

COMPOSITION FOR PREVENTION OR TREATMENT OF URINARY TRACT INFECTION

Field of Invention

- 5 The present invention relates to a composition comprising herbs. More particularly, it relates to a composition for the prevention or treatment of urinary tract infection, and the method of preparation thereof.

Background of the Invention

- 10 Generally, a healthy urinary tract should be capable of preventing colonization of pathogens within the urinary tract and the infection derived thereof. The occurrence of urinary tract infection indicates that a host's defense system is possibly compromised. As such, symptoms which are associated with compromised urinary tract system may emerge. A particular noteworthy symptom is the obstruction of urinary tract.
- 15 Urination normally helps to eliminate bacteria from the bladder while obstruction of urinary tract hinders normal urination and causes incomplete bladder emptying. Such condition may be associated with (a) prostate gland enlargement, (b) kidney stones (calculi) formation, (c) tumor formation, (d) urethral stricture, (e) stroke or related neurological disorder, (f) diabetes, or (g) spinal cord injury. Further, the use of
- 20 anticholinergic drugs may lead to obstruction of urinary tract. Risk factors of urinary tract infection include backflow of urine (vesicoureteral reflux), pregnancy, the use of catheter, the use of spermicide, or the use of contraceptive diaphragms. In females, the urethra is shorter and closer to the anus, thereby increasing the risk of females in developing urinary tract infection.

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Summary of the Invention

- One of the objects of the present invention is to provide a composition for prevention of urinary tract infection. Particularly, the composition can prevent the formation of calculi, which is a common cause of urinary tract infection. The composition also aids
- 30 in the elimination of protein in urine.

Another object of the present invention is to provide a composition for treatment of urinary tract infection. The composition helps to overcome urination problems caused by urinary tract infection.

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At least one of the preceding objects is met, in whole or in part, by the invention, in which the embodiment of the invention describes a composition for prevention and treatment of urinary tract infection comprising a mixture of *Orthosiphon spicatus* extract and *Strobilanthes crispus* extract. The composition may further comprise

10 *Hibiscus sabdariffa* extract.

In the preferred embodiment of the present invention, the weight percentages in relative to the total composition of *Orthosiphon spicatus* extract and *Strobilanthes crispus* extract are 10% to 70% and 5% to 60%, respectively. The mixture may further

15 comprise 5% to 60% of *Hibiscus sabdariffa* extract by weight of total composition.

In a more preferred embodiment of the present invention, the composition comprises a mixture of, by weight of the total composition, 10 % to 70 % of *Orthosiphon spicatus* extract, 5 % to 60 % of *Strobilanthes crispus* extract, and 5 % to 60 % of

20 *Hibiscus sabdariffa* extract.

In the most preferred embodiment of the present invention, the composition comprises a mixture of, by weight of the total composition, 50 % of *Orthosiphon spicatus* extract, 25 % of *Strobilanthes crispus* extract, and 25 % of *Hibiscus sabdariffa* extract.

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In the preferred embodiment of the present invention, the mixture is sieved and fabricated into a dosage form by performing granulation, filling, or tableting process. Preferably, the dosage form comprises 0.10 g to 1.50 g of the mixture.

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tablet, hard-shelled capsule, soft-shelled capsule, enteric-coated capsule, granule, pill, and powder.

The composition may further comprise a pharmaceutically acceptable carrier.

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Detailed Description of the Invention

It is to be understood that the present invention may be embodied in other specific forms and is not limited to the sole embodiment described herein. However, modification and equivalents of the disclosed concepts such as those which readily
10 occur to one skilled in the art are intended to be included within the scope of the claims which are appended thereto.

The present invention relates to a herbal composition for the prevention or treatment of urinary tract infection, and the method of preparation thereof. Particularly, the
15 composition provides treatment for nephritis (kidney inflammation) and uremia by improving kidney function, eliminating protein in urine, and rapidly reducing the levels of serum creatinine and blood urea nitrogen (BUN).

The present invention is a composition comprising majority of three types of
20 medicinal herbs, namely *Orthosiphon spicatus*, *Hibiscus sabdariffa* Linn. and *Strobilanthes crispus*. The composition further comprises extracts and pharmaceutically acceptable carrier for formulation of the disclosed composition into the forms such as tablets, capsules, and granules.

25 In the preferred embodiment of the present invention, the composition for prevention and treatment of urinary tract infection comprises a mixture of *Orthosiphon spicatus* extract and *Strobilanthes crispus* extract. In another preferred embodiment of the present invention, the mixture further comprises *Hibiscus sabdariffa* extract.

30 In the preferred embodiment of the present invention, the composition comprises

10% to 70% of *Orthosiphon spicatus* extract by weight of total composition. A person skilled in the art shall understand that other names are used to refer to *Orthosiphon spicatus*, including *Orthosiphon aristatus* and *Clerodendranthus spicatus*. *O. spicatus* is also commonly known as cat's whisker or "Shen Cha"(肾茶) in Chinese. Analysis of *O. spicatus* showed that it comprises a variety of organic acids, phenolic compounds, steroidal saponins, flavonoid, anthraquinone and inorganic salts. The whole plant of *O. spicatus* is believed to be capable of inducing diuresis, stanching bleeding, inhibiting bacteria growth, reducing inflammation, dissolving calculi, promoting calculi removal, and preventing tumor formation. It is especially effective in treating acute and chronic kidney inflammation, bladder inflammation, urinary tract stone, pharyngitis (sore throat), and rheumatoid arthritis of lower extremities. Research showed that *O. spicatus* exhibits antibacterial activity against *Escherichia coli*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*. Further, *O. spicatus* can be used to treat edema and lower blood pressure by inducing diuresis. It also enhances kidney functions, reduces protein in urine, and promotes the elimination of serum creatinine and blood urea nitrogen from the body. Research also suggested that *O. spicatus* may restore activity of the complement system and cause changes in the fluid dynamics of blood flow and filtration of glomeruli. Side effect of *O. spicatus* has yet to be discovered. *O. spicatus* is often used as a medication or in a form of therapeutic tea by patients to treat urinary tract infection. Despite its health benefits, *O. spicatus* is seldom used for urinary tract infection prevention due to its unpleasant taste and smell.

Preferably, the composition comprises 5% to 60% of *Strobilanthes crispa* extract by weight of total composition. *S. crispa* belongs to the family of *Acanthaceae*. The whole plant of *S. crispa* can be used medicinally. *S. crispa* is able to reduce body heat, remove toxin, improve blood circulation, and lessen swelling. It is used to treat urinary tract infection, urination difficulty, irregular menstruation, amenorrhea (absence of menstruation), bruises, injuries, uterine fibroids, cancer, diabetes, and urinary tract stones. Further, *S. crispa* is used to acidify urine and maintain kidney

health for calculi formation prevention.

The composition may comprise 5% to 60% of *Hibiscus sabdariffa* extract by weight of total composition. *Hibiscus sabdariffa* Linn., or more commonly known as roselle,
5 is an annual herb that belongs to the *Malvaceae* family. *H. sabdariffa* has a slight fragrance and gives a sour taste. The calyx of *H. sabdariffa* can be used as food ingredients and food colorings; it possesses both culinary and medicinal properties. *H. sabdariffa* contains abundant essential minerals, such as iron, calcium and phosphorus. Furthermore, *H. sabdariffa* contains seventeen essential amino acids,
10 such as aspartic acid, glutamic acid, proline, glycine, alanine, lysine, and arginine. It also has a high content of antioxidants such as anthocyanin, polyphenol, furfural, hydroxymethylfurfural, and vitamin C. Besides, it also contains cyanidin-3-glucoside and citric acid. *H. sabdariffa* is useful in regulating and balancing blood lipids, improving calcium absorption, promoting child growth, and promoting digestion. It
15 can reduce body heat, eliminate toxin, induce removal of excess fluid, and reduce blood pressure. The extract of *H. sabdariffa* enhances the effect of glutathione in supporting liver function while the anthocyanin in *H. sabdariffa* inhibits drug-induced oxidative liver damage.

20 In a more preferred embodiment, the composition embodied herein comprises a mixture of, by weight of the total composition, 10 % to 70 % of *O. spicatus* extract, 5 % to 60 % of *S. crispa* extract, and 5 % to 60 % of *H. sabdariffa* extract.

Most preferably, the composition comprises a mixture of, by weight of the total
25 composition, 50 % of *O. spicatus* extract, 25 % of *S. crispa* extract, and 25 % of *H. sabdariffa* extract.

In the preferred embodiment of the present invention, the mixture is sieved and fabricated into a dosage form by performing granulation, filling or tableting process.
30 Particularly, the dosage form comprises 0.10 g to 1.50 g of the mixture. The dosage

form includes, but not limited to, tablet, sugar-coated tablet, film-coated tablet, hard-shelled capsule, soft-shelled capsule, enteric-coated capsule, granule, pill, and powder. The composition may further comprise a pharmaceutically acceptable carrier.

- 5 The recommended intake is two times daily, 2 dosages each time. Preferably, it is ingested with warm water. Plenty of water should be taken after the intake.

The composition embodied herein is safe for use by both men and women and is suitable for use as a complementary treatment by people in sub-health condition.

- 10 Particularly, it is suitable for people experiencing discomfort in the bladder and urethra. It is also suitable for people having urination problems such as urinary hesitancy, frequent urination, urinary incontinence, dysuria (pain, discomfort or burning sensation when urinating), narrow urine stream, bifurcation of urine stream, straining during urination, incomplete emptying of bladder, and nocturia (need to
15 urinate at night).

- The composition disclosed herein can relieve bladder irritation, prevent urinary tract infection, reduce bladder pressure, enhance urinary function, and improve urine flow. It can also be used to overcome urination problems such as nocturia, urinary
20 incontinence, and urinary retention. Further, the composition disclosed herein supports kidney function and ameliorates sexual dysfunction in males.

- The present disclosure includes as contained in the appended claims, as well as that of the foregoing description. Although this invention has been described in its preferred
25 form with a degree of particularity, it is understood that the present disclosure of the preferred form has been made only by way of example and that numerous changes in the details of construction and the combination and arrangements of parts may be resorted to without departing from the scope of the invention.

Claims

1. A composition for prevention and treatment of urinary tract infection comprising a mixture of *Orthosiphon spicatus* extract and *Strobilanthes crispa* extract.
- 5 2. A composition according to claim 1, wherein the mixture further comprises *Hibiscus sabdariffa* extract.
3. A composition according to claim 1, wherein the mixture comprises 10% to 70% of
- 10 *Orthosiphon spicatus* extract by weight of total composition.
4. A composition according to claim 1, wherein the mixture comprises 5% to 60% of *Strobilanthes crispa* extract by weight of total composition.
- 15 5. A composition according to claim 2, wherein the mixture comprises 5% to 60% of *Hibiscus sabdariffa* extract by weight of total composition.
6. A composition according to claim 1 further comprises a pharmaceutically acceptable carrier.
- 20 7. A composition according to claim 1, wherein the mixture is sieved and fabricated into a dosage form by performing granulation, filling, or tableting process.
8. A composition according to claim 7, wherein the dosage form comprises 0.10 g to
- 25 1.50 g of the mixture.
9. A composition according to claim 8, wherein the dosage form is tablet, sugar-coated tablet, film-coated tablet, hard-shelled capsule, soft-shelled capsule, enteric-coated capsule, granule, pill, or powder.

10. A composition for prevention and treatment of urinary tract infection comprising a mixture of, by weight of the total composition, 10 % to 70 % of *Orthosiphon spicatus* extract, 5 % to 60 % of *Strobilanthes crispa* extract, and 5 % to 60 % of *Hibiscus sabdariffa* extract.

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11. A composition according to claim 10, wherein the mixture is sieved and fabricated into a dosage form by performing granulation, filling, or tableting process.

12. A composition according to claim 11, wherein the dosage form comprises 0.10 g
10 to 1.50 g of the mixture.

13. A composition according to claim 12, wherein the dosage form is tablet, sugar-coated tablet, film-coated tablet, hard-shelled capsule, soft-shelled capsule, enteric-coated capsule, granule, pill, or powder.

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14. A composition according to claim 10 further comprises a pharmaceutically acceptable carrier.

15. A composition for prevention and treatment of urinary tract infection comprising a
20 mixture of, by weight of the total composition, 50 % of *Orthosiphon spicatus* extract, 25 % of *Strobilanthes crispa* extract, and 25 % of *Hibiscus sabdariffa* extract.

16. A composition according to claim 15, wherein the mixture is sieved and fabricated into a dosage form by performing granulation, filling, or tableting processes.

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17. A composition according to claim 16, wherein the dosage form comprises 0.10 g
to 1.50 g of the mixture.

18. A composition according to claim 17, wherein the dosage form is tablet, sugar-
30 coated tablet, film-coated tablet, hard-shelled capsule, soft-shelled capsule, enteric-coated capsule, granule, pill, or powder.

19. A composition according to claim 15 further comprises a pharmaceutically acceptable carrier.

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