

A PROPRIETARY CHINESE MEDICINE SUITABLE FOR GLOBAL TOBACCO CONTROL, PREPARATION METHOD AND USE THEREOF

TECHNICAL FIELD

5 This invention relates to traditional Chinese medicines and health products, particularly, to a proprietary Chinese medicine suitable for global tobacco control, preparation method and use thereof, and more particularly, to a liquid composition administrable through nose and suitable for controlling tobacco dependence, preparation method and use thereof.

BACKGROUND ART

10 Nowadays, it is very necessary to control tobacco dependence. It is well known that smoking can lead to artery stenosis, cirrhosis, asthma, memory and vision loss, emphysema, acne, decreased immune function, gastrointestinal
15 dysfunction, a substantial lack of vitamin, more susceptible to illness, and poisoning. Women who smoke are susceptible to genital infection, disruption of hormone balance in the body, and presenility, and smoking during pregnancy may cause premature birth, miscarriage and stillbirth. Passive or indirect exposure to smoking is found more harmful due to smoking in public places.

20 Studies show that, for the smokers among normal population, after 1-9 months when succeeded in tobacco control, coughing and shortness of breath may decrease; after 1 year, the risk of coronary heart disease can be about half of that of a smoker; after 5 years, the risk of stroke can be reduced to that of a nonsmoker; after 10 years,
25 the risk of lung cancer can be reduced to half of that of a smoker, and the risk of mouth, laryngeal, esophagus, bladder, cervical, and pancreatic cancer can be reduced; and after 15 years, the risk of coronary heart disease can be same as that of a nonsmoker. Moreover, excess risk of many diseases related to second-hand smoke in children, such as respiratory system diseases (e.g., asthma) and ear
30 infections, can be reduced. The chances of impotence, having difficulty getting

pregnant, having premature births, babies with low birth weights and miscarriage may also decrease.

At present, tobacco control products in the global market are in circulation in form of foodstuff or health products without strict medical regulatory examination and evaluation of actual effects, and there is no strict product monitoring system in those countries where the products are present. Some countries allow applications of hypnosis, acupuncture, laser therapy, alternative medicine or cigarette alternatives for tobacco control, but no evidence in health science has been found by the World Health Organization to support such applications.

Therefore, the existing technologies and products lack of tobacco control effects on smokers or patients.

SUMMARY OF THE INVENTION

It is an object of this invention to resolve at least one or more of the problems in the prior art as described above. Particularly, it is an object of this invention to provide a liquid composition usable for controlling tobacco dependence. It is also an object of this invention to provide preparation method of the liquid composition. It is also an object of this invention to provide use of the liquid composition.

Accordingly, this invention provides a method for preparing a liquid composition administrable through nose for controlling tobacco dependence, including following steps:

(a) Providing respective parts by weight (pbw) of raw materials as follows: 12-24 pbw of Radix et Rhizoma Rhei, 9-21 pbw of Rhizoma Coptidis, 2-7 pbw of Cortex Phellodendri; 2-8 pbw of Radix Sophorae Flavescentis, 2-7 pbw of Radix Notoginseng, 2-8 pbw of Cortex Moutan, 9-21 pbw of Herba Cissampelotis, 1-3 pbw of Stigma Croci, 4-9 pbw of Pericarpium Citri Reticulatae, 5-12 pbw of Rhizoma Zingiberis, 2-7 pbw of Flos Mume, 2-8 pbw of Radix Curcumae, 2-7 pbw of Herba

Pogostemonis, 1-3 pbw of Fructus Foeniculi, 2-9 pbw of Flos Jasmini Sambac, 0.03-0.2 pbw of Vitamin C, 1-3 pbw of liquid food flavoring; wherein the liquid food flavoring is an aqueous solution of a food flavoring having a concentration of 1.5-3 % (w/w);

5 (b) Pulverizing the raw materials except for the Vitamin C and liquid food flavoring into powder, and extracting the obtained powder with water at 80-100°C to obtain a water extract, wherein the amount of the water used is 5-7 times of the total weight of all the raw materials; and

10 (c) Mixing the water extract with the Vitamin C and liquid food flavoring to obtain the composition.

Preferably, the parts by weight (pbw) of the raw materials are as follows:

15 Radix et Rhizoma Rhei: 18 pbw; Rhizoma Coptidis: 15 pbw; Cortex Phellodendri: 3.5 pbw; Radix Sophorae Flavescens: 4.5 pbw; Radix Notoginseng: 3.5 pbw; Cortex Moutan: 4 pbw; Herba Cissampelotis: 15 pbw; Stigma Croci: 1.5 pbw; Pericarpium Citri Reticulatae: 6 pbw; Rhizoma Zingiberis: 8.5 pbw; Flos Mume: 3.5 pbw; Radix Curcumae: 4.5 pbw; Herba Pogostemonis: 3.5 pbw; Fructus Foeniculi: 1.5 pbw; Flos Jasmini Sambac: 5 pbw; Vitamin C: 0.1 pbw; liquid food flavoring: 1.5 pbw, wherein the liquid food
20 flavoring is an aqueous solution of a food flavoring having a concentration of 2 % (w/w).

25 Preferably, in the step (b), said extracting includes 3-4 times of extractions with the water at said temperature, each time for 4-6 hours, and the water is only added in the first time of extraction.

Preferably, in the step (c), the water extract is mixed with the Vitamin C and liquid food flavoring within 6 hours after obtaining the water extract.

30 Preferably, the water extract obtained in the step (b) is sealed and the

composition obtained in the step (c) is sealed, for later use to avoid volatilization, respectively.

Preferably, the step (b) includes: pulverizing the raw materials except for the Vitamin C and liquid food flavoring into powder, extracting the powder with the water at 80-100°C for 6 hours for 3 times to obtain the water extract, and sealing the water extract for later use, wherein the amount of the water used is 6 times of the total weight of all the raw materials; and

the step (c) includes: mixing the water extract with the Vitamin C and the liquid food flavoring within 6 hours after obtaining the water extract to obtain the composition, and sealing the composition for later use.

It is another aspect of this invention to provide a liquid composition administrable through nose for controlling tobacco dependence prepared according to the method of this invention.

Preferably, the composition is prepared into a dose form for administration through nose.

It is yet another aspect of this invention to provide use of the composition for the manufacturing of a medicament or health product for controlling tobacco dependence.

It is yet another aspect of this invention to provide a method for controlling tobacco dependence, including administering the composition to a smoker through nose.

This invention has achieved the following technical effects:

- (1) The products according to this invention have no toxic and side effects;
- (2) The effective rate of tobacco control for the smokers among normal population

can reach 99% when using the products of this invention for 3-15 days;

(3) The heart rate and blood pressure of some of the smokers among normal population tend to be normal when using the products of this invention for 3 days; the concentration of carbon monoxide in the blood of some of the smokers among normal population can decrease to normal value when using the products of this invention for 10 days; circulation of some of the smokers among normal population can be improved and lung function can be enhanced when using the products of this invention for 15 days.

DESCRIPTION OF SPECIFIC EMBODIMENTS

This invention is now described by way of examples in the following paragraphs, but this invention is not intended to be limited thereto. Various modifications and alterations of this invention will become apparent to those skilled in the art without departing from the spirit and scope of this invention, and therefore, are also within the scope of the invention.

It was surprisingly discovered by the inventor of this invention that the composition prepared from Radix et Rhizoma Rhei, Rhizoma Coptidis, Cortex Phellodendri, Radix Sophorae Flavescentis, Radix Notoginseng, Cortex Moutan, Herba Cissampelotis, Stigma Croci, Pericarpium Citri Reticulatae, Rhizoma Zingiberis, Flos Mume, Radix Curcumae, Herba Pogostemonis, Fructus Foeniculi, Flos Jasmini Sambac, Vitamin C, and food flavoring can provide particularly advantageous effects on controlling tobacco dependence.

Accordingly, this invention provides a health science related product that is suitable for global tobacco control, able to protect current and future generations from damaging effect on health, society, environment and economics caused by tobacco consumption and exposure to second-hand smoke, and thus can be used to further strengthen international cooperation, to vigorously advocate and fully implement the World Health Organization Framework Convention on Tobacco

Control, and to promote the human health.

As used herein, when referring to the liquid composition of this invention, “administrable through nose”, “for administration through nose”, or “administering the same through nose” means that the liquid composition can be administered by smelling or nasally inhaling the same, particularly a vapor thereof. When nasally inhaling the liquid composition, exhaling can be carried out via nose or mouth. Preferably, the liquid composition can be administered by nasally inhaling the same in a deep breathing way, including inhaling via nose and exhaling via mouth, for example, for about 10-20 minutes each time, twice daily.

As used herein, the definition or description of each of the Chinese herbal medicines used in the raw materials are known in the art and can be found in, for example, “Pharmacopoeia of the People's Republic of China”, edited by Chinese Pharmacopoeia Commission, published by China Medical Science Press, 2010, or “Chinese Herbal Medicines” (Schedule 2) in “Chinese Medicine Ordinance” (Chapter 549) issued by the Government of the Hong Kong Special Administrative Region of the People's Republic of China, Version Date: August 6, 1999. The names, definition or description and parts by weight of the ingredients of the raw materials, including the Chinese herbal medicines and adjuvants or additives, used in the composition of this invention are listed in Table 1:

Table 1

Name	Definition or Description	Parts by weight
Radix et Rhizoma Rhei	Root or rhizome of <i>Rheum palmatum</i> L., <i>Rheum tanguticum</i> Maxim. ex Balf or <i>Rheum officinale</i> Baill	12-24
Rhizoma Coptidis	Rhizome of <i>Rhizoma Coptidis chinensis</i> Franch., <i>Rhizoma Coptidis</i>	9-21

	deltoidea C. Y. Cheng et Hsiao or Rhizoma Coptidis teeta Wall.	
Cortex Phellodendri	Bark of Phellodendron chinense Schneid or Phellodendron amurense Rupr	2-7
Radix Sophorae Flavescentis	Root of Sophora flavescens Ait.	2-8
Radix Notoginseng	Root of Panax notoginseng (Burk.) F. H. Chen	2-7
Cortex Moutan	Root bark of Paeonia suffruticosa Andr.	2-8
Herba Cissampelotis	Any or whole part of Cissampelos pareira L. var. hirsuta (Buch. ex DC) Forman	9-21
Stigma Croci	Stigma of Crocus sativus L.	1-3
Pericarpium Citri Reticulatae	Pericarp of the ripe fruit of Citrus reticulata Balanco or its cultivars	4-9
Rhizoma Zingiberis	Rhizome of Zingiber officinale Roscoe	5-12
Flos Mume	Flower bud of Prunus mume (Sieb.) Sieb. et Zucc.	2-7
Radix Curcumae	Root tuber of Curcuma wenyujin Y. H. Chen et C. Ling, Curcuma longa L., Curcuma kwangsiensis S.G. Lee et C. F. Liang or Curcuma phaeocaulis Val.	2-8
Herba Pogostemonis	Aerial part of Pogostemon cablin (Blanco) Benth. of family Labiatae	2-7
Fructus Foeniculi	Mature fruit of Foeniculum vulgare Mill. of family Umbelliferae	1-3

Flos Jasmini Sambac	flowers of Jasminum sambac (L.) Ait	2-9
Vitamin C	L-ascorbic acid or ascorbate	0.03-0.02
liquid food flavoring	Aqueous solution of a food flavoring	1-3

Preferably, the parts by weight (pbw) of the raw materials are as follows:

Radix et Rhizoma Rhei: 18 pbw; Rhizoma Coptidis: 15 pbw; Cortex Phellodendri: 3.5 pbw; Radix Sophorae Flavescens: 4.5 pbw; Radix Notoginseng: 3.5 pbw; Cortex Moutan: 4 pbw; Herba Cissampelotis: 15 pbw; Stigma Croci: 1.5 pbw; Pericarpium Citri Reticulatae: 6 pbw; Rhizoma Zingiberis: 8.5 pbw; Flos Mume: 3.5 pbw; Radix Curcumae: 4.5 pbw; Herba Pogostemonis: 3.5 pbw; Fructus Foeniculi: 1.5 pbw; Flos Jasmini Sambac: 5 pbw; Vitamin C: 0.1 pbw; liquid food flavoring: 1.5 pbw, wherein the liquid food flavoring is an aqueous solution of a food flavoring having a concentration of 2 % (w/w).

As used herein, "food flavoring" includes natural flavoring, nature identical flavoring and artificial flavoring. It can be classified as solid flavoring and liquid flavoring based on the form thereof. Liquid flavoring can be further classified as water-soluble flavoring, oil-soluble flavoring and emulsified flavoring.

In this invention, preferably, the liquid food flavoring is an aqueous solution of a food flavoring with a concentration of 1.5-3 % (w/w); more preferably, the liquid food flavoring is an aqueous solution of a food flavoring with a concentration of 2 % (w/w). The liquid food flavoring is commercially available, and it may be, for example, a floral liquid food flavoring, and preferably, a jasmine liquid food flavoring.

According to one aspect of the invention, there is provided a preparation

method of a liquid composition administrable through nose for controlling tobacco dependence, including the following steps:

(a) Providing the above-described raw materials with the above-described parts by weight;

5 (b) Pulverizing the raw materials except for the Vitamin C and liquid food flavoring into powder, and extracting the obtained powder with water at 80-100℃ to obtain the water extract, wherein the amount of the water used is 5-7 times of the total weight of all the raw materials; and

10 (c) Mixing the water extract with the Vitamin C and liquid food flavoring to obtain the composition.

In the step (b), as for the materials pulverized into powder, the particle diameters of the pulverized materials can be determined according to the practical situation. For example, preferably, it may be the particle diameters commonly used in
15 the art and suitable for extracting procedure. Preferably, the raw materials are first pulverized into powder separately, next mixed, and then extracted.

Preferably, the extraction is carried out under sealed conditions. The pulverized raw materials can be extracted through heating under reflux. An extractor
20 for traditional Chinese medicine may be used to carry out the extraction. The extractor for traditional Chinese Medicine may be an ordinary extracting device for traditional Chinese Medicine, and is commercially available. Generally, the extractor for traditional Chinese medicine is used under sealed conditions and equipped with a reflux condenser and etc. Size of the extractor for traditional Chinese medicine can
25 be selected according to practical needs to obtain a desired amount of the water extract.

Preferably, in the step (b), the extracting includes 3-4 times of extractions with the water at said temperature, each time for 4-6 hours, and the water is only added in
30 the first time of extraction.

Preferably, in the step (b), the amount of the obtained water extract is about 1/2 ~1/4 of the amount of water used, and preferably, is about 1/3 of the amount of water used.

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Preferably, in the step (c), the obtained water extract is mixed with the Vitamin C and liquid food flavoring within 6 hours (such as 4-6 hours) after obtaining the water extract.

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Preferably, the water extract obtained in the step (b) is sealed and the composition obtained in the step (c) is sealed, for later use to avoid volatilization, respectively.

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Preferably, the step (b) is as follows: pulverizing the raw materials except for the Vitamin C and liquid food flavoring into powder; extracting the powder with water at 80-100°C for 6 hours for 3 times to obtain the water extract, and sealing it for later use, wherein the water is only added in the first time of extracting procedure and the amount of the water used is 6 times of the total weight of all the raw materials; and the step (c) is as follows: mixing the obtained water extract with the Vitamin C and the liquid food flavoring within 6 hours to obtain the composition and sealing it for later use.

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The composition may be sealed in sealed bottles for later use. For example, the composition may be sealed for later use in the following manner: 5 mL of the end product of the composition is loaded into each pharmaceutical bottle, which has an aperture diameter of 8 mm and a volume of 6 ml, and then each of the pharmaceutical bottles is sealed. As used herein, "pharmaceutical bottle" refers to such a bottle that is suitable for sealing the compositions, medicaments or health products of this invention, and can be utilized for administration through nose. Such pharmaceutical bottles are commercially available. For example, they may be those

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produced by Cangzhou Mingjie Pharmaceutical Packaging Co., Ltd. (Hebei Province, P. R. China) or other suppliers via vacuum sterile technology.

According to another aspect of the invention, there is provided a liquid composition administrable through nose for controlling tobacco dependence obtained by the above-described method. Preferably, such a composition is a pharmaceutical composition or a health product composition. The pharmaceutical composition or the health product composition may contain pharmaceutically acceptable adjuvants or additives. The pharmaceutic adjuvants or additives, such as antioxidant, stabilizer, or preservative, may be selected and used according to the practical needs.

Preferably, the composition is prepared into a dose form for administration through nose.

According to yet another aspect of the invention, there is provided use of the composition for the manufacturing of a medicament or health product for controlling tobacco dependence.

According to yet another aspect of the invention, there is provided a method for controlling tobacco dependence, including administering the composition to a smoker through nose.

According to yet another aspect of the invention, there is provided a method for controlling tobacco dependence, including using the composition to decrease or eliminate the tobacco dependence of smokers through nose.

The method for controlling tobacco dependence may be performed in the following manner:

(i) Before using the product of the invention, physical conditions of a subject

who smokes and the respective amount of tobacco control are assessed by medical personnel or tobacco control professionals;

(ii) Based on the assessment results of the physical conditions and amount of tobacco control, the medical personnel or tobacco control professionals supervises the subject to use the product properly, and establish service record thereof;

(iii) Next is to open a pharmaceutical bottle containing the composition of this invention and put it at about 2 mm away from the nostrils of the subject, let she or him smell the composition in a deep breathing way, e.g., inhaling via nostrils and exhaling via mouth;

(iv) Each subject is allowed to smell the composition for about 10-20 minutes each time, twice daily, and the lid of the bottle should be screwed tightly after each time;

(v) Additional smelling for about 10 minutes each time is allowed if the subject has tobacco cravings, in addition to the above-described twice-daily smelling, within the time registered for tobacco control by the medical personnel or tobacco control professionals (namely, from the starting date for tobacco control to the estimated ending date).

Tobacco can be effectively controlled within 7-20 days depending on the difference of individual's physical conditions and amount of tobacco control, so as to achieve the object of tobacco control.

It is preferable that each bottle of the product of the invention is used for one person, only. The product of the present invention should not be taken internally, and is not applicable for pregnant women.

The composition of this invention can be stored at ambient temperature.

Hereinafter, this invention will be described in detail with reference to the following Examples, but not limited thereto.

In the following Examples, the extractor for traditional Chinese medicine is a Ultrasonic Extraction and Concentration Unit for Chinese Medicine obtained from Shandong Jining Luchao Ultrasonic Equipment Co., Ltd. (Shandong Province, P. R. China) (Model: LCSR-50); the liquid food flavoring is a jasmine liquid food flavoring with a concentration of 2‰ (w/w) obtained from Qingdao Zhongkai Food Co., Ltd. (Shandong Province, P. R. China); and the pharmaceutical bottles were obtained from Cangzhou Mingjie Pharmaceutical Packaging Co., Ltd. (Hebei Province, P. R. China).

Example 1

The amount of each raw material used for preparing the composition of this Example was as follows:

Radix et Rhizoma Rhei: 900g; Rhizoma Coptidis: 750 g; Cortex Phellodendri: 175g; Radix Sophorae Flavescentis: 225 g; Radix Notoginseng: 175 g; Cortex Moutan: 200 g; Herba Cissampelotis: 750 g; Stigma Croci: 75 g; Pericarpium Citri Reticulatae: 300 g; Rhizoma Zingiberis: 425 g; Flos Mume: 175 g; Radix Curcumae: 225 g; Herba Pogostemonis: 175 g; Fructus Foeniculi: 75 g; Flos Jasmini Sambac: 250 g; Vitamin C: 5 g; liquid food flavoring: 75 g.

The preparation method was as follows:

i: Pulverizing the raw materials with the weights stated above except for Vitamin C and liquid food flavoring into powder, placing the powder into the extractor for traditional Chinese medicine, extracting with 30 kg of water at 80-100℃ for 3 times, each time for 6 hours, to obtain a water extract, and sealing it for later use;

ii: Adding Vitamin C and liquid food flavoring with the weights stated above into the obtained water extract within 6 hours, and mixing them evenly to obtain about 10 kg of final liquid of the composition;

iii: Loading 5 mL aliquot of the final liquid into each pharmaceutical bottle, which has an aperture diameter of 8 mm and a volume of 6 ml, and then sealing the

bottles to avoid volatilization.

Example 2

The amount of each raw material used for preparing the composition of this Example was as follows:

Radix et Rhizoma Rhei: 1150g; Rhizoma Coptidis: 1050 g; Cortex Phellodendri: 300g; Radix Sophorae Flavescentis: 375 g; Radix Notoginseng: 350 g; Cortex Moutan: 350 g; Herba Cissampelotis: 1050 g; Stigma Croci: 150 g; Pericarpium Citri Reticulatae: 400 g; Rhizoma Zingiberis: 600 g; Flos Mume: 350 g; Radix Curcumae: 375 g; Herba Pogostemonis: 300 g; Fructus Foeniculi: 125 g; Flos Jasmini Sambac: 425 g; Vitamin C: 7.5 g; liquid food flavoring: 150 g.

The preparation method was as follows:

i: Pulverizing the raw materials with the weights stated above except for Vitamin C and liquid food flavoring into powder, placing the powder into the extractor for traditional Chinese medicine, extracting with 50 kg of water at 80-100℃ for 4 times, each time for 6 hours, to obtain a water extract, and sealing it for later use;

ii: Adding Vitamin C and liquid food flavoring with the weights stated above into the obtained water extract within 6 hours, and mixing them evenly to obtain about 17.5 kg of final liquid of the composition;

iii: Loading 5 mL aliquot of the final liquid into each pharmaceutical bottle, which has an aperture diameter of 8 mm and a volume of 6 ml, and then sealing the bottles to avoid volatilization.

Example 3

The amount of each raw material used for preparing the composition of this Example was as follows:

Radix et Rhizoma Rhei: 700g; Rhizoma Coptidis: 450 g; Cortex Phellodendri: 150g; Radix Sophorae Flavescentis: 150 g; Radix Notoginseng: 100 g; Cortex Moutan: 200 g; Herba Cissampelotis: 500 g; Stigma Croci: 50 g; Pericarpium Citri

Reticulatae: 300 g; Rhizoma Zingiberis: 350 g; Flos Mume: 100 g; Radix Curcumae: 100 g; Herba Pogostemonis: 100 g; Fructus Foeniculi: 50 g; Flos Jasmini Sambac: 200 g; Vitamin C: 2.5 g; liquid food flavoring: 75 g.

5 The preparation method was as follows:

i: Pulverizing the raw materials with the weights stated above except for Vitamin C and liquid food flavoring into powder, placing the powder into the extractor for traditional Chinese medicine, extracting with 20 kg of water at 80-100℃ for 3 times, each time for 4 hours, to obtain a water extract, and sealing it for later use;

10 ii: Adding Vitamin C and liquid food flavoring with the weights stated above into the obtained water extract within 6 hours, and mixing them evenly to obtain about 6 kg of final liquid of the composition;

15 iii: Loading 5 mL aliquot of the final liquid into each pharmaceutical bottle, which has an aperture diameter of 8 mm and a volume of 6 ml, and then sealing the bottles to avoid volatilization.

Test Example 1: Test for Tobacco Control Effect

20 Tobacco control test was carried out on 100 subjects who smoke (18-70 years old, 3-20 years smoking history, smoking about 10-60 cigarettes daily), using the product obtained in Example 1.

The test procedures are as follows:

25 a. Before the test and on each day during the test, the indexes, such as heart rate, blood pressure, carbon monoxide (CO) level in blood, circulatory system and lung function were measured for each subject to assess the physical conditions and amount of tobacco control thereof;

b. Records for using the product were established based on the assessment results of the physical conditions and amount of tobacco control;

30 c. For each subject, a pharmaceutical bottle of the product was opened and put at about 2 mm away from the nostrils thereof, and then each subject smelled the

product in a deep breathing way, i.e., inhaling via nostrils and exhaling via mouth;

d. Each subject smelled the product for about 10-20 minutes each time, twice daily, and the lid of each bottle was screwed tightly after each time;

e. Additional smelling for about 10 minutes each time was allowed if the subject had tobacco cravings, in addition to the above-described twice-daily smelling, within the time registered for tobacco control.

Results:

It was showed that heart rate and blood pressure tended to be normal when some subjects used the product for 3 days; CO level decreased to normal value when some subjects used the product for 10 days; circulatory system improved and lung function was enhanced when some subjects used the product for 15 days. The product according to this invention exhibited no toxic and side effect on the subjects after use. Statistical data regarding the tobacco dependences of the subjects showed that when using the product for 3-15 days, the effective rate of tobacco control (i.e., the ratio of the number of the subjects who quitted smoking to the total number of the subjects) was as high as 99%.

Test Example 2: Toxicity Test on White Mice

Median lethal dose (LD50) and median lethal concentration (LC50) were determined for the product obtained in Example 1 in accordance with the conventional methods.

Determination of the median lethal dose (LD50): test data were processed by probit analysis, and LD50 for mice intraperitoneally injected once was obtained as 0.15 mL of original liquid/KG.

Determination of the median lethal dose (LC50): static exposure test was carried out, test data were processed by probit analysis, and LC50 for mice inhaling the original liquid was obtained as 0.11 mL of the original liquid/volume.

As used herein, “original liquid” refers to the final liquid of the composition obtained in Example 1.

5 The test results showed that products of this invention had no toxic and side effect on human beings.

CLAIMS

1. A method for preparing a liquid composition administrable through nose for controlling tobacco dependence, including following steps:

5 (a) Providing respective parts by weight of raw materials as follows: 12-24 pbw of Radix et Rhizoma Rhei, 9-21 pbw of Rhizoma Coptidis, 2-7 pbw of Cortex Phellodendri; 2-8 pbw of Radix Sophorae Flavescens, 2-7 pbw of Radix Notoginseng, 2-8 pbw of Cortex Moutan, 9-21 pbw of Herba Cissampelotis, 1-3 pbw of Stigma Croci, 4-9 pbw of Pericarpium Citri Reticulatae, 5-12 pbw of Rhizoma Zingiberis, 2-7 pbw of Flos Mume, 2-8 pbw of Radix Curcumae, 2-7 pbw of Herba Pogostemonis, 1-3 pbw of Fructus Foeniculi, 2-9 pbw of Flos Jasmini Sambac, 0.03-0.2 pbw of Vitamin C, 1-3 pbw of liquid food flavoring; wherein the liquid food flavoring is an aqueous solution of a food flavoring having a concentration of 1.5-3 % (w/w);

15 (b) Pulverizing the raw materials except for the Vitamin C and liquid food flavoring into powder, and extracting the obtained powder with water at 80-100°C to obtain a water extract, wherein the amount of the water used is 5-7 times of the total weight of all the raw materials; and

20 (c) Mixing the water extract with the Vitamin C and liquid food flavoring to obtain the composition.

2. The method according to claim 1, wherein the parts by weight of the raw materials are as follows:

25 Radix et Rhizoma Rhei: 18 pbw; Rhizoma Coptidis: 15 pbw; Cortex Phellodendri: 3.5 pbw; Radix Sophorae Flavescens: 4.5 pbw; Radix Notoginseng: 3.5 pbw; Cortex Moutan: 4 pbw; Herba Cissampelotis: 15 pbw; Stigma Croci: 1.5 pbw; Pericarpium Citri Reticulatae: 6 pbw; Rhizoma Zingiberis: 8.5 pbw; Flos Mume: 3.5 pbw; Radix Curcumae: 4.5 pbw; Herba Pogostemonis: 3.5 pbw; Fructus Foeniculi: 1.5 pbw; Flos Jasmini Sambac: 5 pbw; Vitamin C: 0.1 pbw; liquid food flavoring: 1.5 pbw, wherein the liquid food flavoring is an aqueous

solution of a food flavoring having a concentration of 2 ‰ (w/w).

3. The method according to claim 1, wherein in the step (b), said extracting includes 3-4 times of extractions with the water at said temperature, each time for 4-6 hours, and the water is only added in the first time of extraction.

4. The method according to claim 1, in the step (c), the water extract is mixed with the Vitamin C and liquid food flavoring within 6 hours after obtaining the water extract.

5. The method according to claim 1, wherein the water extract obtained in the step (b) is sealed and the composition obtained in the step (c) is sealed, for later use to avoid volatilization, respectively.

6. The method according to claim 1, wherein the step (b) includes: pulverizing the raw materials except for the Vitamin C and liquid food flavoring into powder, extracting the powder with the water at 80-100°C for 6 hours for 3 times to obtain the water extract, and sealing the water extract for later use, wherein the amount of the water used is 6 times of the total weight of all the raw materials; and

the step (c) includes: mixing the water extract with the Vitamin C and the liquid food flavoring within 6 hours after obtaining the water extract to obtain the composition, and sealing the composition for later use.

7. A liquid composition administrable through nose for controlling tobacco dependence prepared by the method according to any one of claims 1 to 6.

8. The composition according to claim 7, wherein the composition is prepared into a dose form for administration through nose.

9. Use of the composition according to claim 7 or 8 for the manufacturing of a

medicament or health product for controlling tobacco dependence.

10. A method for controlling tobacco dependence, including administering the composition according to claim 7 or 8 to a smoker through nose.