TRADITIONAL CHINESE MEDICINE COMPOSITION FOR TREATING METABOLIC SYNDROME AND PREPARATIONS THEREOF

TECHNICAL FIELD

The present invention relates to the field of medical technologies, in particular to a traditional Chinese medicine composition and preparations thereof.

BACKGROUND

Metabolic syndrome is a clinical syndrome that seriously affects human health. Main connotation of metabolic syndrome includes impaired glucose tolerance, hypertension, hyperlipidemia, and central obesity. Metabolic syndrome has insulin resistance as the common pathological basis and the clustering of a plurality of metabolic diseases as clinical characteristics. At present, one quarter to one third of adults in the world are affected by metabolic syndrome. As the population ages and overweight prevails, morbidity of this disease is increasing on a yearly basis . In the past 20 years, the morbidity of metabolic syndrome among American adults has risen from 21% to 39%. Among the adult population over the age of 20 in China, the morbidity of metabolic syndrome is 14%-18% by using the WHO standard and 12%-21% by using the NCEP-ATPIII standard. Patients with metabolic syndrome have 2-3 times higher morbidity and mortality during cardiovascular events and strokes than those without metabolic syndrome. The risk for non-diabetic patients with metabolic syndrome to develop type 2 diabetes is 5 times higher than those without metabolic syndrome. Among people with metabolic syndrome, around 45% have abnormal glucose metabolism, more than 80% have abnormal blood lipids, and around 90% have elevated blood pressure. At present, western treatment methods mainly involve combined application of a variety of drugs to control metabolic syndrome, which is expensive, inconvenient, and has relatively serious side effects. Neither there is any effective prescription in traditional Chinese medicine. Currently, there is still no international drug dedicated for treating metabolic syndrome due to the complexity of metabolic syndrome, so it is of great significance to carry out clinical research for new drugs dedicated for metabolic syndrome. The present invention will fill the gap in the international field.

SUMMARY

An object of the present disclosure is to provide a traditional Chinese medicine composition, wherein the traditional Chinese medicine composition comprises Coptidis Rhizoma, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Trichosanthis Fructus, Cinnamomi Cortex, and red yeast rice.

In the composition, Aurantii Fructus Immaturus is preferably Aurantii Fructus Immaturus parched with bran, Pinelliae Rhizoma is preferably Pinelliae Rhizoma Praeparatumcum Zingibere Et Alumine, and Trichosanthis Fructus is preferably whole Trichosanthis Fructus. Preferably, the composition comprises 5-80 wt% of Coptidis

Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 0-60 wt% of Pinelliae Rhizoma, 0-40 wt% of Trichosanthis Fructus, 2-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice. More preferably, the composition comprises 10-30 wt% of Coptidis Rhizoma, 10-30 wt% of Aurantii Fructus Immaturus, 10-30 wt% of Pinelliae Rhizoma, 5-30 wt% of Trichosanthis Fructus, 2-10 wt% of Cinnamomi Cortex, and12-36 wt% of red yeast rice. Most preferably, a preferred ratio combination in the composition is as follows: 19.6 wt% of Coptidis Rhizoma, 19.6 wt% of Aurantii Fructus Immaturus, 19.6 wt% of Pinelliae Rhizoma, 26.1 wt% of Trichosanthis Fructus, 2.1 wt% of Cinnamomi Cortex, and 13.0 wt% of red yeast rice.

A second object of the present disclosure is to provide a traditional Chinese medicine composition, wherein the composition comprises Coptidis Rhizoma, Aurantii Fructus Immaturus, red yeast rice, and one or a plurality of optional selections from the group consisting of Pinelliae Rhizoma, Trichosanthis Fructus, and Cinnamomi Cortex. The one or plurality of selections comprise 1, 2, or 3 selections.

The composition comprises 5-80 wt% of Coptidis Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 0-60 wt% of Pinelliae Rhizoma, 0-40 wt% of Trichosanthis Fructus, 0-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice.

The composition comprises 5-80 wt% of Coptidis Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 0-60 wt% of Pinelliae Rhizoma, 5-40 wt% of Trichosanthis Fructus, 2-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice.

The composition comprises 5-80 wt% of Coptidis Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 10-60 wt% of Pinelliae Rhizoma, 0-40 wt% of Trichosanthis Fructus, 2-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice.

The composition comprises 5-80 wt% of Coptidis Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 10-60 wt% of Pinelliae Rhizoma, 5-40 wt% of Trichosanthis Fructus, 0-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice.

The composition comprises 5-80 wt% of Coptidis Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 0-60 wt% of Pinelliae Rhizoma, 0-40 wt% of Trichosanthis Fructus, 2-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice.

The composition comprises 5-80 wt% of Coptidis Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 0-60 wt% of Pinelliae Rhizoma, 5-40 wt% of Trichosanthis Fructus, 0-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice.

The composition comprises 5-80 wt% of Coptidis Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 10-60 wt% of Pinelliae Rhizoma, 0-40 wt% of Trichosanthis Fructus, 0-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice.

Aurantii Fructus Immaturus is preferably Aurantii Fructus Immaturus parched with bran, Pinelliae Rhizoma is preferably Pinelliae Rhizoma Praeparatumcum

Zingibere Et Alumine, and Trichosanthis Fructus is preferably whole Trichosanthis Fructus.

Another object of the present disclosure is to provide a traditional Chinese medicine extract composition, prepared by mixing extracts of the following six traditional Chinese medicinal materials consisting of: Coptidis Rhizoma, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Trichosanthis Fructus, Cinnamomi Cortex, and red yeast rice. The content ratio of the extracts is as follows: a total alkaloids extract of Coptidis Rhizoma (hereinafter referred to Coptidis Rhizoma extract) accounts for 2-30%, and a mixed extract of five traditional Chinese medicinal materials consisting of Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice (of the total amount in prescription,10-100% of the red yeast rice is extracted, 0-90% is pulverized into fine powder as a disintegrant or filler, the same below), Trichosanthis Fructus, and Cinnamomi Cortex accounts for 70-98%. Preferably, the Coptidis Rhizoma extract accounts for 3-25%, and the mixed extract of five traditional Chinese medicinal materials consisting of Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice, Trichosanthis Fructus, and Cinnamomi Cortex accounts for 75-97%. Most preferably, the Coptidis Rhizoma extract accounts for 5-15%, and the mixed extract of five traditional Chinese medicinal materials consisting of Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice, Trichosanthis Fructus, and Cinnamomi Cortex accounts for 85-98%.

Red yeast rice fine powder (0-90% of the total prescription amount) and the Coptidis Rhizoma extract are well mixed with the mixed extract of the five traditional Chinese medicinal materials consisting of Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice, Trichosanthis Fructus, and Cinnamomi Cortex, or with respective extracts of the above five traditional Chinese medicinal materials, to prepare the traditional Chinese medicine extract composition.

The traditional Chinese medicine extract composition contains the following active ingredients (mg/g): 6-122 mg/g of total alkaloids (the sum of berberine hydrochloride, jatrorrhizine hydrochloride, coptisine hydrochloride and palmatine hydrochloride, the same below), which comprise 4-89 mg/g of berberine; 30-315 mg/g of total flavonoids (the sum of three flavonoid glycosides consisting of neohesperidin, hesperidin, and naringin, the same below), which comprise 20-186 mg/g of neohesperidin; and 0.5-9 mg/g of lovastatin.

The traditional Chinese medicine extract composition contains the following active ingredients (mg/g): 12-122 mg/g of total alkaloids, which comprise 9-89 mg/g of berberine; 130-315 mg/g of total flavonoids, which comprise 80-186 mg/g of neohesperidin; and 1-9 mg/g of lovastatin.

The traditional Chinese medicine extract composition preferably contains the following active ingredients (mg/g): 20-85 mg/g of total alkaloids, which comprise 15-62 mg/g of berberine; 140-250 mg/g of total flavonoids, which comprise 90-170 mg/g of neohesperidin; and 1-5 mg/g of lovastatin.

The traditional Chinese medicine extract composition more preferably contains the following active ingredients (mg/g): 30-75 mg/g of total alkaloids, which

comprise 20-50 mg/g of berberine; 110-250 mg/g of total flavonoids, which comprise 60-120 mg/g of neohesperidin; and 1-5 mg/g of lovastatin.

The traditional Chinese medicine extract composition preferably contains the following active ingredients (mg/g): 20-85 mg/g of total alkaloids, which comprise 15-62 mg/g of berberine; 100-250 mg/g of total flavonoids, which comprise 30-170 mg/g of neohesperidin; and 1-5 mg/g of lovastatin.

The traditional Chinese medicine extract composition more preferably contains the following active ingredients (mg/g): 30-75 mg/g of total alkaloids, which comprise 20-50 mg/g of berberine; 110-250 mg/g of total flavonoids, which comprise 40-120 mg/g of neohesperidin; and 1-5 mg/g of lovastatin.

In another aspect, the present disclosure refers to a medicine composition comprising the traditional Chinese medicine extract composition and a pharmaceutically acceptable carrier.

Another object of the present disclosure is to provide a method for preparing a traditional Chinese medicine extract. Coptidis Rhizoma is extracted by using acid water, and filtration, concentration, alkali precipitation, salting-out, filtration, drying, pulverization are performed to prepare a total alkaloids extract. Four medicinal materials consisting of: red yeast rice (10-100% of the prescribed dosage), Aurantii Fructus Immaturus, Pinelliae Rhizoma, and Cinnamomi Cortex, are extracted by using 50-90% ethanol, and filtration is performed. Trichosanthis Fructus is extracted by using 75-95% ethanol, a Trichosanthis Fructus extraction solution is merged with an extraction solution of the four traditional Chinese medicinal materials, ethanol is recovered, decompression concentration, drying, and pulverization are performed to prepare a mixed extract of five traditional Chinese medicinal materials consisting of: Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice, Cinnamomi Cortex, and Trichosanthis Fructus; or five traditional Chinese medicinal materials consisting of: red yeast rice, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Cinnamomi Cortex, and Trichosanthis Fructus, are mixed and extracted by using 50-90% ethanol, filtration is performed, decompression is performed to recover ethanol, concentration, drying, and pulverization are performed to prepare a mixed extract of the five traditional Chinese medicinal materials consisting of: red yeast rice, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Cinnamomi Cortex, and Trichosanthis Fructus; or red yeast rice, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Cinnamomi Cortex, and Trichosanthis Fructus are separately extracted by using 50-90% ethanol, filtration is performed to separately prepare an ethanol extraction solution of the individual traditional Chinese medicinal material, the separately prepared ethanol extraction solutions of the five traditional Chinese medicinal materials are filtered separately, decompression is performed to recover ethanol, and concentration, drying, and pulverization are performed to prepare respective extracts of the five traditional Chinese medicinal materials consisting of: red yeast rice, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Cinnamomi Cortex, and Trichosanthis Fructus. The respective extracts of the five traditional Chinese medicinal materials are mixed to prepare a mixed extract of the five traditional Chinese medicinal materials. The Coptidis Rhizoma extract and the mixed extract of

the five traditional Chinese medicinal materials are mixed to prepare the traditional Chinese medicine extract composition.

In the composition, the Coptidis Rhizoma is extracted by using 0.1-1% sulfuric acid water, filtration is performed, a filtrate is concentrated, calcium hydroxide is

added for alkali precipitation, a precipitate is removed, the pH value of the filtrate is regulated to an acid pH value by using hydrochloric acid, then sodium chloride is added to salt out the precipitate, and the precipitate is separated out, washed, filtered, dried, and pulverized, to prepare the Coptidis Rhizoma extract.

In the composition, four medicinal materials consisting of: red yeast rice (10-100% of the prescribed dosage), Aurantii Fructus Immaturus, Pinelliae Rhizoma, and Cinnamomi Cortex, are extracted by using 50-90% ethanol, and filtration is performed; and Trichosanthis Fructus is extracted by using 75-95% ethanol, a Trichosanthis Fructus extraction solution is merged with an extraction solution of the above four traditional Chinese medicinal materials, ethanol is recovered, decompression concentration, drying, and pulverization are performed to prepare a mixed extract of five traditional Chinese medicinal materials consisting of: Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice, Cinnamomi Cortex, and Trichosanthis Fructus.

In the composition, five traditional Chinese medicinal materials consisting of: red yeast rice, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Cinnamomi Cortex, and Trichosanthis Fructus, are mixed and extracted by using 50-90% ethanol, filtration is performed, decompression is performed to recover ethanol, concentration, drying, and pulverization are performed to prepare a mixed extract of the five traditional Chinese medicinal materials consisting of: red yeast rice, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Cinnamomi Cortex, and Trichosanthis Fructus. Alternatively, red yeast rice, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Cinnamomi Cortex, and Trichosanthis Fructus are separately extracted by using 50-90% ethanol, filtration is performed to separately prepare an ethanol extraction solution of the individual traditional Chinese medicinal material, the separately prepared ethanol extraction solutions of the five traditional Chinese medicinal materials are filtered separately, decompression is performed to recover ethanol, and concentration, drying, pulverization, and mixing are performed to prepare respective extracts of the five traditional Chinese medicinal materials consisting of: red yeast rice, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Cinnamomi Cortex, and Trichosanthis Fructus. In the ethanol-extraction of the mixed extract or the respective extracts of the traditional Chinese medicinal materials consisting of: red yeast rice, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Cinnamomi Cortex, and Trichosanthis Fructus, the ethanol is preferably 60-85% ethanol.

The mixed extract of the five traditional Chinese medicinal materials or the respective extracts of the five traditional Chinese medicinal materials, or the Trichosanthis Fructus extract and the extracts of four medicinal materials consisting of: Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice, and Cinnamomi Cortex are mixed with the Coptidis Rhizoma extract and 0-90% red yeast rice fine powder which is used as a tablet disintegrant or a filler, to prepare the traditional Chinese medicine extract compositioAnother object of the present disclosure is to provide a Chinese medicine composition and an administration dosage thereof.

A daily administration dosage of the traditional Chinese medicine composition of the present disclosure is as follows: 1.5-9 g of Coptidis Rhizoma, 1.5-9 g of Aurantii

Fructus Immaturus, 0-12 g of Pinelliae Rhizoma, 0-12 g of Trichosanthis Fructus, 0-5 g of Cinnamomi Cortex, and 1.5-30 g of red yeast rice. A preferred dosage is 3-6 g of Coptidis Rhizoma, 3-6 g of Aurantii Fructus Immaturus, 3-6 g of Pinelliae Rhizoma, 0-6 g of Trichosanthis Fructus, 0.5-2.5 g of Cinnamomi Cortex, and 1.5-6 g of Red yeast rice. A more preferred dosage is 4.5 g of Coptidis Rhizoma, 4.5 g of Aurantii Fructus Immaturus, 4.5 g of Pinelliae Rhizoma, 6 g of Trichosanthis Fructus, 0.5 g of Cinnamomi Cortex, and 3 g of red yeast rice.

Another object of the present disclosure is to provide a traditional Chinese medicine extract composition and an administration dosage thereof.

An administration dosage of the traditional Chinese medicine extract composition of the present disclosure is 1-15 g per day, a preferred administration dosage is 2-10 g per day, and a more preferred administration dosage is 3-6 g per day.

The traditional Chinese medicine extract composition contains the following active ingredients (mg/g): 6-122 mg/g of total alkaloids, which comprise 4-89 mg/g of berberine; 30-315 mg/g of total flavonoids, which comprise 20-186 mg/g of neohesperidin; and 0.5-9 mg/g of lovastatin.

In some examples, the traditional Chinese medicine extract composition contains the following active ingredients (mg/g): 12-122 mg/g of total alkaloids, which comprise 9-89 mg/g of berberine; 130-315 mg/g of total flavonoids, which comprise 80-186 mg/g of neohesperidin; and 1-9 mg/g of lovastatin.

In some examples, the traditional Chinese medicine extract composition preferably contains the following active ingredients (mg/g): 20-85 mg/g of total alkaloids, which comprise 15-62 mg/g of berberine; 100-250 mg/g of total flavonoids, which comprise 30-170 mg/g of neohesperidin; and 1-5 mg/g of lovastatin. In some examples, the traditional Chinese medicine extract composition more preferably contains the following active ingredients (mg/g): 30-75 mg/g of total alkaloids, which comprise 20-50 mg/g of berberine; 110-250 mg/g of total flavonoids, which comprise 40-120 mg/g of neohesperidin; and 1-5 mg/g of lovastatin.

In some examples, the traditional Chinese medicine extract composition preferably contains the following active ingredients (mg/g): 20-85 mg/g of total alkaloids, which comprise 15-62 mg/g of berberine; 140-250 mg/g of total flavonoids, which comprise 90-170 mg/g of neohesperidin; and 1-5 mg/g of lovastatin. In some examples, the traditional Chinese medicine extract composition more preferably contains the following active ingredients (mg/g): 30-75 mg/g of total alkaloids, which comprise 20-50 mg/g of berberine; 110-250 mg/g of total flavonoids, which comprise 60-120 mg/g of neohesperidin; and 1-5 mg/g of lovastatin.

In another aspect, the present disclosure refers to a use of the traditional Chinese medicine composition in one or a plurality of the following indications or functions atan effective therapeutic dosage: a. treating one or a plurality of the following: metabolic syndrome, obesity, hyperglycemia, hyperlipidemia, and hypertension; b. treating one or a plurality of the following: disorder of blood glucose and lipid metabolism, obesity, hyperglycemia, hyperlipidemia, and hypertension, in the early stage of metabolic syndrome; c. one or a plurality of the following: reducing blood glucose, reducing the hypoglycemic insulin level, improving oral glucose tolerance

abnormality, reducing the glycated hemoglobin (HbAlc) level, increasing the insulin sensitivity index, improving insulin resistance, reducing the blood triglyceride level, reducing total cholesterol, and reducing the blood pressure; d. major functions: clearing heat, eliminating phlegm, and promoting qi circulation to relieve distension; and treating symptoms caused by the stagnation of phlegm-heat, such as obesity, enlarged abdomen, chest distress, excessive phlegm, inappetence and feeling of fullness in stomach and abdomen, dry mouth, thirst, polydipsia, and easy hunger, irritability, flushing and oily face, snoring at night, loose or dry stool, yellow urine, red tongue with yellow coating and slippery pulse.

DETAILED DESCRIPTION

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Coptidis Rhizoma: The main components of Coptidis Rhizoma are berberine hydrochloride, jatrorrhizine hydrochloride, coptisine hydrochloride, palmatine hydrochloride, etc. Coptidis Rhizoma has functions such as reducing blood glucose, reducing serum lipid, antioxidation, antibacteria, and antivirus.

Aurantii Fructus Immaturus: The main components of Aurantii Fructus Immaturus are flavonoids and alkaloids. The main effective components of Aurantii

hour, filtration was performed, decompression was performed to recover ethanol, and concentration and drying were performed to obtain an extract of Pinelliae Rhizoma Praeparatumcum Zingibere Et Alumine.

Medicinal slices of whole Trichosanthis Fructus were prepared according to the prescribed dosage and placed into an ethanol reflux extraction tank, 70% ethanol of 8 times of the amount was added for extraction for two times, with each time lasting 1 hour, filtration was performed, decompression was performed to recover ethanol, and concentration and drying were performed to obtain an extract of whole Trichosanthis Fructus.

Red yeast rice was prepared according to the prescribed dosage and placed into an ethanol reflux extraction tank, 70% ethanol of 8 times of the amount was added for extraction for two times, with each time lasting 1 hour, filtration was performed, decompression was performed to recover ethanol, and concentration and drying were performed to obtain an extract of red yeast rice.

Cinnamomi Cortex was prepared according to the prescribed dosage and placed into an ethanol reflux extraction tank, 70% ethanol of 8 times of the amount was added for extraction for two times, with each time lasting 1 hour, filtration was performed, decompression was performed to recover ethanol, and concentration and drying were performed to obtain an extract of Cinnamomi Cortex.

Aurantii Fructus Immaturus, Cinnamomi Cortex, Pinelliae Rhizoma, Trichosanthis Fructus, and red yeast rice were well mixed to obtain a mixed extract of the five traditional Chinese medicinal materials. The mixed extract of the five traditional Chinese medicinal materials was well mixed with the Coptidis Rhizoma extract to obtain the traditional Chinese medicine extract composition of the present invention.

Content detection results (mg/g): the total alkaloids content is 38.69 mg/g (including 28.10 mg/g of berberine), the total flavonoids content is 204.49 mg/g (including 123.2 mg/g of neohesperidin); and the lovastatin content is 2.27 mg/g.

Comparative example 1

Prescription: 0 g (0 wt%) of Coptidis Rhizoma, 4.5 g (24.32 wt%) of Aurantii Fructus Immaturus, 4.5 g (24.32 wt%) of Pinelliae Rhizoma, 6 g (32.43 wt%) of Trichosanthis Fructus, 0.5 g (2.70 wt%) of Cinnamomi Cortex, and 3 g (16.21 wt%) of red yeast rice, with a total daily administration dosage of 18.5 g. The amount of prepared extracts is 5.9 g, with a yield of 31.9%.

Preparation method: preparation was performed according to the extraction method of the corresponding ingredients in Example 6.

Content detection results (mg/g): the total alkaloids content is 0 mg/g (including 0 mg/g of berberine), the total flavonoids content is 34.16 mg/g (including 20.11 mg/g of neohesperidin); and the lovastatin content is 0.14 mg/g.

Comparative example 2

Prescription: 4.5 g (24.32 wt%) of Coptidis Rhizoma, 0g (0 wt%) of Aurantii Fructus Immaturus, 4.5 g (24.32 wt%) of Pinelliae Rhizoma, 6 g (32.43 wt%) of Trichosanthis Fructus, 0.5 g (2.70 wt%) of Cinnamomi Cortex,

and 3 g (16.21 wt%) of red yeast rice, with a total daily administration dosage of 18.5 g. The amount of prepared extracts is 4.06 g, with a yield of 21.9%.

Preparation method: preparation was performed according to the extraction method of the corresponding ingredients in Example 6.

Content detection results (mg/g): the total alkaloids content is 9.53 mg/g (including 6.98 mg/g of berberine), the total flavonoids content is 0 mg/g (including 0 mg/g of neohesperidin); and the lovastatin content is 0.55 mg/g.

Comparative example 3

Prescription: 4.5 g (22.5 wt%) of Coptidis Rhizoma, 4.5 g (22.5 wt%) of Aurantii Fructus Immaturus, 4.5 g (22.5 wt%) of Pinelliae Rhizoma, 6 g (30 wt%) of Trichosanthis Fructus, 0.5 g (2.5 wt%) of Cinnamomi Cortex, and 0 g (0 wt%) of red yeast rice, with a total daily administration dosage of 20 g. The amount of prepared extracts is 5.71 g, with a yield of 28.55%.

Preparation method: preparation was performed according to the extraction method of the corresponding ingredients in Example 6.

Content detection results (mg/g): the total alkaloids content is 6.88 mg/g (including 4.96 mg/g of berberine), the total flavonoids content is 36.01 mg/g (including 21.67 mg/g of neohesperidin); and the lovastatin content is 0 mg/g.

Comparative example 4

Prescription: 4.5 g (50 wt%) of Coptidis Rhizoma, 4.5 g (50 wt%) of Aurantii Fructus Immaturus, 0 g (0 wt%) of Pinelliae Rhizoma, 0 g (0 wt%) of Trichosanthis Fructus, 0 g (0 wt%) of Cinnamomi Cortex, and 0 g (0 wt%) of red yeast rice, with a total daily administration dosage of 9 g. The amount of prepared extracts is 2.66 g, with a yield of 9.56%.

Preparation method: preparation was performed according to the extraction method of the corresponding ingredients in Example 6.

Content detection results (mg/g): the total alkaloids content is 15.11 mg/g (including 10.65 mg/g of berberine), the total flavonoids content is 76.71 mg/g (including 46.62 mg/g of neohesperidin); and the lovastatin content is 0 mg/g.

Comparative example 5

Prescription: 4.5 g (29.03 wt%) of Coptidis Rhizoma, 0 g (0 wt%) of Aurantii Fructus Immaturus, 4.5 g (29.03 wt%) of Pinelliae Rhizoma, 6 g (38.71 wt%) of Trichosanthis Fructus, 0.5 g (3.22 wt%) of Cinnamomi Cortex, and 0 g (0 wt%) of red yeast rice, with a total daily administration dosage of 15.5 g. The amount of prepared extracts is 3.46 g, with a yield of 22.32%.

Preparation method: preparation was performed according to the extraction method of the corresponding ingredients in Example 6.

Content detection results (mg/g): the total alkaloids content is 11.88 mg/g (including 8.12 mg/g of berberine), the total flavonoids content is 0 mg/g (including 0 mg/g of neohesperidin); and the lovastatin content is 0 mg/g.

Drug prescriptions and active ingredient content detection results in Examples 1-7 and Comparative examples 1-5 are summarized as follows:

Table I. Drug prescriptions

		Coptidis Rhizoma	Aurantii Fructus Immaturus	Pinelliae Rhizoma	Trichosanthis Fructus	Cinnamomi Cortex	Red yeast rice	Total prescription dosage
Example 1	Weight (g)	1.5	6	3	0	2.5	6	19
	Proportion (%)	7.89	31.57	15.79	0	13.16	31.57	
Example 2	Weight (g)	4.5	3	0	0.5	0.5	1.5	10
	Proportion (%)	45	30	0	5	5	15	
Example 3	Weight (g)	4.5	4.5	0	0	0	12	21
	Proportion (%)	21.4	21.4	0	0	0	57.2	
Example 4	Weight (g)	4.5	4.5	0	0	0.5	4.5	14
	Proportion (%)	32.1	32.1	0	0-	3.57	32.1	
Example 5	Weight (g)	6	1.5	6	0	1.25	3	17.75
	Proportion (%)	33.8	8.5	33.8	0	7	16.9	
Example 6	Weight (g)	4.5	4.5	4.5	6	0.5	3	23
	Proportion (%)	19.57	19.57	19.57	26.1	2.17	13.04	
Example 7	Weight (g)	4.5	4.5	4.5	6	0.5	3	23
	Proportion (%)	19.57	19.57	19.57	26.1	2.17	13.04	

Weight range		1.5-6	1.5-6	0-6	0-6	0-2.5	1.5-12	
Optimal prescription (Example 6)		4.5	4.5	4.5	6	0.5	3	Daily Dose
Comparative example 1	Weight (g)	0	4.5	4.5	6	0.5	3	18.5
	Proportion (%)	0	24.32	24.32	32.43	2.7	16.21	
Comparative example 2	Weight (g)	4.5	0	4.5	6	0.5	3	18.5
	Proportion (%)	24.32	0	24.32	32.43	2.7	16.21	
Comparative example 3	Weight (g)	4.5	4.5	4.5	6	0.5	0	20
	Proportion (%)	22.5	22.5	22.5	30	2.5	0	
Comparative example 4	Weight (g)	4.5	4.5	0	0	0	0	9
	Proportion (%)	50	50	0	0	0	0	
Comparative example 5	Weight (g)	4.5	0	4.5	6	0.5	0	15.5
	Proportion (%)	29.03	0	29.03	38.71	3.22	0	

CLAIMS

What is claimed is:

1. A traditional Chinese medicine composition, wherein the traditional Chinese medicine composition comprises Coptidis Rhizoma, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Trichosanthis Fructus, Cinnamomi Cortex and red yeast rice, a daily administration dosage of the traditional Chinese medicine composition is 10-50g, preferably 14-38g.

2. The traditional Chinese medicine composition according to claim 1, wherein the Aurantii Fructus Immaturus is preferably Aurantii Fructus Immaturus parched with bran, the Pinelliae Rhizoma is preferably Pinelliae Rhizoma Praeparatumcum Zingibere Et Alumine, and the Trichosanthis Fructus is preferably whole Trichosanthis Fructus.

3. The traditional Chinese medicine composition according to claim 1 or 2, wherein the composition comprises 5-80 wt% of Coptidis Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 10-60 wt% of Pinelliae Rhizoma, 5-40 wt% of Trichosanthis Fructus, 2-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice; preferably, the composition comprises 10-30 wt% of Coptidis Rhizoma, 10-30 wt% of Aurantii Fructus Immaturus, 10-30 wt% of Pinelliae Rhizoma, 5-30 wt% of Trichosanthis Fructus, 2-10 wt% of Cinnamomi Cortex, and 12-36 wt% of red yeast rice; more preferably, a ratio combination in the composition is as follows: 19.6 wt% of Coptidis Rhizoma, 19.6 wt% of Aurantii Fructus Immaturus, 19.6 wt% of Pinelliae Rhizoma, 26.1 wt% of Trichosanthis Fructus, 2.1 wt% of Cinnamomi Cortex, and 13.0 wt% of red yeast rice.

4. A traditional Chinese medicine composition, wherein the composition comprises Coptidis Rhizoma, Aurantii Fructus Immaturus, red yeast rice, and one or a plurality of optional selections from the group consisting of Pinelliae Rhizoma, Trichosanthis Fructus, and Cinnamomi Cortex.

5. The traditional Chinese medicine composition according to claim 4, wherein the composition comprises 5-80 wt% of Coptidis Rhizoma, 5-70 wt% of Aurantii Fructus Immaturus, 0-60 wt% of Pinelliae Rhizoma, 0-40 wt% of Trichosanthis Fructus, 0-12 wt% of Cinnamomi Cortex, and 10-60 wt% of red yeast rice.

6. A traditional Chinese medicine extract composition, prepared by mixing extracts of the following six traditional Chinese medicinal materials: Coptidis Rhizoma, Aurantii Fructus Immaturus, Pinelliae Rhizoma, Trichosanthis Fructus, Cinnamomi Cortex, and red yeast rice, a daily administration dosage of the traditional Chinese medicine extract composition is 1-15g, preferably 2-10g.

7. The traditional Chinese medicine extract composition according to claim 6, wherein the content ratio of the extracts of the six traditional Chinese medicinal materials is as follows: a Coptidis Rhizoma extract accounts for 2-30%, and a mixed extract of five traditional Chinese medicinal materials consisting of Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice, Trichosanthis Fructus, and Cinnamomi Cortex accounts for 70-98%; preferably, the content ratio of the extracts of the six traditional Chinese medicinal materials is preferably as follows: the Coptidis Rhizoma extract accounts for 3-25%, and the mixed extract of five traditional Chinese medicinal materials consisting of Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice,

Trichosanthis Fructus, and Cinnamomi Cortex accounts for 75-97%; more preferably, the content ratio of the extracts of the six traditional Chinese medicinal materials is preferably as follows: the Coptidis Rhizoma extract accounts for 5-15%, and the mixed extract of five traditional Chinese medicinal materials consisting of Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice, Trichosanthis Fructus, and Cinnamomi Cortex accounts for 85-95%.

8. A traditional Chinese medicine extract composition, prepared by mixing extracts of Coptidis Rhizoma, Aurantii Fructus Immaturus, red yeast rice, and optional one or more selections from the group consisting of Pinelliae Rhizoma, Trichosanthis Fructus, and Cinnamomi Cortex.

9. The traditional Chinese medicine extract composition according to claim 8, wherein the Coptidis Rhizoma extract accounts for 2-30%, preferably 3-25%, more preferably 5-15%, and the extracts of the remaining traditional Chinese medicinal materials account for 70-98%, preferably 75-97%, more preferably 85-95%

10. The traditional Chinese medicine extract composition according to any one of claims 6-9, wherein the traditional Chinese medicine extract composition contains the following active ingredients (mg/g): 6-122 mg/g of total alkaloids, 30-315 mg/g of total flavonoids, and 0.5-9 mg/g of lovastatin, the total alkaloids comprise four alkaloids: berberine hydrochloride, jatrorrhizine hydrochloride, coptisine hydrochloride, and Barmartine hydrochloride, and the total flavonoids comprise three flavonoid glycosides: neohesperidin, hesperidin, and naringin; preferably, the traditional Chinese medicine extract composition contains the following active ingredients (mg/g): 6-122 mg/g of total alkaloids, which comprise 4-89 mg/g of berberine; 30-315 mg/g of total flavonoids, which comprise 20-186 mg/g of neohesperidin; and 0.5-9 mg/g of lovastatin.

11. A medicine composition, comprising the traditional Chinese medicine extract composition according to any one of claims 6-10 and a pharmaceutically acceptable carrier.

12. A method for preparing the traditional Chinese medicine extract composition according to any one of claims 6-10, wherein:

(a-1) Coptidis Rhizoma is extracted by using acid water, and filtration, concentration, alkali precipitation, salting-out, filtration, drying, pulverization are performed to prepare a total alkaloids extract of Coptidis Rhizoma;

(a-2) four medicinal materials consisting of: red yeast rice (10-100% of the prescribed dosage), Aurantii Fructus Immaturus, Pinelliae Rhizoma, and Cinnamomi Cortex, are extracted by using 50-90% ethanol, and filtration is performed;

(a-3) Trichosanthis Fructus is extracted by using 75-95% ethanol, a Trichosanthis Fructus extraction solution is merged with an extraction solution of the four traditional Chinese medicinal materials, decompression is performed to recover ethanol, concentration, drying, and pulverization are performed to prepare a mixed extract of five traditional Chinese medicinal materials consisting of: Aurantii Fructus Immaturus, Pinelliae Rhizoma, red yeast rice, Cinnamomi Cortex, and Trichosanthis Fructus; and

(a-4) the total alkaloids extract of Coptidis Rhizoma, the mixed extract of the five traditional Chinese medicinal materials, and red yeast rice fine powder (0-90% of the

prescribed dosage) are well mixed to prepare the traditional Chinese medicine extract composition.

13. A pharmaceutical preparation, comprising the traditional Chinese medicine composition according to any one of claims 1-5 or the traditional Chinese medicine extract composition according to any one of claims 6-10, wherein the pharmaceutical preparation comprises injections, tablets, capsules, granules, and oral liquids.

14. Use of the traditional Chinese medicine composition according to any one of claims 1-5 or the traditional Chinese medicine extract composition according to any one of claims 6-10 or the pharmaceutical preparation according to claim 13 in one or a plurality of the following indications or functions at an effective therapeutic dosage:

a. treating one or a plurality of the following: metabolic syndrome, obesity, hyperglycemia, hyperlipidemia, and hypertension;

b. treating one or a plurality of the following: disorder of blood glucose and lipid metabolism, obesity, hyperglycemia, hyperlipidemia, and hypertension, in the early stage of metabolic syndrome;

c. one or a plurality of the following: reducing blood glucose, reducing the hypoglycemic insulin level, improving oral glucose tolerance abnormality, reducing the glycated hemoglobin (HbAlc) level, increasing the insulin sensitivity index, improving insulin resistance, reducing the blood triglyceride level, reducing total cholesterol, and reducing the blood pressure;

d. major functions: clearing heat, eliminating phlegm, and promoting qi circulation to relieve distension; and treating symptoms caused by the stagnation of phlegm-heat, such as obesity, enlarged abdomen, chest distress, excessive phlegm, inappetence and feeling of fullness in stomach and abdomen, dry mouth, thirst, polydipsia, and easy hunger, irritability, flushing and oily face, snoring at night, loose or dry stool, yellow urine, red tongue with yellow coating and slippery pulse.