\pm$ 39.2	31.4 $\pm$ 1.5
Male	0.22g/kgbw	10	51.7 $\pm$ 8.2	185.7 $\pm$ 15.9	134.0 $\pm$ 13.9	436.7 $\pm$ 43.2	30.7 $\pm$ 2.1
Male	0.67g/kgbw	10	51.4 $\pm$ 5.8	192.5 $\pm$ 19.2	141.1 $\pm$ 17.3	458.0 $\pm$ 52.2	30.8 $\pm$ 2.2
Male	2.00g/kgbw	10	53.4 $\pm$ 4.9	188.0 $\pm$ 34.4	134.6 $\pm$ 32.0	435.2 $\pm$ 70.4	30.7 $\pm$ 4.0
Female	Control	10	47.6 $\pm$ 9.3	166.9 $\pm$ 14.8	119.3 $\pm$ 10.0	430.3 $\pm$ 35.4	27.8 $\pm$ 2.4
Female	0.22g/kgbw	10	48.2 $\pm$ 4.8	176.1 $\pm$ 21.4	127.9 $\pm$ 20.4	462.7 $\pm$ 56.2	27.6 $\pm$ 3.1
Female	0.67g/kgbw	10	49.7 $\pm$ 5.5	159.8 $\pm$ 19.1	110.1 $\pm$ 19.4	426.6 $\pm$ 39.1	25.8 $\pm$ 3.7
Female	2.00g/kgbw	10	48.3 $\pm$ 6.6	157.5 $\pm$ 28.8	109.2 $\pm$ 30.7	391.8 $\pm$ 75.2	27.6 $\pm$ 5.2

**Table 6 - Sea Buckthorn Rich Flavone Extraction towards 30-days Rat Blood Examinations (Average  $\pm$  SD)**

Sex	Group	Animal Count	RBC $10^6/\text{mm}^3$	Hb (g/L)	WBC $10^3/\text{mm}^3$	Lobocyte (%)	Lymphocyte (%)
Male	Control	10	7.95 $\pm$ 0.82	150.1 $\pm$ 5.9	7.06 $\pm$ 2.76	17.5 $\pm$ 6.0	82.1 $\pm$ 5.7
Male	0.22g/kgbw	10	7.94 $\pm$ 0.58	143.9 $\pm$ 8.5	6.65 $\pm$ 1.01	19.4 $\pm$ 3.1	79.6 $\pm$ 3.2
Male	0.67g/kgbw	10	7.79 $\pm$ 0.80	153.2 $\pm$ 12.3	5.84 $\pm$ 1.02	21.8 $\pm$ 4.7	77.7 $\pm$ 4.7
Male	2.00g/kgbw	10	8.21 $\pm$ 1.30	148.2 $\pm$ 17.4	7.81 $\pm$ 3.06	19.5 $\pm$ 4.2	79.4 $\pm$ 3.9
Female	Control	10	7.60 $\pm$ 0.54	149.0 $\pm$ 10.5	6.55 $\pm$ 1.36	22.5 $\pm$ 4.8	76.9 $\pm$ 4.7
Female	0.22g/kgbw	10	7.66 $\pm$ 0.50	150.8 $\pm$ 12.1	6.71 $\pm$ 1.26	16.3 $\pm$ 3.6*	83.0 $\pm$ 3.9*
Female	0.67g/kgbw	10	6.69 $\pm$ 1.03	145.6 $\pm$ 11.5	6.25 $\pm$ 1.46	16.5 $\pm$ 3.8*	83.1 $\pm$ 3.8*
Female	2.00g/kgbw	10	6.93 $\pm$ 0.76	144.9 $\pm$ 12.2	5.92 $\pm$ 1.85	15.8 $\pm$ 3.4*	83.6 $\pm$ 3.6*

\* There are significant differences comparisons to control group (P<0.05).

## Overview - The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance

**Table 7 - Sea Buckthorn Rich Flavone Extraction towards 30-days Rat Blood Biochemistry Examinations (Average  $\pm$  SD)**

Sex	Group	Animal Count	GPT (IU/L)	Total Protein (g/L)	Albumin (g/L)	Cholesterol (mmol/L)	Triglyceride (mmol/L)	BUN (mmol/L)	Glucose (mmol/L)
Male	Control	10	37.8 $\pm$ 3.6	75.4 $\pm$ 3.2	34.1 $\pm$ 1.2	1.71 $\pm$ 0.25	0.63 $\pm$ 0.15	6.87 $\pm$ 1.28	6.37 $\pm$ 0.72
Male	0.22g/kgbw	10	45.2 $\pm$ 9.0	73.4 $\pm$ 2.4	33.4 $\pm$ 0.7	1.80 $\pm$ 0.18	0.79 $\pm$ 0.28	7.61 $\pm$ 1.42	6.17 $\pm$ 0.94
Male	0.67g/kgbw	10	44.3 $\pm$ 9.7	73.2 $\pm$ 4.5	33.5 $\pm$ 1.5	1.82 $\pm$ 0.30	0.61 $\pm$ 0.10	7.43 $\pm$ 0.79	6.62 $\pm$ 0.68
Male	2.00g/kgbw	10	41.9 $\pm$ 6.5	74.1 $\pm$ 4.2	34.1 $\pm$ 0.9	1.77 $\pm$ 0.28	0.93 $\pm$ 0.35	7.96 $\pm$ 1.07	5.84 $\pm$ 1.04
Female	Control	10	46.4 $\pm$ 11.2	74.0 $\pm$ 2.7	34.8 $\pm$ 0.8	2.14 $\pm$ 0.39	0.86 $\pm$ 0.29	8.03 $\pm$ 1.56	5.49 $\pm$ 0.91
Female	0.22g/kgbw	10	42.1 $\pm$ 6.18	73.8 $\pm$ 2.3	34.7 $\pm$ 1.4	2.18 $\pm$ 0.40	0.67 $\pm$ 0.16	8.22 $\pm$ 1.12	5.53 $\pm$ 1.00
Female	0.67g/kgbw	10	43.5 $\pm$ 10.1	74.1 $\pm$ 3.0	34.2 $\pm$ 1.3	2.22 $\pm$ 0.42	0.64 $\pm$ 0.13	7.58 $\pm$ 0.73	5.40 $\pm$ 0.79
Female	2.00g/kgbw	10	39.2 $\pm$ 8.1	72.8 $\pm$ 3.4	34.9 $\pm$ 1.0	2.21 $\pm$ 0.31	0.70 $\pm$ 0.24	7.77 $\pm$ 0.92	5.80 $\pm$ 0.82

**Table 8 - Sea Buckthorn Rich Flavone Extraction towards 30-days Rat Organ Weights and Organ-Weight/Body-Weight Ratio (Average  $\pm$  SD)**

Sex	Group	Animal Count	Liver		Kidney		Spleen	
			Organ Weight (g)	Organ/Body (%)	Organ Weight (g)	Organ/Body (%)	Organ Weight (g)	Organ/Body (%)
Male	Control	10	6.58 $\pm$ 0.83	3.30 $\pm$ 0.19	1.42 $\pm$ 0.13	0.71 $\pm$ 0.03	0.45 $\pm$ 0.07	0.23 $\pm$ 0.04
Male	0.22g/kgbw	10	5.72 $\pm$ 0.69	3.11 $\pm$ 0.23	1.32 $\pm$ 0.10	0.72 $\pm$ 0.03	0.43 $\pm$ 0.10	0.23 $\pm$ 0.05
Male	0.67g/kgbw	10	6.35 $\pm$ 0.77	3.38 $\pm$ 0.51	1.40 $\pm$ 0.12	0.75 $\pm$ 0.10	0.36 $\pm$ 0.12	0.19 $\pm$ 0.07
Male	2.00g/kgbw	10	6.13 $\pm$ 1.34	3.29 $\pm$ 0.29	1.36 $\pm$ 0.21	0.74 $\pm$ 0.05	0.40 $\pm$ 0.15	0.21 $\pm$ 0.06
Female	Control	10	5.42 $\pm$ 0.64	3.25 $\pm$ 0.26	1.37 $\pm$ 0.10	0.82 $\pm$ 0.03	0.39 $\pm$ 0.07	0.24 $\pm$ 0.05
Female	0.22g/kgbw	10	5.57 $\pm$ 0.84	3.21 $\pm$ 0.31	1.40 $\pm$ 0.16	0.81 $\pm$ 0.08	0.42 $\pm$ 0.11	0.24 $\pm$ 0.06
Female	0.67g/kgbw	10	5.37 $\pm$ 0.92	3.43 $\pm$ 0.68	1.31 $\pm$ 0.13	0.83 $\pm$ 0.06	0.37 $\pm$ 0.09	0.23 $\pm$ 0.05
Female	2.00g/kgbw	10	5.25 $\pm$ 1.15	3.30 $\pm$ 0.29	1.31 $\pm$ 0.25	0.83 $\pm$ 0.06	0.40 $\pm$ 0.16	0.25 $\pm$ 0.07

## Overview - The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance

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**Other adverse substances are limited by following P. R. China Industry Standards:**

Document Digest

**Green Trade Standards of Importing & Exporting Medicinal Plants & Preparations**

P. R. China Foreign Trade Industry Standards

WM2-2001

Ministry of Foreign Trade and Economic Cooperation, PRC

(Ministry of Commerce P. R. China)

2001-04-23 Published

2001-07-01 Implemented

#### **4. Limited Quantity Indexes**

4. 1. Heavy Metal and Arsenate

4. 1. 1. Total Heavy Metal  $\leq 20.0$  mg/kg

4. 1. 2. Pb  $\leq 5.0$  mg/kg

4. 1. 3. Cd  $\leq 0.3$  mg/kg

4. 1. 4. Hg  $\leq 0.2$  mg/kg

4. 1. 5. Cu  $\leq 20.0$  mg/kg

4. 1. 6. As  $\leq 2.0$  mg/kg

4. 2. Aflatoxin Content

4. 2. 1. B1(Aflatoxin)  $\leq 5$   $\mu$  g/kg

4. 3. Pesticide Residual Quantity

4. 3. 1. BHC  $\leq 0.1$  mg/kg

4. 3. 2. DDT  $\leq 0.1$  mg/kg

4. 3. 3. PCNB  $\leq 0.1$  mg/kg

4. 3. 4. Aldrin  $\leq 0.02$  mg/kg

4. 4. Microbiology Indexes: Escherichia coli -- 0/g or 0/ml

Staphylococcus aureus -- 0/g or 0/ml

Pseudomonas aeruginosa -- 0/g or 0/ml

**My signature by myself you can contact me if you have any questions**

*Han Xu*

Han Xu, M.D.

Pharm1 Medicine Technology INC.

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