METHOD OF PREPARING A DRY POWDER FROM A WATER BACTERIA EXTRACT-CONCENTRATE

A method to produce a dry powder cancer treatment substance from a cultured bacterial growth in water includes the steps of culturing a desired bacterial growth in a solvent to produce a bacterial mass, which is then homogenized to a homogenate. Solid particulates are then removed from the homogenate by passing the homogenate through a first filter. The filtered homogenate is collected and filtered through a second filter to remove high molecular weight chemicals from the solution. The homogenate is concentrated by separating the solvent from the homogenate yielding an extract to increase the solids content and produce a concentrated homogenate. The concentrated homogenate is dried to evaporate remaining solvent and transform the concentrated homogenate to a powder. The powder is encapsulated in individual capsules, which in turn are packaged in blister packs.
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CROSS-REFERENCE TO RELATED APPLICATIONS

This PCT application claims the benefit of co-pending United States Provisional Patent Application Serial No. 61/388,304, filed on 30 September, 2010.

BACKGROUND OF THE INVENTION

Technical Field

The present disclosure generally relates to apparatuses and methods for producing a dry powder from a water bacteria concentration. More particularly, the present disclosure relates to a method of producing a dry powder cancer treatment substance from a cultured bacterial growth in water.

Background Art

Cancer in all of its various forms has been an ever-increasing health problem to millions of people worldwide. Over the past century we have witnessed a seemingly ever rising incidence of the dreaded disease with new treatments being regularly introduced in attempts to provide a cure or at least drive the cancers into remission. Health professionals and researchers have continually viewed cancer as a disease and have directed their research and curative effort along the lines of traditional disease prevention and treatment.

Specifically, the model that these professionals use it that of: (1) First determining the cause of the disease, assuming that there is a traditional cause and effect relationship. Namely, that there is present in the environment a direct cause of the cancer or that a genetic abnormality may be an inducing factor in the genesis of the cancer onset. (2) Next the introduction of an outside force into the body to destroy
the cause. This is typically accomplished by the administration of chemicals such as those used in current chemotherapy, or by means of gene modification. Finally, (3) the health professionals help the patient’s body to overcome the disease. This can be accomplished through further chemical therapy to counteract the side effects of the chemotherapy, through nutrition, or physical therapy. Most typically, a combination of all three is employed to help the patient to recovery. Yet, at the conclusion the cancer is not considered cured, just in remission with periodic monitoring to determine its status over time.

Thus, the possibility exists that effective treatment and curing of cancer may not follow the protocol of the above-described model for treating other known diseases, but may require an alternate treatment protocol. In establishing a new protocol, the characteristics of the cancer must be taken into consideration and the protocol must be optimized to those characteristics. The characteristics of cancer are best evaluated in light of human evolution as a cause of cancer. Human evolution is an ongoing process and has never ceased. Cancer is an uncontrolled growth of anaerobic tissue (i.e. tissue that does not need oxygen to live and grow) and that is why killing cancer tissue is so difficult. Most of our pharmaceutically based treatments build on deprivation of oxygen to the diseased tissue or to infecting bacteria with reason to kill it. However, cancer does not require oxygen and thus effectively makes the cancer indestructible. Further, cancer tissue has a barrier that prohibits our immune system from recognizing the cancer as a foreign body and therefore the immune system’s ability to kill the cancer.

Early in the 20th Century, the French scientist L. Cenot published the “Theory of Ppreadaptation.” In this theory, adaptation is not developed by natural selection or functional mutation as taught by Darwinian evolutionary theory. Ppreadaptation Theory postulates that adaptation characteristics already exist as a characteristic of the organism, and that those organism characteristics are merely awaiting certain conditions to surface and manifest themselves in the organism. Ppreadaptation is an anatomical structure, physiological process, or behavior pattern in an organism that is by chance highly suited to a new habitat to which the organism migrates or that improves the chance of organism survival following a change in environmental conditions such as the development of lungs in an organism when moving from an
aquatic environment to one of dry land. Thus, the implication is that all life forms have the prerequisite genetic material necessary to insure survival in future generations when changes in the external environment threaten the organism's existence.

One such change is the oxygen concentration in the earth's atmosphere. During the past 600 million years (the Phanerozoic period) the concentration of atmospheric oxygen has been increasing. However, the increase has not been linear and in periods of low oxygen there were concurrent periods of mass extinction. The extinction wasn't directly caused by hypoxia due to the gradual disappearance of oxygen, but rather by the inability of some organisms to adapt to the directional changes in oxygen concentrations. The specific level of oxygen in the atmosphere is not an issue because the concentration varies from approximately 15% at the North Pole to 23% at the equator. The real issue is the up or down trend of oxygen over time because cells react according to the trend by initializing Preadaptational mechanisms that in some cases may look like diseases. As a result of an increasing ratio of human population to photosynthesis masses and as a result of increased oxygen consumption from energy conversion (i.e. burning of fossil fuels) the current trend is now a reduction of atmospheric oxygen. Thus, the future of earth is one trending more and more anaerobic.

With the future trending to anaerobic, for an organism to survive, living tissues in the distant future will carry many of the same characteristics as the anaerobic tissue found in the cancer tissues that we experience in the present as a lethal illness. Therefore, in reality, today's deadly cancer tissue found in our bodies is as though we have advanced many years into the future in adaptation to an anaerobic environment. In the future, cancer-like tissue will be normal and subject to regulation by our body's immune system. The only way to treat this kind of aberration is to signal the tissue that the future has already come in the present. This will stop the aggression of the cancer tissue and allow our immune system to destroy it. Therefore, the means to fight cancer is by introducing a medicine to trick the cancer that time and evolution has progressed to an anaerobic environment and is thus subject to the body's immune system.
Therefore, a medicine to signal the cancer tissue that it is in an anaerobic environment and subject to regulation by the body’s immune system and a method of producing the medicine is needed.
DISCLOSURE OF THE INVENTION

The present disclosure is generally directed to a method to produce a dry powder cancer treatment substance from a cultured bacterial growth in water and includes the steps of culturing a desired bacterial growth in a solvent to produce a bacterial mass, which is then homogenized to a homogenate. Solid particulates are then removed from the homogenate by passing the homogenate through a first filter. The filtered homogenate is collected and filtered through a second filter to remove high molecular weight chemicals from the solution. The homogenate is concentrated by separating the solvent from the homogenate yielding an extract to increase the solids content and produce a concentrated homogenate. The concentrated homogenate is dried to evaporate remaining solvent and transform the concentrated homogenate to a powder. The powder is encapsulated in individual capsules, which in turn are packaged in blister packs.

Another aspect of the disclosure is directed to a method for treating cancer and includes beginning the patient on a specialized diet including two herbal mixtures and at least one cereal meal selected from the grain group consisting of buckwheat, rice, whole grain soft wheat, and millet. After waiting a time period comprising three to five days beginning administration to the patient of an anti-cancer agent intravenously once per day in an amount at least 200 milligrams anti-cancer agent per 200 milliliters of 0.9% saline solution and further wherein the anti-cancer agent includes at least one peptide from the group consisting of H-Glycine-Alanine-OH, H-Glycine-Alanine-Asparagine-OH, H-Glycine-Alanine-Asparagine-Aspartic Acid-OH, H-Glycine-Alanine-Asparagine-Cysteine-OH, H-Glycine-Alanine-Asparagine-Threonine-OH, and H-Glycine-Alanine-Asparagine-Proline-OH. Ceasing administration of the anti-cancer agent after a time period of between two to three weeks.

These and other features, aspects, and advantages of the invention will be further understood and appreciated by those skilled in the art by reference to the following written specification, claims and appended drawings.
BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described, by way of example, with reference to the accompanying drawings, where like numerals denote like elements and in which

FIG. 1 presents a schematic diagram of a system for producing medicinal capsules for a bacteria-water culture; and

FIG. 2 presents a flow chart of the steps required to produce medicinal capsules from a bacteria-water culture.

Like reference numerals refer to like parts throughout the various views of the drawings.
MODES FOR CARRYING OUT THE INVENTION

The following detailed description is merely exemplary in nature and is not intended to limit the described embodiments or the application and uses of the described embodiments. As used herein, the word “exemplary” or “illustrative” means “serving as an example, instance, or illustration.” Any implementation described herein as “exemplary” or “illustrative” is not necessarily to be construed as preferred or advantageous over other implementations. All of the implementations described below are exemplary implementations provided to enable persons skilled in the art to make or use the embodiments of the disclosure and are not intended to limit the scope of the disclosure, which is defined by the claims. For purposes of description herein, the terms “upper”, “lower”, “left”, “rear”, “right”, “front”, “vertical”, “horizontal”, and derivatives thereof shall relate to the invention as oriented in FIG. 1. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the inventive concepts defined in the appended claims. Hence, specific dimensions and other physical characteristics relating to the embodiments disclosed herein are not to be considered as limiting, unless the claims expressly state otherwise.

Taking preadaptation as a precept wherein bio-evolution is a process of transformation of conditions favoring survival, and assured by an increased resistance to an oxygen deficit. The role of oxygen in the human body is to accept H+ ions protecting tissue from acidosis. In anaerobic tissue, pyruvate is transformed into lactate, and eliminates total dependency on oxygen.

Cancer is essentially an uncontrolled growth of anaerobic tissue. With respect to their development, tumors can be classified as three types; (1) slow growth and highly differentiated, (2) intermediate growth and well differentiated, and (3) rapid growth and poorly differentiated. Within this development there is seen an increase of anaerobism and a decrease in the quantity of mitochondria which are responsible for aerobic oxidative phosphorylation. Much work has shown that as a poorly differentiated tumor increases in size, the tumor tends to take on properties of fetal
tissue, particularly with respect to its isozyme patterns and its bioenergetics properties.

Discovery of the HIF-1a (hypoxia-inducible transcriptional factor) gene connects low oxygen concentration to tumor growth and demonstrates a relationship between environmental conditions and carcinogenesis. When oxygen levels decrease, a transcriptional response is mediated by HIF-1a. Knocking out the HIF-1a gene in mice has been shown to significantly cut tumor growth. These mice also lack cephalic vascularization and other normal developmental characteristics. HIF-1a thus appears to play an important role in controlling embryonic and tumorigenic responses to changes in oxygen levels in the body. Cancer development can then be seen as an evolutionary process, and applying the theory of preadaptation one can conclude that cancer is not a disease but is a preadaptational syndrome that has developed prematurely.

Therefore, in lieu of conducting cancer treatment according to traditional disease prevention and treatment protocols, treatment must follow a preadaptational protocol. Specifically, the cause of the cancer is the result of a future adaptation being experienced in the present. Since the cause of the cancer is related to perceived future environmental conditions, it can’t be destroyed, but rather the main characteristics of the abnormality must be examined to determine the perceived future environment that the cancer has prematurely adapted to. A messenger must then be introduced that will telegraph the organism that the future has already arrived and therefore stop hostility against the present condition.

From outward appearances, the preadaptational syndrome presents itself as an “illness” but its etiology is completely different from that of the disease model. Cancer can be identified as a preadaptational syndrome by correlating the character of the abnormality with the trend of environmental changes (i.e. decreasing oxygen concentration in the atmosphere).

An effective anti-cancer drug should thus be a messenger to the cancerous cells telegraphing to the cells that the future conditions to which it has prematurely adapted has already arrived. Sarcoma growth in vitro has been successfully arrested using non-hormonal factor received from fetal bone marrow fibroblasts. Peptides
from microorganisms or fungi that developed in a time when earth was anaerobic or with a very low oxygen level will possess strong anti-cancer activity. Such microorganisms must be cultured in quantity and processed into a form suitable for ingestion by a cancer patient.

Turning to the drawings, Figure 1 shows a production system 100 for producing medicinal capsules from a bacteria-water culture possessing the desired anti-cancer characteristics, which is one of the preferred embodiments of the present invention and illustrates its various components. System 100 includes a bioreactor 102 in which microorganisms such as bacteria are cultured and grown to a desired mass in anaerobic conditions. Since the biologic fermentation process creates a significant amount of heat, the bioreactor includes a refrigeration system to maintain the bioprocess at a constant temperature optimal for fermentation of the bacteria. The solvent or medium, such as water, in which the bacteria are fermented, can also include the necessary nutrients to feed the bacteria. Bioreactor can also include an agitator to mix the nutrients and keep the fermentation process homogenous.

Once a desired bacterial mass has been achieved in bioreactor 102, the bacterial mass 103 is transferred to sonicator 104 wherein bacterial mass 103 is subjected to sound energy, usually in the form of ultrasonic sound, to halt the fermentation process. The sonic energy further acts to disrupt the individual cell membranes of the bacteria in bacterial mass 103 and thereby release the cellular contents into the solvent. The broken down bacterial solution 105 can then be transferred to a homogenizer 106 wherein the cellular contents and the solvent are homogenized into a unified solution 107.

After homogenization, the homogenized solution 107 is passed through a first filter 108 to remove solid particulates 110 upon which the filtered homogenate 112 is collected in cooling tank 114 where filtered homogenate 112 is cooled to a desired processing temperature. Once cooled, the cooled and filtered homogenate 116 is passed through a second filtering system or separator having special size filters where high molecular weight chemicals 120 are removed. The resulting filtered homogenate 122 is then stored in a temperature controlled storage 124.
Stored homogenate 126 is then transferred to a reverse osmosis plant 128 where the solvent 129 is separated from homogenate 126 to produce an extract 130 that is highly concentrated with the cellular contents of the bacterial mass. Reverse osmosis plant typically employs four membrane elements with a spiral membrane area of 4 – 56 square meters and a permeated spiral capacity of 20 – 200 gallons per hour at pressures up to 600 psig and temperatures up to 200 degrees Fahrenheit. At least a portion of the permeate 129 from the reverse osmosis process can be recycled to cooling tank 114 to aid in the optimization and efficiency of the process. Reverse osmosis plant 128 can concentrate up to a certain level of concentration, but does not completely remove all solvent. When optimal concentration is reached, the reverse osmosis process is halted and extract 130 is transferred to spray dryer 132 in a continuous drying process.

Spray dryer 132 receives extract 130 at an atomizer 140 where extract 130 is transformed into small droplets and introduced into drying chamber 134. A flow of hot air 136 is also introduced into drying chamber via air inlet 138 to evaporate the solvent such as water whereupon the extract 130 is transformed to a powder 142. Powder 142 is further transferred to a first cyclone 144 whereupon the powder undergoes a first separation process from the warm wet air 150 of the drying chamber 134. The powder is transferred to powder cooling system 146 where it is subjected to cool dry air. The cooled powder 148 is then transferred to a second cyclone to remove additional wet air 150 to achieve a desired relative humidity of less than 2.5%. The dried powder 154 is then transferred to dry room 155.

Because dried powder 154 is hygroscopic, dry room 155 is maintained at a relative humidity of 2.5%. Dry room 155 contains a capsule filling machine 156 where dried powder 154 is dosed and the individual doses are encapsulated into a desire capsule size, which is convenient for administration to a patient to be treated. Also contained in dry room 155 is a blister machine 158 which packages a plurality of capsules 157 output from capsule filling machine 156 into known forms of blister packs 160 for distribution to health care professionals engaged in treating cancer patients.

Referring now to FIG. 2, a flow chart 200 represents a method of producing a dry powder cancer treatment substance from a cultured bacterial growth in water. The
process begins at step 202 where in step 204 a bacterial growth is cultured or fermented in a solvent such as water to produce a desired bacterial mass. The resulting bacterial mass is then homogenized with the solvent in step 206 to produce a homogenate for further processing. In step 208, the homogenate is passed through a first filter to remove solid particulates from the homogenate. The filtered homogenate is collected in step 210 and then subjected to a second filtering process to remove high molecular weight chemicals in step 212. In step 214 the homogenate is concentrated by separating the at least a portion of the solvent from the homogenate to yield a concentrated extract having increased solids content. The concentrated extract is dried by evaporating the remaining solvent in step 216 to produce a powder. In step 218 the powder is encapsulated in individual capsules, which are then packaged into blister packs in step 220 whereupon the process ends at step 222.

The encapsulated powder produced from the bacterial mass includes one or more peptides derived from L-amino acids extracted from the above described homogenized bacterial mass. The peptides so derived are: H-Glycine-Alanine-OH, H-Glycine-Alanine-Asparagine-OH, H-Glycine-Alanine-Asparagine-Aspartic Acid-OH, H-Glycine-Alanine-Asparagine-Cysteine-OH, H-Glycine-Alanine-Asparagine-Threonine-OH, and H-Glycine-Alanine-Asparagine-Proline-OH.

Utilizing the derived peptides, a cancer therapy system is designed to attack cancer in two ways, by simultaneously detoxifying the body with a special diet and destroying cancer cells using a drug including the peptides, which has been shown to decrease tumor size and metastases with minimal side effects in animal models. The cancer treatment system is designed to eliminate the environment that allows the cancer to thrive while cancer cells are attacked directly with a non-toxic drug.

The cancer treatment system decreases side-effects from standard cancer therapies like chemotherapy and radiation, and destroy cancer cells with anti-cancer agents. The multi-faceted approach of the treatment system ensures the best quality of life possible, by treating the cancer as well as the circumstances that allowed the cancer to thrive. The cancer therapy system combines the anti-cancer agent, administered as an IV injection, with a strict diet of two specialized herbal mixtures and four types of cereal meal: buckwheat, rice, whole grain soft wheat, and millet. This system, which is administered for 2-3 weeks, kills cancer cells while detoxifying
the body, thereby enhancing its ability to eliminate the myriad of proteins and waste created in the process.

The cancer therapy system is a one-of-a-kind approach to killing cancer cells while enhancing general health and minimizing side-effects of other cancer therapies, such as chemotherapy and radiation. The anti-cancer agent including at least one of the above peptides is a combination of molecular signals derived from special bacteria, which interfere with normal functioning of cancer cells but are harmless to normal cell processes. Preliminary results from in vivo studies in mice injected with melanoma shown in Graph 1 and Graph 2 below demonstrate that injections of the anti-cancer agent decreased tumor size and the number of metastases when compared with controls (p<0.05), with no toxicity. Besides being non-toxic, the anti-cancer agent can be combined with any standard cancer therapies to enhance their effectiveness and improve the speed of recovery of cancer patients. Overall, cancer patients benefit from an effective, non-toxic therapy option that is compatible with all other cancer therapies on the market.

![Graph 1](image)

Graph 1 illustrates tumor volume in mice injected with B16 melanoma. Groups 1 and 2, represented in the graph by squares and circles, respectively are results obtained from mice injected with melanoma and treated with the anti-cancer agent while Group 3 represents control mice. As shown, by day 21 tumor size in both
anti-cancer agent treated groups were significantly small than in the control group (p<0.05).

Graph 2 illustrates a normalized number of metastases in the lungs of mice injected with B16 melanoma. Experimental groups 1 and 2 represent results obtained from mice injected with melanoma and treated with the anti-cancer agent, while Group 3 represents control mice. These results show that the number of metastases in the lungs of both anti-cancer agent treated groups were significantly smaller than in the control group (p<0.05).

The cancer therapy system combines the anti-cancer agent with a strict diet specially designed to enhance the anti-cancer agent’s effectiveness and improve the patient’s quality of life. The diet includes creating a steady regimen that combines two unique herbal mixtures with one of four types of cereal meal: buckwheat, rice, whole grain soft wheat, and millet. The cereal meal helps to re-establish homeostasis between organ systems by removing potentially harmful materials that have accumulated in the intestines throughout the life of the patient, thereby easing the burden on the immune system that regulates intestinal flora. With time, this decreases the detoxification load on the liver and the amount of pathogenic bacterial flora that the immune system surrounding the intestines has to keep in check. In turn, this aids the immune system in detecting the cancer while the liver clears out the toxins that allowed the cancer cells to thrive. Typically, the treatment regimen begins with the
patient starting the specialized diet. Administration of the anti-cancer agent begins 3-5
days after the start of the diet and is administered intravenously once per day (200mg
per 200mL 0.9% NaCl saline). The anti-cancer agent is administered for 2-3 weeks.
Additional supplements and therapies may be considered depending on the status of
the patient's disease.

Since many modifications, variations, and changes in detail can be made to the
described preferred embodiments of the invention, it is intended that all matters in the
foregoing description and shown in the accompanying drawings be interpreted as
illustrative and not in a limiting sense. Thus, the scope of the invention should be
determined by the appended claims and their legal equivalence.
What is claimed is:

1. A method to produce a dry powder cancer treatment substance from a cultured bacterial growth in water, said method comprising the steps:
   - culturing a desired bacterial growth in a solvent to produce a bacterial mass;
   - homogenizing the bacterial mass in the solvent to produce a homogenate;
   - removing solid particulates from the homogenate by passing the homogenate through a first filter;
   - collecting the filtered homogenate;
   - filtering the homogenate through a second filter to remove high molecular weight chemicals from the solution;
   - concentrating the homogenate by separating the solvent from the homogenate yielding an extract to increase the solids content and produce a concentrated homogenate;
   - drying the concentrated homogenate to evaporate remaining solvent and transform the concentrated homogenate to a powder;
   - encapsulating the powder in individual capsules; and
   - packaging the individual capsules in blister packs.

2. The method according to claim 1 wherein said homogenizing step includes producing a homogenate having L-amino acids as a component thereof.

3. The method according to claim 2 further including the step of:
   - extracting from the L-amino acids at least one peptide from the group consisting of H-Glycine-Alanine-OH, H-Glycine-Alanine-Asparagine-OH, H-Glycine-Alanine-Asparagine-Aspartic Acid-OH, H-Glycine-

4. The method according to claim 3 wherein in said encapsulating step, the powder in the individual capsules includes at least one peptide from the group consisting of H-Glycine-Alanine-OH, H-Glycine-Alanine-Asparagine-OH, H-Glycine-Alanine-Asparagine-Aspartic Acid-OH, H-Glycine-Alanine-Asparagine-Cysteine-OH, H-Glycine-Alanine-Asparagine-Threonine-OH, and H-Glycine-Alanine-Asparagine-Proline-OH.

5. A method of treating cancer in a patient comprising the steps of:

   beginning the patient on a specialized diet including an herbal mixture; and

   administering an anti-cancer agent.

6. The method of treating cancer according to claim 5 wherein said specialized diet further includes two herbal mixtures.

7. The method of treating cancer according to claim 5 wherein said specialized diet further includes a cereal meal selected from the group of grains consisting of buckwheat, rice, whole grain soft wheat, and millet.

8. The method of treating cancer according to claim 5 further including after the beginning step the step of:

   waiting a time period between three and five days.
9. The method of treating cancer according to claim 5 wherein said administering step comprises:

administering to the patient an anti-cancer agent intravenously.


11. The method of treating cancer according to claim 9 wherein said administering step comprises:

administering to the patient an anti-cancer agent intravenously once per day in an amount at least 200 milligrams anti-cancer agent per 200 milliliters of 0.9% saline solution.

12. The method of treating cancer according to claim 11 further including after the administering step, the step of:

ceasing administration of the anti-cancer agent after a time period of between two and three weeks.

13. A method of treating cancer in a patient comprising the steps of:

beginning the patient on a specialized diet including two herbal mixtures and at least one cereal meal selected from the grain group consisting of buckwheat, rice, whole grain soft wheat, and millet;
waiting a time period between three and five days;

administering to the patient an anti-cancer agent intravenously once per day in an amount at least 200 milligrams anti-cancer agent per 200 milliliters of 0.9% saline solution and further wherein the anti-cancer agent includes at least one peptide from the group consisting of H-Glycine-Alanine-OH, H-Glycine-Alanine-Asparagine-OH, H-Glycine-Alanine-Asparagine-Aspartic Acid-OH, H-Glycine-Alanine-Asparagine-Cysteine-OH, H-Glycine-Alanine-Asparagine-Threonine-OH, and H-Glycine-Alanine-Asparagine-Proline-OH; and

cessing administration of the anti-cancer agent after a time period of between two and three weeks.
BEGIN

CULTURE BACTERIAL MASS

HOMOGENIZE BACTERIAL MASS

REMOVE SOLID PARTICULATES

COLLECT FILTERED HOMOGENATE

FILTER OUT HIGH MOLECULAR CHEMICALS

CONCENTRATE HOMOGENATE

DRY HOMOGENATE TO POWDER

ENCAPSULATE POWDER IN INDIVIDUAL CAPSULES

PACKAGE CAPSULES IN BLISTER PACKS

END

FIG. 2