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— *of inventorship (Rule 4.17(iv))*

(54) **Title:** A HERBAL COMPOSITION FOR MANAGEMENT OF SEXUAL DYSFUNCTION

(57) **Abstract:** The present invention relates to a herbal composition for management of libido in both men and women, wherein, said composition has no or minimal side effects. More particularly, the present invention relates to a herbal composition comprising of component A and component B. Component A is a combination of amino acids L-Arginine and L-Citrulline in a defined ratio. The component B according to the present invention is a polyherbal mixture of Fenugreek *(Trigonella foenum graecum)*,*Tribulus terrestris*, grape seed extract, and piperine (95%) in defined weight percentages for the management of low libido in men and women.

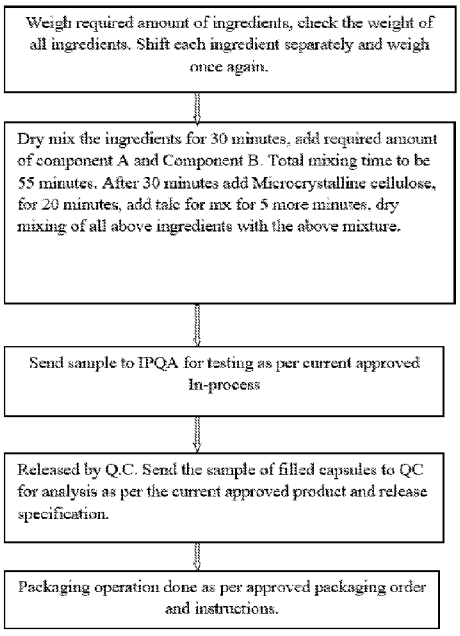

Figure 1

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[Continued on next page]

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A HERBAL COMPOSITION FOR MANAGEMENT OF SEXUAL DYSFUNCTION

FIELD OF THE INVENTION

The present invention relates to a herbal composition for management of sexual dysfunction. More particularly, the present invention relates to a herbal composition for management of libido in both men and women, wherein the composition has no or minimal side effects.

BACKGROUND OF THE INVENTION

Sexual dysfunction is characterized by disturbances in sexual desire and in the psychophysiological changes associated with the sexual response cycle (American Psychiatric Association, 1994). One of the common sexual dysfunctions is linked to low libido which is prevalent in both men and women. The libido is a sexual drive-in individual that can be determined and influenced by several factors, such as social, psychological, and hormonal factors. The etiology of the disorder is multifactorial and in men is mainly attributed to psychogenic, organic (neurogenic, hormonal, arterial, cavernosal or drug-induced), or mixed psychogenic and organic. The etiology in female is linked to vasculogenic, neurogenic, hormonal, or psychogenic factors.

Despite the increasing availability of proper medical treatments, plant-derived and herbal medications still is a promising alternative for both men and women seeking to improve their sex life. The reason for the same can be linked to reduced side effects. Nevertheless, the efficacy of most herbal agents in treating sexual problems remains uncertain.

Aung *et al*; (H.H. AUNG et al. / The American Journal of Chinese Medicine, Vol. 32, No. 2, 161–173); discloses alternative therapies for male and female sexual dysfunction. The article discloses the use of herbal medicines like Yohimbine, Ginkgo

biloba, Tribulus terrestris/Protodioscin, Ginseng, and Damiana for treating male sexual dysfuntion. Further the document discloses a nutritional supplement containing ginseng (30% ginseng extract), ginkgo (24% flavone glycosides and 6% terpene lactones), damiana leaf, L-Arginine, along with vitamins A, B6, B12, biotin, folate, niacin, pantothenic acid, riboflavin, thiamin, antioxidant vitamins (C and E), calcium, iron, and zinc, for enhancement of female sexual function.

Elizabeth Westand Michael Krychman (Sex Med Rev 2015; 3:279–288) discloses the most popular and currently used aphrodisiac products marketed in the United States. Research has demonstrated that the risks of yohimbine, Spanish fly, mad honey, and Bufo toad outweigh any benefit, and these products should be avoided. Other products, such as Maca, Tribulus, Ginkgo, and ginseng, have limited. The document further discloses "ArginMax", which is a combination supplement containing an array of vitamins marketed toward women (A, B-complex, C, E), zinc, as well as L-Arginine, Korean ginseng, Ginkgo, and Damiana leaf. The proposed mechanism of action is through enhancement of the NO pathway. L-Arginine is a precursor of NO, which causes central to smooth muscle relaxation, vascular dilatation, and vaginal wall engorgement.

WO2020/115274 discloses compositions comprising L-Arginine and L-Citrulline in specific ratios and the use thereof for improving the sexual function in a sexually healthy human subject on demand.

WO2021/030698 discloses a topical composition for improving the sensitivity of the skin and improving blood flow to the skin comprising sweet almond oil, cinnamon bark oil, coriander seed oil, L-Arginine, and L-Citrulline in an oil-in-water emulsion.

The existing treatments for the above disorder are either having side effects or very less data available on the efficacy of such herbal formulations is known. Further, treatment alternatives for low libido in females is less explored and a single treatment for both men and women is still a challenge. In light of the above, there exists a need to explore new alternative therapies for managing the low libido in both men and women.

OBJECT OF THE INVENTION

The main object of the present invention is to provide a composition for management of sexual dysfunction.

Another object of the present invention is to provide a composition for management of libido in both men and women.

Yet another object of the present invention is to provide a herbal composition having no or minimal side effects.

SUMMARY OF THE INVENTION

The present invention relates to a herbal composition for management of libido in both men and women in a short time period without any side effects.

In an embodiment, the present invention provides a herbal composition for the management of libido, comprising of a component A, a component B and an excipient. The component A is a combination of amino acids including L-Citrulline and L-Arginine in a ratio of 0.5:1, 1:1 or 1:3. The component B is a combination of polyherbal mixture including Fenugreek (*Trigonella foenum graecum*), *Tribulus terrestris*, grape seed extract and piperine (95%) in a ratio ranging from 0.05 to 1.

In another embodiment of the present invention, a method of preparing a herbal composition is provided, said method comprising the steps of weighing and drying a predefined amount of the amino acids of component A and a predefined amount of the polyherbal mixture of component B. The amino acids of component A and polyherbal mixture of component B are dried and mixed for 55 minutes to form a mixture followed by addition of microcrystalline cellulose and polysorbate 80 in the mixture for 20 minutes followed by mixing talc for 5 more minutes to form another mixture that is then dried and mixed with the mixture obtained above to form a herbal composition. The predefined amount of the amino acids of component A is in a range of 150 mg –

300 mg and the predefined amount of the polyherbal mixture is in a range of 380 mg – 460 mg.

The above objects and advantages of the present invention will become apparent from the hereinafter set forth brief description of the drawings, detailed description of the invention, and claims appended herewith.

BRIEF DESCRIPTION OF DRAWINGS

An understanding of the herbal composition of the present invention may be obtained by reference to the following drawings:

Figure 1 is a flow chart depicting the process of preparing the herbal composition, according to an embodiment of the present invention.

Figure 2 is a graphical representation showing comparative dissolution data in 90 ml water with respect to % release profile of the drug, according to the present invention.

Figure 3 is a graphical representation showing comparative dissolution data in 900 ml water for capsules with respect to % release profile of the drug, according to the present invention.

Figure 4 is a graphical representation showing comparative dissolution data in 900 ml water for capsule composition with respect to % release profile of the drug, according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention now will be described hereinafter with reference to the detailed description, in which some, but not all embodiments of the invention are indicated. Indeed, the invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like

numbers refer to like elements throughout. The present invention is described fully herein with non-limiting embodiments and exemplary experimentation.

The present invention relates to a herbal composition for management of libido in both men and women with no or minimal side effects as well as in a short time interval.

In a preferred embodiment, the present invention provides a herbal composition for management of libido, comprising of: a component A; a component B; and an excipient; wherein, the component A is a combination of amino acids including L-Citrulline and L-Arginine in a ratio of 0.5:1, 1:1 or 1:3; the component B is a polyherbal mixture including Fenugreek (*Trigonella foenum graecum*), *Tribulus terrestris*, grape seed extract, and piperine (95%) in a ratio ranging from 0.05 to 1.

Here, the amino acids of component A includes 17.05% of L-Citrulline and 17.05% of L-Arginine. The polyherbal mixture of component B includes 22.72% of Fenugreek (*Trigonella foenum graecum*); 17.05% of *Tribulus terrestris*; 11.36% of grape seed extract; and 1.14% of piperine (95%). Further, the excipient is a pharmaceutically acceptable ingredient, which is selected from microcrystalline cellulose or methyl cellulose, polysorbate 80, sodium lauryl sulphate, talc, silica or magnesium stearate, and is essentially a mixture of 48 mg of microcrystalline cellulose, 2 mg of talc and 2 mg of magnesium stearate.

Further, the amino acids of component A includes 75 mg of L-citrulline and 75 mg of L-Arginine, while the polyherbal mixture of component B includes 100 mg of Fenugreek (*Trigonella foenum graecum*); 75 mg og *Tribulus terrestris*; 50 mg of grape seed extract; and 5 mg of piperine (95%). The herbal composition is in the form of a tablet, a capsule, a sachet, oral capsules, granules, a paste, a pill, a syrup or liquid. The libido is managed in a period ranging from 30 days to 90 days. Additionally, the herbal composition helps in managing libido in a single dosage form of the amino acids of component A and the polyherbal mixture of component B in a range of 150 mg – 230 mg, while in a double dosage form, the libido is managed by the amino acids of component A and the polyherbal mixture of component B in a range of 300 mg – 460 mg and the herbal composition possess minimal side effects.

In another preferred embodiment of the present invention, a method of preparing a herbal composition comprising the steps of: a) weighing and drying a predefined amount of the amino acids of the component A and a predefined amount of the polyherbal mixture of the component B; b) drying and mixing the amino acids of the component A and the polyherbal mixture of the component B of step (a) for 55 minutes to form a mixture; c) adding microcrystalline cellulose and polysorbate 80 in the mixture obtained in step (b) for 20 minutes followed by mixing talc for 5 more minutes to form another mixture; and d) drying and mixing the another mixture obtained in step (c) with the mixture obtained in step (b) to form a herbal composition; wherein, the predefined amount of the amino acids is 150 mg; and the predefined amount of the polyherbal mixture is 380 mg.

Fenugreek (*Trigonella foenum graecum*) is native to southern Europe and the Mediterranean region, fenugreek is cultivated in central and southeastern Europe, western Asia, India, and northern Africa.

Tribulus terrestris is an annual plant in the caltrop family (Zygophyllaceae) widely distributed around the world. It is native to warm temperate and tropical regions in southern Eurasia and Africa.

The grape seed is native to Asia and it is well-known from pre-history. The part of the grape seed that was used in the present invention was seed that was procured from the Konark Herbals & Healthcare Pvt. Ltd.

Piperine is found in Black Pepper, which is native to the Malabar Coast of India and is one of the earliest spices known. Widely used as a spice around the world, pepper also has a limited usage in medicine as a carminative (to relieve flatulence) and as a stimulant of gastric secretions. The part of piperine that was used in the present invention was fruit that was procured from the Konark Herbals & Healthcare Pvt. Ltd.

The amino acid L-Arginine was procured from Ningbo Zhenhai Haide Biotech Co., Ltd., China while the another amino acid i.e., L-Citrulline was procured from Luoyang Huarong Biotechnology Co., Ltd.

Referring to **Figure 1** showing a flow chart depicting the process of preparing the herbal composition.

EXAMPLE 1

Ingredients of Herbal Composition

The ingredients of herbal composition comprising of component A having 75 mg (17.05%) of L-Citrulline and 75 mg (17.05%) of L-Arginine and component B having 100 mg (22.72%) of Fenugreek (*Trigonella foenum graecum*), 75 mg (17.05%) of *Tibulus terrestris*, 50 mg (11.36%) of grape seed extract, 5 mg (1.14%) of Piperine (95%). Further, the excipients include 48 mg (10.9%) of microcrystalline cellulose, 2 mg (0.45%) of talc and 10 mg (2.28%) of polysorbate 80 **(Table 1)**.

Table 1: Ingredients of Herbal Composition

S. No.	Ingredients	Quantity in mg	Percentage
Component A			
1	L-Citrulline	75	17.05
2	L-Arginine	75	17.05
Component B			
3	Fenugreek (*Trigonella foenum graecum*)	100	22.72
4	*Tribulus terrestris.*	75	17.05
5	Grape seed extract	50	11.36
6	Piperine (95%)	5	1.14
	Excipients		
a)	Microcrystalline cellulose	48	10.9
b)	Talc	2	0.45
c)	Polysorbate 80	10	2.28
	Total		100%

Figure 2 shows a graphical representation depicting the comparative dissolution data in 90 ml water with respect to % release profile of the drug.

EXAMPLE 2

Clinical Study

An open label clinical trial was conducted for testing efficacy in 90 patients suffering from Libido and copulatory performance. The inclusion criteria includes ability and acceptance to provide written consent, fluent in English, patients with history of Libido and copulatory performance issues. The patients include men or women between 18-75 years. On the other hand, there were some exclusions such as patients who had undergone major surgery, suffering from trauma, illness or are immobile for 3 or more days within the past month, women who are pregnant, and the patients with a positive test for drugs of abuse at the screening or evaluation visit were not allowed to participate in the trial. The trial was conducted by giving the test molecule (TM) orally in the form of capsules to each patient. The objective was to determine the efficacy of capsule in Libido and copulatory performance and to evaluate the safety of the TM capsules in patients with Libido and copulatory performance. The dosage was given only one time and the trial was conducted for 3 months **(Table 2)**.

The endpoint result of this clinical trial was seen to be positive having improvement in libido and copulatory performance in patients.

Table 2: Study Details

Title	An open label, trial for efficacy product in patients with Libido and copulatory performance
Name of the Sponsor	Swayamacare
Protocol Number	SW-01-22
Regulatory submission	Internal review

Phase of development	Pilot phase
Investigational product	Test Molecule (TM) Placebo
Type of Formulation	Capsules
Mode of administration	Oral
Dosage recommendation	Test arm 1: TM Capsule BID
Indication	Libido and Copulatory performance
Study Design	Open label trial
Sample Size	90 patients Total 90 evaluable patients
Objectives	**Primary Objective:** • To determine the efficacy of capsule in Libido and copulatory performance **Secondary Objective:** • To evaluate the safety of the TM Capsules in patients with Libido and copulatory performance
Endpoints	**Primary endpoint:** Improvement in libido and copulatory performance
Main Inclusion/Exclusion Criteria	**Inclusion Criteria:** 1. Ability and acceptance to provide written consent, fluent in English. 2. Subjects with history of Libido and copulatory performance issues. 3. Men or women between 18-75 years. **Exclusion Criteria:** 1. Major surgery, trauma, illness or immobile

	for 3 or more days within the past month. 2. Pregnancy or recent pregnancy (within 6 weeks). 3. A positive test for drugs of abuse at the screening or evaluation visit.
Study Duration	3 months

EXAMPLE 3

Testing of Formulation

The above formulation has been formulated in tablet, capsule, sachet, oral caplets form. The most suitable embodiment was in the form of capsules as a dosage form 2 times bid preferably for a period of 30 – 90 days.

The product was tested in almost 90 patients, of which 30 were females and 60 were males over a period of 45-60 days. The males were in the age group of 45 to 70 years, while female were in the age group of 35-55 years. Patients had different co-morbidities along with libido and copulatory performance. The patients enrolled were given capsules with the composition as stated in **Example 1**. Patients were assessed based on the diary, which was given to them as an assessment diary. There were no side effects associated with the product by any of the subjects who had taken the capsules.

Efficacy: From the efficacy standpoint, the statistical value of p=5 was reached, as almost all the patients had marked improvement in the results.

Safety: The product is herbal composition and has been proven to give better results as explained in **Table 3**.

The following results were obtained from the test:

Table 3: Results of the herbal product composition

Gender	N= population exposed	Duration of treatment (days)	Problems associated	% of efficacy	Side effect
Male	60	45	Libido and copulatory performance	95% patients had excellent results	No patient in this group complained of side effect
Female	30	45	Libido and copulatory performance	94% patients had excellent results	No patient in this group complained of side effect.

EXAMPLE 4

Capsules

The ingredients of capsules include component A comprising 75 mg (17.05%) of L-Citrulline and 75 mg (17.05%) of L-Arginine and component B comprising 100 mg (22.72%) of Fenugreek (*Trigonella foenum graecum*), 75 mg (17.05%) of *Tribulus terrestris*, 50 mg (11.36%) of grape seed extract, 5 mg (1.14%) of Piperine (95%). Further, the excipients include 48 mg (13.18%) of microcrystalline cellulose and 2 mg (0.45%) of talc **(Table 4)**.

Table 4: Capsules

S. No.	Ingredients	Quantity in mg	Percentage
Component A			
1	L-Citrulline	75	17.05
2	L-Arginine	75	17.05

Component B			
3	Fenugreek (*Trigonella foenum graecum*)	100	22.72
4	*Tribulus terrestris.*	75	17.05
5	Grape seed extract	50	11.36
6	Piperine (95%)	5	1.14
	Excipients		
a)	Microcrystalline cellulose	48	13.18
b)	Talc	2	0.45
	Total		100%

Figure 3 shows a graphical representation of comparative dissolution data in 900 ml water for capsules with respect to % release profile of the drug.

EXAMPLE 5

Capsule Composition

The capsule composition includes component A having 75 mg (17.05%) of L-Citrulline and 75 mg (17.05%) of L-Arginine and component B having 100 mg (22.72%) of Fenugreek (*Trigonella foenum graecum*), 75 mg (17.05%) of *Tribulus terrestris*, 50 mg (11.36%) of grape seed extract, 5 mg (1.14%) of Piperine (95%). Further, the excipients include 48 mg (12.73%) of microcrystalline cellulose, 2 mg (0.45%) of talc and 2 mg (0.45%) of magnesium stearate **(Table 5)**.

Table 5: Capsule Composition

S. No.	Ingredients	Quantity in mg	Percentage
Component A			
1	L-Citrulline	75	17.05
2	L-Arginine	75	17.05
Component B			
3	Fenugreek (*Trigonella foenum graecum*)	100	22.72
4	*Tribulus terrestris.*	75	17.05

5	Grape seed extract	50	11.36
6	Piperine(95%)	5	1.14
	Excipients		
a)	Microcrystalline cellulose	48	12.73
b)	Talc	2	0.45
c)	Magnesium stearate	2	0.45
	Total		100%

Figure 4 is a graphical representation showing comparative dissolution data in 900 ml water for capsule composition with respect to % release profile of the drug.

Many modifications and other embodiments of the invention set forth herein will readily occur to one skilled in the art to which the invention pertain having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

CLAIMS

I claim:

1. A herbal composition for the management of libido, comprising of:
a component A; a component B; and an excipient;
wherein,
said component A is a combination of amino acids including L-Citrulline and L-Arginine in a ratio of 0.5:1, 1:1 or 1:3; and
said component B is a polyherbal mixture including Fenugreek (*Trigonella foenum graecum*), *Tribulus terrestris*, grape seed extract and piperine (95%) in a ratio ranging from 0.05 to 1.

2. The herbal composition as claimed in claim 1, wherein said amino acids of component A includes 17.05% of L-Citrulline and 17.05% of L-Arginine.

3. The herbal composition as claimed in claim 1, wherein said polyherbal mixture of component B includes 22.72% of Fenugreek (*Trigonella foenum graecum*); 17.05% of *Tribulus terrestris*; 11.36% of grape seed extract; and 1.14% of piperine (95%).

4. The herbal composition as claimed in claim 1, wherein said excipient is a pharmaceutically acceptable ingredient selected from microcrystalline cellulose or methyl cellulose, polysorbate 80, sodium lauryl sulphate, talc, silica or magnesium stearate.

5. The herbal composition as claimed in claim 1, wherein said excipient is a mixture of 48 mg of microcrystalline cellulose, 2 mg of talc and 2 mg of magnesium stearate.

6. The herbal composition as claimed in claim 1, wherein said amino acids of component A includes 75 mg of L-Citrulline and 75 mg of L-Arginine.

7. The herbal composition as claimed in claim 1, wherein said polyherbal mixture of component B includes 100 mg of Fenugreek (*Trigonella foenum graecum*); 75 mg of *Tribulus terrestris*; 50 mg of grape seed extract; and 5 mg of piperine (95%).

8. The herbal composition as claimed in claim 1, wherein said herbal composition is in the form of tablet, capsule, sachet, oral caplets, granules, paste, pill, syrup or liquid.

9. The herbal composition as claimed in claim 1, wherein said herbal composition manages libido in a period ranging from 30 days to 90 days.

10. The herbal composition as claimed in claim 1, wherein said herbal composition manages libido in a single dosage form of said amino acids of component A and said polyherbal mixture of component B in a range of 150 mg – 230 mg.

11. The herbal composition as claimed in claim 1, wherein said herbal composition manages libido in a double dosage form of said amino acids of component A and said polyherbal mixture of component B in a range of 300 mg – 460 mg.

12. A method of preparing a herbal composition, comprising the steps of:

a) weighing and drying a predefined amount of said amino acids of said component A and a predefined amount of said polyherbal mixture of said component B;
b) drying and mixing said amino acids of said component A and said polyherbal mixture of said component B of step (a) for 55 minutes to form a mixture;
c) adding microcrystalline cellulose and polysorbate 80 in said mixture obtained in step (b) for 20 minutes followed by mixing talc for 5 more minutes to form another mixture; and

d) drying and mixing said another mixture obtained in step (c) with said mixture obtained in step (b) to form a herbal composition;

wherein,

said predefined amount of said amino acids is in a range of 150 mg – 300 mg; and

said predefined amount of said polyherbal mixture is in a range of 380 mg – 460 mg.

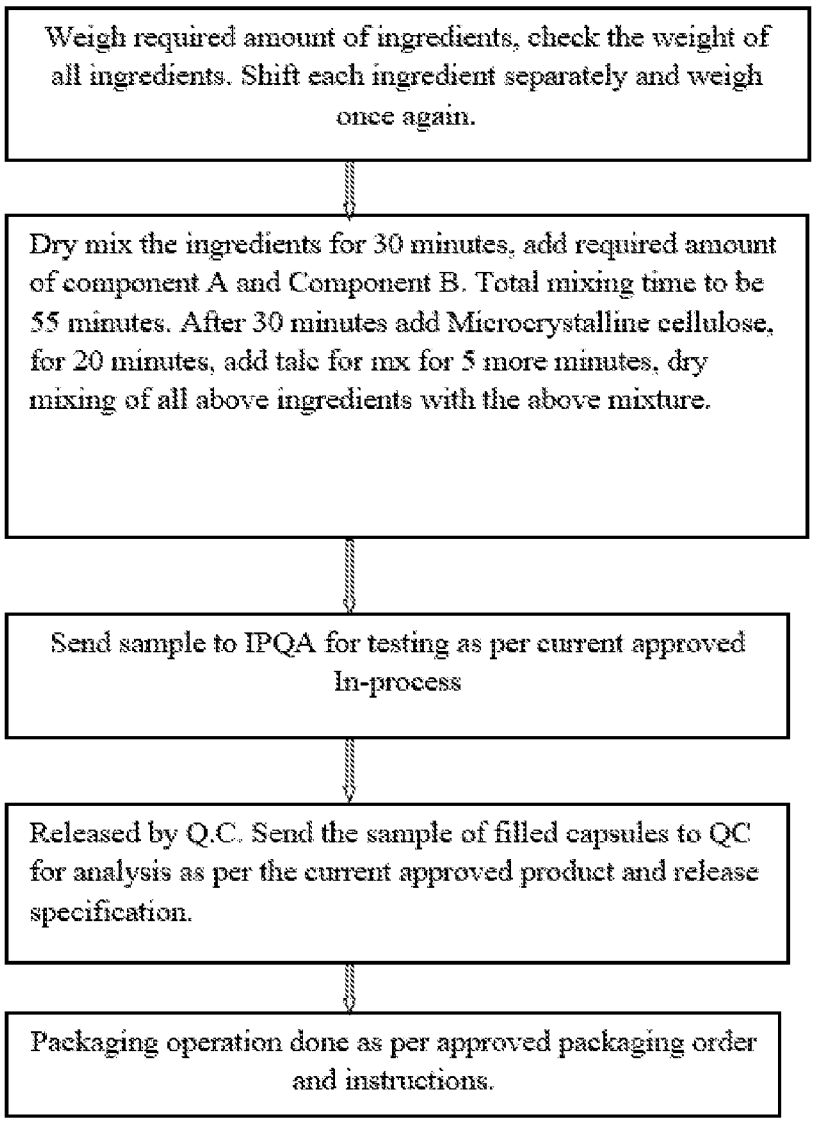
Weigh required amount of ingredients, check the weight of all ingredients. Shift each ingredient separately and weigh once again.
Dry mix the ingredients for 30 minutes, add required amount of component A and Component B. Total mixing time to be 55 minutes. After 30 minutes add Microcrystalline cellulose, for 20 minutes, add talc for mx for 5 more minutes, dry mixing of all above ingredients with the above mixture.
Send sample to IPQA for testing as per current approved In-process
Released by Q.C. Send the sample of filled capsules to QC for analysis as per the current approved product and release specification.
Packaging operation done as per approved packaging order and instructions.

Figure 1

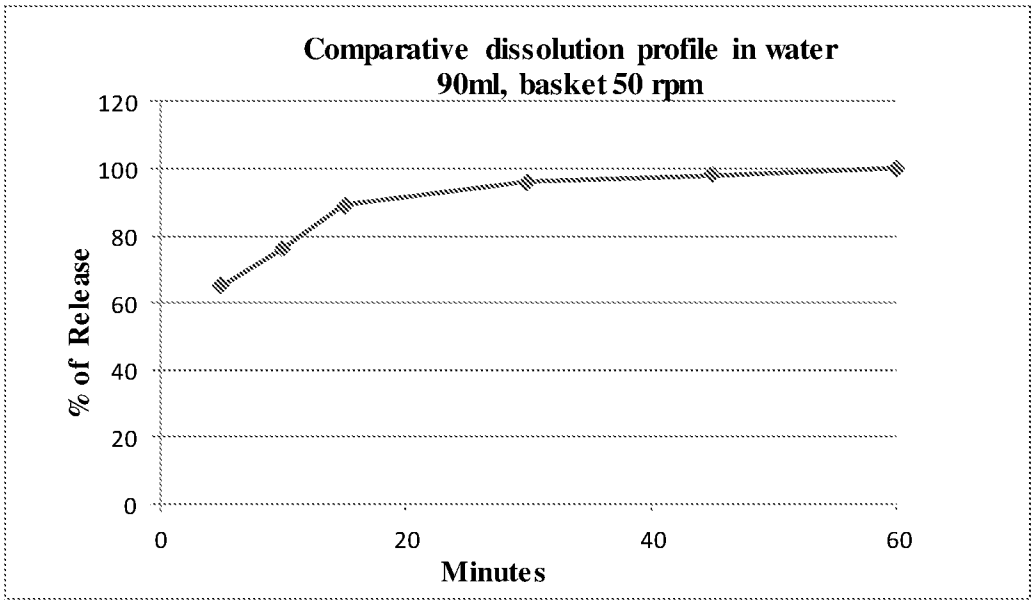

Figure 2

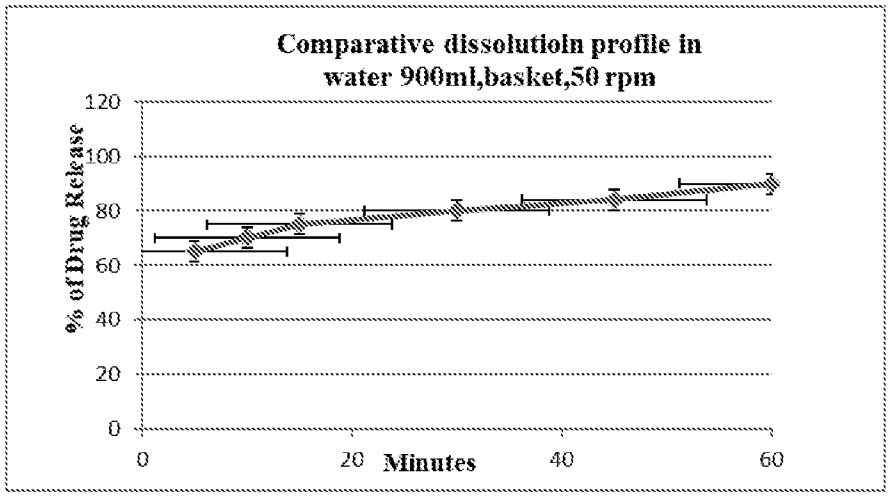

Figure 3

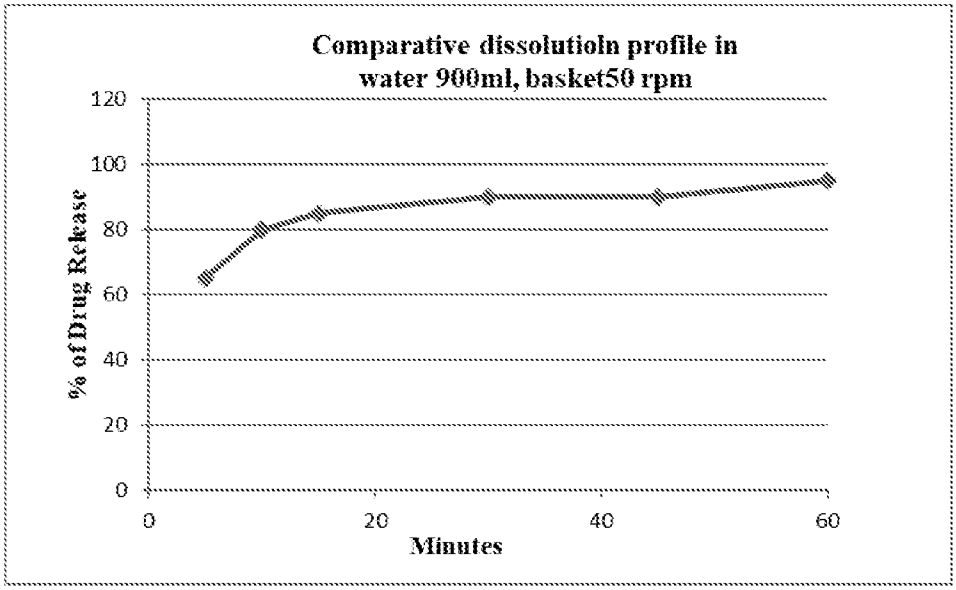
Comparative dissolutioln profile in water 900ml, basket50 rpm
% of Drug Release
120
100
80
60
40
20
0
0
20
40
60
Minutes

Figure 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2023/061275

A. CLASSIFICATION OF SUBJECT MATTER
A61K36/185,A61K36/48,A61K36/87,A61K31/198,A61P15/00 Version=2024.01

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)

A61K, A61P

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

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

Database: PatSeer, IPO Internal Database
Keywords: L-Citrulline, L-Arginine, Libido, Fenugreek, Tribulus terrestris

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP3890718A1; (INXO AS); Oct 13, 2021 (13-10-2021) *Whole document especially abstract, page 6 and claims 1-2*	1-12
Y	IN 702MUM2005 A; (L' AMAR NATURAL PRODUCTS PVT LTD); Aug 03, 2007 (03-08-2007) *Whole document especially abstract and claim 10*	1-12
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INTERNATIONAL SEARCH REPORT
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