**ABSTRACT**

The present invention provides a composition for supporting sexual function and general wellbeing comprising combination of herbal extracts including extracts of *Tribulus terrestris*, *Mucuna pruriens*, *Ginkgo biloba* and *Yohimbe* bark with L-Arginine and Zinc to provide the synergistic activity on physiological parameters of libido, erection, orgasm and improvement in semen parameters. The compositions are formulated in the form of nutraceutical or pharmaceutical formulations.



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**WE CLAIM**

1. A composition for supporting sexual function and general wellbeing, wherein composition comprises herbal extracts including *Tribulus terrestris, Mucuna pruriens, Ginko biloba and Yohimbe* Bark along with Zinc and L-arginine, optionally with a suitable carrier or excipient.
2. The composition as claimed in claim 1, wherein the *Tribulus terrestris* extract is present in an amount ranging from 50 mg to 2500 mg.
3. The composition as claimed in claim 1, wherein the *Mucuna pruriens* extract is present in an amount ranging from 5 mg to 2500 mg.
4. The composition as claimed in claim 1, wherein the *Ginkgo biloba* extract is present in an amount ranging from 5 mg to 200 mg.
5. The composition as claimed in claim 1, wherein the Yohimbe bark extract is present in an amount ranging from 1mg to 100 mg.
6. The composition as claimed in claim 1, wherein the L- Arginine is present in an amount ranging from 50 mg to 5000 mg.
7. The composition as claimed in claim 1, wherein the Zinc is present in an amount ranging from 10 mg to 50 mg.



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8. A method for treating male sexual dysfunction by promoting the physiological process of libido, erection and orgasm including improvement of sperm parameters in a subject, comprising administering to said subject in need thereof an effective amount of a composition according to claim 1.

Dated this 16th day of May, 2010.

FOR UNI-SANKYO LTD.
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**Field of the invention**

The present invention relates to a composition comprising combination of herbal extracts, trace elements and amino acid for supporting male sexual functions and general wellbeing. More particularly the present invention provides a composition comprising combination of extracts including *Tribulus terrestris, Mucuna pruriens, Ginko biloba and Yohimbe* Bark along with Zinc and L-arginine and formulations thereof.

**Background of the Invention**

Sexual function is a fundamental aspect of a man's wellbeing and man's sexual health (or dysfunction) has also been found to be a key factor in determining the capacity for maintaining healthy relationships. Sexual dysfunction disorders are generally classified into four categories: sexual desire disorders, sexual arousal disorders, orgasm disorders, and sexual pain disorders (in females). Persistently or recurrently deficient (or absent) sexual desire for sexual activity results in a complete or almost complete lack of desire to have any type of sexual relation, leading to marked distress or interpersonal difficulty. Erectile dysfunction is a problem with sexual arousal that can be defined as the difficulty in achieving or maintaining an erection sufficient for sexual activity or penetration, at least 50% of the time, for a period of six months. It is known to be a common sexual problem among the aging males. It results in significant psychological, social and physical morbidity, and annihilates his essence of masculinity.



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Untreated, sexual dysfunction can have detrimental effects on one's self-esteem, overall health, marriage, and even career. For a male sexual performance is an identity of manhood and a sense of self-esteem particularly in male dominated parts of the world. Sexual performance has been given a great precedence and for a man it is not easy to admit symptoms of loss of any of the components for a normal healthy sexual function which includes, libido, erection and orgasm and accepting it openly in a society is unthinkable and is considered a blot on his male image.

Current estimates and epidemiological data have suggested that nearly 100 million men around the world report of some form of sexual dysfunction. In the diabetic population, the incidence of sexual dysfunction is higher, and with India being declared the hub or the world headquarters for diabetes, the incidence is expected to go even higher. Changing food habits, stress, adopting intoxicants further aggravates the situation and the sexual dysfunction.

Only 10% of the total population with sexual dysfunction seek medical help while the rest depend on tonics, animal products such as bear testicles, tiger organs and other wild animals which are symbols of aggression and manliness, consume herbal products to correct components of sexual activities or depend on quacks

Although modern medicine may be available around the world to treat sexual dysfunction, they have their own limitations and they are associated with side effects such as hepatatotoxicity, effect on vision, effect on lipid metabolism in blood to increase LDL and decrease HDL, which may cause cardiovascular diseases and impair general wellbeing. The most popular medications such as Sildenafil, and the



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other PDE5 Inhibitors besides having side effects, have their own limitations in that they are excellent agents for improving penile erection, however in the absence of the male hormone Testosterone, these drugs may not act. Most of the medications cannot improve libido, erection and orgasm as a single entity, and many a times concomitant therapy is required for achieving either of the components of sexual function.

Common forms of such concomitant or even used as a standalone therapies include, hormonal therapy and dopamine agonists, intracavernous injection therapy, vacuum constriction devices, intraurethral therapy, transluminal angioplasty, venoablation, or topical agents.

Hormonal therapy includes testosterone or androgen preparations administered orally, injected or as applied as dermal patches. However they have side-effects which include, aggression, violent behaviour, mood swings, irritability and last but not the least, the serum concentrations are in the form of troughs and peaks which are responsible for the behavioural changes. Various health agencies have time and again raised concerns regarding the indiscriminate usage of hormonal preparations either orally or in the injectable form.

Various devices though appears to be attractive option, they are expensive, cumbersome to use and most importantly, they do not treat the root cause but just provide momentary symptomatic relief resulting in usage in limited conditions and in very limited population.



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Many people in developed countries have therefore begun to turn to alternative or complementary therapies, including traditional medicines. The World Health Organization has estimated that 60–80% of the population of non-industrialized countries rely on traditional healthcare for their basic health care needs, either on its own or in conjunction with modern medical care. After the launch of Viagra, a search for the equivalent in the plant kingdom is being pursued with renewed interest. However, a particular herb may work or provide a specific effect and may not address or support overall sexual function as well as improve overall wellbeing. The majority of research in this area has been either single ingredients in large doses or a combination of ingredients, which somehow do not exert the full spectrum of action on the physiological parameters including libido, erection, orgasm and improvement in semen parameters.

Therefore, there is a need for a safer holistic approach by providing a combination of components which can support the sexual function including improving libido, increase sexual desire and alleviate erectile dysfunction and ejaculation problems as well as better general wellbeing.

**Summary of the Present Invention**

Therefore, it is an object of the present invention to provide a composition to support sexual function and general wellbeing which can exert the spectrum of action on the physiological parameters of libido, erection, orgasm and improvement in semen parameters.



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Accordingly, in general aspect the present invention provides a composition comprising combination of herbal extracts, trace elements and amino acid for supporting male sexual functions and general wellbeing which can exert the full spectrum of action on the physiological parameters of libido, erection, orgasm and improvement in semen parameters.

In one aspect the present invention provides a composition comprising synergistic combination of extracts including *Tribulus terrestris*, *Mucuna pruriens*, *Ginko biloba* and *Yohimbe* Bark along with Zinc and L-arginine.

In another aspect the present invention provides formulations comprising synergistic combination of extracts including *Tribulus terrestris, Mucuna pruriens, Ginko biloba* and *Yohimbe* Bark along with Zinc and L-arginine in specified quantities optionally with a suitable carrier or excipients.

Various other objects, features and attendant advantages of the present invention will become more fully appreciated as the same becomes better understood in view of the following detailed description.

**Description of the Present Invention**

The present invention provides a composition comprising combination of herbal extracts, trace elements and amino acid for supporting male sexual functions and general wellbeing which can exert the spectrum of action on the physiological parameters of libido, erection, orgasm and improvement in semen parameters.



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The herbal extracts that may be comprised in the composition of the present invention may be selected from variety of herbs including but not limited to *Tribulus terrestris, Mucuna pruriens, Ginkgo biloba, Yohimbe* bark and/or mixture thereof.

In one embodiment the present invention provides a composition comprising a combination of herbal extracts including *Tribulus terrestris, Mucuna pruriens, Ginkgo biloba* and *Yohimbe* bark with L- Arginine and Zinc to provide the synergistic activity on physiological parameters of libido, erection, orgasm and improvement in semen parameters.

Elemental zinc may be included in the salt of zinc suitable for human consumption.

In preferred embodiment zinc is incorporated in the form of zinc sulphate monohydrate.

Herbal extracts as mentioned above, may be obtained by conventional techniques or by techniques which would become known to a person skilled in the art subsequently for incorporating in the composition of the present invention. Such methods include extraction with water or solvents or supercritical fluids to obtain extract suitable for being used for the purposes of this invention.

Herbal extracts for incorporation in the composition of the present invention may be standardised with the help of pre-determined content of certain chemical characteristic components of the extract.



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For preparing the herbal extracts, various parts of the plants can be used, as they contain the active constituents required for the specified activities. *Tribulus terrestris* extract is obtained from the aerial parts, preferably from the fruits or seeds, *Mucuna pruriens* extract is obtained from the aerial parts, preferably from the fruit pods or seeds, *Ginkgo biloba* extract is prepared from the aerial parts, preferably from the leaves, while *Yohimbe* bark extract is preferably prepared by extraction from the bark of the trunk.

As an alternative to the herbal extracts, the corresponding isolated active ingredients may be used in the composition of the present invention.

The herbal extracts, trace elements and amino acid may be incorporated per unit dose in the composition of the present invention in an amount required for supporting male sexual functions and improve general well being, more preferably in an amount sufficient to act synergistically which can exert the spectrum of action on the physiological parameters of libido, erection, orgasm and improvement in semen parameters in male. *Tribulus terrestris* extract may be present in a composition of the present invention in an amount ranging from 50 mg to 2500 mg, preferably from 100 mg to 1000 mg.

Mucuna pruriens extract may be present in a composition of the present invention in an amount ranging from 5 mg to 2500 mg, preferably from 10 mg to 250 mg.

*Ginkgo biloba* extract may be present in a composition of the present invention in an amount ranging from 5 mg to 200 mg, preferably from 10 mg to 50 mg.



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Yohimbe bark extract may be present in a composition of the present invention in an amount ranging from 1mg to 100 mg, preferably from 1 mg to 10 mg.

L- Arginine may be present in a composition of the present invention in an amount ranging from 50 mg to 5000 mg, preferably from 100 mg to 1000 mg.

Zinc may be present in a composition of the present invention in an amount ranging from 10 mg to 50 mg, preferably from 10 mg to 25 mg.

The composition of the present invention may optionally further comprise additional chemical active agents to support the male sexual function including libido, orgasm and erection as well as improve the general wellbeing.

The composition of the present invention can be used for a subject in need thereof. Such subject may include those suffering from male sexual dysfunctions. Examples of the male sexual dysfunction include, but are not limited to, reduced sexual desire, premature ejaculation, sexual nerve hypersensitivity, ejaculation disorder, ejaculation contract disorder, orgasm disorder, impotence, etc. The composition of the present invention to support the male sexual function and general wellbeing is pro-sexual composition.

The composition of the present invention may be formulated in a variety of formulations including but not limiting to nutraceutical formulations or pharmaceutical formulations.

In preferred embodiment the composition of the present invention may be formulated in the form of nutraceutical formulations or functional food



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supplements. Examples of suitable forms of administration of the compositions of the invention include granules, powders, tablets, soft and hard gelatin capsules, suppositories and drinkable preparations using the ingredients and their quantities on weight basis per unit dosage form as mentioned herein above. The pharmaceutical formulations of the sexual composition of the present invention can be administered orally or parenterally, i.e., by way of injection, or topically that is by way of ointment. The nutraceutical formulation of the composition of the present invention however is preferably administered to the subject in an oral form.

The amount of the composition to be administered can be properly determined according to the formulation, the administration route, the purpose of use and the subject's age, weight, symptoms, frequency of treatment, or the effect desired.

The composition of the present invention formulated in the form of nutraceutical formulation or food supplement can be prepared according to conventional processes in the art, for example, in the form of a powdered stock material, a capsule, a tablet, granules, or a liquid preparation.

The amount of the nutraceutical preparation to be administered may be determined according to the formulation, the administration route, the patient's age, weight symptoms, frequency of treatment, or the effect desired.

The nutraceutical formulation of the composition according to the present invention, depending on the desired type of the composition can include one or more ingredients selected from the group consisting of conventional supplements, additives, and sweetening agents, for example, soya oil, permitted natural colours,



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hydrogenated vegetable oil, acidity regulator, Class II preservatives, antioxidants, beeswax, licorice, vitamin C, citric acid, nicotinic acid, sodium benzoate, aspartame, saccharine, pectin, glycerin, mannitol, sorbitol, xylitol, guar gum, skimmed milk, oligosaccharides, etc, flavoring agents, purified water or other suitable agents in order to increase preference or taste of the composition.

It is preferable to use the above ingredient in about 0.01-90 weight % based on the weight of the total composition.

The composition of the present invention formulated in the form of pharmaceutical formulation can be prepared in combination with a conventional pharmaceutically acceptable carrier. Generally, the active components are mixed with a pharmaceutically acceptable liquid or solid carrier. If necessary, additives such as solvents, dispersants, emulsifiers, buffers, stabilizers, diluents, binders, disintegrants, lubricants, etc. can be used. The composition may take the form of solid formulations such as tablets, granules, powders or capsules, or liquid formulations such as normal liquids, suspensions or oils. These formulations may also be made as dry preparations which can be used in liquid form by addition to a proper carrier before use.

The pharmaceutically acceptable carriers may be selected according to the mode of administration and formulation. In case of oral formulations, for example, the carriers include starch, lactose, refined sugar, mannite, carboxymethylcellulose, corn starch, or inorganic salts. In the preparation of oral formulations, binders,



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disintegrants, surfactants, lubricants, fluidity enhancers, sweetening agents, coloring agents or spices can be additionally used.

The parenteral formulation may be prepared by dissolving or suspending the composition containing the extracts derived from herbs and nutritional elements of the present invention compositions in a diluent, such as distilled water for injection, physiological salt solution, aqueous glucose solution, vegetable oil for injection, sesame oil, peanut oil, soybean oil, corn oil, propylene glycol or polyethylene glycol and, if necessary, adding disinfectants, stabilizers or tonic agents.

The formulations mentioned above can be taken at a specified time period during the day time not just immediately before sexual intercourse, although in some individuals the response may be observed, within 30 -60 minutes of taking the formulation. The formulation may be taken for a prolonged period.

Prolonged administration of the compositions of the invention does not cause any significant side effects, is well tolerated, and does not alter the delicate hormone balances, especially the androgen/oestrogen balance, which governs major physiological events in men.

The composition of the present invention, comprising of multi-ingredients herbal extracts, amino acid and Zinc is used to support male sexual dysfunction and general well being and promote the physiological process of libido, erection and orgasm including improvement of sperm parameters, by promoting improvement in endogenous testosterone levels, Nitric oxide, hypothalamic hormones and improving neurotransmitter levels essential for male sexual functioning.



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The combination of herbal extracts including *Tribulus terrestris, Mucuna pruriens, Ginko biloba* Extract and *Yohimbe* Bark along with Zinc and L-arginine, represent a safe and natural approach to enhancing sexual desire, performance and satisfaction.

The composition of the present invention promotes testosterone concentrations and nitrix-oxide for improvement in penile blood flow and Zinc to further enhance the levels of testosterone by reducing the levels of 5-alpha reductase and prevent conversion of testosterone to estrogen. The biochemical properties of the ingredients, also act by reducing stress levels, improving antioxidant levels and also improving the sperm parameters.

While the particular embodiments of the present invention have been described with reference to various embodiments, it would be obvious to those skilled in the art that various changes and modifications can be made without departing from the spirit and scope of the invention.

The following example is given to illustrate the invention rather than to limit its scope.

**EXAMPLE**

**Example 1 Preparation of a** Soft Gelatin Capsules

Each 1000 mg soft gelatin capsule contains:



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*Tribulus terrestris* extract 200 mg, *Mucuna pruriens* extract 20 mg, *Ginkgo biloba* extract 20 mg, *Yohimbe* bark extract 1 mg L- Arginine hydrochloride 500 mg, Zinc as Zinc sulphate monohydrate 10 mg, Polysorbate 80 15 mg and Soya oil 234.00 mg



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**WE CLAIM**

1. A composition for supporting sexual function and general wellbeing, wherein composition comprises herbal extracts including *Tribulus terrestris, Mucuna pruriens, Ginko biloba and Yohimbe* Bark along with Zinc and L-arginine, optionally with a suitable carrier or excipient.
2. The composition as claimed in claim 1, wherein the *Tribulus terrestris* extract is present in an amount ranging from 50 mg to 2500 mg.
3. The composition as claimed in claim 1, wherein the *Mucuna pruriens* extract is present in an amount ranging from 5 mg to 2500 mg.
4. The composition as claimed in claim 1, wherein the *Ginkgo biloba* extract is present in an amount ranging from 5 mg to 200 mg.
5. The composition as claimed in claim 1, wherein the Yohimbe bark extract is present in an amount ranging from 1mg to 100 mg.
6. The composition as claimed in claim 1, wherein the L- Arginine is present in an amount ranging from 50 mg to 5000 mg.
7. The composition as claimed in claim 1, wherein the Zinc is present in an amount ranging from 10 mg to 50 mg.



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8. A method for treating male sexual dysfunction by promoting the physiological process of libido, erection and orgasm including improvement of sperm parameters in a subject, comprising administering to said subject in need thereof an effective amount of a composition according to claim 1.

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