

Traditional Chinese Medicine Composition to Treat Bronchial Asthma and Preparation Method thereof

Field of the Invention

The present invention relates to a traditional Chinese medicine composition for treating bronchial asthma and preparation method thereof, and it belongs to the field of Chinese herbal medical art.

Background of the Invention

Bronchial asthma (hereinafter “asthma”), is a common chronic lung disease. At present, about 200 million people worldwide suffer from asthma, and there are about 20 million asthma patients in China. The data from five major Chinese cities show that asthma incidence rate of 3-14 years old students is 3% to 5%. Generally, it is believed that the incidence rate is higher in children than in adults, and almost same with adult men and women. About 40% of patients have family history. A survey shows that 33% of asthma patients required hospitalization or emergency treatment because of asthma in the past year, 58% of the patients incurred time loss of work due to asthma, 79% of asthma patients could not perform normal sports and leisure activities, 63% of asthma patients had to change their original way of living, 68% of asthma patients suffered sleep disorders because of asthma, and 74% of asthma patients could not perform normal physical labor. Asthma is a modern disease. Its incidence rate will not decrease with the improvement of people's health and living standards. Instead, the incidence rate of asthma keeps increasing.

In the past 20 years, people have been actively seeking effective methods of preventing and treating asthma, which is a subject of tireless exploration of the medical profession. In China as well as abroad, commonly used western drugs to treat this disease are from the following categories: inhaled corticosteroids, β_2 agonists, inhaled anticholinergic drugs, theophyllines, leukotriene antagonists, antagonists of other inflammatory mediators and cytokine antagonists, bone marrow eosinophil progenitor cell inhibitors, and allergen-specific immunotherapy and gene therapy. In recent years, these drugs achieved some clinical effects. However, the main aim of these drugs is to ease a series of episodes of bronchial inflammation and symptoms. They still do not solve the problems generally concerned by the respiratory professionals, which are the reduction in frequency and long-term control of clinical symptoms. In addition, there are many more problems in the treatment of asthma patients, such as the length of the treatment, when to

reduce the dosage, how to reduce the dosage, when to take the patients off the medicine, which method or program can achieve the goal of controlling asthma, and which is more effective and safe for asthma patients. These problems not only challenge the clinicians, but also add more difficulties to continued treatment of the patients. Meanwhile, some adverse side effects of the western medicines have seriously affected continued treatment of the patients. According to a survey, nearly half of the asthma patients in China do not have not an ideal control of their asthma, and most asthma patients in the basic level and rural areas do not even have an effective control of their disease.. It is a long way to achieve the goal of generally improving the effectiveness of asthma prevention and treatment methods and medicines.

Traditional Chinese medicine has over thousands of years of history in the prevention and treatment of bronchial asthma. Ancient doctors had constantly explored treatment principles, methods, prescriptions and medicines for asthma, and had discovered a lot of effective prescriptions..Pharmacological studies have shown that treating asthma with traditional Chinese medicine has comprehensive effects of regulating immune system, anti-allergy, relieving asthma, preventing cough, expelling phlegm, anti-inflammatory and so on. Traditional Chinese medicine can reduce airway inflammation and airway hyperresponsiveness. Clinical studies have shown that the treatment with traditional Chinese medicine has less adverse effects than western medicine, and can significantly relieve symptoms such as wheezing, chest distress, coughing, phlegm and so on. Most patients can enter remission phase of asthma during the treatment period, or reduce the dose of hormone, and improve their quality of life.

Dingchuan decoction, recorded in "She Sheng Zhong Miao Fang" (a traditional Chinese medicine formulations book), is composed of honey-baking *Herba Ephedrae*, stir-fry *Semen Ginkgo*, *Cortex Mori*, *radix scutellariae*, *Semen Armeniacae Amarum*, *Rhizoma Pinelliae*, *Fructus Perillae*, *radix paeoniae rubra*, *lumbricus*, *Periostracum Cicadae*, *radix trichosanthis* and *Fructus Forsythiae*. It is a famous prescription for treating asthma. Experiments showed that Dingchuan decoction has a protective effect on experimental asthma induced by histamine and acetyl choline chloride spray, and can antagonize histamine-induced contraction of isolated tracheal smooth muscle in guinea pigs [Li, zhengmu et al., pharmacology research of Dingchuan decoction in treating bronchial asthma. *Traditional Chinese Medicinal Materials*. 1999,22 (8):411]. It can further promote the secretion of phenol red in mice respiratory tract. These results prove, from a

pharmacological perspective, that Dingchuan decoction has a satisfactory effect on relieving asthma and expelling phlegm.

Summary of the Invention

The traditional Chinese medicine composition in this invention is made from pure natural herbal materials, and comprises *Herba Ephedrae*, *Cortex Mori*, *Radix Scutellariae*, *Semen Armeniacae Amarum*, *Rhizoma Pinelliae*, *Fructus Perillae*, *Flos Farfarae* and so on. This composition significantly relieves the symptoms of bronchial asthma, such as wheezing, chest distress, coughing, stethocatharsis, and its effect is clearly better than that of Dingchuan decoction.

Content of the Invention

One aspect of the present invention is to provide a traditional Chinese medicine composition for treating bronchial asthma.

Another aspect of the present invention is to provide a preparation method of the traditional Chinese medicine composition for treating bronchial asthma.

A traditional Chinese medicine composition of present invention is prepared from the following raw medicinal materials by weight :

Herba Ephedrae 40-90 parts, *Cortex Mori* 136-300 parts, *Lumbricus* 146-300 parts,
Semen Ginkgo 46-151 parts, *Flos Farfarae* 46-151 parts, *Rhizoma Pinelliae* 46-151 parts,
Fructus Perillae 46-151 parts, *Radix Paeoniae Rubra* 146-300 parts,
Semen Armeniacae Amarum 46-151 parts, *Radix Scutellariae* 46-151 parts,
Periostracum Cicadae 46-151 parts, *Herba Houttuyniae* 146-300 parts,
Radix Trichosanthis 146-300 parts, and *Fructus Forsythiae* 46-151 parts.

Another traditional Chinese medicine composition of present invention is prepared from the following raw medicinal materials by weight :

Herba Ephedrae 77-88 parts, *Cortex Mori* 136-165 parts, *Lumbricus* 255-300 parts,
Semen Ginkgo 46-65 parts, *Flos Farfarae* 110-151 parts, *Rhizoma Pinelliae* 46-65 parts,
Fructus Perillae 105-151 parts, *Radix Paeoniae Rubra* 146-165 parts,
Semen Armeniacae Amarum 46-65 parts, *Radix Scutellariae* 103-151 parts,
Periostracum Cicadae 46-65 parts, *Herba Houttuyniae* 255-300 parts,
Radix Trichosanthis 255-300 parts, and *Fructus Forsythiae* 103-151 parts.

Preferablely, a traditional Chinese medicine composition of present invention is prepared from following raw medicinal materials by weight :

Herba Ephedrae 50-76 parts, Cortex Mori 166-253 parts, Lumbricus 166-253 parts,
Semen Ginkgo 66-101 parts, Flos Farfarae 66-101 parts, Rhizoma Pinelliae 66-101 parts,
Fructus Perillae 66-101 parts, Radix Paeoniae Rubra 166-253 parts,
Semen Armeniacae Amarum 66-101 parts, Radix Scutellariae 66-101 parts,
Periostracum Cicadae 66-101 parts, Herba Houttuyniae 166-253 parts,
Radix Trichosanthis 166-253 parts, and Fructus Forsythiae 66-101 parts.

Preferablely, a traditional Chinese medicine composition of present invention is prepared from the following raw medicinal materials by weight:

Herba Ephedrae 50 parts, Cortex Mori 253 parts, Lumbricus 166 parts,
Semen Ginkgo 66 parts, Flos Farfarae 101 parts, Rhizoma Pinelliae 101 parts,
Fructus Perillae 66 parts, Radix Paeoniae Rubra 166 parts,
Semen Armeniacae Amarum 101 parts, Radix Scutellariae 66 parts,
Periostracum Cicadae 66 parts, Herba Houttuyniae 253 parts,
Radix Trichosanthis 253 parts, and Fructus Forsythiae 66 parts.

Preferablely, a traditional Chinese medicine composition of present invention is prepared from the following raw medicinal materials by weight:

Herba Ephedrae 76 parts, Cortex Mori 166 parts, Lumbricus 253 parts,
Semen Ginkgo 101 parts, Flos Farfarae 66 parts, Rhizoma Pinelliae 66 parts,
Fructus Perillae 101 parts, Radix Paeoniae Rubra 253 parts,
Semen Armeniacae Amarum 66 parts, Radix Scutellariae 101 parts,
Periostracum Cicadae 101 parts, Herba Houttuyniae 166 parts,
Radix Trichosanthis 166 parts, and Fructus Forsythiae 101 parts.

Preferablely, a traditional Chinese medicine composition of present invention is prepared from the following raw medicinal materials by weight:

Herba Ephedrae 70 parts, Cortex Mori 241 parts, Lumbricus 245 parts,
Semen Ginkgo 98 parts, Flos Farfarae 94 parts, Rhizoma Pinelliae 95 parts,
Fructus Perillae 94 parts, Radix Paeoniae Rubra 230 parts,

Semen Armeniacae Amarum 92 parts, Radix Scutellariae 91 parts,
Periostracum Cicadae 97 parts, Herba Houttuyniae 237 parts,
Radix Trichosanthis 231 parts, and Fructus Forsythiae 91 parts.

Preferably, a traditional Chinese medicine composition of present invention is prepared from the following raw medicinal materials by weight:

Herba Ephedrae 63 parts, Cortex Mori 210 parts, Lumbricus 210 parts,
Semen Ginkgo 84 parts, Flos Farfarae 84 parts, Rhizoma Pinelliae 84 parts,
Fructus Perillae 84 parts, Radix Paeoniae Rubra 210 parts,
Semen Armeniacae Amarum 84 parts, Radix Scutellariae 84 parts,
Periostracum Cicadae 84 parts, Herba Houttuyniae 210 parts,
Radix Trichosanthis 210 parts, and Fructus Forsythiae 84 parts.

Preferably, a traditional Chinese medicine composition of present invention is prepared from the following raw medicinal materials by weight:

Herba Ephedrae 61 parts, Cortex Mori 198 parts, Lumbricus 223 parts,
Semen Ginkgo 78 parts, Flos Farfarae 92 parts, Rhizoma Pinelliae 73 parts,
Fructus Perillae 85 parts, Radix Paeoniae Rubra 188 parts,
Semen Armeniacae Amarum 87 parts, Radix Scutellariae 88 parts,
Periostracum Cicadae 79 parts, Herba Houttuyniae 221 parts,
Radix Trichosanthis 218 parts, and Fructus Forsythiae 81 parts.

Preferably, the raw medicinal materials of the traditional Chinese medicine composition in the present invention are: Herba Ephedrae is honey-baking Herba Ephedrae, Semen Ginkgo is stir-fry Semen Ginkgo, Rhizoma Pinelliae is alum processed Rhizoma Pinelliae, Fructus Perillae is stir-fry Fructus Perillae, and Semen Armeniacae Amarum is stir-fry Semen Armeniacae Amarum.

The raw medicinal materials of present invention can be substituted by traditional Chinese medicinal materials having same or similar functions, and these materials can be processed in accordance with the "National Standard of Traditional Chinese Medicine Processing" or "Great Dictionary of Traditional Chinese medicine".

The traditional Chinese medicine composition of present invention is prepared from raw medicinal materials, and "prepared" can be understood as any general process used in the

preparation of tradition Chinese medicine, such as preparing traditional Chinese medicine composition after direct pulverizing or concentrating the extract from conventional solvent extraction. It also includes additional refining methods after the conventional solvent extraction, such as refining through the macroporous resin column.

Furthermore, the inventive composition can be prepared in various dosage forms, including capsule, tablet, powder, oral liquid, soft capsule, pill, tincture, syrup, suppository, gel and spray.

Preferably, the traditional Chinese medicine composition of present invention is prepared using the following method:

a) taking Radix Scutellariae and 1/3—3/4 amount of Rhizoma Pinelliae according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking of the relative amounts of Herba Ephedrae, Semen Ginkgo, Cortex Mori, Flos Farfarae, Fructus Perillae, Semen Armeniacae Amarum and Herba Houttuyniae according to the formulation and the rest of Rhizoma Pinelliae, adding 6-10 times amount of 50-80% ethanol, heating and refluxing extract thrice, 1-3 hours each time, recovering ethanol from extract solution under reduced pressure, and concentrating the solution to obtain the extract with a relative density of 1.05 - 1.10 at 60°C for later use;

c) taking the relative amount of Lumbricus, Radix Paeoniae Rubra, Periostracum Cicadae, Radix Trichosanthis and Fructus Forsythiae according to the formulation, adding 7- 10 times amount of water, decocting twice, 1-4 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05 - 1.10 at 60°C, and combining the extract with extract of step b) for later use;

d) mixing the fine powder of step a) with the combined extract of step c) to obtain the traditional Chinese medicine composition. The composition can further be prepared to clinical acceptable dosage forms, including capsule, tablet, powder, oral administration liquid, soft capsule, pill, tincture, syrup, suppository, gel and spray, through routine processes.

As used here, “adding X times amount of” solvent refers to weight/volume ratio, for example, “adding 6-8 times amount of solvent in raw medicinal materials” refers to adding 6-8 liters of solvent to 1 kilogram of raw medicinal materials.

In order to achieve the desired dosage forms, it is necessary to add pharmaceutically acceptable excipients in the preparation of these forms, such as fillers, disintegrating agents, lubricants,

suspending agents, binders, sweeteners, flavoring agents, preservatives, etc. Fillers include starch, pregelatinized starch, lactose, mannitol, chitosan, microcrystalline cellulose, sucrose, etc. Disintegrating agents include starch, pregelatinized starch, microcrystalline cellulose, sodium carboxymethyl starch, cross-linked polyvinylpyrrolidone, low substituted hydroxypropyl cellulose, crosslinked sodium carboxymethyl cellulose, etc. Lubricants include magnesium stearate, sodium lauryl sulfate, talc, silica, etc. Suspending agents include polyvinyl pyrrolidone, microcrystalline cellulose, sucrose, agar, hydroxypropyl methyl cellulose, etc. Binders include starch, polyvinylpyrrolidone, hydroxypropyl methyl cellulose, etc. Sweeteners include saccharin, aspartame, sucrose, sodium cyclamate, glycyrrhetic acid, etc. Flavoring agents include sweeteners and various flavors. Preservatives including: nipagins, benzoic acid, sodium benzoate, sorbic acid and its salts, benzalkonium bromide, Chlorhexidine Acetate, eucalyptus oil, etc.

Another embodiment of the present invention provides a preparation method of preparing tablet dosage form of the traditional Chinese medicine composition. This method includes the following steps:

a) taking *Radix Scutellariae* and half amount of *Rhizoma Pinelliae* according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of *Herba Ephedrae*, *Semen Ginkgo*, *Cortex Mori*, *Flos Farfarae*, *Fructus Perillae*, *Semen Armeniacae Amarum* and *Herba Houttuyniae* according to the formulation and the rest of *Rhizoma Pinelliae* in proportion, adding 6-10 times amount of 50-80% ethanol, heating and refluxing extract thrice, 1-3 hours each time, recovering ethanol from extract solution under reduced pressure, concentrating the solution to obtain the extract with a relative density of 1.05 - 1.10 at 60°C for later use;

c) taking the relative amounts of *Lumbricus*, *Radix Paeoniae Rubra*, *Periostracum Cicadae*, *Radix Trichosanthis* and *Fructus Forsythiae* according to the formulation, adding 7- 10 times amount of water, decocting twice, 1-4 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05 - 1.10 at 60°C, and combining the extract with extract of step b) for later use;

d) Mixing the fine powder of step a) and the extract of step c), adding an appropriate amount of adjuvant into the mixture, and spraying granulation to obtain granules and sifting the granules through a mesh after drying, standing by. ; and

e) preparing the granules of step d) to a tablet dosage form through routine processes.

Preferably, the preparation method of a tablet dosage form of the traditional Chinese medicine composition includes the following steps:

a) taking Radix Scutellariae and half amount of Rhizoma Pinelliae according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of Herba Ephedrae, Semen Ginkgo, Cortex Mori, Flos Farfarae, Fructus Perillae, Semen Armeniacae Amarum and Herba Houttuyniae according to the formulation and the rest of Rhizoma Pinelliae in proportion, adding 8 times amount of 60% ethanol, heating and refluxing extract thrice, 1.5 hours each time, recovering ethanol from extract solution under reduced pressure, concentrating the solution to obtain the extract with a relative density of 1.05 - 1.10 at 60°C for later use;

c) taking the relative amounts of Lumbricus, Radix Paeoniae Rubra, Periostracum Cicadae, Radix Trichosanthis and Fructus Forsythiae according the formulation, adding 9 times amount of water, decocting twice, 2 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05 - 1.10 at 60°C, and combining the extract with the extract of step b) for later use;

d) Mixing the fine powder of step a) and the extract of step c), adding an appropriate amount of adjuvant into the mixture, and spraying granulation to obtain granules and sifting the granules through a mesh after drying, standing by. ; and;

e) preparing the granules of step d) to a tablet dosage form through routine processes.

According to total weight of the raw medicinal materials of the traditional Chinese medicine composition of the present invention, the dosage of the composition is 15 - 30 g/day, and it can be taken once daily or 2-4 times daily; preferably the dosage is 22 g / day, and to be taken three times a day.

To confirm the activity of the inventive traditional Chinese medicine composition (hereinafter “the inventive composition”), the tablet dosage form of the inventive composition prepared using method disclosed in Example 1 was crushed into powder, and pharmacological tests were conducted to demonstrate the inventive composition’s effect on treating bronchial asthma. Also, the therapeutic effect of the primary pharmacodynamic part of the tablet was compared to that of Dingchuan decoction, prepared according to a published method: adding 9 grams of each of Herba

Ephedrae, Flos Farfarae, Semen Armeniacae Amarum and Rhizoma Pinellia, 12 grams of Semen Ginkgo (stir-fry to yellowish), 6 grams of each of Fructus Perillae, Cortex Mori and Radix Scutellariae, and 3 grams of Radix Glycyrrhizae to water and decocting the ingredients to obtain the Dingchuan decoction. [Ha, xiaobo and Xiao, xian. Talking about Dingchuan decoction , KAI JUAN YOU YI.QIU YI WEN YAO, 2001 (11):21.] The experiment confirms that this inventive composition is more therapeutically effective than Dingchuan decoction in treating asthma.

It has been confirmed that this inventive composition has good therapeutic effect on treating bronchial asthma by relieving asthma and coughing, resolving phlegm, anti-inflammation and so on. Bronchial asthma is a common chronic lung disease. This inventive composition has a wide safety range, plays a regulatory role from several aspects, and treats both the symptoms and the causes of the disease. It not only avoids the side effects of single targeting associated with western medicine, but also treats chronic diseases for a long period. Acute toxicity test results indicate that this inventive composition exhibited no significant toxicity in mice, which were intragastrically administered with 254.4g crude drug/kg at peak concentration for 3 times a day, and observed continuously for 14 days. This dosage is equivalent to 687.57 times of human clinical dosage. The experimental results of the long-term toxicity test in rats also show that this inventive composition exhibited no significant toxicity in rats administered with dosages of 22g, 11g, and 5.5g crude drug/kg for a long period (26 weeks).

The following experiments and examples are used to further illustrate but not limit to the present invention.

Experiment 1: Anti-asthmatic experiment

I. The effect of the inventive composition on early-phase reaction of bronchial asthma

1. Experimental material

1.1 Animals: pure-white healthy Hartley guinea pigs with a body mass of 200 ± 25 g, half males and half females, were purchased from Experimental Animal Center of National Institute for the Control of Pharmaceutical and Biological Products. Certification number is SCXK (BJ)2002-0010.

1.2 Drugs and reagents :

(1) Testing drugs: The inventive composition drug, batch number: 20060801, was provided by Shijiazhuang Yiling Pharmaceutical Co., Ltd. 1 gram of the final composition drug corresponds to 4.5g of crude drug. The human clinical dosage of the drug is 22g crude drug/day. The drug was combined with 0.5% CMC – Na (sodium carboxymethyl cellulose) to prepare a solution of required concentration before use.

(2) Positive control drug: Aminophylline tablet suitable for treating bronchus asthma and obstructive pulmonary emphysema was produced by Peking Zizhu Pharmaceutical Co., Ltd., batch number: 20061103.

(3) Dingchuan decoction: provided by Shijiazhuang Yiling Pharmaceutical Co., Ltd. The dosage for human use is 69g crude drug/day. The drug is combined with 0.5%CMC – Na (sodium cellulose glycolate) to prepare a solution with required concentration before use. As used here, “.....g crude drug/day” means the dosage of the raw medicinal materials per day.

(4) Ovalbumin: Product of Sigma Company.

(5) Acecolex: Product of Sigma Company.

1.3 Apparatus: Yadu medical vaporizer, model YC-Y800B, produced by Beijing Yadu Technology Co., Ltd.

2. Methods and results

1. Groups and drug administration of the animals:

After grouping, 80 guinea pigs were put into an air-tight organic glass cover (4L) in batches. An asthma inducing solution (isometric intermixture of 2% acecolex and 0.1% histamine phosphate) was atomized and sprayed into the glass cover by ultrasonic atomizer at a rate of 15 seconds/time, where the atomization volume was 4ml/min and atomization particle diameter was 1-5 μ m. After atomization, the latent period of wheezing convulsion of guinea pigs within 6 min was observed. Guinea pigs having a latent period of wheezing convulsion exceeding 120 seconds were excluded from further experiment. 66 eligible guinea pigs were selected and randomly divided into 6 groups: asthma model group, aminophylline group, Dingchuan decoction group, high, medium and low dosages of the inventive composition groups. Asthma model group was intragastrically administrated with same volume of solvent; aminophylline group was intragastrically

administrated with aminophylline at 0.06g/kg (corresponds to 7 times of human clinical dosage); Dingchuan decoction group is intragastrically administrated 8.1 g/kg of the decoction (correspond to 7 times of human clinical dosage); high, medium and low dosages of the inventive composition groups were intragastrically administrated with the composition at 5.1g/kg, 2.6g/kg, and 1.3g/kg, respectively (correspond to 14, 7 and 3.5 times of human clinical dosage, respectively). Each group was administered with the respective drug for 4 continuous days. The experiment began at 1h after the last administration.

2. Anti-asthmatic effect on drug induced asthma in guinea pigs

Animals in each group were placed into air-tight organic cover and asthma was induced by the method described above. After atomization, latency of asthmatic convulsion of guinea pigs was observed in 6min. If no asthmatic convulsion was observed, the latency was deemed as 6 min. Statistical analyses of variance and t test were carried out by SPSS 10.0. The results showed that significant prolongation of latency of asthma induced by acecolex and histamine phosphate was observed in guinea pigs in the high and medium dosages groups of this inventive composition. The group administered with the low dosage of the inventive composition also showed some effect on prolonging latency of asthma in guinea pigs, but there was no significant statistical difference compared to asthma model group. See table 1-1.

Table 1-1: Anti-asthmatic effect of the inventive composition on asthma induced by drug in guinea pigs ($\bar{x} \pm s$)

Group	Dosage (mg/kg)	# of Animals	Latency of induced asthma(s)	
			Wheeze	Fall
Asthma model group	—	12	24.6±9.0	40.8±14.5
Aminophylline group	0.06g/kg	12	38.3±13.0**	74.3±36.0**
Dingchuan decoction group	8.1 g/kg	12	33.9±9.1*	50.3±18.3
The inventive composition groups: high, medium, and low	5.1g/kg	10	42.2±11.5**	81.3±38.1**
	2.6 g/kg	10	37.7±16.9*	57.1±21.9*
	1.3 g/kg	10	31.6±12.5	47.3±17.8

Note: Compared with Asthma model group, * p<0.05, ** p<0.01.

After breathing in a liquid mixture of histamine and acecolex, asthma would be induced in normal guinea pigs. The inventive composition with high and medium dosages (5.1g/kg and 2.6

g/kg, respectively) can significant prolong the appearance time of wheezing and falling in asthmatic guinea pigs ($p<0.05$ and $p<0.01$, respectively). After sensitization by Ovalbumin (OVA), guinea pigs produce anti-OVA IgE antibody which combines with mast cells. When antigen OVA is inhaled, degranulation is caused by the combination of OVA and IgE on cell surface, and asthma attack is induced by the release of inflammatory mediators. Administration of the high and medium dosages (5.1g/kg and 2.6g/kg, respectively) of the inventive composition can significantly prolong latency of asthma in guinea pigs. In addition, This inventive composition showed better anti-asthmatic effect than that of Dingchuan decoction.

II. The effect of the inventive composition on late-phase reaction of bronchial asthma

1. Groups and drug administration of the animals: 60 healthy pure-white guinea pigs were randomly divided into 6 groups: Asthma model group, high, medium and low dosages of the inventive composition groups (5.1g/kg, 2.6 g/kg, and 1.3 g/kg, respectively), Dingchuan decoction group (8.1g/kg), and aminophylline positive control group (intragastrically administered aminophylline at 0.06g/kg). Animals in asthma model group was administered with a solvent of same volume. Guinea pigs were intragastrically administered with respective drugs for 3 days before asthma induction, and then for 4 continuous days after.

2. Anti-asthmatic effect of this inventive composition on asthma induced by OVA in guinea pigs: Guinea pigs in each group were sensitized by intramuscular injection of 0.2ml 4% OVA saline solution in the hind leg and intraperitoneal injection of 0.2ml 4% aluminum hydroxide latex. Guinea pigs were sensitized again by the same method at the 7th day. One hour after the last injection, asthma was induced by spraying the animals with ultrasonic nebulized asthma inducing solution for 6 minutes. The asthma inducing solution was 2% OVA saline solution, and the atomization volume was not less than 4ml/min. Latency of asthmatic convulsion in guinea pigs was observed in 6 min. If no asthmatic convulsion was observed, the latency was deemed as 6 min. Results were analyzed using variance and T test. All analyses were carried out using SPSS 10.0. The results showed that significant prolongation of latency of induced asthma in guinea pigs sensitized by OVA was observed in groups administered with high and medium dosages of the inventive composition. The low dosage inventive medicine composition group also showed some effect of prolonging latency of induced asthma, but there was no significant statistical difference

compared with Asthma model group. See table 1-2.

Table1-2:The effect on latency of induced asthma sensitized by OVA of guinea pigs ($\bar{x} \pm s$)

Group	Dosage (ml/kg)	# of Animals	Latency of induced asthma(s)	
			Wheeze	Fall
Asthma model group	-	10	62.4±24.2	104.2±53.1
Aminophylline group	0.06g/kg	10	163.2±89.1**	238.0±76.9**
Dingchuan decoction	8.1 g/kg	10	86.5±30.7*	154.5±60.0*
The inventive	5.1g/kg	10	166.6±87.0**	206.6±99.2*
composition groups: high, medium and low	2.6 g/kg	10	118.0±62.6*	167.6±77.6*
	1.3 g/kg	10	71.7±26.3	110.2±41.0

Note: Compared with asthma model group, * p<0.05, ** p<0.01.

Experimental model of airway inflammation caused mainly by eosinophils (EOS) infiltration can be established by sensitizing guinea pigs with OVA and attacking the animals by multiple inhalation with atomized OVA. That is known as the allergic bronchial asthma guinea pig model. This experiment showed that guinea pigs administered with high and medium dosages (5.1g/kg and 2.6 g/kg, respectively) of the inventive composition exhibited significantly prolonged latency of OVA induced asthma, and decreased number of EOS in whole blood were observed in animals from these two groups (p<0.05 and p<0.01, respectively). It suggests that high and medium dosages of the inventive composition have better effect on delayed bronchial asthma in guinea pigs than that of Dingchuan decoction.

Experiment 2: Experiment of Relieving Cough, Removing Phlegm and Anti-inflammation

I. Experimental study on the inventive composition's effect of relieving cough

1. Experimental materials

1.1 Experimental animals

72 healthy KM mice, half males and half females, with a body mass of 18-20g, were purchased from Beijing Vital River Experimental animal Technical Co. Ltd, certification number: SCXK (BJ)2002-0003. Mice were marked with 5% picric acid and fed in captivity at 5 mice/cage. Mice were fed in the Pharmacological Laboratory of Pharmaceutical Research Institute of Hebei

Medical University, in an environment of 12h light/day, temperature between 20~23℃, and relative humidity between 40-60%. Mice were fed with whole value grain feedstuff obtained from Experimental Animal Center of Hebei Province and unlimited water intake. Mice were initiated onto their diets and environment for 3 days.

1.2 Experimental drugs

The inventive composition: 1 gram of the dry powder corresponds to 4.5g of crude drug. The dosage of the drug for human clinical use is 22g crude drug/day, i.e., 0.37g crude drug/kg weight (standard body weight 60kg). The drug was provided by Shijiazhuang Yiling Pharmaceutical Co., Ltd, batch number : 20060801. The medicine was combined with 0.5%CMC – Na to prepare a suspension with required concentration before use.

Dingchuan decoction: Provided by Shijiazhuang Yiling Pharmaceutical Co., Ltd. The human clinical dosage of this medicine is 69g crude drug/day. This medicine was combined with 0.5%CMC – Na to prepare a solution with required concentration before use.

Compound Codeine Phosphate Solution: 0.9mg/ml, Hong Kong Aomei Pharmaceutical Factory, batch number: 060115.

1.3 Experimental reagent

Concentrated sulfuric acid: analytical pure, Beijing Chemical Factory, batch number: 20020809.

2. Experimental method

2.1 Principle of dosage setting

The maximum clinical dosage of the inventive composition is 22g crude drug/day, i.e., 0.37g crude drug/kg (standard body weight is 60kg). The dosages administered to mice were 5, 10, and 20 times of the clinical dosage, i.e., mice were given 1.85g, 3.7g, and 7.4g crude drug/kg/day (low, medium and high dosage groups, respectively). Dingchuan decoction group was administered at 11.5g crude drug/kg/day, which is 10 times of clinical dose. Control group and positive drug groups were separately established.

2.2 Administration routes and dosages

Between 9:00-10:00 AM everyday, mice were intragastrically administered with drugs corresponding to their groups and consistent with oral administration route recommended in clinic. Drugs were administered for 5 continuous days at 0.1ml/10g body weight.

2.3 Administration dosages and grouping

According to the above principle of dosage setting, mice were divided into the following 5 groups, see table 2-1:

Table2-1 Groups and administration dosages in the experiment of relieving mice cough with the

inventive composition			
Group	# of Animals	Dosage (g crude drug /kg.d)	relations to human clinical dosage (times)
Control group	12	--	--
Codeine phosphate solution group	12	0.03	10
Dingchuan decoction group	12	11.5	10
The inventive composition groups:	12	1.85	5
low, medium and high	12	3.70	10
	12	7.40	20

2.4 Experimental procedures

2.4.1 Preparation of sulfur dioxide: took a 250ml flask with side port which was connected with bladder by rubber tube; the flask was loaded with hydrosulfite of sodium; fixed a buret on the bottle stopper, and loaded the buret with concentrated sulfuric acid; opened the piston of buret to allow the dropping of concentrated sulfuric acid; gas sulfur dioxide was produced and the gas filled in the bladder; clamped the bladder with a haemostat; took 4-10ml of the gas with a syringe before using.

2.4.2 KM mice were randomly divided into 6 groups, 12 mice each group with half males and half females. The groups were control group, Dingchuan decoction group, the codeine phosphate group, high, medium and low dosages of the inventive composition groups. All groups were administered intragastrically with corresponding drugs at 0.1ml/10g for 5 continuous days. Control group was administrated with 0.5%CMC-Na. 0.5 hour after the last administration, mice of each group were subsequently put into a 250ml jar injected with sulfur dioxide. Latency (the time from sulfur dioxide injection to the occurrence of coughing) and frequency of cough were observed in 2 minutes. Typical cough in mice shows abdominal contractions and wide opening of the mouth at the same time, and sometimes it is accompanied with coughing sound. Cough relieving rate was calculated using the following formula:

Cough relieving rate (%) = (cough reaction time of the administration group/cough reaction time of the control group) ×100%.

3. Statistical method

Experimental data were analyzed with SPSS 11.5. Statistical results are expressed by mean number±standard deviation($\bar{x} \pm s$); difference between groups was performed by one-factor analysis of variance.

4. Experimental results

The effect of the inventive composition on cough induced by sulfur dioxide was observed and shown in table 2.2. The results show that the latency of cough induced in mice in the control group was 19.58±8.17 seconds and cough frequency in 2 minutes was 69.25±26.93 times. Latency of cough in mice in the low, medium and high dosages of the inventive composition groups were 54.58±35.57 seconds, 57.67±30.53 seconds and 73.50±37.81 seconds, respectively. The lengths of latency in these groups were remarkably prolonged compared with that of the control group ($P < 0.05$ or $P < 0.01$); cough frequencies in 2 minutes were 27.42±22.86 times, 27.08±17.17 times and 11.92±19.44 times, respectively. Cough frequencies remarkably reduced compared to that of the control group ($P < 0.01$).

Table 2-2 The effect of the inventive composition on cough induced by sulfur dioxide($\bar{x} \pm s$)

Group	Dose (g crude drug /kg.d)	# of Animals(n)	Weight (g)	Cough latency (s)	Cough frequency (n)
The control group	--	12	26.0±2.6	19.58±8.17	69.25±26.93
Codeine	0.03	12	25.8±1.8	48.83±22.93*	23.00±18.46**
Dingchuan	11.5	12	26.1±2.3	54.42±39.72	28.34±20.19**
Low dose group	1.85	12	26.8±2.2	54.58±35.57	27.42±22.86**
Medium dose group	3.70	12	26.3±2.4	57.67±30.53*	27.08±17.17**
High dose group	7.40	12	26.9±2.6	73.50±37.81**	11.92±19.44**

Note: Compared with the control group, * $P < 0.05$, ** $P < 0.01$.

It is observed that cough latency and cough frequency of groups administered with high and medium dosage of the inventive composition were remarkably prolonged compared to those of the Dingchuan decoction group ($P < 0.05$). It suggests that this inventive composition has a significant effect on relieving cough, and its effect is better than that of Dingchuan decoction.

II Experimental study of the inventive composition's effect on removing phlegm

1. Experimental materials

1.1 Experimental animals

72 healthy KM mice, half males and half females, with a body mass of 18-20g, were purchased from Beijing Vital River Experimental animal Technical Co. Ltd, certification number: SCXK (BJ) 2002-0003. Mice were marked with 5% picric acid and fed in captivity at 5 mice/cage. Mice were fed in Pharmacological Laboratory of Pharmaceutical Research Institute of Hebei Medical University in a condition of 12h light/day, temperature between 20~23℃, and relative humidity between 40-60%. Mice were fed with whole value grain feedstuff obtained from Experimental Animal Center of Hebei Province and unlimited water supply. Mice were initiated for 3 continuous days.

1.2 Experimental drugs

The inventive composition: 1 gram of the dry powder composition drug corresponds to 4.5g crude drug. The clinical dosage for adults is 22g crude drug/day, i.e., 0.37g crude drug/kg body weight (standard bodyweight is 60kg). The medicine was provided by Shijiazhuang Yiling Pharmaceutical Co., Ltd, batch number: 20060801. The drug was combined with 0.5%CMC – Na to prepare a suspension with required concentration before use.

Dingchuan decoction: provided by Shijiazhuang Yiling Pharmaceutical Co., Ltd. Clinical dosage of the drug for human is 69g crude drug/day. The drug was combined with 0.5%CMC – Na to prepare a solution with required concentration before use.

Ammonium chloride: 30mg/tablet, obtained from Xinan Pharmaceutical Co., Ltd, batch number: 66050005.

2. Experimental methods

2.1 Principle of dosage setting

The maximum clinical dosage of this inventive composition is 22g crude drug/day, that is, 0.37g crude drug/kg (standard bodyweight is 60kg). The dosages administered to mice were 5, 10 and 20 times of the clinical dosage, that is, mice were given 1.85g, 3.7g and 7.4g crude drug/kg/day (low, medium and high dosage group, respectively); Dingchuan decoction group: the drug was administrated at 11.5g crude drug/kg/day, that is, 10 times of clinical dosage. The control

group and the positive drug group were separately established.

2.2 Administration routes and dosages

Between 9:00-10:00 AM everyday, mice were intragastrically administered with medicine corresponding to their group and consistent with oral administration route recommended in clinic. Dosage was set at 0.1ml/10g bodyweight for 5 continuous days.

2.3 Administration dosages and groups

According to the principle of dosage setting, mice were divided into the following 6 groups, see table 2-3:

Table2-3 Groups and administration dosages in experiment of relieving mice cough by the

Group	# of Animals	inventive composition	
		Dose (g crude drug /kg.d)	Relations to human clinical dosage (times)
The control group	12	--	--
The ammonium chloride group	12	1.00	10
Dingchuan decoction group	12	11.5	10
The inventive composition groups: low,	12	1.85	5
Medium	12	3.70	10
High	12	7.40	20

2.4 Experimental procedures

KM mice were divided randomly into 6 groups, 12 mice in each group with half males and half females. The groups were: the control group, the ammonium chloride, Dingchuan decoction group, low, medium and high dosages of the inventive composition groups. All groups were administrated with corresponding medicine intragastrically at 0.1ml/10g for 5 continuous days. The control group was given 0.5%CMC-Na. 0.5 hour after the last administration, mice of each group (after fasting for 16h) were injected with phenol red 0.1ml(5mg)/10g weight by intraperitoneal injection. At 0.5 hour after injection, mice were killed. Tissues around organs were peeled to expose the trachea and cut the trachea located between thyroid cartilage and tracheal branch; put the trachea into the test tube with 2ml saline followed by adding 0.1ml (or 1-2 drops) sodium hydroxide, then mixed well; OD values were measured by enzyme-labeling measuring

instrument 540nm, and phenol red was used to establish standard curve and to calculate the content of phenol red according to the curve($\mu\text{g/ml}$), and compared that with the control group.

2.5 Statistical method

Experimental data were analyzed using SPSS 11.5. Statistical results are expressed by mean number $\pm$ standard deviation($\bar{x} \pm s$). Difference between groups was performed by one-factor analysis of variance.

3. Experimental results

The phlegm removing effect of this inventive composition was observed using the trachea phenol red method. The results, which are shown in table 2.4, indicate that phenol red content in the trachea of mice in the control group was 0.43 ± 0.12 $\mu\text{g/ml}$, phenol red contents in trachea of mice in the low, medium and high dosages of the inventive composition groups were 0.82 ± 0.34 $\mu\text{g/ml}$, 1.23 ± 0.31 $\mu\text{g/ml}$ and 1.48 ± 0.61 $\mu\text{g/ml}$, respectively.

Table 2-4 Results of phlegm removing effect of the inventive medicine composition ($\bar{x} \pm s$)

Group	Dose (g crude drug/kg.d)	Relations to human clinical dosage (times)	# of Animals	Phenol red content in trachea($\mu\text{g/ml}$)
Control group	--	--	12	0.43 ± 0.12
Ammonium chloride group	1.00	10	12	$1.41 \pm 0.41^{**}$
Dingchuan decoction group	11.5	10	12	$0.89 \pm 0.37^{**}$
Low dosage group	1.85	5	12	$0.82 \pm 0.34^{**}$
Medium dosage group	3.70	10	12	$1.23 \pm 0.31^{**}$
High dosage group	7.40	20	12	$1.48 \pm 0.61^{**}$

Note: Compare with the model group: * $P < 0.05$, ** $P < 0.01$.

Remarkable increases in phenol contents were observed in the inventive composition groups, compared to those in the model group and Dingchuan decoction group ($P < 0.01$ or $P < 0.05$). It suggests that this inventive composition has a significant effect on removing phlegm, and its effect

is better than that of Dingchuan decoction.

III Anti-general inflammation effect of this inventive composition

1 Experimental materials

1.1 Animals : SD rats, half males and half females, with a body weight of 160-180g, were purchased from Beijing Vital River Experimental animal Technical Co. Ltd, certification number: SCXK (BJ)2002-0003.

1.2 Drugs and reagents

(1) Testing drugs: 1g of the dry powder inventive composition corresponds to 4.5g crude drug. The clinical dose for adult is 22g crude drug/day, that is, 0.37g crude drug/kg weight (standard weight is 60kg). The medicine was provided by Shijiazhuang Yiling Pharmaceutical Co., Ltd, batch number: 20060801. The medicine was combined with 0.5%CMC – Na to prepare a suspension with required concentration before use.

(2) Positive control drug: Dexamethasone tablets were produced by Tianjin Tianyao Pharmaceutical Co., Ltd, batch number: 20060711. License number: guo yao zhun zi H12020686. The drug was combined with 0.5% CMC before use.

(3) Carrageenin: Product of Sigma Company. At one day before use, the drug was pulverized into fine powder, combined with saline for injection to prepare 1% uniform suspension, and stored in 4°C refrigerator.

1.3 Apparatus: Instrument for determining rats' foot volume (drainage).

2. Methods and results

2.1 Groups and drug administration: 60 rats for experiment were randomly divided into 6 groups: the model group (administered intragastrically the same volume of 0.5%CMC), Dingchuan decoction group (administered intragastrically 8.7g/kg , equal to 7.5 times of clinical dose for human), the positive drug (administered intragastrically dexamethasone 0.1g/kg , equal to 7.5 times of clinical dose for human), high, medium and low doses of this inventive composition (administrated intragastrically of 5.6g/kg, 2.8g/kg and 1.4g/kg , respectively; equal to 15, 7.5, 3.75 times of clinical doses for human, respectively); each group had 10 rats. Drugs were administered for 3 continuous days, and models were established at 60 minutes after last administration.

2.2 Voix Pedis Swelling Method: according to the reference [Chen, Qi. chief editor. Study

Methodology of Pharmacology of Traditional Chinese Medicine, People's Health Publishing House, 1993, 364p], the volume of each rat's left post voix pedis was determined and recorded before drug administration; 60 minutes after last administration, subcutaneously injected 0.1ml/rat 1% carrageenin suspension in each rat's left post voix pedis, then measured and recorded the left post voix pedis volume every hour, and measured 6 times continuously. Recorded the results and calculated the swelling degree and the inhibition rate according to the following formula:

$$\text{swelling rate (\%)} = (\text{volume of voix pedis after induced inflammation} - \text{volume of voix pedis before induced inflammation}) / \text{volume of voix pedis before induced inflammation} \times 100\%$$

$$\text{inhibition rate (\%)} = (\text{average swelling degree of the control group} - \text{average swelling degree of the administration group}) / \text{average swelling degree of the control group} \times 100\%$$

Statistical analyses of variance and group T test were carried out using SPSS 10.0

2.3 Results of the anti-general inflammation effect of the inventive composition are shown in table 2-5. Voix pedis swelling in rats induced by carrageenin injection was significantly inhibited by injecting the inventive composition with the doses of 5.6g /kg and 2.8g /kg. At 1h after model had been established, the inhibition rates were significantly different from that of the control group, and the inhibitive effect lasted for 6h ($p < 0.05$ and $p < 0.01$, respectively). The results showed that high and medium doses of this inventive composition significantly inhibited voix pedis swelling induced by injecting carrageenin in rats. 5.6g /kg and 2.8g /kg of this inventive composition also significantly inhibited the formation of granuloma of rat's tampon, compared with that of the control group ($p < 0.01$ and $p < 0.05$, respectively). These effects of the inventive composition were all better than that of Dingchuan decoction group.

Table 2-5. The effect of the inventive medicine composition on voix pedis swelling induced by carrageenin in rats

Group	Dose (g crude drug/kg)	# of Animals	Swelling degree (%)					
			1h	2h	3h	4h	5h	6h
The model group	—	10	47.6±13.4	67.2±16.3	94.1±28.4	120.8±31.1	117.9±24.7	110.6±30.1
Dexamethaso	0.1	10	29.1±16.4*	31.4±15.2**	34.6±13.8**	42.0±15.7**	45.5±19.3**	54.7±25.2**

ne group	mg/kg		(38.85%)	(53.22%)	(63.20%)	(65.25%)	(61.35%)	(50.53%)
Dingchuan								
decoction	8.7	10	45.3±16.5 (4.83%)	51.9±26.3 (22.77%)	66.9±21.8* (28.91%)	89.8±27.8* (25.67%)	93.2±23.7* (20.95%)	110.1±25.2 (0.45%)
group								
High medium	5.6	10	44.1±18.4 (7.38%)	49.3±14.9* (26.61%)	65.7±23.5* (30.15%)	76.3±33.5** (36.85%)	83.4±22.1** (29.23%)	103.2±30.1 (6.75%)
and low doses								
of the	2.8	10	41.6±17.6 (12.58%)	50.2±13.4* (25.38%)	66.7±23.1* (29.15%)	77.7±24.8** (35.63%)	93.3±25.3* (20.88%)	106.5±24.3 (3.77%)
inventive								
composition	1.4	10	42.3±16.9 (11.16%)	52.0±25.7 (27.76%)	68.6±27.6 (27.09%)	92.8±33.1* (26.03%)	95.3±31.4 (19.10%)	110.8±23.9 (-0.17%)
groups								

Note: Compared with the model group, *p<0.05, **p<0.01. (The numbers in bracket are inhibition rate of swelling)

3. Conclusion: This inventive composition has significant inhibitive effect on general inflammation, and the effect is better than that of Dingchuan decoction.

Bronchial asthma is a chronic inflammation disease caused by multiple cells and cellular components. It can cause airway hyperreactivity which induces wheezing, dyspnea, chest distress and repeated attacks of coughing. The etiology is related to atopic allergy. At the same time, the etiology of some patients is undetermined. Symptomatic treatment and etiological treatment are both adopted. Because herbal compounds have multi-link comprehensive effects, they have unique advantages in treating bronchial asthma. Therefore, the pharmacodynamic studies of this inventive composition were based on its effect of dispersing lung-qi, relieving asthma, clearing heat and removing phlegm, and focus on improving the symptoms by removing phlegm, relieving cough and anti-inflammation. At the same time, these studies observed the inventive composition's effects on related mechanisms such as allergy reactions, mast cells degranulation, immunoregulation and so on to comprehensively evaluate the medicine's therapeutic effects and mechanisms.

The pharmacodynamic study results suggest that high and medium doses of the inventive composition can both significantly prolong the time of appearance of wheezing and falling in guinea pigs with asthma induced by mixed solution of histamine and acetylcholine chloride, and also can significantly prolong the latency in guinea pigs with asthma induced by OVA. For late-phase reaction asthma induced by multiple attacks of OVA, high and medium doses of this inventive composition can significantly prolong the latency of last asthma induced by OVA,

decrease the proportions of eosinophils in whole blood and in bronchoalveolar lavage fluid. In addition, high and medium doses of this inventive composition can inhibit Leukotriene B₄ production in bronchoalveolar lavage fluid. Histopathology of bronchoalveolar also suggests that high, medium and low doses of this inventive composition can all decrease the infiltration number of eosinophils in bronchial wall and improve pathological injuries caused by inflammation in bronchopulmonary tissue. These results suggest that this inventive composition has significant treatment effects on both late-phase reaction and early-phase reaction of bronchial asthma, and has significant inhibitive effects on the production of relevant inflammatory cells and mediators.

Animal experiments of relieving cough, removing phlegm, antiinflammation and so on were adopted to observe clinical related symptoms and the symptom improvement effect of this inventive composition. The results suggest that high, medium and low doses of this inventive composition significantly prolonged the cough latent period in mice induced by sulfur dioxide and reduced the frequencies of coughing in mice. Trachea phenol red experiment results suggest that high, medium and low doses of this inventive composition significantly increased secretion of phenol red of mice trachea. Anti-inflammation experiment results suggest that high and medium doses of this inventive composition significantly inhibited voix pedis swelling in rats induced by injecting carrageenin and the formation of granuloma of rat's tampon. At 1h after model establishment, compared to control group, significant difference was found in the inventive composition groups, and the difference lasted for 6h. The above results suggest that this inventive composition has significant effects on relieving cough, removing phlegm and anti-inflammation, and has a good assistant effect on the improvement of asthma symptoms.

The preparation of the present inventive traditional Chinese medicine composition is illustrated through the following examples but not limited to the range of the present invention.

Examples

Example 1

The preparation of tablets of the inventive composition (temporarily named: LIAN HUA asthma relieving tablets):

Formulation:

Herba Ephedrae (honey-baking) 63g, Cortex Mori 210g, Lumbricus 210g,
Semen ginkgo 84g, Flos Farfarae 84g, Rhizoma Pinelliae (alum processed) 84g,
Fructus Perillae (stir-fried) 84g, Radix Paeoniae Rubra 210 g,
Semen Armeniacae Amarum (stir-fried) 84g, Radix Scutellariae 84g,
Periostracum Cicadae 84g, Herba Houttuyniae 210g,
Radix Trichosanthis 210g, and Fructus Forsythiae 84g.

Preparation method:

a) taking 84g of Radix Scutellariae and 42g of Rhizoma Pinelliae, pulverizing them into fine powder for later use;

b) taking the relative amounts of Herba Ephedrae, Semen Ginkgo, Cortex Mori, Flos Farfarae, Fructus Perillae, Semen Armeniacae Amarum and Herba Houttuyniae according to the formulation and the rest of Rhizoma Pinelliae, adding 8 times amount of 60% ethanol, heating and refluxing extract thrice, 1.5 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.08 at 60°C for later use;

c) taking the relative amounts of Lumbricus, Radix Paeoniae Rubra, Periostracum Cicadae, Radix Trichosanthis and Fructus Forsythiae according to the formulation, adding 9 times amount of water, decocting twice, 2 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.08 at 60°C, and combining the extract with extract of step b) for later use;

d) Mixing the fine powder of step a) and the extract of step c), adding an appropriate amount of adjuvant into the mixture, and spraying granulation to obtain granules and sifting the granules through a mesh after drying, standing by. ; and

e) preparing the granules of step d) to obtain tablets of the inventive composition through routine processes.

Example 2

The preparation of capsules of the inventive composition:

Formulation:

Herba Ephedrae 61g, Cortex Mori 198g, Lumbricus 223g,
Semen ginkgo 78g, Flos Farfarae 92g, Rhizoma Pinelliae 73g,
Fructus Perillae 85g, Radix Paeoniae Rubra 188g, Semen Armeniacae Amarum 87g,
Radix Scutellariae 88g, Periostracum Cicadae 79g, Herba Houttuyniae 221g,
Radix Trichosanthis 218g, and Fructus Forsythiae 81 g.

Preparation method:

- a) taking 88g of Radix Scutellariae and 36.5g of Rhizoma Pinelliae, pulverizing them into fine powder for later use;
- b) taking the relative amounts of Herba Ephedrae, Semen Ginkgo, Cortex Mori, Flos Farfarae, Fructus Perillae, Semen Armeniacae Amarum and Herba Houttuyniae according to the formulation, and the rest of Rhizoma Pinelliae adding 6 times amount of 50% ethanol, heating and refluxing extract thrice, 1 hour each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05 at 60°C for later use;
- c) taking the relative amounts of Lumbricus, Radix Paeoniae Rubra, Periostracum Cicadae, Radix Trichosanthis and Fructus Forsythiae according to the formulation, adding 7 times amount of water, decocting twice, 1 hour each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05 at 60°C, and combining the extract with extract of step b) for later use;
- d) Mixing the fine powder of step a) and the extract of step c), adding an appropriate amount of adjuvant into the mixture, and spraying granulation to obtain granules and sifting the granules through a mesh after drying, standing by. ; and
- e) preparing the granules of step d) to obtain capsules of the inventive composition through routine processes.

Example 3

The preparation of powder of the inventive composition:

Formulation:

Herba Ephedrae 50g, Cortex Mori 253g, Lumbricus 166g,
Semen ginkgo 66g, Flos Farfarae 101g, Rhizoma Pinelliae 101g,

Fructus Perillae 66g, Radix Paeoniae Rubra 166g, Semen Armeniacae Amarum 101g,
Radix Scutellariae 66g, Periostracum Cicadae 66g, Herba Houttuyniae 253g,
Radix Trichosanthis 253g, and Fructus Forsythiae 66 g.

Preparation method:

a) taking Radix Scutellariae and half amount of Rhizoma Pinelliae according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of Herba Ephedrae, Semen Ginkgo, Cortex Mori, Flos Farfarae, Fructus Perillae, Semen Armeniacae Amarum and Herba Houttuyniae according to the formulation and the rest of Rhizoma Pinelliae, adding 10 times amount of 80% ethanol, heating and refluxing extract thrice, 3 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.10 at 60°C for later use;

c) taking the relative amounts of Lumbricus, Radix Paeoniae Rubra, Periostracum Cicadae, Radix Trichosanthis and Fructus Forsythiae according to the formulation, adding 10 times amount of water, decocting twice, 4 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) making the fine powder of step a) and combined extract of step c) into powder through routine processes.

Example 4

The preparation of oral solution of the inventive composition:

Formulation:

Herba Ephedrae 76g, Cortex Mori 166g, Lumbricus 253g,
Semen ginkgo 101g, Flos Farfarae 66g, Rhizoma Pinelliae 66g,
Fructus Perillae 101g, Radix Paeoniae Rubra 253g, Semen Armeniacae Amarum 66g,
Radix Scutellariae 101g, Periostracum Cicadae 101g, Herba Houttuyniae 166g,
Radix Trichosanthis 166g, and Fructus Forsythiae 101 g.

Preparation method:

a) taking Radix Scutellariae and half amount of Rhizoma Pinelliae according to the formulation proportion, pulverizing them into fine powder;

b) taking the relative amounts of *Herba Ephedrae*, *Semen Ginkgo*, *Cortex Mori*, *Flos Farfarae*, *Fructus Perillae*, *Semen Armeniacae Amarum* and *Herba Houttuyniae* according to the formulation and the rest of *Rhizoma Pinelliae*, adding 6 times amount of 80% ethanol, heating and refluxing extract thrice, 1 hour each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C for later use;

c) taking the relative amount of *Lumbricus*, *Radix Paeoniae Rubra*, *Periostracum Cicadae*, *Radix Trichosanthis* and *Fructus Forsythiae* according to the formulation, adding 7 times amount of water, decocting twice, 1 hour each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) making the fine powder of step a) and combined extract of step c) into oral solution through routine processes.

Example 5

The preparation of soft capsules of the inventive composition:

Formulation:

Herba Ephedrae 70g, *Cortex Mori* 241g, *Lumbricus* 245g,

Semen ginkgo 98g, *Flos Farfarae* 94g, *Rhizoma Pinelliae* 95g,

Fructus Perillae 94g, *Radix Paeoniae Rubra* 230g, *Semen Armeniacae Amarum* 92g,

Radix Scutellariae 91g, *Periostracum Cicadae* 97g, *Herba Houttuyniae* 237g,

Radix Trichosanthis 231g, and *Fructus Forsythiae* 91 g.

Preparation method:

a) taking *Radix Scutellariae* and 1/3 amount of *Rhizoma Pinelliae* according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of *Herba Ephedrae*, *Semen Ginkgo*, *Cortex Mori*, *Flos Farfarae*, *Fructus Perillae*, *Semen Armeniacae Amarum* and *Herba Houttuyniae* according to the formulation and the rest of *Rhizoma Pinelliae*, adding 10 times amount of 50% ethanol, heating and refluxing extract thrice, 3 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C for later use;

c) taking the relative amounts of *Lumbricus*, *Radix Paeoniae Rubra*, *Periostracum Cicadae*, *Radix Trichosanthis* and *Fructus Forsythiae* according to the formulation, adding 10 times amount of water, decocting twice, 4 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) making the fine powder of step a) and the combined extract of step c) into soft capsules through routine processes.

Example 6

The preparation of pills of the inventive composition:

Formulation:

Herba Ephedrae 76g, *Cortex Mori* 253g, *Lumbricus* 253g,
Semen ginkgo 101g, *Flos Farfarae* 101g, *Rhizoma Pinelliae* 101g,
Fructus Perillae 101g, *Radix Paeoniae Rubra* 253g, *Semen Armeniacae Amarum* 101g,
Radix Scutellariae 101g, *Periostracum Cicadae* 101g, *Herba Houttuyniae* 253g,
Radix Trichosanthis 253g, and *Fructus Forsythiae* 101 g.

Preparation method:

a) taking *Radix Scutellariae* and 2/3 amount of *Rhizoma Pinelliae* according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of *Herba Ephedrae*, *Semen Ginkgo*, *Cortex Mori*, *Flos Farfarae*, *Fructus Perillae*, *Semen Armeniacae Amarum* and *Herba Houttuyniae* according to the formulation and the rest of *Rhizoma Pinelliae*, adding 8 times amount of 60% ethanol, heating and refluxing extract thrice, 1.5 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60 °C for later use;

c) taking the relative amounts of *Lumbricus*, *Radix Paeoniae Rubra*, *Periostracum Cicadae*, *Radix Trichosanthis* and *Fructus Forsythiae* according to the formulation, adding 8 times amount of water, decocting twice, 3 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) making fine powder of step a) and combined extract of step c) into pills through routine

processes.

Example 7

The preparation of tincture of the inventive composition:

Formulation:

Herba Ephedrae 50g, Cortex Mori 166g, Lumbricus 166g,

Semen ginkgo 66g, Flos Farfarae 66g, Rhizoma Pinelliae 66g,

Fructus Perillae 66g, Radix Paeoniae Rubra 166g, Semen Armeniacae Amarum 66g,

Radix Scutellariae 66g, Periostracum Cicadae 66g, Herba Houttuyniae 166g,

Radix Trichosanthis 166g, and Fructus Forsythiae 66 g.

Preparation method:

a) taking Radix Scutellariae and half amount of Rhizoma Pinelliae according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of Herba Ephedrae, Semen Ginkgo, Cortex Mori, Flos Farfarae, Fructus Perillae, Semen Armeniacae Amarum and Herba Houttuyniae according to the formulation and the rest of Rhizoma Pinelliae, adding 9 times amount of 75% ethanol, heating and refluxing extract thrice, 2.5 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60 °C for later use;

c) taking the relative amounts of Lumbricus, Radix Paeoniae Rubra, Periostracum Cicadae, Radix Trichosanthis and Fructus Forsythiae according to the formulation, adding 8.5 times amount of water, decocting twice, 2.5 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) making fine powder of step a) and combined extract of step c) into tincture composition through routine processes.

Example 8

The preparation of syrup of the inventive composition:

Formulation:

Herba Ephedrae 50g, Cortex Mori 166g, Lumbricus 166g,

Semen ginkgo 66g, Flos Farfarae 66g, Rhizoma Pinelliae 66g,

Fructus Perillae 66g, Radix Paeoniae Rubra 166g, Semen Armeniacae Amarum 66g,
Radix Scutellariae 66g, Periostracum Cicadae 66g, Herba Houttuyniae 166g,
Radix Trichosanthis 166g, and Fructus Forsythiae 66 g.

Preparation method:

- a) taking Radix Scutellariae and half amount of Rhizoma Pinelliae according to the formulation proportion, pulverizing them into fine powder for later use;
- b) taking the relative amounts of Herba Ephedrae, Semen Ginkgo, Cortex Mori, Flos Farfarae, Fructus Perillae, Semen Armeniacae Amarum and Herba Houttuyniae according to the formulation and the rest of Rhizoma Pinelliae, adding 7.5 times amount of 70% ethanol, heating and refluxing extract thrice, 1.5 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C for later use;
- c) taking the relative amounts of Lumbricus, Radix Paeoniae Rubra, Periostracum Cicadae, Radix Trichosanthis and Fructus Forsythiae according to the formulation, adding 8 times amount of water, decocting twice, 2 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and
- d) making fine powder of step a) and combined extract of step c) into syrup through routine processes.

Example 9

The preparation of suppository of the inventive composition:

Formulation:

Herba Ephedrae 50g, Cortex Mori 253g, Lumbricus 166g,
Semen ginkgo 66g, Flos Farfarae 101g, Rhizoma Pinelliae 101g,
Fructus Perillae 66g, Radix Paeoniae Rubra 166g, Semen Armeniacae Amarum 101g,
Radix Scutellariae 66g, Periostracum Cicadae 66g, Herba Houttuyniae 253g,
Radix Trichosanthis 253g, and Fructus Forsythiae 66 g.

Preparation method:

- a) taking Radix Scutellariae and 2/3 amount of Rhizoma Pinelliae according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of *Herba Ephedrae*, *Semen Ginkgo*, *Cortex Mori*, *Flos Farfarae*, *Fructus Perillae*, *Semen Armeniacae Amarum* and *Herba Houttuyniae* according to the formulation and the rest of *Rhizoma Pinelliae*, adding 6 times amount of 50% ethanol, heating and refluxing extract thrice, 3 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C for later use;

c) taking the relative amounts of *Lumbricus*, *Radix Paeoniae Rubra*, *Periostracum Cicadae*, *Radix Trichosanthis* and *Fructus Forsythiae* according to the formulation, adding 7 times amount of water, decocting twice, 1 hour each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) making fine powder of step a) and combined extract of step c) into suppository through routine processes.

Example 10

The preparation of gelata of the inventive composition:

Formulation:

Herba Ephedrae 76g, *Cortex Mori* 166g, *Lumbricus* 253g,

Semen ginkgo 101g, *Flos Farfarae* 66g, *Rhizoma Pinelliae* 66g,

Fructus Perillae 101g, *Radix Paeoniae Rubra* 253g, *Semen Armeniacae Amarum* 66g,

Radix Scutellariae 101g, *Periostracum Cicadae* 101g, *Herba Houttuyniae* 166g,

Radix Trichosanthis 166g, and *Fructus Forsythiae* 101 g.

Preparation method:

a) taking *Radix Scutellariae* and 3/4 of *Rhizoma Pinelliae* according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of *Herba Ephedrae*, *Semen Ginkgo*, *Cortex Mori*, *Flos Farfarae*, *Fructus Perillae*, *Semen Armeniacae Amarum* and *Herba Houttuyniae* according to the formulation and the rest of *Rhizoma Pinelliae*, adding 10 times amount of 50% ethanol, heating and refluxing extract thrice, 3 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C for later use;

c) taking the relative amounts of *Lumbricus*, *Radix Paeoniae Rubra*, *Periostracum Cicadae*, *Radix Trichosanthis* and *Fructus Forsythiae* according to the formulation, adding 10 times amount of water, decocting twice, 4 hours each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) making fine powder of step a) and combined extract of step c) into gelata through routine processes.

Example 11

The preparation of spray of the inventive composition:

Formulation:

Herba Ephedrae 70g, *Cortex Mori* 241g, *Lumbricus* 245g,
Semen ginkgo 98g, *Flos Farfarae* 94g, *Rhizoma Pinelliae* 95g,
Fructus Perillae 94g, *Radix Paeoniae Rubra* 230g, *Semen Armeniacae Amarum* 92g,
Radix Scutellariae 91g, *Periostracum Cicadae* 97g, *Herba Houttuyniae* 237g,
Radix Trichosanthis 231g, and *Fructus Forsythiae* 91 g.

Preparation method:

a) taking *Radix Scutellariae* and half amount of *Rhizoma Pinelliae* according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of *Herba Ephedrae*, *Semen Ginkgo*, *Cortex Mori*, *Flos Farfarae*, *Fructus Perillae*, *Semen Armeniacae Amarum* and *Herba Houttuyniae* according to the formulation and the rest of *Rhizoma Pinelliae*, adding 6 times amount of 80% ethanol, heating and refluxing extract thrice, 3 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C for later use;

c) taking the relative amounts of *Lumbricus*, *Radix Paeoniae Rubra*, *Periostracum Cicadae*, *Radix Trichosanthis* and *Fructus Forsythiae* according to the formulation, adding 10 times amount of water, decocting twice, 1 hour each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) making fine powder of step a) and combined extract of step c) into spray through routine

processes.

Example 12

The preparation of powder of the inventive composition:

Herba Ephedrae 82g, Cortex Mori 150g, Lumbricus 270g,

Semen ginkgo 50g, Flos Farfarae 130g, Rhizoma Pinelliae 55g,

Fructus Perillae 130g, Radix Paeoniae Rubra 155g, Semen Armeniacae Amarum 55g,

Radix Scutellariae 130g, Periostracum Cicadae 55g, Herba Houttuyniae 280g,

Radix Trichosanthis 280g, and Fructus Forsythiae 130 g.

Preparation method:

Taking the formulation amounts of each raw medicinal material, pulverizing them into powder, sieving the powder, and then making them into powder.

CLAIMS

1. A traditional Chinese medicine composition for treating Bronchial Asthma, wherein said composition is prepared from the following raw medicinal materials formulation:

Herba Ephedrae 40-90 parts, Cortex Mori 136-300 parts, Lumbricus 146-300 parts,
Semen Ginkgo 46-151 parts, Flos Farfarae 46-151 parts, Rhizoma Pinelliae 46-151 parts,
Fructus Perillae 46-151 parts, Radix Paeoniae Rubra 146-300 parts,
Semen Armeniacae Amarum 46-151 parts,
Radix Scutellariae 46-151 parts, Periostracum Cicadae 46-151 parts,
Herba Houttuyniae 146-300 parts, Radix Trichosanthis 146-300 parts, and
Fructus Forsythiae 46-151 parts.

2. The traditional Chinese medicine composition according to Claim 1, wherein said composition is prepared from the following raw medicinal materials formulation:

Herba Ephedrae 50-76 parts, Cortex Mori 166-253 parts, Lumbricus 166-253 parts,
Semen Ginkgo 66-101 parts, Flos Farfarae 66-101 parts, Rhizoma Pinelliae 66-101 parts,
Fructus Perillae 66-101 parts, Radix Paeoniae Rubra 166-253 parts,
Semen Armeniacae Amarum 66-101 parts, Radix Scutellariae 66-101 parts,
Periostracum Cicadae 66-101 parts, Herba Houttuyniae 166-253 parts,
Radix Trichosanthis 166-253 parts, and Fructus Forsythiae 66-101 parts.

3. The traditional Chinese medicine composition according to Claim 2, wherein said composition is prepared from the following raw medicinal materials formulation:

Herba Ephedrae 70 parts, Cortex Mori 241 parts, Lumbricus 245 parts,
Semen Ginkgo 98 parts, Flos Farfarae 94 parts, Rhizoma Pinelliae 95 parts,
Fructus Perillae 94 parts, Radix Paeoniae Rubra 230 parts,
Semen Armeniacae Amarum 92 parts, Radix Scutellariae 91 parts,
Periostracum Cicadae 97 parts, Herba Houttuyniae 237 parts,
Radix Trichosanthis 231 parts, and Fructus Forsythiae 91 parts.

4. The traditional Chinese medicine composition according to Claim 2, wherein said composition is prepared from the following raw medicinal materials formulation:

Herba Ephedrae 63 parts, Cortex Mori 210 parts, Lumbricus 210 parts,
Semen Ginkgo 84 parts, Flos Farfarae 84 parts, Rhizoma Pinelliae 84 parts,

Fructus Perillae 84 parts, Radix Paeoniae Rubra 210 parts,
Semen Armeniacae Amarum 84 parts, Radix Scutellariae 84 parts,
Periostracum Cicadae 84 parts, Herba Houttuyniae 210 parts,
Radix Trichosanthis 210 parts, and Fructus Forsythiae 84 parts.

5. The traditional Chinese medicine composition according to Claim 2, wherein said composition is prepared from the following raw medicinal materials formulation:

Herba Ephedrae 61 parts, Cortex Mori 198 parts, Lumbricus 223 parts,
Semen Ginkgo 78 parts, Flos Farfarae 92 parts, Rhizoma Pinelliae 73 parts,
Fructus Perillae 85 parts, Radix Paeoniae Rubra 188 parts,
Semen Armeniacae Amarum 87 parts, Radix Scutellariae 88 parts,
Periostracum Cicadae 79 parts, Herba Houttuyniae 221 parts,
Radix Trichosanthis 218 parts, and Fructus Forsythiae 81 parts.

6. The traditional Chinese medicine composition according to Claim 1, wherein said composition is prepared from the following raw medicinal materials formulation:

Herba Ephedrae 77-88 parts, Cortex Mori 136-165 parts, Lumbricus 255-300 parts,
Semen Ginkgo 46-65 parts, Flos Farfarae 110-151 parts, Rhizoma Pinelliae 46-65 parts,
Fructus Perillae 105-151 parts, Radix Paeoniae Rubra 146-165 parts,
Semen Armeniacae Amarum 46-65 parts, Radix Scutellariae 103-151 parts,
Periostracum Cicadae 46-65 parts, Herba Houttuyniae 255-300 parts,
Radix Trichosanthis 255-300 parts, and Fructus Forsythiae 103-151 parts.

7. The traditional Chinese medicine composition according to any of claim 1-6, wherein Herba Ephedrae is honey-baking Herba Ephedrae, Semen Ginkgo is stir-fried Semen Ginkgo, Rhizoma Pinelliae is alum processed Rhizoma Pinelliae, Fructus Perillae is stir-fried Fructus Perillae, Semen Armeniacae Amarum is stir-fried Semen Armeniacae Amarum.

8. The traditional Chinese medicine composition according to any of claim 1-6, wherein clinical dosage forms of said composition are capsule, tablet, powder, oral solution, soft capsule, pill, tincture, syrup, suppository, gel, spray or injection.

9. The traditional Chinese medicine composition according to any of claim 1-6, wherein said composition is prepared by following method:

a) taking Radix Scutellariae and 1/3—3/4 amount of Rhizoma Pinelliae according to the

formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of *Herba Ephedrae*, *Semen Ginkgo*, *Cortex Mori*, *Flos Farfarae*, *Fructus Perillae*, *Semen Armeniacae Amarum* and *Herba Houttuyniae* according to the formulation and the rest of *Rhizoma Pinelliae*, adding 6-10 times amount of 50-80% ethanol, heating and refluxing extract thrice, 1-3 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C for later use;

c) taking the relative amounts of *Lumbricus*, *Radix Paeoniae Rubra*, *Periostracum Cicadae*, *Radix Trichosanthis* and *Fructus Forsythiae* according to the formulation, adding 7-10 times amount of water, decocting twice, 1-4 hour each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) mixing the fine powder of step a) and the combined extract of step c) to obtain the inventive traditional Chinese medicine composition.

10. A preparation method of tablet of the traditional Chinese medicine composition according to any one of claim 1-6, comprising the following steps:

a) taking *Radix Scutellariae* and half amount of *Rhizoma Pinelliae* according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of *Herba Ephedrae*, *Semen Ginkgo*, *Cortex Mori*, *Flos Farfarae*, *Fructus Perillae*, *Semen Armeniacae Amarum* and *Herba Houttuyniae* according to the formulation and the rest of *Rhizoma Pinelliae*, adding 6-10 times amount of 50-80% ethanol, heating and refluxing extract thrice, 1-3 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C for later use;

c) taking the relative amounts of *Lumbricus*, *Radix Paeoniae Rubra*, *Periostracum Cicadae*, *Radix Trichosanthis* and *Fructus Forsythiae* according the formulation, adding 7-10 times amount of water, decocting twice, 1-4 hour each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d)Mixing the fine powder of step a) and the extract of step c), adding an appropriate amount

of adjuvant into the mixture, and spraying granulation to obtain granules and sifting the granules through a mesh after drying, standing by; and

e) preparing the granules of step d) to obtain tablets of the traditional Chinese medicine composition through routine processes.

11. A preparation method of tablet of the traditional Chinese medicine composition according to claim 10, comprising the following steps:

a) taking Radix Scutellariae and half amount of Rhizoma Pinelliae according to the formulation proportion, pulverizing them into fine powder for later use;

b) taking the relative amounts of Herba Ephedrae, Semen Ginkgo, Cortex Mori, Flos Farfarae, Fructus Perillae, Semen Armeniacae Amarum and Herba Houttuyniae according to the formulation and the rest of Rhizoma Pinelliae, adding 8 times amount of 60% ethanol, heating and refluxing extract thrice, 1.5 hours each time, recovering ethanol under reduced pressure from extract solution, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60 °C for later use;

c) taking the relative amounts of Lumbricus, Radix Paeoniae Rubra, Periostracum Cicadae, Radix Trichosanthis and Fructus Forsythiae according to the formulation, adding 9 times amount of water, decocting twice, 2 hour each time, filtering the water decoction, combining decoctions, concentrating the solution to obtain the extract with a relative density of 1.05-1.10 at 60°C, and combining the extract with extract of step b) for later use; and

d) Mixing the fine powder of step a) and the extract of step c), adding an appropriate amount of adjuvant into the mixture, and spraying granulation to obtain granules and sifting the granules through a mesh after drying, standing by. ; and

e) preparing the granules of step d) to obtain tablets of the traditional Chinese medicine composition through routine processes.