FORM 2

THE PATENTS ACT, 1970
(39 of 1970)
THE PATENTS RULES, 2003

COMPLETE SPECIFICATION
(Section 10 and Rule 13)

1. TITLE OF THE INVENTION:

A THERAPEUTIC AYURVEDIC FORMULATION AND PROCESS THEREOF

2. APPLICANT:

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3. PREAMBLE TO THE DESCRIPTION

The following specification particularly describes the invention and the manner in which it is to be performed:

FIELD OF THE INVENTION

The present invention relates to a therapeutic ayurvedic formulation. More specifically, the present invention relates an ayurvedic formulation comprising of bioactive fraction from cow urine distillate and giloy, with other active ingredients. The invention also provides process of preparation of an ayurvedic formulation comprising of bioactive fraction from cow urine distillate and giloy, with other active ingredients.

BACKGROUND OF THE INVENTION

Background description includes information that may be useful in understanding the present invention. It is not an admission that any of the information provided herein is prior art or relevant to the presently claimed invention, or that any publication specifically or implicitly referenced is prior art.

Indian cow breeds are unique and distinct species, both in their appearance and characteristics. Cow is the backbone of Indian culture and rural economy, and sustains our life, represent cattle wealth and bio-diversity. It is known as “Kamdhenu” and “Gaumata” because of its nourishing nature like mother, the giver of all riches to humanity and is a storehouse of medicines.

Treatment with modern allopathic medicines is causing multiple drug resistance in microorganisms, presence of antibiotic residues in food chain and/or associated allergies and autoimmune disorders in man and animals. The wonder drugs “antibiotics” of twentieth century will not remain useful and will become almost

ineffective with time. Immunity is reducing drastically as a result of the environmental pollution, use of agrochemicals in agriculture and presence of pesticides, heavy metals, fungal toxins etc. in the food chain.

In these circumstances, the approach is to think over the alternative therapeutic medicines to control the infections and to enhance immunity. One of such alternative approaches is to revisit the ancient traditional knowledge and arurvedic system of medicines to prepare new medicinal preparations.

Cow urine has been described in ‘Sushrita Samhita’ and ‘Ashtanga Sangraha’ to be the most effective substance/secretion of animal origin with innumerable therapeutic values. Taken in measured quantities, cow urine or gau mutra has a unique place in Ayurveda and is suggested for improving general health and is being used to produce a whole range of Ayurvedic drugs.

Cow urine along with the antibiotics also prevents the development of resistance in microorganisms against the antibiotics. Cow urine as such and/or after addition of neem leaves is a wonderful biopesticides which do not accumulate in the food chain and as such do not have the harmful effects like chemical pesticides.

Urine of Indian cows has many beneficial properties particularly in the areas of agriculture and therapeutics, which is lacking in the urine of crossbred, exotic cows,

buffaloes, etc. Recent researches showed that Indian cow urine enhances the immune status of an individual through activating the macrophages and augmenting their engulfment power as well as bactericidal activity. It is universal medicine for mankind and cures various sorts of disorders.

Cow urine contents are water 95%, urea 2.5%, minerals, salt, hormones, and enzymes-2.5%. It contains iron, calcium, phosphorus, salts, carbonic acid, potash, nitrogen, ammonia, manganese, iron, sulphor, phosphates, potassium, urea, uric acid, amino acids, enzymes, cytokine and lactose etc. It contains 24 types of salts and the medicines made from cow urine are used to cure several diseases.

Most of the medicines are made by distilling urine and collecting vapors. The ark (distillate) is useful for many diseases. A number of ailments could be treated and this therapy is being used even for dreaded diseases like cancer, AIDS, diabetes and skin problems. It is antibacterial antifungal, antiviral antineoplatcis (anticancer), anticonvulsive, antispasmodic and non-toxic.

US 2015/0004246 A1 discloses a formulation of cow urine powder and skim milk powder for the treatment of diabetes.

A cow urine distillate fraction has been identified as a bioenhancer of the activities of commonly used antibiotics, anti-fungal and anti-cancer drugs. The activity of

Rifampicin, a front-line anti-tubercular drug used against tuberculosis, increases by about 5-7 folds against E. coli and 3-11 folds against Gram-positive bacteria. Potency of 'Taxol' (paclitaxel) has been observed to get increase against MCF-7, a human breast cancer cell line in in-vitro assays (US Patent No. 6,410,059). Bio enhancement has also been observed with other drugs viz. Ampicillin, Isoniazid, Clotrimazole, Cyanocobalamine etc. Bioenhancer activity has been found to reduce the antibiotic dose per day and duration of treatment in tuberculosis patients (Joshi, 2002).

Research works carried out by Go-Vigyan Anusandhan Kendra (cow science research center) at Nagpur revealed the beneficial properties of cow urine in the treatment of cancers. Studies highlight the role of cow urine in treating cancers and that cow urine enhances the efficacy and potency of anti-cancer drugs. US patent no. 6896907 discloses a novel pharmaceutical composition comprising an effective amount of bio-active fraction from cow urine distillate as a bioavailability facilitator and pharmaceutically acceptable additives selected from anticancer compounds, antibiotics, drugs, therapeutic and nutraceutic agents, ions and similar molecules which are targeted to the living system.

The Indigenous cow urine contains "Rasayan" tatva, which is responsible to modulate immune system and act as bioenhancer. The biological activity of the cow urine needs to be explored with various other ingredients to obtain synergistic formulations to boost immune system, cure various diseases and/or to reduce the drug dosage used for various

diseases. One of the indigenous herbs, Giloy has its medicinal effects. All parts of *Tinospora Cordifolia* or Guduchi or Giloy plant are used in Ayurvedic medicine. However, the stem is thought to have the most beneficial compounds for metabolic and immune system benefits. The present invention aims to provide a therapeutic ayurvedic formulation of bioactive fraction from cow urine distillate and giloy, with other active ingredients.

OBJECT AND SUMMARY OF THE INVENTION

Accordingly, the main object of the present invention is to provide a therapeutic ayurvedic formulation of bioactive fraction from cow urine distillate and giloy.

Another object of the present invention is to provide a therapeutic ayurvedic formulation of bioactive fraction from cow urine distillate and giloy with other active ingredients depending on climate, nature of the disease, and nature of user's body.

Yet another object of the present invention is to provide a process to obtain a therapeutic ayurvedic formulation of bioactive fraction from cow urine distillate and giloy.

Yet another object of the present invention is to provide a process to obtain a therapeutic ayurvedic formulation of bioactive fraction from cow urine distillate and giloy with other active ingredients.

Accordingly, the present invention provides an ayurvedic formulation comprising of bioactive fraction from cow urine distillate and giloy, with other active ingredients.

The other ingredients are selected from, but not limited to, clove (*Syzygium aromaticum*), kesar (*Crocus sativus*), tulsi (*Ocimum tenuiflorum*). The *Syzygium aromaticum, Crocus sativus*, *Ocimum tenuiflorum* are used with bioactive fraction from cow urine distillate and giloy, either alone or in any combination as desired.

In one of the embodiments, the formulation comprises distillate obtained from 10 L cow urine and about 30 g to about 60 g giloy.

The giloy is preferably the neem giloy, which is the giloy that grows on a neem tree and said to possess the most medicinal qualities since it also absorbs neem's properties.

In an another embodiment, the formulation comprises distillate obtained from 10 L cow urine, about 30 g to about 60 g giloy, and about 3 g to about 7 g clove. The formulation comprising distillate obtained from cow urine, giloy, and clove is used to prevent and cure various diseases and to enhance immunity during hot temperatures such as during summers and monsoons.

In a further embodiment, the formulation comprises distillate obtained from 10 L cow urine, about 30 g to about 60 g giloy, about 1 g to about 2 g kesar, and about 30 g to

about 60 g tulsi. The formulation comprising distillate obtained from cow urine, giloy, kesar, and tulsi is used to prevent and cure various diseases and to enhance immunity during low temperatures such as during winters.

The formulation may be administered orally in specific doses. The formulation may be inhaled for relief in respiratory diseases.

The process to obtain the formulation of the present invention comprises the distillation of the ingredients of the formulation in specific proportion under specific reaction conditions, such as, but not limited to, specific temperature.

The formulation of the present invention inhances immunity, provide relief in respiratory distress, and helps in cure of thyroid problem, diabetes and also act as blood thinner.

DETAILED DESCRIPTION OF THE INVENTION

Those skilled in the art will be aware that the present disclosure is subject to variations and modifications other than those specifically described. It is to be understood that the present disclosure includes all such variations and modifications. The disclosure also includes all such steps, features, compositions, and compounds referred to or indicated in this specification, individually or collectively, and any and all combinations of any or more of such steps or features.

The terms “comprise” and “comprising” are used in the inclusive, open sense, meaning that additional elements may be included. It is not intended to be construed as “consists of only”.

Throughout this specification, unless the context requires otherwise the word “comprise”, and variations such as “comprises” and “comprising”, will be understood to imply the inclusion of a stated element or step or group of element or steps but not the exclusion of any other element or step or group of element or steps.

Ratios, concentrations, amounts, and other numerical data may be presented herein in a range format. It is to be understood that such range format is used merely for convenience and brevity and should be interpreted flexibly to include not only the numerical values explicitly recited as the limits of the range, but also to include all the individual numerical values or sub-ranges encompassed within that range as if each numerical value and sub-range is explicitly recited.

In a first embodiment of the present disclosure, there is provided an ayurvedic formulation comprising of distillate obtained from cow urine and bioactive fraction of neem-giloy leaves/stems.

In a second embodiment of the present disclosure, there is provided an ayurvedic formulation comprising of distillate of cow urine and bioactive fractions of neem-giloy

leaves/stems with other active ingredients depending on climate, nature of the ailment or disease, and nature of user's body.

In a third embodiment of the present disclosure, the other active ingredients are herbal ingredients selected from the clove (*Syzygium aromaticum*) flower buds, kesar (*Crocus sativus*) threads, tulsi (*Ocimum tenuiflorum*) leaves, chirayta (*Swertia Chirayita*) flowers , harad (*Terminalia chebula*) fruits, beheda (*Terminalia bellirica*) fruits, amla (*Phyllanthus emblica*) fruits, sahjan (*Moringa oleifera*) leaves, Mahalim (*Ailanthus excelsa*) leaves and kutki (*Picrorhiza kurroa*) roots.

In a fourth embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate of cow urine, and bioactive fractions from giloy leaves/stems, clove flower buds.

In a fifth embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate of cow urine, and bioactive fractions from giloy leaves/stems, tulsi leaves.

In a sixth embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate of cow urine, and bioactive fractions from giloy leaves/stems, kesar threads, tulsi leaves.

In a seventh embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate of cow urine, and bioactive fractions of giloy leaves/stems, clove flower buds, amla fruis, kesar threads, tulsi leaves, chirayta flowers, harad fruits, beheda fruits, sahjan leaves, mahalim leaves, kutki leaves.

In an eighth embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate obtained from 10 L cow urine, and bioactive fractions of herbal ingredients in a range of neem-giloy leaves/stems 4.5 g to 60 g, clove flower buds 0 to 20 g, amla fruits 0 to 20 g, kesar threads 0 to 1 g, tulsi leaves 1 to 2.25 g, chirayta (*Swertia Chirayita*) flowers 0 to 50 g, harad fruits 0 to 20 g, beheda fruits 0 to 20 g, , sahjan leaves 0 to 500 g, mahalim leaves 0 to 50 g, kutki roots 0 to 50 g.

In a nineth embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate obtained from mixture of cow urine 10 L, and neem-giloy leaves/stems 4.5 g, clove flower buds 20 g, amla fruits 20 g, kesar threads 1 g, tulsi leaves 2.250 g, chirayta flowers 50 g, harad fruits 20 g, beheda fruits 20 g, sahjan leaves 500 g , mahalim leaves 50 g and kutki roots 50 g, reduced to 0.8 to 1.2 L of distillate.

In a tenth embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate obtained from 10 L cow urine and 30 g to about 60 g neem-giloy leaves/stems.

In a eleventh embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate obtained from 10 L cow urine, 30 g to 60 g giloy leaves/stems and 20 g clove flower buds.

In a twelveth embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate obtained from 10 L cow urine, 30 g to 60 g giloy, 1 g kesar threads and 2.25 g tulsi leaves.

In a thriteenth embodiment of the present disclosure, there is provided an ayurvedic formulation comprising distillate obtained from cow urine 10 L, and bioactive fractions of neem-giloy leaves/stems 4.5 g, clove flower buds 20 g, amla fruits 20 g, kesar threads 1 g, tulsi leaves 2.250 g, chirayta flowers 50 g, harad fruits 20 g, beheda fruits 20 g, sahjan leaves 500 gm, mahalim leaves 50 g, kutki roots 50 g. The disctillate obtained is 0.8 L to 1.2 L.

The ingredients are mixed in 10 L urine and put in a covered large earthern pot. The earthen pot with cover is installed with a transparent tube for vapour outlet. Other end of the tube is attached with another covered small earthern pot put over cold water to cool the vapour and get it condensed. The large earthern pot is put over mild fire for heating and the vapour coming through the tube is collected in the small earthern pot. The vapour is allowed to collect in the small earthern pot till the time it appears clear in the tube. The quantity of distillate obtained ranges between 0.8 L to 1.2 L (approx. 1 L).

The residue in the large eartheren pot is used as organic pesticide.

The cow urine used in the formulation is obtained from Malaviya/Malvi cow breed of Rajasthan, India.

The formulation is administered orally in a therapeutically effective amount. The dose of ayurvedic formulation of the present invention for adult is 1 ml to 5 ml after diluting in water in formulation : water ratio ranging from 1:50 to 4:50, once a day to thrice a day, depending on nature and severity of ailment.

The therapeutic ayurvedic formulation exhibits therapeutic efficacy against viral fever, high cholesterol, high blood pressure, cancer, hyperthyroidism, obesity, gallstone and related disorders and acts as a blood thinner.

In an embodiment, the dose is 2 ml in 100 ml luke warm water, trice a day for 3 days in viral fever.

In another embodiment, the dose is 2 ml in 100 ml luke warm water twice a day for 1 to 2 days in stomachache.

The formulation is used to reduce the cholesterol in the blood and to decrease the excess weight.

The formulation is used as bioenhancer in combination with other drugs.

The formulation acts as blood thinner. The formulation also has bioenhancer properties in the treatment of gallstone, cancer and cardiovascular diseases.

EXAMPLES

The subjects were administered the gomutra formulation of the present invention and various parameters such as total blood count and WBC were analysed. The results are as below in Table 1:

Table 1

	Value before treatment	**Value after treatment**	Reference Range
WBC	3.6	**10.29**	**3.5-9.5**
Neutrophil%	34.6	91.9	40-75
Lymphocyte%	51.1	27.2	20-50
Monocyte%	13.3	2.6	3 to 10
Eisophils%	0.6	0	0.4-8
Basophil%	0.4	0.3	0-1
RBC mgm/L	5	5.63	3.8-5.8
HGB g/Dl	12.9	14.5	11.5-17.5
HCT%	39.7	45.2	35-50
MCV fL	79.5	80.3	82-100
MCH pg	25.8	25.8	27-34
MCHC g/Dl	32.4	32.2	31.6-35.4
RDW-CV%	13	13.4	11 to 16
RDW-SD fL	41.9	43.4	35-56
PLT mgm/L	187	192	125-350

MPV fL	11.8	14.2	6.5-12
PCT%	0.221	0.272	0.108-0.282

The data shows that the formulation of the present invention is useful in the treatment of infections and improvement of blood parameters.

The serum light chains were analysed and the data is as below in Table 2:

Table 2:

	Value before treatment	**Value after treatment**	Range
Kappa free light chain	320.77	**25.4**	**3.3-19.4**
Lambda free light chain	10.62	8.5	5.71-26.3
Kappa lambda ration	30.204	**2.9**	0.26-1.65

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Table 3. Analysis of Microglobulin:

	Value before treatment	**Value after treatment**	Range
B2 microglobulin serum	3805	**2409**	609-2366

Table 4:

Test	**After the treatment**	**Before the treatment**	**Normal range**
S. Bilirubin Total	**0.9**	2.4	0.4-1.1 mg/gl
S. Bilirubin Direct	**0.4**	0.5	0.1-0.3 mg/gl
S. Bilirubin Indirect	0.5	0.5	0.2-0.4 mg/gl
S.G.O.T.	**28.0**	56	5-36 U/L
S.G.P.T.	**31.3**	50	0-40 U/L
Alkaline P'tase	115.0	140	15-145 IU/L
Total Protein	6.9	7.5	6.5-8.4 g/dl
Albumin	3.7	4.2	3.5-5.0 g/dl
Globulin	3.2	3.9	2.3-3.6 g/dl

A/G Ratio	1:6:1	1.1	1.0-2.5:1
Urea	**38.0**	54	10-45 mg/dl
S. Creatinine	**1.33**	2.6	0.6-1.3 mg/dl

The data shows that the formulation of the present invention is useful in the treatment of liver disorders.

ADVANTAGES OF THE INVENTION

The present disclosure provides a formulation that exhibits desired therapeutic efficacy against viral fever, high cholesterol, high blood pressure, cancer, hyperthyroidism, obesity and related disorders.

The present disclosure provides a formulation that exhibits desired therapeutic efficacy against viral fever, high cholesterol, high blood pressure, cancer, hyperthyroidism and related disorders while being substantially devoid of side effects.

Bone marrow Biopsy indicates plasma cell increase by 20%.

The present disclosure provides a cost effective herbal formulatiom that exhibits desired therapeutic efficacy against viral fever, high cholesterol, high blood pressure, cancer, hyperthyroidism and related disorders.

The present disclosure provides a cost effective herbal formulation that exhibits desired therapeutic efficacy against viral fever, high cholesterol, high blood pressure, cancer, hyperthyroidism and related disorders that is easy to manufacture and can be scaled up for industrial production.

The present disclosure provides a process for preparation of a formulation that exhibits desired therapeutic efficacy against viral fever, high cholesterol, high blood pressure, cancer, hyperthyroidism and related disorders.

I claim:

1. A therapeutic ayurvedic formulation comprising distillate of cow urine, and bioactive fractions from neem-giloy leaves/stems, clove (*Syzygium aromaticum*) flower buds, amla (*Phyllanthus emblica*) fruits, kesar (*Crocus sativus*) threads, tulsi (*Ocimum tenuiflorum*) leaves, chirayta (*Swertia Chirayita*) flowers, harad (*Terminalia chebula*) fruits, beheda (*Terminalia bellirica*) fruits, sahjan (*Moringa oleifera*) leaves, mahalim (*Ailanthus excelsa*) leaves and kutki (*Picrorhiza kurroa*) roots.

2. The therapeutic ayurvedic formulation as claimed in claim 1, wherein said formulation comprises cow urine distillate in the range of 0.8 L to 1.2 L and distillate of bioactive fractions of herbal ingredients comprises in a range of neem-giloy leaves/stems 4.5 g to 60 g, clove flower buds 0 to 20 g, amla fruits 0 to 20 g, kesar threads 0 to 1 g, tulsi leaves 1 to 2.25 g, chirayta (*Swertia Chirayita*) flowers 0 to 50 g, harad fruits 0 to 20 g, beheda fruits 0 to 20 g, , sahjan leaves 0 to 500 g, mahalim leaves 0 to 50 g, kutki roots 0 to 50 g.

3. The therapeutic ayurvedic formulation as claimed in claim 1, wherein said formulation comprises distillate in the range of 0.8 L to 1.2 L obtained from 10 L cow urine and bioactive fractions of 30 g to 60 g neem-giloy leaves/stems and 1 g to 2.25 g tulsi leaves.

4. The therapeutic ayurvedic formulation as claimed in claim 1, wherein said formulation comprises distillate in the range of 0.8 L to 1.2 L obtained from 10 L cow urine, bioactive fractions of neem-giloy leaves/stems 4.5 g, clove flower buds 20 g, amla fruits 20 g, kesar threads 1 g, tulsi leaves 2.250 g, chirayta flowers 50 g, harad fruits 20 g, beheda fruits 20 g, sahjan leaves 500 g, mahalim leaves 50 g and kutki roots 50 g.

5. The therapeutic ayurvedic formulation as claimed in claim 1, wherein said formulation comprises distillate in the range of 0.8 L to 1.2 L obtained from 10 L cow urine and bioactive fractions of 30 g to 60 g neem-giloy leaves/stems and 20 g clove flower buds.

6. The therapeutic ayurvedic formulation as claimed in claim 1, wherein said formulation comprises distillate in the range of 0.8 L to 1.2 L obtained from 10 L cow urine and bioactive fractions of 30 g to 60 g neem-giloy leaves/stems, 1 g kesar threads and 2.25 g tulsi leaves.

7. The therapeutic ayurvedic formulation as claimed in claim 1, wherein said cow urine is obtained from Malaviya/Malvi cow breed.

8. A process to obtain a therapeutic ayurvedic formulation as claimed in claim 1, wherein said process comprises

- making mixture of desired quantity of herbal ingredients comprising neem-giloy leaves/stems, clove flower buds, amla fruits, kesar threads, tulsi leaves, chirayta flowers, harad fruits, beheda fruits, , sahjan leaves mahalim leaves, kutki roots in pre-determined quantity of cow urine in a large earthen pot,
- putting the large earthen pot on mild fire for heating so that vapour of the mixture is formed and passes through a connecting tube to a small earthern pot,
- collecting the vapour in the small earthern pot which is kept over cold water to cool the vapour and get it condensed to a distillate.
- collecting the distillate in bottles of inert material such as glass bottles for storage.

9. The process to obtain a therapeutic ayurvedic formulation as claimed in claim 1, wherein said desired quantity of herbal ingredients is in a range of neem-giloy leaves/stems 4.5 g to 60 g, clove flower buds 0 to 20 g, amla fruits 0 to 20 g, kesar threads 0 to 1 g, tulsi leaves 1 to 2.25 g, chirayta (*Swertia Chirayita*) flowers 0 to 50 g, harad fruits 0 to 20 g, beheda fruits 0 to 20 g, , sahjan leaves 0 to 500 g, mahalim leaves 0 to 50 g, kutki roots 0 to 50 g and pre-determined quantity of cow urine is 10 L.

10. The therapeutic ayurvedic formulation as claimed in claim 1, wherein said formulation is administered in a therapeutically effective amount after diluting in

water in formulation : water ratio ranging from 1:50 to 4:50 and exhibits therapeutic efficacy against viral fever, high cholesterol, high blood pressure, cancer, hyperthyroidism, obesity, gallstone and related disorders and acts as a blood thinner.

Dated this the 6th day of September 2022.



Dr. Bharti Jain

IN/PA-1507

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To

The Controller of Patents

The Patent Office, Delhi

ABSTRACT

A THERAPEUTIC AYURVEDIC FORMULATION AND PROCESS THEREOF

The invention discloses a therapeutic ayurvedic formulation comprising distillate of cow urine, and bioactive fractions from neem-giloy leaves/stems, clove (*Syzygium aromaticum*) flower buds, amla (*Phyllanthus emblica*) fruits, kesar (*Crocus sativus*) threads, tulsi (*Ocimum tenuiflorum*) leaves, chirayta (*Swertia Chirayita*) flowers, harad (*Terminalia chebula*) fruits, beheda (*Terminalia bellirica*) fruits, sahjan (*Moringa oleifera*) leaves, mahalim (*Ailanthus excelsa*) leaves and kutki (*Picrorhiza kurroa*) roots.