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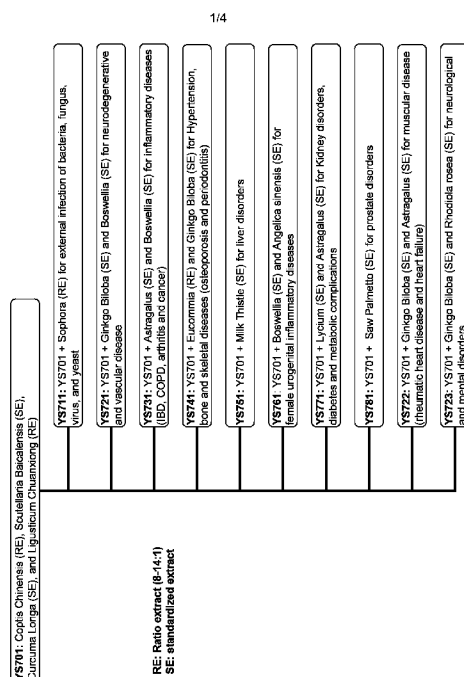
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- (71) **Applicant (for all designated States except US):** INNOVATIVE DRUG DISCOVERY INC. [US/US]; P.O. Box 2232, Garnet Valley, PA (US).
- (72) **Inventor; and**
- (75) **Inventor/Applicant (for US only):** SHI, Yi [US/US]; 21 North Valentine Drive, Garnet Valley, PA 19061 (US).
- (74) **Agent:** SEGAL, Marc, S.; Ballard Spahr Andrews & Ingersoll, LLP, Suite 1000, 999 Peachtree Street, Atlanta, GA 30309-3915 (US).

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[Continued on next page](54) **Title:** HERBAL PHARMACEUTICAL COMPOSITIONS TO TREAT INFLAMMATION AND INFLAMMATION ASSOCIATED CONDITIONS AND DISEASES

(57) **Abstract:** The invention relates to herbal pharmaceutical compositions and supplements comprising: a water extract of *Coptis chinensis* (Chinese goldthread), a hydroalcoholic extract of *Ligusticum chuanxiong* (*Ligustici wallichii* or *Ligusticum sinenses*), a standardized hydroalcoholic extract of *Curcuma longa* (turmeric), and a standardized hydroalcoholic extract of *Scutellaria baicalensis* (Chinese skullcap) and methods for preventing or treating inflammation and inflammation-associated diseases using these compositions.

Figure 1. Herbal formulas & variations.





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HERBAL PHARMACEUTICAL COMPOSITIONS TO TREAT INFLAMMATION AND INFLAMMATION ASSOCIATED CONDITIONS AND DISEASES

BACKGROUND OF THE INVENTION

[0001] This invention relates to herbal pharmaceutical compositions and supplements that can be used to prevent and treat inflammation. In particular, the present invention is based on novel combinations of herbal extracts to prepare herbal pharmaceutical compositions and herbal supplements for treating inflammation. The invention also relates to methods for using such herbal pharmaceutical compositions and supplements to treat a variety of diseases which have an inflammatory component.

[0002] A variety of chronic diseases have inflammation as an underlying or additional component. Treatment of the inflammation may therefore be useful, and sometimes essential, to cure the disease. In particular, a variety of chronic inflammatory diseases, cardiovascular diseases, neurological diseases, bone and joint diseases, muscular and skeletal diseases, cancers and diabetes and obesity related complications have inflammatory components.

[0003] Traditional Chinese medicine has been used for centuries to treat a variety of conditions, including inflammation. One component of traditional Chinese medicine is the preparation and administration of herbal extracts to treat disease. Herbal therapies have been used in medical practice for centuries. Herbal therapies may increase the effectiveness of modern drug treatments or replace them completely. The compositions and methods of the present invention may be used for preventing and treating diseases in which inflammation is a common basis or contributing cause to the disease. In particular, the compositions and methods of the present invention may be used as both pharmaceutically active and supplement preparations to prevent or treat inflammation and the various diseases that result from inflammation.

SUMMARY OF THE INVENTION

[0004] The present invention relates to an herbal pharmaceutical composition or herbal supplement composition which comprises a water extract of *Coptis chinensis* (Chinese goldthread), a hydroalcoholic extract of *Ligusticum chuanxiong* (*Ligustici wallichii* or *Ligusticum sinenses*), a standardized hydroalcoholic extract of *Curcuma longa* (turmeric), and a standardized hydroalcoholic extract of *Scutellaria baicalensis* (Chinese skullcap).

[0005] The herbal composition above may be formulated such that it comprises from about 10% to about 30% by weight of the extract of (Rhizome) *Coptis chinensis*; from about 10% to about 30% by weight of the extract of (Rhizome) *Ligusticum chuanxiong*; from about 10% to about 40% by weight of the extract of (Rhizome) *Curcuma longa*; and from about 10% to about 30% by weight of the extract of (Radix) *Scutellaria baicalensis*.

[0006] The herbal formulation above may be prepared wherein Rhizome *Coptis chinensis* is extracted by water at a weight ratio of about 10 parts of dried raw herb per 1 part of extract; Rhizome *Ligusticum chuanxiong* is extracted by water and alcohol at a weight ratio of about 10 parts of dried raw herb per 1 part of extract; Rhizome *Curcuma longa* is extracted by water and alcohol at a weight ratio of 50-100 parts of dried raw herb per 1 part of extract; Radix *Scutellaria baicalensis* is extracted by water and alcohol at a weight ratio of about 8-10 parts of dried raw herb per 1 part of extract.

[0007] In one aspect of the present invention, the extract of Rhizome *Coptis chinensis* may comprise Berberine; the extract of Rhizome *Ligusticum chuanxiong* may comprise ligustrazine;

the extract of Rhizome *Curcuma longa* may comprise Curcumin; and the extract of Radix *Scutellaria baicalensis* may comprise Baicalin.

[0008] Additional embodiments of the compositions of the present invention include the compositions presented above and further include one or more herbs selected from a water extract of *Sophora flavescens*, a hydroalcoholic extract of *Ginkgo biloba* leaves; a hydroalcoholic extract of *Boswellia serrata* oleo-gum-resin, a water extract of *Astragalus membranaceus* root, a water extract of *Eucommia ulmoides* cortex, a hydroalcoholic extract of Milk thistle seeds, a hydroalcoholic extract of *Angelica sinensis* root, a water extract of *Lycium barbarum* fruit, a hydroalcoholic extract of *Astragals membranaceus* radix, a hydroalcoholic extract of Saw palmetto fruit, a hydroalcoholic extract of *Angelica sinensis* root, and a hydroalcoholic extract of *Rhodiola rosea* root.

[0009] In another aspect, the present invention provides a method of preventing or treating inflammation in a mammal comprising administering to the mammal an herbal pharmaceutical composition comprising: a water extract of *Coptis chinensis* (Chinese goldthread), a hydroalcoholic extract of *Ligusticum chuanxiong* (*Ligustici wallichii* or *Ligusticum sinenses*), a standardized hydroalcoholic extract of *Curcuma longa* (Turmeric), and a standardized hydroalcoholic extract of *Scutellaria baicalensis* (Chinese skullcap). This method may comprise orally administering the composition in an amount and for a time period sufficient to reduce the inflammation.

[0010] The methods of the present invention may be used to prevent or treat an inflammation-associated cardiovascular and muscular disease selected from the group consisting of coronary artery disease, carotid artery disease, peripheral artery disease, cerebral artery

disease, migraine, fibromyalgia, hypertension, stroke, erectile dysfunction, cardiomyopathy, and heart failure.

[0011] In another aspect, the methods of the present invention may be used to prevent or treat an inflammation-associated neurological and neurodegenerative disease selected from the group consisting of depression, chronic fatigue syndrome, sleep disorders, Alzheimer's disease, dementia, Parkinson's disease, and amyotrophic lateral sclerosis.

[0012] In another aspect, the methods of the present invention may be used to prevent or treat an inflammation-associated disease selected from the group consisting of inflammatory bowel disease (IBD), chronic obstructive pulmonary disease (COPD), rheumatoid arthritis (RA), psoriasis, lupus, chronic pancreatitis, hepatitis, fatty liver disease, cirrhosis, nephritis, kidney dysfunction, cervicitis, pelvic and vaginal inflammation, prostatitis, and benign prostatic hyperplasia.

[0013] In yet another aspect, the methods of the present invention may be used to prevent or treat an inflammation-associated bone and skeletal disease selected from the group consisting of osteoporosis, osteoarthritis, degenerative disc disease, and muscular dystrophy.

[0014] In yet another aspect, the methods of the present invention may be used to prevent or treat metabolic diseases and complications selected from the group consisting of type 2 diabetes, insulin resistance, and metabolic syndrome.

[0015] In yet another aspect, the methods of the present invention may be used to prevent or treat cancer selected from the group consisting of lung cancer, colon cancer, liver cancer, breast

cancer, stomach cancer, gall bladder cancer, prostate cancer, ovarian cancer, cervical cancer and leukemia.

[0016] In yet another aspect, the herbal compositions of the present invention may be administered externally in an amount and for a time period sufficient to reduce inflammation. For example, the external administration of the herbal compositions of the present invention may be used to prevent or treat an external infection selected from the group consisting of bacterial infection, yeast infection, fungal infection, and viral infection.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Figure 1 provides examples of formulations which may be used for specific disease states. YS701 is a basic formulation, which includes four essential herbs. This figure also illustrates ten additional formulations derived from YS701. Each formulation includes one or two additional herbal extracts.

[0018] Figure 2 is a flowchart illustrating an herbal ratio extraction (RE) using water extraction.

[0019] Figure 3 is a flowchart illustrating an herbal ratio extraction (RE) using ethanol extraction.

[0020] Figure 4 is a flowchart illustrating a standardized herbal extract (SE) of *Curcuma longa*.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0021] The present invention is directed to herbal pharmaceutical compositions and supplements which are used to treat and prevent a variety of diseases, in particular, diseases that involve inflammation. The invention also provides methods for using these pharmaceutical compositions and supplements.

[0022] Inflammation is a normal response of the body to protect tissues from infection, injury or disease. The inflammatory response begins with the production and release of chemical agents by cells in the infected, injured, or diseased tissue. These agents cause redness, swelling, pain, heat and loss of function. Inflamed tissues generate additional signals that recruit inflammatory cells to the site of inflammation. These cells destroy any infective or injurious agent, and remove cellular debris from damaged tissue. In acute situations, or at low levels, inflammation deals with the abnormality and promotes healing. When chronically sustained at high levels, inflammation can seriously damage viable host tissue.

[0023] Accumulating evidence suggests that chronic inflammation may be a root cause of a wide range of progressive diseases, such as chronic inflammatory, cardiovascular, neurological, bone, muscular and skeletal diseases, diabetes and metabolic diseases and cancer. The present invention relates to herbal pharmaceutical compositions and supplements which reduce or eliminate inflammation and therefore can be used to treat a variety of diseases having an inflammatory component.

[0024] In one embodiment, the present invention is directed to an herbal pharmaceutical composition comprising a water extract of *Coptis chinensis* (Chinese goldthread), a

hydroalcoholic extract of *Ligusticum chuanxiong* (*Ligustici wallichii* or *Ligusticum sinenses*), a standardized hydroalcoholic extract of *Curcuma longa* (turmeric), and a standardized hydroalcoholic extract of *Scutellaria baicalensis* (Chinese skullcap).

[0025] A variety of other herbs may be added to the compositions of the present invention to prevent or treat specific inflammation-related diseases. Each of these additional herbs and active ingredients are discussed below.

[0026] A variety of extraction methods are known in the art to obtain an herbal extract. Such methods include extraction of the full spectrum of desired ingredients using a solvent which can be water, alcohol, or a mixture of water and alcohol. By way of example, the following types of herbal extracts are disclosed: water extract, hydroalcoholic extract, and standardized hydroalcoholic extract. Three process examples are provided (Figures 2-4). The term “standardized” as used with “standardized water extract” and “standardized hydroalcoholic extract” refers to a substance that is extracted with a standardized procedure which yields consistent ingredient(s) that can be measured and used as reference. This reference may be an active ingredient, or just one that is easily determined.

[0027] As illustrated in Figure 2, by way of example, an herbal ratio extract based on water extraction begins with comminution (crushing and grinding into small pieces) of the dried raw material followed by water extraction with heat and pressure for one or more times. This is followed by decompression (relieving pressure) and repeated precipitation and centrifugation steps. After drying (using spray, vacuum or other methods) and removal of impurities by passing through 80 mesh screen, herbal extract (powder) will be sterilized and packed.

[0028] As illustrated in Figure 3, by way of example, an herbal ratio extract based on ethanol extraction begins with dried raw herbal material. This material is then crushed into small pieces followed by mixing with water-ethanol mixture in the presence of heat and pressure for one or more times. This is followed by decompression (relieving pressure) and repeated precipitation and centrifugation steps. After drying (using spray, vacuum or other methods) and removal of impurities by passing through 80 mesh screen, herbal extract (powder) will be sterilized and packed.

[0029] Figure 4 illustrates an exemplary process for a standardized herbal extract, in this example *Curcuma longa*. In this process, the dried raw material is crushed into small particles and extracted through water and alcohol in the presence of heat and pressure for one or more times. This is followed by decompression, percolation (passing through a filtering system) and repeated precipitation and centrifugation steps. After drying (using spray, vacuum or other methods) and removal of impurities by passing through 80 mesh screen, herbal extract will be tested for curcumin.

[0030] One embodiment of the present invention is an herbal pharmaceutical composition which includes *Coptis chinensis*, *Ligusticum chuanxiong*, *Curcuma longa* (tumeric) and *Scutellaria baicalensis*.

[0031] *Coptis chinensis* is also known as Chinese goldthread or Huang lian. *Coptis chinensis* has been documented as an herbal medicine for over a thousand years (Shen Nong Ben Cao Jing, 225 BC). According to Chinese pharmacopoeia "Ben Cao Gang Mu" (1596) and Chinese Medical Herbology and Pharmacology, *Coptis chinensis* is one of the strongest herbs to clear heat, dry dampness, and eliminate toxins. It has been used as a main drug for treating

damp-heat syndromes, particularly for intestinal and lung infections. The pharmacological active ingredients of Coptis are in the dried rhizome, which include, but are not limited to, berberine, coptisin, palmatine, jatrorrhizine, epiberberine, worenine, columbamine, magnoflorine.

Pharmacological effects of Coptis include broad spectrum of antibiotic and anti-inflammatory effects. Modern research has revealed various mechanisms underlying anti-inflammatory activity of Coptis. It reduces nitric oxide (NO) generation and expression of inducible nitric oxide synthase (iNOS), blocks NF kappa B dependent pathway, and inhibits proinflammatory cytokines such as TNF-alpha and Interleukin-1 beta. Recent data also suggest other benefits of Coptis. For example, it reduces high blood pressure and blood sugar, lowers cholesterol and decreases oxidative stress.

[0032] Preferably, the rhizome of Coptis chinensis is extracted by water to obtain a full spectrum of water-soluble ingredients. In the present invention, it is desirable for the composition to have about 10 to about 30% by weight of the extract of rhizome Coptis chinensis. The rhizome Coptis chinensis is preferably extracted by water at a weight ratio of about 10 parts of raw herb per 1 part of water-soluble extract such that, as an example, 10 grams of raw herb yields 1 gram of extract in a solid, preferably powder form following extraction.

[0033] Ligusticum chuanxiong is also known as Ligustici wallichii, Ligusticum sinenses, or Chuan xiong. Ligusticum chuanxiong improves circulation and has positive effects on the heart and liver functions. Rhizoma Chuanxiong contains volatile oil, alkaloids (e.g., ligustrazine), phenolic substances (e.g., ferulic acid), lactone, vitamin A, folic acid, sterols, sucrose, fatty oil, etc. Active ingredients of Ligusticum chuanxiong exert antibacterial, antifungal and antiinflammatory effects. Additional benefits of Ligusticum chuanxiong include inhibition of

vascular smooth muscle contraction, increased blood flow in the coronary artery, brain and limbs, improved myocardial hypoxia and microcirculation, reduced myocardial oxygen consumption and prevention of platelet activation and thrombosis.

[0034] The rhizome of *Ligusticum chuanxiong* is preferably extracted by water/alcohol mixture. In the present invention, it is desirable for the composition to have about 10% to about 30% by weight of the hydroalcoholic extract of rhizome *Ligusticum chuanxiong*. The rhizome of *Ligusticum chuanxiong* is preferably extracted by water/alcohol at a weight ratio of about 10 parts dried raw herb per 1 part of extract such that, as an example, 10 grams of raw herb would yield 1 gram of extract in a solid, preferably powder form following the extraction.

[0035] *Curcuma longa* is also known as Tumeric, or Jiang huang. The use of *Curcuma longa* for treatment of different inflammatory diseases has been described in traditional Chinese and Indian medicine for thousands of years. The active component of *Curcuma longa* responsible for antiinflammatory activity, curcumin, was identified almost two centuries ago. Since then, there have been over 1,800 citations in Medline relating to the biologic effect of curcumin. Modern science has revealed that curcumin mediates its effects by modulation of several important molecular targets, including transcription factors (e.g., NF-kappa B, AP-1, Egr-1, beta-catenin, and PPAR-gamma), enzymes (e.g., COX2, 5-LOX, iNOS, and hemeoxygenase-1), cell cycle proteins (e.g., cyclin D1 and p21), cytokines (e.g., TNF, IL-1, IL-6, and chemokines), receptors (e.g., EGFR and HER2), and cell surface adhesion molecules. It is widely used in traditional Indian medicine to treat biliary disorders, anorexia, cough, diabetic wounds, hepatic disorders, rheumatism, and sinusitis. It is also believed to reduce blood cholesterol; prevent low-density lipoprotein oxidation; inhibit platelet aggregation and

thrombosis; suppress diabetes, rheumatoid arthritis, multiple sclerosis, and Alzheimer's disease; inhibit HIV replication; enhance wound healing; protect from liver injury; and has anti-atherosclerotic and anti cancer activity.

[0036] The rhizome of *Curcuma longa* is preferably extracted by water/alcohol mixture. In the present invention, it is desirable for the composition to have about 10 to about 40% by weight of the hydroalcoholic extract of *Curcuma longa* in compositions of the present invention. The rhizome *Curcuma longa* is preferably extracted by water/alcohol at a weight ratio of about 50-100 parts dried raw herb to 1 part hydroalcoholic extract. Preferably, a standardized extract of *Curcuma longa*, which contains about 95% curcumin, is used to prepare the compositions of the present invention.

[0037] *Scutellaria baicalensis* is also known as Chinese skullcap, Scute or Huang qin. *Scutellaria baicalensis* is one of the most utilized herbs in traditional Chinese medicine. Its root is a rich source of over 35 flavonoids. The main active ingredients modulating inflammation include wogonin, a xanthine oxidase inhibitor, and baicalin; both wogonin and baicalin are potent free radical scavengers. In addition to anti-inflammatory, antibacterial, antifungal and antiviral properties, they also inhibit angiogenesis, affect cell growth and apoptosis. Recent research also reveals anti-cancer and anti-allergy effects and benefits for treating diabetes and high blood pressure. The antiinflammatory actions of *Scutellaria* include reducing production of NO and free radicals, proinflammatory mediators such as cyclooxygenase-2, leukotriene B₄ (inhibition of the 5-lipoxygenase enzyme), interleukin-1 β , 12-lipoxygenase and prostaglandin E₂.

[0038] The radix of *Scutellaria baicalensis* is extracted in a water/alcohol mixture. It is preferable for the compositions of the present invention to have about 10 to about 30% by weight of *Scutellaria* extract. Preferably, the *Scutellaria baicalensis* is extracted at a ratio of about 8-10 parts dried raw herb per 1 part hydroalcoholic extract. Preferably, a standardized extract of *Scutellaria baicalensis*, which contains about 85-95% baicalin, is used to prepare the compositions of the present invention.

[0039] In certain embodiments, it may be desirable to replace one or more of the herbs above with one or more specific compounds found in the herb. In some embodiments, the compound will be what is considered to be the active, or one of the active, ingredient(s) present in the herb.

[0040] Berberine is a constituent of Rhizome *Coptis chinensis*. In a preferred embodiment, berberine is present in the extract used to prepare the compositions of the invention.

[0041] Ligustrazine is a constituent of *Ligusticum chuanxiong* and in a preferred embodiment, ligustrazine is present in the extract used to prepare compositions of the present invention.

[0042] Curcumin is a constituent of *Curcuma longa* and in a preferred embodiment, Curcumin is present in the extract used to prepare the compositions of the present invention.

[0043] Baicalin is a constituent of *Scutellaria baicalensis*, and in a preferred embodiment, Baicalin is present in the extract used to prepare the compositions of the present invention.

[0044] In certain embodiments, additional herbs are added to the present composition. These additional herbs may be beneficial in enhancing therapeutic effects for treating certain kinds of disease states or inflammation. In one embodiment, a water extract of the radix of *Sophora flavescens* is added to the herbal pharmaceutical compositions of the present invention (YS711). Preferably, the radix *Sophora flavescens* comprises about 20 to about 30% of the herbal composition. The radix of *Sophora flavescens* is preferably extracted in water at a weight ratio of about 10 parts dried raw herb to 1 part soluble extract.

[0045] In yet another embodiment, the herbal compositions of the present invention comprise a hydroalcoholic extract of *Ginkgo biloba* leaves and a hydroalcoholic extract of *Boswellia serrata* oleo-gum-resin (YS721). Preferably the herbal composition comprises about 10 to about 20% by weight of extract of *Ginkgo biloba* leaves and about 10 to about 30% by weight of extract of *Boswellia serrata*. Preferably, a standardized extract of *Ginkgo biloba*, which contains about 24% glycosides and about 6% terpene lactones, and a standardized extract of *Boswellia serrata* oleo-gum-resin, which contains about 65 % to about 85% of boswellic acid, are used to prepare the compositions of the present invention.

[0046] In other embodiments, the herbal compositions of the present invention include a water extract of the radix of *Astragalus membranaceus* and a hydroalcoholic extract of *Boswellia serrata* oleo-gum-resin (YS731). Preferably, the *Astragalus membranaceus* extract comprises about 10 to about 30% by weight of the herbal composition, and the *Boswellia serrata* extract comprises about 10 to about 30% by weight of the herbal composition. In a preferred embodiment, a standardized extract of *Astragalus membranaceus*, which contains about 50 to about 70% of polysaccharides, and a standardized extract of *Boswellia serrata* oleo-gum-resin,

which contains about 65 % to about 85% of boswellic acid, are used to prepare the compositions of the present invention.

[0047] In another embodiment, the herbal composition of the present invention contains a water extract of *Eucommia ulmoides* and a hydroalcoholic extract of *Ginkgo biloba* leaves (YS741). In a preferred embodiment, the herbal composition includes about 10 to about 30% by weight of the extract of *Eucommia ulmoides* cortex and about 10 to about 20% by weight of extract of *Ginkgo biloba* leaves. In a preferred embodiment, the *Eucommia ulmoides* cortex is prepared by extraction in water at a weight ratio of about 14 parts dried raw herb to 1 part extract, and the *Ginkgo biloba* leaves are prepared by a standardized extract, which contains about 24% glycosides and about 6% terpene lactones.

[0048] In another embodiment, the herbal composition of the present invention includes a water and alcohol extract of Milk thistle seeds (YS751). Preferably, the Milk thistle comprises about 10 to about 30% by weight of the herbal composition. In a preferred embodiment, the Milk thistle is extracted by water and alcohol at a weight ratio of about 20 parts dried raw herb to 1 part extract. Preferably, a standardized extract of Milk thistle containing about 80% of Silymarin is used to prepare the compositions of the present invention.

[0049] In another embodiment, the herbal composition of the present invention includes a hydroalcoholic extract of *Boswellia serrata* oleo-gum-resin and a hydroalcoholic extract of *Angelica sinensis* root (YS761). Preferably, the *Boswellia serrata* extract comprises about 10 to about 30% by weight of the herbal composition and, the *Angelica sinensis* extract comprises about 10 to about 30% by weight of the herbal composition. In a preferred embodiment, a standardized extract of *Boswellia serrata* oleo-gum-resin, which contains about 65 % to about

85% of boswellic acid, and a standardized extract of *Angelica sinensis* root, which contains about 1% of ligustilide and about 0.1-0.3 % of ferulic acid, are used to prepare the compositions of the present invention.

[0050] In another embodiment, the herbal composition of the present invention includes a water extract of *Lycium barbarum* fruit and a water extract of the radix of *Astragalus membranaceus* (YS771). Preferably, the *Lycium barbarum* extract comprises about 10 to about 30% by weight of the herbal composition, and the *Astragalus membranaceus* extract comprises about 10 to about 30% by weight of the herbal composition. In a preferred embodiment, a standardized extract of *Lycium barbarum* fruit, which contains about 50 % of polysaccharides, and a standardized extract of *Astragalus membranaceus* radix, which contains about 50% to about 70% of polysaccharides, are used to prepare the compositions of the present invention.

[0051] In another embodiment, the herbal composition of the present invention includes a water and alcohol extract of Saw palmetto fruit (YS781). Preferably, the Saw palmetto extract comprises about 10 to about 30% by weight of the herbal composition. In a preferred embodiment, a standardized extract of Saw palmetto fruit, which contains about 25-90 % of fatty acids, is used to prepare the compositions of the present invention.

[0052] In another embodiment, the herbal composition of the present invention includes a hydroalcoholic extract of *Ginkgo biloba* leaves and a water extract of the radix of *Astragalus membranaceus* radix (YS722). Preferably, the *Ginkgo biloba* extract comprises about 10 to about 20% by weight of the herbal composition, and the *Astragalus membranaceus* extract composes about 10 to about 30% by weight of the herbal composition. Preferably, a standardized extract of *Ginkgo biloba* leaves, which contains about 24% glycosides and about 6% terpene lactones, and

a standardized extract of *Astragalus membranaceus* radix, which contains about 50 to about 70% of polysaccharides, are used to prepare the compositions of the present invention.

[0053] In another embodiment, the herbal composition of the present invention includes a hydroalcoholic extract of *Ginkgo biloba* leaves and a hydroalcoholic extract of *Rhodiola rosea* root (YS723). Preferably, the *Ginkgo biloba* extract comprises about 10 to about 20% by weight of the herbal composition, and the *Rhodiola rosea* extract comprises about 10 to about 30% by weight of the herbal composition. In a preferred embodiment, a standardized extract of *Ginkgo biloba* leaves, which contains about 24% glycosides and about 6% terpene lactones, and a standardized extract of *Rhodiola rosea* root, which contains about 3% of rosavin and about 1% of salidroside, are used to prepare the compositions of the present invention.

[0054] As discussed above, the present herbal pharmaceutical compositions and supplements are used to treat and/or prevent inflammation. One method of the present invention to prevent or treat inflammation in a mammal comprises administering to the mammal an herbal pharmaceutical composition comprising water-soluble extract of *Coptis chinensis*, a hydroalcoholic extract of *Ligusticum chuanxiong*, a standardized hydroalcoholic extract of *Curcuma longa* and a standardized hydroalcoholic extract of *Scutellaria baicalensis*. Similarly, any of the compositions described above may be prepared to treat and/or prevent inflammation.

[0055] The compositions of the present invention may also be used in methods to treat or prevent a variety of external infections (bacteria, yeast, fungus, and virus). Examples of such infection include, but are not limited to, vaginitis, nail fungus, and skin infections with bacterial or yeast.

[0056] One embodiment of the present invention which may be used for treating external infections adds a water extract of *Sophora flavescens* in addition to the basic four-herb composition (*Coptis chinensis*, *Ligusticum chuanxiong*, *Curcuma longa* and *Scutellaria baicalensis*) as described above. Preferably, the *Sophora flavescens* extract comprises about 20 to about 40% by weight of the herbal composition.

[0057] The compositions of the present invention may also be used in methods to treat or prevent a variety of neurodegenerative and vascular diseases that have an inflammatory component. Examples of such diseases include, but are not limited to, Alzheimer's Disease, dementia, Parkinson's Disease, amyotrophic lateral sclerosis, degenerative disc disease, atherosclerosis, coronary artery disease, carotid artery disease, peripheral artery disease, cerebral artery disease, stroke, erectile dysfunction, fibromyalgia, and migraine.

[0058] One embodiment of the present invention which may be used for treating neurodegenerative diseases adds a standardized extract of *Ginkgo biloba* leaves and a standardized extract of *Boswellia serrata* oleo-gum-resin in addition to the basic four-herb composition (*Coptis chinensis*, *Ligusticum chuanxiong*, *Curcuma longa* and *Scutellaria baicalensis*) as described above. Preferably, the *Ginkgo biloba* extract comprises about 10 to about 20% by weight of the herbal composition, and the *Boswellia serrata* extract comprises about 10 to about 30% by weight of the herbal composition.

[0059] The compositions of the present invention are used in methods to treat or prevent cancer and diseases that have inflammatory condition as a primary component of the disease and which are seen as "inflammatory" diseases. Examples of such diseases include, but are not limited to, cancer (lung cancer, colon cancer, liver cancer, breast cancer, stomach cancer, gall

bladder cancer, skin cancer, prostate cancer, cervical cancer, and leukemia), Inflammatory Bowel Disease (IBD), Chronic Obstructive Pulmonary Disease (COPD), Rheumatoid Arthritis (RA), psoriasis, chronic pancreatitis, and lupus.

[0060] One embodiment of the present invention which may be used for treating inflammatory diseases adds a standardized extract of *Astragalus membranaceus* radix and a standardized extract of *Boswellia serrata* oleo-gum-resin to the basic four-herb composition. Preferably, the *Astragalus membranaceus* extract comprises about 10 to about 30% by weight of the herbal composition, and the *Boswellia serrata* extract comprises about 10 to about 30% by weight of the herbal composition.

[0061] The compositions of the present invention may also be used in methods to prevent or treat high blood pressure, bone and skeletal diseases that have an inflammatory component. Examples of such diseases include, but are not limited to, hypertension, osteoporosis, osteoarthritis, and periodontitis.

[0062] One embodiment of the present invention which may be useful for treating hypertension, bone and skeletal diseases adds a water extract of *Eucommia ulmoides* cortex and a standardized extract of *Ginkgo biloba* leaves to the basic four-herb composition. Preferably, the *Eucommia ulmoides* extract comprises about 10 to about 30% by weight of the herbal composition, and the *Ginkgo biloba* extract comprises about 10 to about 20% by weight of the herbal composition.

[0063] The compositions of the present invention may also be used in methods to treat liver disorders that have an inflammatory component. Examples of such diseases include, but are not limited to, hepatitis, fatty liver disease, cirrhosis, and liver cancer.

[0064] One embodiment of the present invention which may be useful for treating liver disorders adds a standardized extract of Milk thistle seeds to the basic four-herb composition. Preferably, the Milk thistle extract comprises about 10 to about 30% by weight of the herbal composition.

[0065] The compositions of the present invention are used in methods to treat or prevent female urogenital diseases that have inflammatory component. Examples of such diseases include, but are not limited to cervicitis, pelvic and vaginal inflammation.

[0066] One embodiment of the present invention which may be used for treating female urogenital diseases adds a standardized extract of *Boswellia serrata* oleo-gum-resin and a standardized extract of *Angelica sinensis* root to the basic four-herb composition. Preferably, the *Astragalus membranaceus* extract comprises about 10 to about 30% by weight of the herbal composition, and the *Boswellia serrata* extract comprises about 10 to about 30% by weight of the herbal composition.

[0067] The compositions of the present invention may also be used in methods to treat kidney diseases and metabolic disorders that have an inflammatory component. Examples of such diseases include, but are not limited to, nephritis, kidney dysfunction, type-2 diabetes, insulin resistance and metabolic syndrome.

[0068] One embodiment of the present invention which may be used for treating kidney diseases and metabolic disorders adds a standardized extract of Lycium fruit and a standardized extract of Astragalus membranaceus radix to the basic four-herb composition. Preferably, the Lycium extract comprises about 10 to about 30% by weight of the herbal composition, and the Astragalus membranaceus extract comprises about 10 to about 30% by weight of the herbal composition.

[0069] The compositions of the present invention may also be used in methods to treat prostate disorders that have an inflammatory component. Examples of such diseases include, but are not limited to, prostatitis, benign prostatic hyperplasia, and prostate cancer.

[0070] One embodiment of the present invention which may be used for treating prostate disorders adds a standardized extract of Saw palmetto fruit to the basic four-herb composition. Preferably, the Saw palmetto extract comprises about 20 to about 30% by weight of the herbal composition.

[0071] The compositions of the present invention may be used in methods to prevent or treat muscular diseases. A variety of muscular diseases are known to have an inflammatory component. Examples of such diseases include, but are not limited to, cardiomyopathy, congestive heart failure, rheumatic heart disease, and muscular dystrophy.

[0072] One embodiment of the present invention which may be useful for treating muscular diseases adds a standardized extract of Ginkgo biloba leaves and a standardized extract of Astragalus membranaceus radix to the basic four-herb composition. Preferably, the Ginkgo biloba extract comprises about 10 to about 30% by weight of the herbal composition, and the

Astragalus membranaceus extract comprises about 10 to about 30% by weight of the herbal composition.

[0073] The compositions of the present invention may be used in methods to prevent or treat neurological and mental diseases. A variety of neurological and mental diseases are known to have an inflammatory component. Examples of such diseases include, but are not limited to, major depression, anxiety, chronic fatigue syndrome, migraine, and chronic pain.

[0074] One embodiment of the present invention which may be useful for treating neurological and mental diseases adds a standardized extract of Ginkgo biloba leaves and a standardized extract of Rhodiola rosea root to the basic four-herb composition. Preferably, the Ginkgo biloba extract comprises about 10 to about 20% by weight of the herbal composition, and the Rhodiola rosea extract comprises about 10 to about 30% by weight of the herbal composition.

[0075] The compositions of the present invention may additionally comprise conventional carriers, adjuvants or diluents. The following formulation methods and excipients are merely exemplary and in no way limit the invention.

[0076] The herbal composition according to the present invention can be provided as a pharmaceutical composition containing pharmaceutically acceptable carriers, adjuvants or diluents, e.g., lactose, dextrose, sucrose, sorbitol, mannitol, xylitol, erythritol, maltitol, starches, acacia rubber, alginate, gelatin, calcium phosphate, calcium silicate, cellulose, methyl cellulose, polyvinyl pyrrolidone, water, methylhydroxy benzoate, propylhydroxy benzoate, talc, magnesium stearate and mineral oil. The formulations may additionally include fillers, anti-agglutinating agents, lubricating agents, wetting agents, flavoring agents, emulsifiers, preservatives and the

like. The compositions of the invention may be formulated so as to provide quick, sustained or delayed release of the active ingredient after their administration to a patient by employing any of the procedures well known in the art.

[0077] For example, the compositions of the present invention can be dissolved in oils, propylene glycol or other solvents which are commonly used to produce an injection. Suitable examples of the carriers include physiological saline, polyethylene glycol, ethanol, vegetable oils, isopropyl myristate, etc., but are not limited to them. For topical administration, the compounds of the present invention can be formulated in the form of ointments and creams.

[0078] Pharmaceutical formulations containing the compositions of the present invention may be prepared in any form, such as oral dosage form (powder, tablet, capsule, soft capsule, aqueous medicine, syrup, elixirs pill, powder, sachet, granule), or topical preparation (cream, ointment, lotion, gel, balm, patch, paste, spray solution, aerosol and the like), or injectable preparation (solution, suspension, emulsion).

[0079] The complex herbal composition of the present invention in pharmaceutical dosage forms may be used in the form of their pharmaceutically acceptable salts, and also may be used alone or in appropriate association, as well as in combination with other pharmaceutically active compounds.

[0080] In a preferred method, the herbal pharmaceutical composition above is orally administered in an amount and for a time period sufficient to reduce or prevent inflammation. The compositions of the present invention may be administered to prevent inflammation in an animal, preferably a mammal, in particular, a human. The animal may be in need of treatment

given an existing disease state or potential to develop a disease state or undesirable inflammation.

[0081] The compositions may be administered in therapeutically-effective amounts. The desirable dose of the composition varies depending on the condition and the weight of the subject, severity, drug form, route and period of administration, and may be chosen by those skilled in the art. Any suitable amount of the herbal composition of the invention may be administered and dosage levels will vary according to the nature of the disease to be treated or prevented and the subject. In general, it is preferable to administer the compositions orally in a daily dosage of at least about 300 mg on a daily basis for about four weeks.

[0082] The pharmaceutical composition of present invention can be administered to a subject animal such as mammals (rat, mouse, domestic animals or human) via various routes. All modes of administration are contemplated, for example, administration can be made orally, rectally, topically or by intramuscular, subcutaneous, intracutaneous, intrathecal, and epidural modes.

[0083] The compositions of the present invention may also be used as an herbal supplement. The term "supplement," as used herein refers to product taken by mouth that contains a dietary or herbal ingredient and intends to supplement the diet. The herbal supplements are not drugs and can be sold on the market and taken without prescription. The present invention, used at lower dose, may be used as herbal supplement for the prevention of inflammation and disease.

EXAMPLES

Example 1**YS701: Formulation for treating inflammatory conditions and diseases**

[0084] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

[0085] Suggested use as therapeutics: Take two to six capsules daily, preferably two to three times a day for 6-8 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	100
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	100
Ligusticum chuanxiong rhizome extract (10:1)	100

Example 2**YS711: Formulation for treating external inflammatory conditions**

[0086] Suggested use: Use externally multiple times a day.

Ingredients	% by Weight
Scutellaria baicalensis radix extract (85% Baicalin)	20
Curcuma longa rhizome extract (95% Curcuminoids)	10
Coptis chinensis rhizome extract (10:1)	30
Ligusticum chuanxiong rhizome extract (10:1)	10
Sophora flavescens radix extract (10:1)	30

Example 3**YS721: Formulation for treating neurodegenerative diseases and stroke**

[0087] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

[0088] Suggested use as therapeutics: Take two to six capsules daily, preferably two to three times a day for 6-8 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	80
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	80
Ligusticum chuanxiong rhizome extract (10:1)	80
Ginkgo biloba leaves extract (24% glycosides, 6% terpene lactones, acid<5ppm)	60
Boswellia serrata oleo-gum-resin extract (65 % of boswellic acid)	100

Example 4**YS731: Formulation for treating cancer and inflammatory diseases**

[0089] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

[0090] Suggested use as therapeutics: Take two to six capsules daily, preferably two to three times a day for 6-8 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	80
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	80
Ligusticum chuanxiong rhizome extract (10:1)	80
Astragalus membranaceus radix extract (50% Polysaccharides)	125
Boswellia serrata oleo-gum-resin extract (65 % of boswellic acid)	100

Example 5**YS741: Formulation for treating hypertension and bone diseases**

[0091] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 4-6 weeks followed by two-week break before restarting use.

[0092] Suggested use as therapeutics: Take two to six capsules daily, preferably two to three times a day for 4-6 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	80
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	60
Ligusticum chuanxiong rhizome extract (10:1)	80
Eucommia ulmoides cortex extract (14:1)	100
Ginkgo biloba leaves extract (24% glycosides, 6% terpene lactones, acid<5ppm)	65

Example 6**YS751: Formulation for treating liver disease & hepatitis**

[0093] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

[0094] Suggested use as therapeutics: Take two to six capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	80
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	60
Ligusticum chuanxiong rhizome extract (10:1)	80
Milk thistle seed extract (80% Silymerin)	120

Example 7

YS761: Formulation for treating female urogenital inflammatory diseases

[0095] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

[0096] Suggested use as therapeutics: Take two to six capsules daily, preferably two to three times a day for 6-8 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	80
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	80
Ligusticum chuanxiong rhizome extract (10:1)	80
Angelica sinensis root extract (1% of ligustilide, 0.1~0.3 % of ferulic acid)	120
Boswellia serrata oleo-gum-resin extract (65 % of boswellic acid)	100

Example 8**YS771: Formulation for treating kidney and metabolic diseases**

[0097] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

[0098] Suggested use as therapeutics: Take two to six capsules daily, preferably two to three times a day for 6-8 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	80
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	80
Ligusticum chuanxiong rhizome extract (10:1)	80
Astragalus membranaceus radix extract (50% Polysaccharides)	150
Lycium barbarum fruit extract (50 % of polysaccharides)	100

Example 9**YS781: Formulation for treating prostate disorders**

[0099] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

[00100] Suggested use as therapeutics: Take two to six capsules daily, preferably two to three times a day for 6-8 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	100
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	60
Ligusticum chuanxiong rhizome extract (10:1)	80
Saw palmetto fruit extract (25 % of fatty acids)	100

Example 10**YS722: Formulation for treating muscular diseases**

[00101] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

[00102] Suggested use as therapeutics: Take two to six capsules daily, preferably two to three times a day for 6-8 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	80
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	60
Ligusticum chuanxiong rhizome extract (10:1)	80
Astragalus membranaceus radix extract (50% Polysaccharides)	150
Ginkgo biloba leaves extract (24% glycosides, 6% terpene lactones, acid<5ppm)	60

Example 11**YS723: Formulation for treating neurological and mental disorders**

[00103] Suggested use as herbal supplements: Take one to two capsules daily, preferably two times a day for 6-8 weeks followed by two-week break before restarting use.

[00104] Suggested use as therapeutics: Take two to six capsules daily, preferably two to three times a day for 6-8 weeks followed by two-week break before restarting use.

Ingredients	mg/capsule
Scutellaria baicalensis radix extract (85% Baicalin)	100
Curcuma longa rhizome extract (95% Curcuminoids)	150
Coptis chinensis rhizome extract (10:1)	80
Ligusticum chuanxiong rhizome extract (10:1)	100
Ginkgo biloba leaves extract (24% glycosides, 6% terpene lactones, acid<5ppm)	60
Rhodiola rosea root extract (3% rosavin, 1% salidroside)	150

[00105] Although the present invention has been described with respect to a specific preferred embodiment thereof, various changes and modifications may be suggested to one skilled in the art and it is intended that the present invention encompass such changes and modifications as fall within the scope of the appended claims.

Claims

We claim:

1. An herbal pharmaceutical or supplement composition comprising: a water extract of *Coptis chinensis* (Chinese goldthread), a hydroalcoholic extract of *Ligusticum chuanxiong* (*Ligustici wallichii* or *Ligusticum sinenses*), a standardized hydroalcoholic extract of *Curcuma longa* (turmeric), and a standardized hydroalcoholic extract of *Scutellaria baicalensis* (Chinese skullcap).
2. The herbal composition according to claim 1, comprising:
 - a. from about 10% to about 30% by weight of the extract of (Rhizome) *Coptis chinensis*;
 - b. from about 10% to about 30% by weight of the extract of (Rhizome) *Ligusticum chuanxiong*;
 - c. from about 10% to about 40% by weight of the extract of (Rhizome) *Curcuma longa*;
 - d. from about 10% to about 30% by weight of the extract of (Radix) *Scutellaria baicalensis*.
3. The herbal composition according to claim 2, wherein said:
 - a. Rhizome *Coptis chinensis* is extracted by water at a weight ratio of about 10 parts of dried raw herb per 1 part of extract;
 - b. Rhizome *Ligusticum chuanxiong* is extracted by water and alcohol at a weight ratio of

about 10 parts of dried raw herb per 1 part of extract;

c. Rhizome *Curcuma longa* is extracted by water and alcohol at a weight ratio of about 50-100 parts of dried raw herb per 1 part of extract;

d. Radix *Scutellaria baicalensis* is extracted by water and alcohol at a weight ratio of about 8-10 parts of dried raw herb per 1 part of extract.

4. The herbal composition according to claim 2, wherein said:

a. extract of Rhizome *Coptis chinensis* comprises Berberine;

b. extract of Rhizome *Ligusticum chuanxiong* comprises ligustrazine;

c. extract of Rhizome *Curcuma longa* comprises 95% Curcumin;

d. extract of Radix *Scutellaria baicalensis* comprises 85% Baicalin.

5. The herbal composition of claim 1 further comprising a water extract of *Sophora flavescens*.

6. The herbal composition of claim 5, comprising from about 20% to about 40% by weight of the extract of (Radix) *Sophora flavescens*.

7. The herbal composition according to claim 6, wherein said Radix *Sophora flavescens* is extracted by water at a weight ratio of about 10 parts of dried raw herb per 1 part of extract.

8. The herbal composition of claim 1 further comprising a hydroalcoholic extract of Ginkgo

biloba leaves and a hydroalcoholic extract of *Boswellia serrata* oleo-gum-resin.

9. The herbal composition of claim 8 comprising from about 10 to about 20% by weight of the extract of *Ginkgo biloba* leaves and about 10 to about 30% by weight of the extract of *Boswellia serrata* oleo-gum-resin.

10. The herbal composition according to claim 9, wherein said *Ginkgo biloba* extract is a standardized extract, which comprises about 24% glycosides and about 6% terpene lactones.

11. The herbal composition according to claim 9, wherein said *Boswellia serrata* extract is a standardized extract, which comprises about 65% to about 85% of boswellic acid.

12. The herbal composition of claim 1 further comprising a water extract of *Astragalus membranaceus* and a hydroalcoholic extract of *Boswellia serrata* oleo-gum-resin.

13. The herbal composition according to claim 12 comprising from about 10 to about 30% by weight of the extract of *Astragalus membranaceus* Radix and about 10 to about 30% by weight of the extract of *Boswellia serrata* oleo-gum-resin.

14. The herbal composition according to claim 13, wherein said *Astragalus membranaceus* extract is a standardized extract, which comprises about 50% to about 70% of polysaccharides.

15. The herbal composition according to claim 13, wherein said *Boswellia serrata* extract is a standardized extract, which comprises about 65% to about 85% of boswellic acid.

16. The herbal composition of claim 1 further comprising a water extract of *Eucommia*

ulmoides cortex and a hydroalcoholic extract of Ginkgo biloba leaves.

17. The herbal composition according to claim 16 comprising from 10 to about 30% by weight of the extract of Eucommia ulmoides cortex and about 10 to about 20% by weight of the extract of Ginkgo biloba leaves.

18. The herbal composition according to claim 17, wherein said Eucommia ulmoides cortex is extracted by water at a weight ratio of about 14 parts of dried raw herb per 1 part of extract.

19. The herbal composition according to claim 17, wherein said extract of Ginkgo biloba leaves is a standardized extract, which comprises about 24% glycosides and about 6% terpene lactones.

20. The herbal composition of claim 1 further comprising a hydroalcoholic extract of Milk thistle seeds.

21. The herbal composition according to claim 20 comprising from about 10 to about 30% by weight of the extract of Milk thistle seeds.

22. The herbal composition according to claim 21, wherein said Milk thistle extract is a standardized extract, which comprises about 80% silymarin.

23. The herbal composition of claim 1 further comprising a hydroalcoholic extract of Boswellia serrata oleo-gum-resin and a hydroalcoholic extract of Angelica sinensis root.

24. The herbal composition according to claim 23 comprising from about 10 to about 30% by

weight of the extract of *Boswellia serrata* oleo-gum-resin and about 10 to about 30% by weight of the extract of *Angelica sinensis* root.

25. The herbal composition according to claim 24, wherein said extract of *Boswellia serrata* oleo-gum-resin is a standardized extract, which comprises about 65% to about 85% boswellic acid.

26. The herbal composition according to claim 24, wherein said extract of *Angelica sinensis* root is a standardized extract, which comprises 1% of ligustilide and about 0.1-0.3 % of ferulic acid.

27. The herbal composition of claim 1 further comprising a water extract of *Lycium barbarum* fruit and a hydroalcoholic extract of *Astragalus membranaceus* radix.

28. The herbal composition according to claim 27 comprising from about 10 to about 30% by weight of the extract of *Lycium barbarum* fruit and about 10 to about 30% by weight of the extract of *Astragalus membranaceus* radix.

29. The herbal composition according to claim 28, wherein said *Lycium barbarum* fruit extract is a standardized extract, which comprises about 50% of polysaccharides.

30. The herbal composition according to claim 28, wherein said *Astragalus membranaceus* Radix extract is a standardized extract, which comprises about 50 to about 70% of polysaccharides.

31. The herbal composition of claim 1 further comprising a hydroalcoholic extract of Saw

palmetto fruit.

32. The herbal composition according to claim 31 comprising from about 10 to about 30% by weight of the extract of Saw palmetto fruit.

33. The herbal composition according to claim 32, wherein said Saw palmetto fruit extract is a standardized extract, which comprises about 25 to about 90% of fatty acids.

34. The herbal composition of claim 1 further comprising a hydroalcoholic extract of Ginkgo biloba leaves and a hydroalcoholic extract of Astragalus membranaceus radix.

35. The herbal composition according to claim 34 comprising from about 10 to about 30% by weight of the extract of Ginkgo biloba leaves and about 10 to about 30% by weight of the extract of Astragalus membranaceus radix.

36. The herbal composition according to claim 35, wherein said extract of Ginkgo biloba leaves is a standardized extract, which comprises about 24% glycosides and about 6% terpene lactones.

37. The herbal composition according to claim 35, wherein said extract of Astragalus membranaceus radix is a standardized extract, which comprises about 50 to about 70% of polysaccharides.

38. The herbal composition of claim 1 further comprising a hydroalcoholic extract of Rhodiola rosea root and a hydroalcoholic extract of Ginkgo biloba leaves.

39. The herbal composition according to claim 38 comprising from about 10% to about 30% by weight of the extract of *Rhodiola rosea* root and about 10 to about 30% by weight of the extract of *Ginkgo biloba* leaves.
40. The herbal composition according to claim 39, wherein said extract of *Rhodiola rosea* root is a standardized extract, which comprises about 3% of rosavin and about 1% of salidroside.
41. The herbal composition according to claim 39, wherein said extract of *Ginkgo biloba* leaves is a standardized extract, which comprises about 24% glycosides and about 6% terpene lactones.
42. A method of preventing or treating inflammation in a mammal comprising administering to said mammal the herbal composition of claim 1.
43. The method according to claim 42, wherein the herbal composition is administered orally in an amount and for a time period sufficient to reduce the inflammation.
44. The method according to claim 43, wherein the herbal composition is in a form suitable for oral administration and is orally administered in a daily dosage of at least about 300 mg on a daily basis for about 4 weeks.
45. The method according to claim 42, wherein the herbal composition is used to prevent or treat an inflammation-associated cardiovascular and muscular disease selected from the group consisting of coronary artery disease, carotid artery disease, peripheral artery disease, cerebral artery disease, migraine, fibromyalgia, hypertension, stroke, erectile dysfunction,

cardiomyopathy, and heart failure.

46. The method according to claim 42, wherein the herbal composition is used to prevent or treat an inflammation-associated neurological and neurodegenerative disease selected from the group consisting of depression, chronic fatigue syndrome, sleep disorders, Alzheimer's disease, dementia, Parkinson's disease, and amyotrophic lateral sclerosis.

47. The method according to claim 42, wherein the herbal composition is used to prevent or treat an inflammation-associated disease selected from the group consisting of inflammatory bowel disease (IBD), chronic obstructive pulmonary disease (COPD), rheumatoid arthritis (RA), psoriasis, lupus, chronic pancreatitis, hepatitis, fatty liver disease, cirrhosis, nephritis, kidney dysfunction, cervicitis, pelvic and vaginal inflammation, prostatitis, and benign prostatic hyperplasia.

48. The method according to claim 42, wherein the herbal composition is used to prevent or treat an inflammation-associated bone and skeletal disease selected from the group consisting of osteoporosis, osteoarthritis, degenerative disc disease, and muscular dystrophy.

49. The method according to claim 42, wherein the herbal composition is used to prevent or treat metabolic diseases and complications selected from the group consisting of type 2 diabetes, insulin resistance, and metabolic syndrome.

50. The method according to claim 42, wherein the herbal composition is used to prevent or treat cancer selected from the group consisting of lung cancer, colon cancer, liver cancer, breast cancer, stomach cancer, gall bladder cancer, prostate cancer, skin cancer, ovarian cancer, cervical

cancer and leukemia.

51. The method according to claim 42, wherein the herbal composition is administered externally in an amount and for a time period sufficient to reduce the inflammation.

52. The method according to claim 51, wherein the herbal composition is in a form suitable for topical administration and is administered in a daily dosage of at least about 100 mg on a daily basis for 3 days.

53. The method according to claim 42, wherein the herbal composition is used to prevent or treat an external infection selected from the group consisting of bacterial infection, yeast infection, fungal infection, and viral infection.

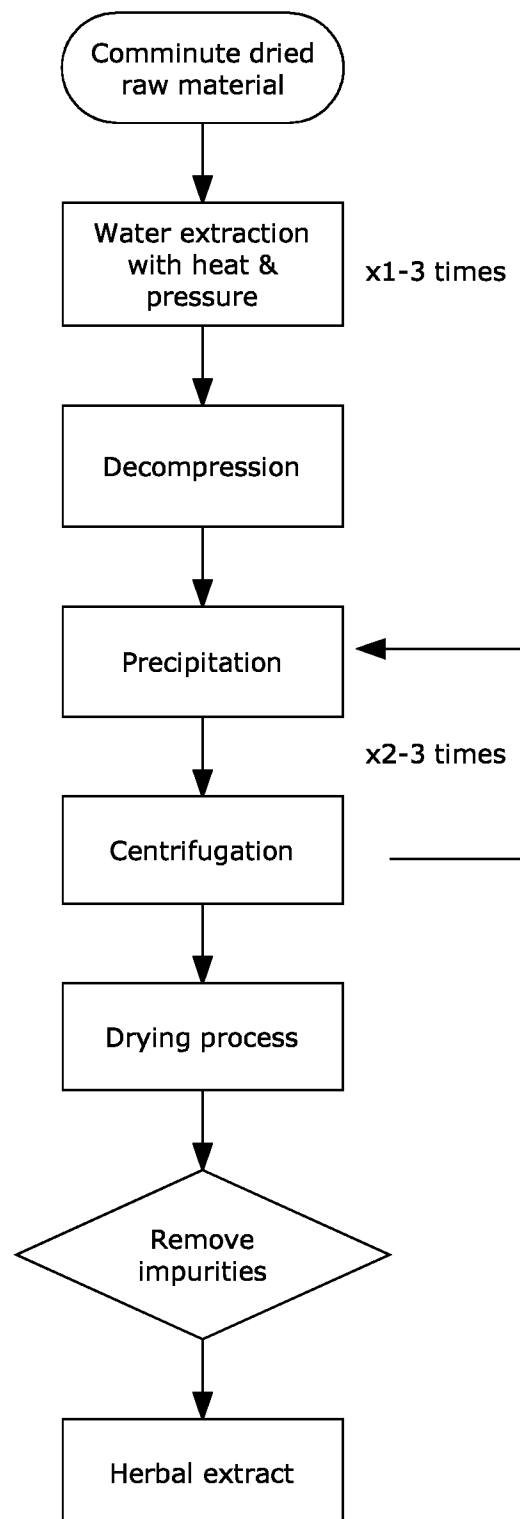
Figure 1. Herbal formulas & variations.

YS701: Coptis Chinensis (RE), Scutellaria Baicalensis (SE), Curcuma Longa (SE), and Ligusticum Chuanxiong (RE)	
	YS711: YS701 + Sophora (RE) for external infection of bacteria, fungus, virus, and yeast
	YS721: YS701 + Ginkgo Biloba (SE) and Boswellia (SE) for neurodegenerative and vascular disease
	YS731: YS701 + Astragalus (SE) and Boswellia (SE) for inflammatory diseases (IBD, COPD, arthritis and cancer)
	YS741: YS701 + Eucommia (RE) and Ginkgo Biloba (SE) for Hypertension, bone and skeletal diseases (osteoporosis and periodontitis)
	YS751: YS701 + Milk Thistle (SE) for liver disorders
	YS761: YS701 + Boswellia (SE) and Angelica sinensis (SE) for female urogenital inflammatory diseases
	YS771: YS701 + Lycium (SE) and Astragalus (SE) for Kidney disorders, diabetes and metabolic complications
	YS781: YS701 + Saw Palmetto (SE) for prostate disorders
	YS722: YS701 + Ginkgo Biloba (SE) and Astragalus (SE) for muscular disease (rheumatic heart disease and heart failure)
	YS723: YS701 + Ginkgo Biloba (SE) and Rhodiola rosea (SE) for neurological and mental disorders

RE: Ratio extract (8-14:1)
SE: standardized extract

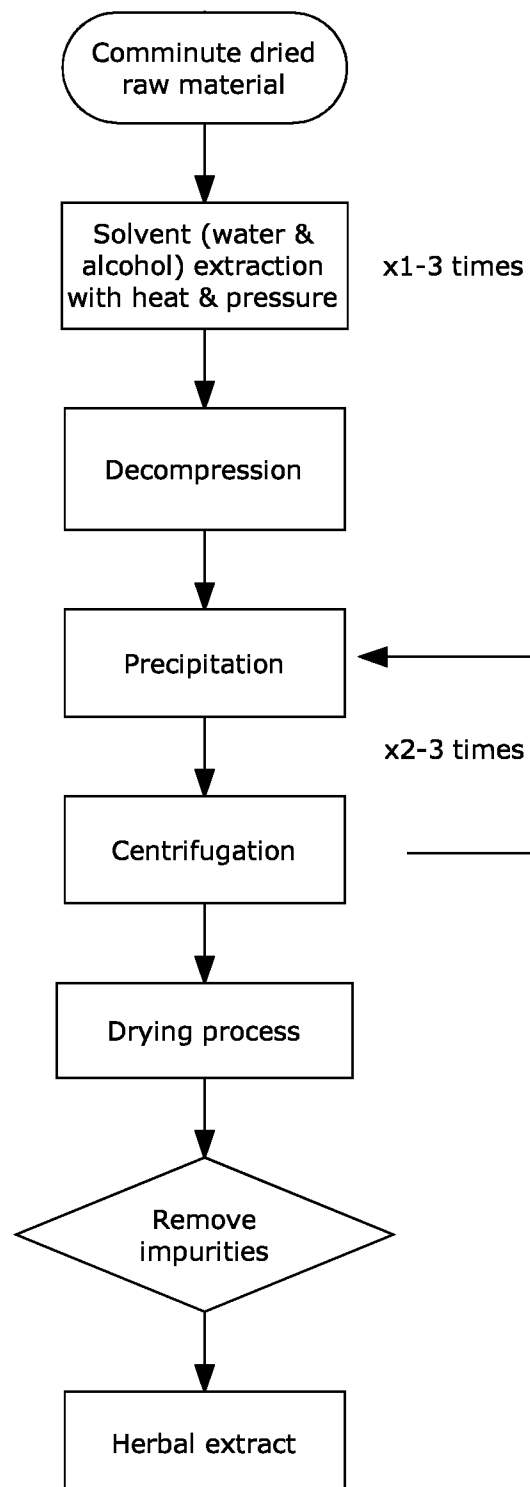
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Figure 2. Process flow chart
for herbal ratio extract
(water extract)



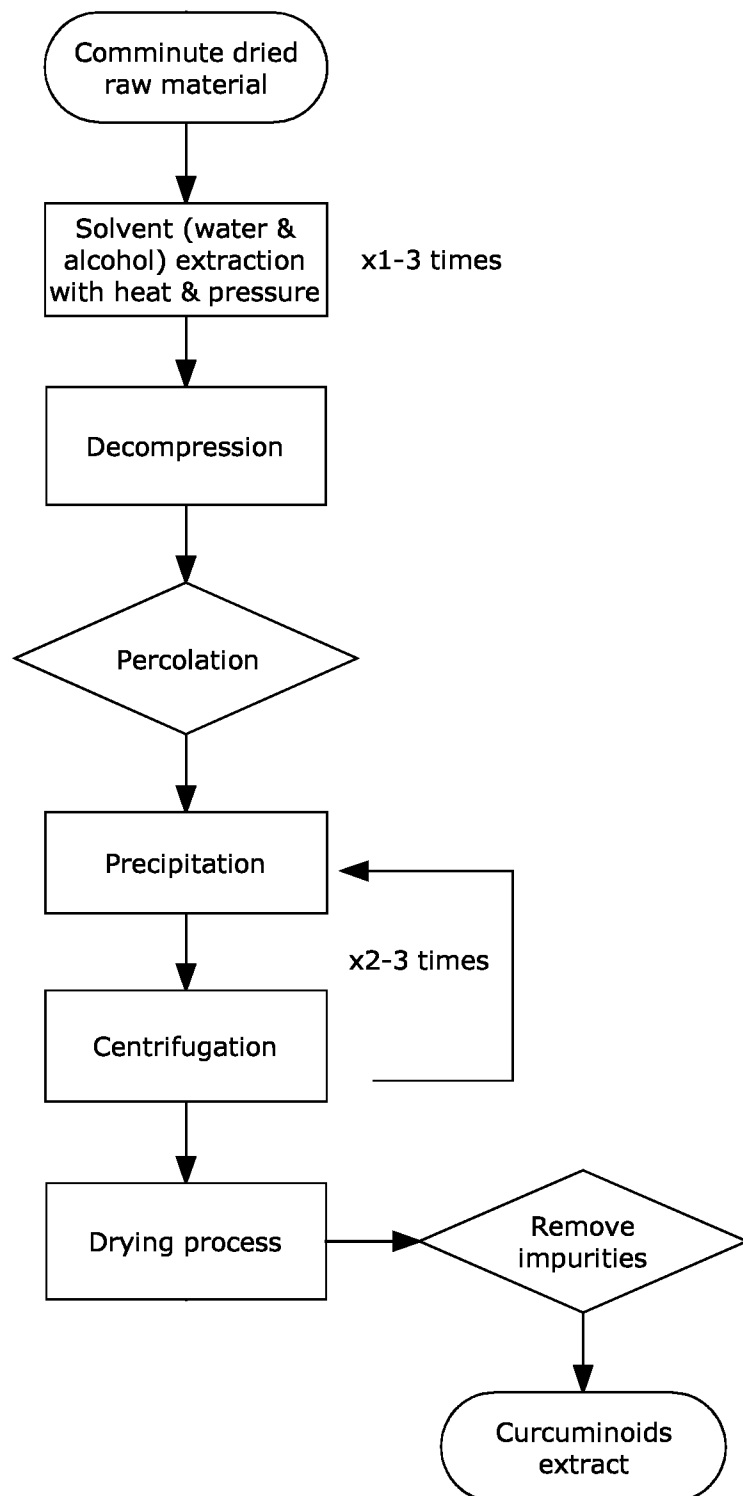
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Figure 3. Process flow chart for herbal ratio extract (hydroalcoholic extract)



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Figure 4. Process flow chart for standardized extract (*Curcuma longa*)



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/32615

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A01N 65/00; A61K 36/00 (2009.01)

USPC - 424/725

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

USPC: 424/725

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC: 424/682; 424/732; 424/754 (see keywords below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST: DB=PGPB,USPT,USOC,EPAB,JPAB; Google: Scholar/Patents: goldthread ligusticum turmeric skullcap inflammation, cancer, diabetes

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,264,995 B1 (NEWMARK et al.) 24 July 2001 (24.07.2001) col 6, ln 58-61, ln 65-67; col 7, ln 1-22; col 11, ln 2-12; col 12, ln 33-34, ln 39, ln 52, ln 59-60, ln 67; col 13, ln 1-7	1-53
Y	US 2006/0068045 A1 (YONG et al.) 30 March 2006 (30.03.2006) para [0016], [0021];[0039]-[0040];[0046]-[0048]	1-53
Y	US 2006/0024385 A1 (PEDERSEN et al.) 02 February 2006 (02.02.2006) para [0116]	2-4
Y	US 6,350,476 B1 (HOU) 26 February 2002 (26.02.2002) col 6, ln 19-20, ln 34-35; col 11, ln 12-14, ln 20-26, ln 45; col 33, ln 43-46; col 36, ln 3-5	5-7
Y	US 7,241,461 B2 (MYHILL et al.) 10 July 2007 (10.07.2007) col 6, ln 44-47; col 8, ln 12-56; col 23, ln 34-42; col 42, ln 19-24; col 57, ln 1-6, ln 20-22	4, 8-11, 16-22, 34-41, 45-50, 53
Y	US 6,200,594 B1 (ERNEST et al.) 13 March 2001 (13.03.2001) col 4, ln 61-65; col 8, ln 42-43	31-33
Y	US 5,629,351 A (TANEJA et al.) 13 May 1997 (13.05.1997) col 3, ln 39-47; col 4, ln 1-13; col 5, ln 11-23	8-15, 23-26

☒ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

01 March 2009 (01.03.2009)

Date of mailing of the international search report

11 MAR 2009

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

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PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/32615

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/0147699 A1 (WU et al.) 07 July 2005 (07.07.2005) para [0004], [0006], [0016]-[0017], [0034], [0070]	12-15, 27-30, 34-37
Y	US 2005/0276873 A1 (LI et al.) 15 December 2005 (15.12.2005) para [0029], [0031], [0033]-[0034]	16-19, 23-26
Y	US 2006/0198810 A1 (MURRAY et al.) 07 September 2006 (07.09.2006) para [0043]; table 1	26
Y	US 2006/0024339 A1 (MURAD et al.) 02 February 2006 (02.02.2006) para [0006], [0017]-[0019], [0065]	27-30
Y	US 2006/0211721 A1 (ROBERTS et al.) 21 September 2006 (21.09.2006) para [0059]-[0060]	38-41