

***A Novel formulation for anticancer Drug***

I claim,

1. A novel formulation for anticancer drug for treating chromosomal aberration comprising Ursolic acid,  $\beta$  sitosterol and sitosterol 3 O glucoside
2. The formulation as claimed in 1, wherein the purity of commercial ursolic acid is  $\geq 90\%$
3. The formulation as claimed in 1, wherein the purity of commercial  $\beta$  sitosterol is  $\geq 95\%$
4. The formulation as claimed in 1, wherein the commercial sitosterol 3 O glucoside used were analytical standard
5. The formulation as claimed in 1, wherein the wt. percentage of Ursolic acid 16.66-49.98%.
6. The formulation as claimed in 1, wherein the wt. percentage of  $\beta$  sitosterol 16.66-49.98%.
7. The formulation as claimed in 1, wherein the wt. percentage of sitosterol 3 O glucoside 16.66-49.98%.

  
Signature :

Name :MAHUYA HOM CHOWDHURY

IN/PA502

**Field of Invention:** The present invention relates to a new formulation of a potent anti-cancer drug with active molecules viz. ursolic acid, beta sitosterol and sitosterol-3-O-glucoside.

**Background of the Invention:**

**Cancer** is a multifaceted disease characterized by an increase in the number of abnormal cells derived from a given normal tissue, with these cells typically invading adjacent tissues, or metastasizing by spreading through the blood to other regions of the body. **Cancer** typically progresses through a multistep process that begins with minor preneoplastic changes, which may progress to neoplasia, the neoplastic lesions possibly developing an increasing capacity for invasion, growth, metastasis, and heterogeneity.

There is an enormous variety of cancers, with examples including **cancer** of the lung, colon, rectum, prostate, breast, brain, and intestine. The incidence of **cancer** continues to climb as the general population ages, as new cancers develop, and as susceptible populations grow. A tremendous demand exists for new methods and compositions that can be used to treat patients with **cancer**.

As a one specific example, most men will in their lifetime experience problems that stem from diseases in their prostate. Malignancies of the prostate gland are the most common form of **cancer** to occur among men in the United States, affecting over 180,000 men.

Current therapy may involve surgery, chemotherapy, hormonal therapy and/or radiation treatment to eradicate neoplastic cells in a patient. Other therapies involve biological therapy or immunotherapy. All of these approaches pose significant drawbacks for the patient. Surgery, for example, may be contraindicated due to the health of a patient or may be unacceptable to the patient. Additionally, surgery may not completely remove neoplastic tissue. Radiation therapy is only effective when the neoplastic tissue exhibits a higher sensitivity to radiation than normal tissue. Radiation therapy can also often elicit serious side effects. Hormonal therapy is rarely given as a single agent. Although

hormonal therapy can be effective, it is often used to prevent or delay recurrence of *cancer* after other treatments have removed the majority of *cancer* cells. Biological therapies and immunotherapies are limited in number and may produce side effects such as rashes or swellings, flu-like symptoms, including fever, chills and fatigue, digestive tract problems or allergic reactions.

Cancer is a life threatening disease, and is the cause of death of millions of people all over the globe. According to the World Health Organization, in 2008 approximately 7.6 million people died worldwide due to cancer and it was the leading cause of death worldwide accounting to 8.2 million in 2012.

Tumors may be caused by conditions other than an overgrowth of neoplastic cells, however. Cysts (such as sebaceous cysts) are also referred to as tumors, even though they have no neoplastic cells. A neoplasm can be caused by an abnormal proliferation of tissues, which can be caused by genetic mutations. Not all types of neoplasms cause a tumorous overgrowth of tissue. Various ionizing radiations as X-ray,  $\gamma$ -rays etc have been reported to cause chromosomal aberrations leading to cancer. There are different chemical and pharmacological treatment in this field to cure. Nowadays different medicinal plant extract is used for different type of disease treatment.

One major risk for gamma radiation has also been reported for the period 1950-69 where 231 cases of breast cancer were identified among 63,275 female atomic bomb survivors and nonexposed controls; 187 were among survivors for whom dose estimates were available. The estimated absolute risk per rad was 1.9 excess cases per 10<sup>sup</sup> 6/ person-years at risk over this period for women who were 10 years old or older at the time of bombing (ATB), substantially less than published estimates largely based on X-ray and fluoroscopy data from smaller samples of younger North American women. An identifiable radiation effect was evident before 1955. Exposed to high or medium doses were experiencing a much greater excess of breast cancer than was observed in women.

( Ref: McGregor, D.H. (Radiation Effects Research Foundation, Hiroshima); Land, C.E.; Choi, K.; Tokuoka, S.; Liu, P.I.; Wakabayashi, T.; Beebe, G.W.) .

Thus, mutagenesis, tumour and gamma radiationis is of today's major concern for scientific research. However no data has been reported till date to use plant extract for curing above three major diseases.

Ursolic acid is a kind of organic acid, which could be widely found in a variety of plants. It is recently proved that the ursolic acid is effective for inhibiting cancers, inflammations, and some sorts of genes in therapeutic applications.

Nowadays, the pharmacological action of the ursolic acid is still limited on the researching stage. That is to say, there is no mature and effective pharmaceutical formation had been unveiled into the market. In China, some researchers had applied a patent application about the ursolic acid medicine which could be formed in tablet, capsule, injection, oral liquid and so on, the application could be indexed with an application No. 99126892-X. Unfortunately, the water solubility of such ursolic acid was far from satisfaction for most users. With such poor water solubility, it was rather difficult to be absorbed by human body. In short, the application of the ursolic acid was only concentrated on normal raw form of such acid, there is no nanometer scale ursolic acid had been referred or introduced internationally.

$\beta$  sitosterol is one of the phytosterols that has structure similar to cholesterol. It is a white waxy powder with a characteristic odor. It is widely available in varieties of plants and plant parts as *Nigella sativa*, *Serenoa repens* (saw palmetto), avocados, *Pygeum africanum*, cashew fruit, rice bran, *Cucurbita pepo* (pumpkin seed), wheat germ, corn oils, soybeans, sea-buckthorn and *Wrightia tinctoria* etc. This sterol is used in the treatment of benign prostatic hyperplasia (BPH) and prostatic carcinoma.

Sitosterol-3-O-glucoside is present in extract of roots of *Senecio bonariensis*. Methanolic extracts of seeds of *Ceratonia siliqua* L. has a rich source of natural anti oxidants, which contains  $\beta$  sitosterol-3-O-glucoside.

However, None of the prior art attempts, individually or collectively, proposed the system and embodiments indicated and disclosed by the present invention.

To achieve the foregoing and, and in accordance with the purposes of the present invention, as embodied and broadly described herein, the present invention provides a formulation of anticancer drug.

#### **Object of the invention:**

The object of the present invention is to provide a novel formulation of anticancer drug

Another objective of the present invention is to provide a potent drug for cancer

Further Objective of the present invention is to provide a cost effective formulation of anticancer drug.

#### **Summary of the invention**

To achieve the foregoing and in accordance with the purposes of the present invention, as embodied and broadly described herein, the present invention provides a novel formulation using ursolic acid, beta sitosterol and sitosterol-3-O-glucoside.

The process involves formulation of the ursolic acid, beta sitosterol and sitosterol-3-O-glucoside in definite weight percentage and treating the patients and identified the effective decrease in chromosomal aberration.

#### **Detailed Description of the invention**

The present invention is concerned with the formulation of an anticancer drug Ursolic acid ( $\geq 90\%$ ) (Fig (iv)), beta sitosterol (synthetic  $\geq 95\%$ ) (Fig (v)) and sitosterol 3 O glucoside (analytical standard) (Fig (vi)) were all purchased from Sigma-Aldrich®. They were mixed in five different proportions each in a suitable solvent containing Water for Injections

The present invention is now demonstrated in the following example, which are intended as illustrative only, since numerous modifications and variations will be apparent to those skilled in the art. More particularly, the invention can be demonstrated by way of illustrative non limiting examples. The following specific examples will serve further to illustrate the practice and advantages of this invention.

Preparation & Formulation of the Drug

Table (i): Five different proportions of the active ingredients mixed in Water For Injections IP in each case.

SI No	Proportions	Ursolic Acid	Beta sitosterol	Sitosterol-3-O glucoside
1	Proportion A	1 Part	1 Part	1 Part
2	Proportion B	1 Part	2 Parts	3 Parts
3	Proportion C	2 Parts	3 Parts	1 Part
4	Proportion D	3 Parts	2 Parts	1 Parts
5	Proportion E	3 Parts	1 Part	2 Parts

Treatment of the formulations to patients

In this case control study, 5 different patients (average age 65 years, male) diagnosed with squamous cell carcinoma of lungs (both right and left lungs) were treated with the five different proportions A, B, C, D and E, while the same number of individuals served as control. The patients showed the symptoms of hemoptysis of 13-14 times per day (average), severe respiratory distress and gradual weight loss. Biopsy of lungs tissue revealed nests of polygonal cells and airways in between the tissues confirming carcinogenesis. Also, cells stacking together giving rise to non small cell lung cancer is prominent in the slides indicating squamous cell carcinoma of the lungs (Fig (i)). It was a randomized,

non-placebo treatment. The compositions were administered twice daily orally postprandialy. After approximately four months of treatment, hemoptysis decreased to once in alternate day, respiratory distress was much less and weight was also gained (from average 40 kg to average 60 kg), and among all the proportions, Proportion D (ursolic acid: beta sitosterol: sitosterol 3 O glucoside-3:2:1) was found to be the most effective composition. Tissue biopsy disclosed that the cells were normal in size, indicating cure (Fig (ii)). Besides biopsy, mutagenesis was enumerated in terms of chromosomal aberrations of the patients and percentage chromosomal aberration was also calculated (Table (ii), Fig (iii)).

Table (ii): Chromosomal aberrations of the patients before and after treatment

Sl No.	Proportions	% chromosomal aberrations before treatment	% chromosomal aberrations after treatment
1	Proportion A	66.28%	50.22% (decrease in 16.06%)
2	Proportion B	66.28%	49.26% (decrease in 17.02%)
3	Proportion C	66.28%	40.16% (decrease in 26.12%)
4	Proportion D	66.28%	30.32% (decrease in 35.96%)
5	Proportion E	66.28%	43.11% (decrease in 23.17%)

The formulation can be part or all of any device that can deliver a drug, including pills, capsules, gels, depots, medical implantable devices (e.g., stents, including self-expanding stents, balloon-expandable stents, drug-eluting stents and stent-grafts, grafts (e.g., aortic grafts), artificial heart valves, cerebrospinal fluid shunts, pacemaker electrodes, endocardial leads, bioerodable implants and the like), and externally manipulated devices (e.g. drug devices and catheters, including catheters which can release a drug, e.g. as a

result of heating the tip of the catheter). The formulation may be, for example, a liquid, a suspension, a solid (such as a tablet, pill, and capsule, including a microcapsule), emulsion, micelle, ointment, gel, emulsion, depot (including a subcutaneously implanted depot), or coating on an implanted device, e.g. a stent or the like.

The term "drug" means a material which is biologically active in a human being or other mammal, locally and/or systemically. Examples of drugs are disclosed in the Merck Index, the Physicians Desk Reference, and in column 11, line 16, to column 12, line 58, of U.S. Pat. No. 6,297,337, and in paragraph 0045 of US 2003/0224974, the entire disclosures of which are incorporated by reference herein for all purposes. Drugs can for example be substances used for the treatment, prevention, diagnosis, cure or mitigation of a disease or illness, including vitamins and mineral supplements; substances which affect the structure or the function of a mammal; pro-drugs, which are substances which become biologically active or more active after they have been placed in a physiological environment; and metabolites of drugs. Examples of diagnostic agents are imaging agents containing radioisotopes, contrasting agents containing for example iodine, enzymes, fluorescent substances and the like.

The formulation of this invention may also contain suitable additives. These additives can be included in the formulation at any stage of the preparation of the formulation. The desired concentrations of the additives in the formulation for conferring the intended effect, as recognized by those skilled in the art, can be assayed using conventional methods.

#### **Brief Description of the Drawing:**

Other objects, features and advantages of the inventions are described from the following description of a preferred embodiment and the accompanying drawings, in which:

Fig.1: Squamous Cell Carcinoma of lungs

Fig 2: Healthy cells indicating cure

Fig. 3: Graphical representation of Chromosomal aberrations of the patients before and after treatment

Fig.4: Structure of ursolic acid



Fig.5 : Structure of  $\beta$  sitosterol

Fig.6: Structure of Sitosterol-3-O-glucoside

The present invention is further elaborately explained with reference to some specific non-limiting examples:

#### EXAMPLES

The following examples are given by way of illustration of the present invention and should not be construed to limit the scope of present invention.

#### Example 1

Ursolic Acid-1 part i.e 33%

Beta sitosterol-1part i.e 33%

Sitosterol-3-O glucoside-1part i.e 33%

% chromosomal aberrations before treatment	% chromosomal aberrations after treatment
66.28%	50.22% ( decrease in 16.06%)

#### Example 2:

Ursolic Acid-1 part i.e 16.66%

Beta sitosterol-2part i.e 33%

Sitosterol-3-O glucoside-3 part i.e 49.98%

% chromosomal	% chromosomal
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aberrations before treatment	aberrations after treatment
66.28%	49.26% (decrease in 17.02%)

Example 3:

Ursolic Acid-2 part i.e 33%

Beta sitosterol-3 part i.e 49.98%

Sitosterol-3-O glucoside-1 part i.e 16.66%

% chromosomal aberrations before treatment	% chromosomal aberrations after treatment
66.28%	40.16% (decrease in 26.12%)

Example 4:

Ursolic Acid-3 part i.e 49.98%

Beta sitosterol-2 part i.e 33%

Sitosterol-3-O glucoside-1 part i.e 16.66%

% chromosomal aberrations before treatment	% chromosomal aberrations after treatment
66.28%	30.32% (decrease in 35.96%)

The most effective and potent combination as per decrease in chromosomal aberration result.

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Example 5:

Ursolic Acid-3 part i.e 49.98%

Beta sitosterol-1 part i.e 16.66%

Sitosterol-3-O glucoside-2 part i.e 33%

% chromosomal aberrations before treatment	% chromosomal aberrations after treatment
66.28%	43.11% ( decrease in 23.17%)

The present invention has been described with reference to some preferred embodiments and examples revealing experimental data, purely for the sake of understanding the performance of the invention and not by way of any sort of limitation and it is clarified explicitly that the present invention includes all legitimate developments/modifications within the ambit of the description as hereinbefore and the claims as appended hereinafter.

Different embodiments of the invention are possible to achieve the best method of performance. It will be understood that the invention may be carried out into practice by skilled persons with many modifications, variations and adaptations without departing from its spirit or exceeding the scope of claims in describing the invention for the purpose of illustration. Following claim describes the invention

**ABSTRACT**

The present invention relates to a new formulation of a potent anti-cancer drug with active molecules viz. ursolic acid, beta sitosterol and sitosterol-3-O-glucoside.



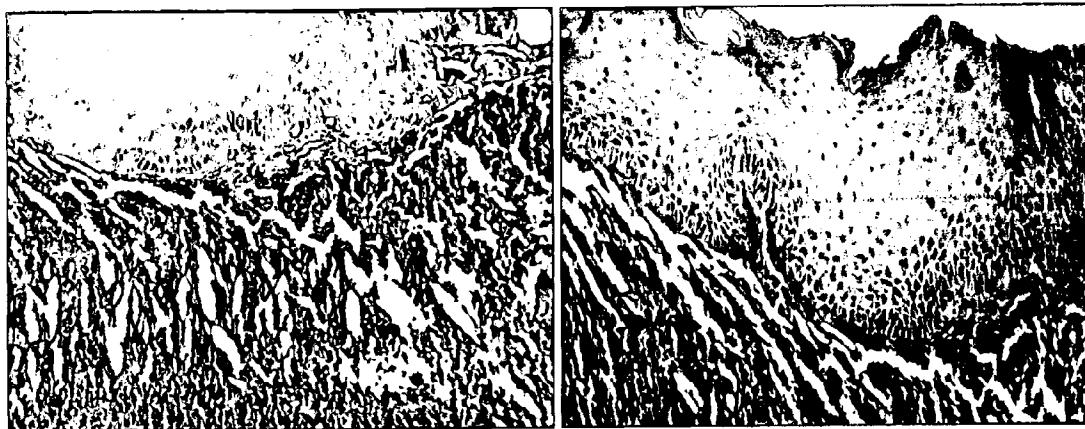
Mahuya Hom Choudhury

Applicant's Agent

(IN/PA/502)

**Annexure I**

**Drawings**



Nests of polygonal cells and airways in between the tissues   Cells stacking together giving raise to non small cell lung cancer

Fig (i): Squamous Cell Carcinoma of lungs

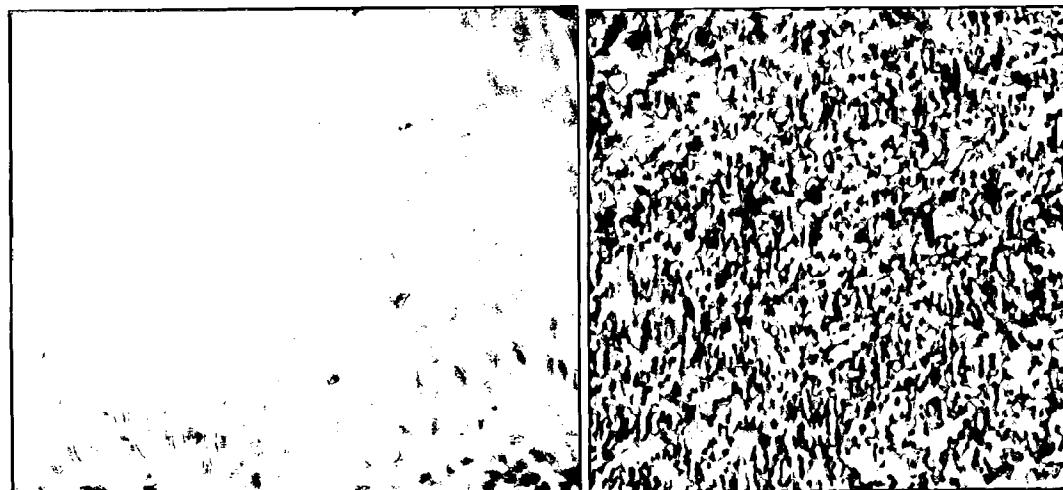


Fig (ii): Healthy cells indicating cure

A handwritten signature in black ink, enclosed in a circle. The signature appears to read 'Dr. Pranab Kumar Das'.

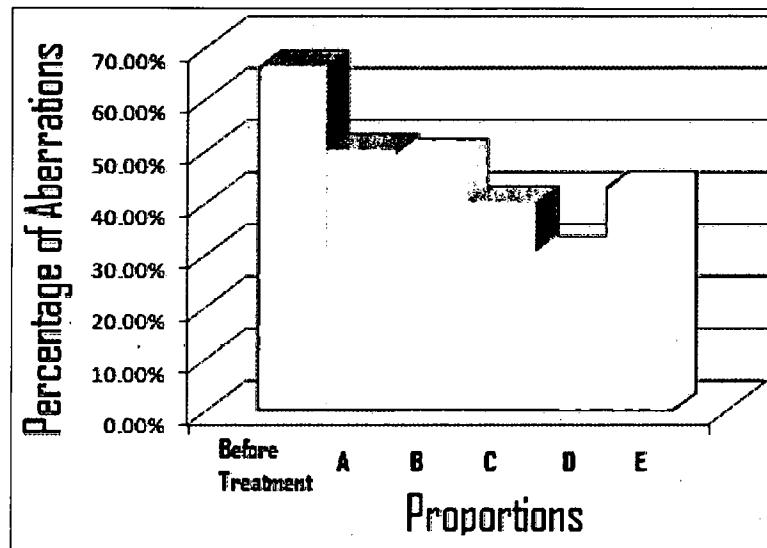


Fig (iii): Graphical representation of Chromosomal aberrations of the patients before and after treatment.

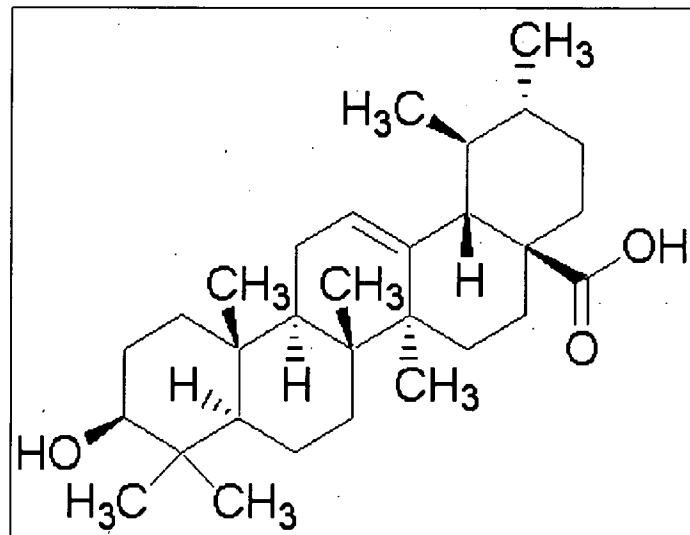


Fig (iv): Structure of ursolic acid

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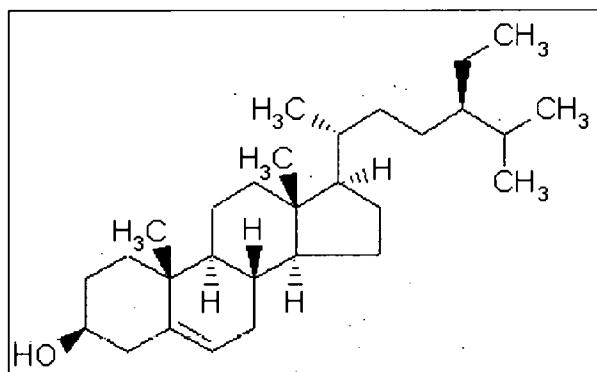
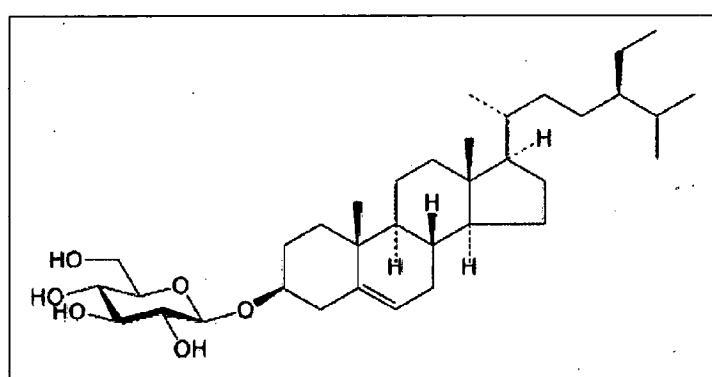


Fig (v): Structure of  $\beta$  sitosterol



**Fig (vi): Structure of Sitosterol-3-O-glucoside**

 Mahuya Hom Choudhury

**Applicant's Agent**

(IN/PA/502)

**THE PATENTS ACT 1970**

**COMPLETE SPECIFICATION**  
**(See section 10 and rule 13)**

**TITLE OF THE INVENTION**

*A Novel formulation for anticancer Drug*

**APPLICANT**

Dr. Pranab Kumar Das

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

**Field of Invention:** The present invention relates to a new formulation of a potent anti-cancer drug with active molecules viz. ursolic acid, beta sitosterol and sitosterol-3-O-glucoside.

**Background of the Invention:**

**Cancer** is a multifaceted disease characterized by an increase in the number of abnormal cells derived from a given normal tissue, with these cells typically invading adjacent tissues, or metastasizing by spreading through the blood to other regions of the body. **Cancer** typically progresses through a multistep process that begins with minor preneoplastic changes, which may progress to neoplasia, the neoplastic lesions possibly developing an increasing capacity for invasion, growth, metastasis, and heterogeneity.

There is an enormous variety of cancers, with examples including **cancer** of the lung, colon, rectum, prostate, breast, brain, and intestine. The incidence of **cancer** continues to climb as the general population ages, as new cancers develop, and as susceptible populations grow. A tremendous demand exists for new methods and compositions that can be used to treat patients with **cancer**.

As a one specific example, most men will in their lifetime experience problems that stem from diseases in their prostate. Malignancies of the prostate gland are the most common form of **cancer** to occur among men in the United States, affecting over 180,000 men.

Current therapy may involve surgery, chemotherapy, hormonal therapy and/or radiation treatment to eradicate neoplastic cells in a patient. Other therapies involve biological therapy or immunotherapy. All of these approaches pose significant drawbacks for the patient. Surgery, for example, may be contraindicated due to the health of a patient or may be unacceptable to the patient. Additionally, surgery may not completely remove neoplastic tissue. Radiation therapy is only effective when the neoplastic tissue exhibits a higher sensitivity to radiation than normal tissue. Radiation therapy can also often elicit serious side effects. Hormonal therapy is rarely given as a single agent. Although hormonal therapy can be effective, it is often used to prevent or delay recurrence of **cancer** after other treatments have removed the majority of **cancer** cells. Biological

therapies and immunotherapies are limited in number and may produce side effects such as rashes or swellings, flu-like symptoms, including fever, chills and fatigue, digestive tract problems or allergic reactions.

Cancer is a life threatening disease, and is the cause of death of millions of people all over the globe. According to the World Health Organization, in 2008 approximately 7.6 million people died worldwide due to cancer and it was the leading cause of death worldwide accounting to 8.2 million in 2012.

Tumors may be caused by conditions other than an overgrowth of neoplastic cells, however. Cysts (such as sebaceous cysts) are also referred to as tumors, even though they have no neoplastic cells. A neoplasm can be caused by an abnormal proliferation of tissues, which can be caused by genetic mutations. Not all types of neoplasms cause a tumorous overgrowth of tissue. Various ionizing radiations as X-ray,  $\gamma$ -rays etc have been reported to cause chromosomal aberrations leading to cancer. There are different chemical and pharmacological treatment in this field to cure. Nowadays different medicinal plant extract is used for different type of disease treatment.

One major risk for gamma radiation has also been reported for the period 1950-69 where 231 cases of breast cancer were identified among 63,275 female atomic bomb survivors and nonexposed controls; 187 were among survivors for whom dose estimates were available. The estimated absolute risk per rad was 1.9 excess cases per 10<sup>sup</sup> 6/ person-years at risk over this period for women who were 10 years old or older at the time of bombing (ATB), substantially less than published estimates largely based on X-ray and fluoroscopy data from smaller samples of younger North American women. An identifiable radiation effect was evident before 1955. Exposed to high or medium doses were experiencing a much greater excess of breast cancer than was observed in women.

( Ref: McGregor, D.H. (Radiation Effects Research Foundation, Hiroshima); Land, C.E.; Choi, K.; Tokuoka, S.; Liu, P.I.; Wakabayashi, T.; Beebe, G.W.) .

Thus, mutagenesis, tumour and gamma radiation is of today's major concern for scientific research. However no data has been reported till date to use plant extract for curing above three major diseases.

Ursolic acid is a kind of organic acid, which could be widely found in a variety of plants. It is recently proved that the ursolic acid is effective for inhibiting cancers, inflammations, and some sorts of genes in therapeutic applications.

Nowadays, the pharmacological action of the ursolic acid is still limited on the researching stage. That is to say, there is no mature and effective pharmaceutical formation had been unveiled into the market. In China, some researchers had applied a patent application about the ursolic acid medicine which could be formed in tablet, capsule, injection, oral liquid and so on, the application could be indexed with an application No. 99126892-X. Unfortunately, the water solubility of such ursolic acid was far from satisfaction for most users. With such poor water solubility, it was rather difficult to be absorbed by human body. In short, the application of the ursolic acid was only concentrated on normal raw form of such acid, there is no nanometer scale ursolic acid had been referred or introduced internationally.

$\beta$  sitosterol is one of the phytosterols that has structure similar to cholesterol. It is a white waxy powder with a characteristic odor. It is widely available in varieties of plants and plant parts as *Nigella sativa*, *Serenoa repens* (saw palmetto), avocados, *Pygeum africanum*, cashew fruit, rice bran, *Cucurbita pepo* (pumpkin seed), wheat germ, corn oils, soybeans, sea-buckthorn and *Wrightia tinctoria* etc. This sterol is used in the treatment of benign prostatic hyperplasia (BPH) and prostatic carcinoma.

Sitosterol-3-O-glucoside is present in extract of roots of *Senecio bonariensis*. Methanolic extracts of seeds of *Ceratonia siliqua* L. has a rich source of natural anti oxidants, which contains  $\beta$  sitosterol-3-O-glucoside.

However, none of the prior art attempts, individually or collectively, proposed the system and embodiments indicated and disclosed by the present invention.

To achieve the foregoing and, and in accordance with the purposes of the present invention, as embodied and broadly described herein, the present invention provides a formulation of anticancer drug.

## **Object of the invention:**

The object of the present invention is to provide a novel formulation of anticancer drug

Another objective of the present invention is to provide a potent drug for cancer

Further Objective of the present invention is to provide a cost effective formulation of anticancer drug.

## **Summary of the invention**

To achieve the foregoing and in accordance with the purposes of the present invention, as embodied and broadly described herein, the present invention provides a novel formulation using ursolic acid, beta sitosterol and sitosterol-3-O-glucoside.

The process involves formulation of the ursolic acid, beta sitosterol and sitosterol-3-O-glucoside in definite weight percentage and treating the patients and identified the effective decrease in chromosomal aberration.

## **Detailed Description of the invention**

The present invention is concerned with the formulation of an anticancer drug Ursolic acid ( $\geq 90\%$ ) (Fig (iv)), beta sitosterol (synthetic  $\geq 95\%$ ) (Fig (v)) and sitosterol 3 O glucoside (analytical standard) (Fig (vi)) were all purchased from Sigma-Aldrich®. They were mixed in five different proportions each in a suitable solvent containing Water for Injections IP

The present invention is now demonstrated in the following example, which are intended as illustrative only, since numerous modifications and variations will be apparent to those skilled in the art. More particularly, the invention can be demonstrated by way of illustrative non limiting examples. The following specific examples will serve further to illustrate the practice and advantages of this invention.

## **EXAMPLES**

The following examples are given by way of illustration of the present invention and

should not be construed to limit the scope of present invention.

**Example:1**

**In preferred embodiment,**

Preparation & Formulation of the Drug

Table (i): Five different proportions of the active ingredients mixed in Water For Injections IP in each case.

Sl No	Proportions	Ursolic Acid	Beta sitosterol	Sitosterol-3-O glucoside
1	Proportion A	1 Part	1 Part	1 Part
2	Proportion B	1 Part	2 Parts	3 Parts
3	Proportion C	2 Parts	3 Parts	1 Part
4	Proportion D	3 Parts	2 Parts	1 Parts
5	Proportion E	3 Parts	1 Part	2 Parts

Treatment of the formulations to patients

In this case control study, 5 different patients (average age 65 years, male) diagnosed with squamous cell carcinoma of lungs (both right and left lungs) were treated with the five different proportions A, B, C, D and E, while the same number of individuals served as control. The patients showed the symptoms of hemoptysis of 13-14 times per day (average), severe respiratory distress and gradual weight loss. Biopsy of lungs tissue revealed nests of polygonal cells and airways in between the tissues confirming carcinogenesis. Also, cells stacking together giving rise to non small cell lung cancer is prominent in the slides indicating squamous cell carcinoma of the lungs (Fig (i)). It was a randomized, non-placebo treatment. The compositions were administered twice daily orally postprandialy. After approximately four months of treatment, hemoptysis decreased to once in alternate day, respiratory distress was much less and weight was also gained (from average 40 kg to average 60 kg), and among all the proportions, Proportion D (ursolic acid: beta sitosterol: sitosterol 3 O glucoside- 3:2:1) was found to be the most effective composition. Tissue biopsy disclosed

that the cells were normal in size, indicating cure (Fig (ii)). Besides biopsy, mutagenesis was enumerated in terms of chromosomal aberrations of the patients and percentage chromosomal aberration was also calculated (Table (ii), Fig (iii)).

Table (ii): Chromosomal aberrations of the patients before and after treatment

<b>Sl No.</b>	<b>Proportions</b>	<b>% chromosomal aberrations before treatment</b>	<b>% chromosomal aberrations after treatment</b>
1	Proportion A	66.28%	50.22% (decrease in 16.06%)
2	Proportion B	66.28%	49.26% (decrease in 17.02%)
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5	Proportion E	66.28%	43.11% (decrease in 23.17%)

The formulation can be part or all of any device that can deliver a drug, including pills, capsules, gels, depots, medical implantable devices (e.g., stents, including self-expanding stents, balloon-expandable stents, drug-eluting stents and stent-grafts, grafts (e.g., aortic grafts), artificial heart valves, cerebrospinal fluid shunts, pacemaker electrodes, endocardial leads, bioerodabile implants and the like), and externally manipulated devices (e.g. drug devices and catheters, including catheters which can release a drug, e.g. as a result of heating the tip of the catheter). The formulation may be, for example, a liquid, a suspension, a solid (such as a tablet, pill, and capsule, including a microcapsule), emulsion, micelle, ointment, gel, emulsion, depot (including a subcutaneously implanted depot), or coating on an implanted device, e.g. a stent or the like.

The formulation of this invention may also contain suitable additives. These additives can be included in the formulation at any stage of the preparation of the formulation. The desired concentrations of the additives in the formulation for conferring the intended effect, as recognized by those skilled in the art, can be assayed using conventional methods.

**Brief Description of the Drawing:**

Other objects, features and advantages of the inventions are described from the following description of a preferred embodiment and the accompanying drawings, in which:

Fig.1: Squamous Cell Carcinoma of lungs

Fig 2: Healthy cells indicating cure

Fig. 3: Graphical representation of Chromosomal aberrations of the patients before and after treatment

Fig.4: Structure of ursolic acid

Fig.5 : Structure of  $\beta$  sitosterol

Fig.6: Structure of Sitosterol-3-O-glucoside

Different embodiments of the invention are possible to achieve the best method of performance and to obtain the effective nano composite. It will be understood that the invention may be carried out into practice by skilled persons with many modifications, variations and adaptations without departing from its spirit or exceeding the scope of claims in describing the invention for the purpose of illustration. Following claim describes the invention

I claim,

1. A novel formulation for anticancer drug for treating chromosomal aberration comprising Ursolic acid,  $\beta$  sitosterol and sitosterol 3 O glucoside
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3. The formulation as claimed in 1, wherein the purity of commercial  $\beta$  sitosterol is  $\geq 95\%$
4. The formulation as claimed in 1, wherein the commercial sitosterol 3 O glucoside used were analytical standard
5. The formulation as claimed in 1, wherein the wt. percentage of Ursolic acid 16.66-49.98%.
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## **ABSTRACT**

The present invention relates to a new formulation of a potent anti-cancer drug with active molecules viz. ursolic acid, beta sitosterol and sitosterol-3-O-glucoside.

  
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