The present invention relates to nutraceutical, food, drink or supplement compositions derived from fruits or vegetables. More particularly, the invention relates to compositions comprising an extract of the banana, alone or in combination with other ingredients and fruit and/or vegetable extracts for the purpose of providing health and beauty benefits. Methods of producing the extracts and nutraceuticals are also provided. Methods of treating various ailments or conditions using the extracts or nutraceutical compositions of the invention are also provided.
IMPROVED MEANS OF SUPPLYING ESSENTIAL ELEMENTS AND NUTRIENTS

BACKGROUND OF THE INVENTION

Consumer awareness of health issues, particularly the importance of the use of naturally occurring "nutraceuticals" and healthy food products has been rapidly increasing. Bananas and other fruits and vegetables have been shown through a variety of clinical trials and publications to be an important part of a healthy diet including providing health benefits to a host of ailments.

Fruits often include sugars, starches and other ingredients that can act counter to the inherent healthy benefits. In addition, fruits can often contain useful targeted ingredients that rely on the appropriate process to unlock their benefits.

SUMMARY OF THE INVENTION

The present invention relates to compositions of matter that are fruit or vegetable extracts and methods of making the compositions.

The present invention provides fruit and/or vegetable extracts which are extract compositions having at least some, if not all, of the following characteristics: for a banana extract: less than about 0.5g sugar per 100g extract composition, less than about 1g fat per 100g extract composition, more than about 15g fiber per 100g extract composition, more than about 12g protein per 100g extract composition, more than about 400IU Vitamin A per 100g extract composition, more than about 3mg pantothenic acid per 100g extract composition, more than about 72mg calcium per 100g extract composition, more than about 3mg iron per 100g extract composition, more than about 200mg magnesium per 100g extract composition, more than about 2500mg potassium per 100g extract composition, more than about 2mg Vitamin B6 per 100g extract composition, more than about 250mg phosphorus per 100g extract composition, more than about 4mg niacin per 100g extract composition, more than about 0.5mg riboflavin per 100g extract composition.
extract composition, more than about 300mcg folic acid per 100g extract composition, more than about 2mg zinc per 100g extract composition, more than about 4mg manganese per 100g extract composition, and more than about 0.9mg copper per 100g extract composition.

The present invention also provides methods of preparing fruit and/or vegetable extract compositions which include the steps of combining the fruit or vegetable with water or a suitable solvent, pulverizing the fruit or vegetable, optionally removing large particles or clumps of fruit or vegetable, optionally washing fruit or vegetable particles to remove residual sugar, removing sugar from the fruit or vegetable biomass by, among other methods such as chemical processing, fermenting with microorganisms in a bioreactor, removing microorganisms separately collecting the liquid supernatant and solid fractions, and optionally drying the collected solids - all performed without significant loss of targeted ingredients including but not limited to vitamins, minerals, proteins, fibers. The collected solids having at least some, if not all, of the aforementioned characteristics.

Additional steps can be included in the process in order to provide the extract in a desired physical form, or with a desired chemical content. For example, in one aspect, the method can further comprise drying the aqueous extract to a solid or semi-solid state. In some aspects, the extract can be dried into a powder form. One or more excipients, such as binders and stabilizers can be added to the extract. Additionally, one or more positive health benefit imparting agents can be added to the extract to provide additional desired therapeutic effects.

The fruit and/or vegetable extracts of this invention can be formulated as edible products, including food, functional food, beverages, functional beverages, dairy products, dietary supplements, nutraceuticals and pharmaceuticals. The fruit and/or vegetable extracts of the invention can be used in edible products such as chocolate, cereal, cookies, cakes, energy bars, yoghurt, ice cream, milk, tea, coffee, juices and carbonated beverages. The extracts of the invention can also be formulated as cosmetics, skin care products, oral care products and personal care products. The extracts of the invention can also be formulated as products that are smelled and/or absorbed through the olfactory senses.

The extracts can be formulated in a dosage form such as caplets, capsules, tablets, powders, flakes, immediate release forms, rapid release forms, slow release forms, sustained release forms,
controlled release forms, dissolving forms, and injectable forms. The extracts of the invention can also be in a powder form, liquid form or a dough form. The extracts of the invention can be used in products that are in the form of a suppository, soap, cream, ointment, mask or skin patch.

The compositions of the invention can be supplemented to include additional ingredients or additional amounts of existing ingredients. Examples of such ingredients include as anti-oxidants, Vitamin D, resveratrol, potassium, flavonol, hawthorn, bitter melon, citrulline broccoli, glutamic acid, guava, cocoa, acai, pomegranate, goji, cherries, GRAS ingredients, pharmaceutical ingredients or combinations thereof.

The compositions or formulations of the invention can be administered to mammal for treating a health condition or improving a mammal's overall state of health, comprising administering the composition of claim 1 to a mammal in need thereof. Examples of some health conditions that can be treated with the compositions or formulations of the invention include, but are not limited to, hypertension, stroke, nervous system disorders, kidney disorders, osteoporosis, anemia, nausea, stress, anxiety, depression, mood disorders, menopause, morning sickness, pregnancy-related temperature disorders, heartburn, ulcers, cancer, constipation, diarrhea, macular degeneration, Crohn's disease, cardiovascular disease, diabetes, obesity, nicotine withdrawal, mosquito bites, autoimmune diseases, inflammation, HIV infection, and metabolic syndromes.

In further aspects of the invention, the separated and collected liquid supernatant of the methods of the invention can be further treated to yield alcohol and water. Specifically, the supernatant can be subjected to reverse osmosis followed by distillation to separate alcohol and water. The alcohol can be collected for use in biofuels. The water can be recycled for use in the initial steps of the fruit and/or vegetable extraction methods of the invention.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1 is a flow diagram of an extraction process of the invention including the steps of removing yeast and pre-treating target material;

Figure 2 is a flow diagram of an extraction process of the invention including the steps of removing yeast by centrifuging, pre-treating target material by washing and optionally filtering the target material with a transversal flow filter;
Figure 3 is a flow diagram of an extraction process of the invention including the step of removing yeast without pre-treating target material prior to filtering;

Figure 4 is a flow diagram of an extraction process of the invention including the step of removing yeast by filtering with a transversal flow filter;

Figure 5 is a flow diagram of an extraction process of the invention including the step of removing large particles from the starting material;

Figure 6 is a flow diagram of an extraction process of the invention including the steps centrifuging to remove large particles or clumps from the starting material, washing the particles, and optionally treating the large particles with amylase at elevated temperatures;

Figure 7 is a flow diagram of an alternative extraction process of the invention including the step of removing large particles from the starting material;

Figure 8 is a flow diagram of an alternative extraction process of the invention including the steps centrifuging to remove large particles or clumps from the starting material, washing the particles, and optionally treating the large particles with amylase at elevated temperatures;

Figure 9A is a Certificate of Analysis showing the nutritional content of the composition in the liquid solution form of the invention;

Figure 9B is a table showing the nutrition facts of the composition in the liquid solution form of the invention;

Figure 10A is a Certificate of Analysis showing the nutritional content of the composition in the dough form of the invention;

Figure 10B is a table showing the nutrition facts of the composition in the dough form of the invention;

Figure 11 is a Certificate of Analysis showing the nutritional content of the composition in a partially lyophilized form of the invention;

Figures 12A and 12B is a table showing the nutritional content of 100g of a banana extract in a partially lyophilized form of the invention compared to 100g of banana fruit and 100g of dehydrated banana fruit; and

Figure 13 is a table showing the nutritional content of 100g of a banana extract in a partially lyophilized form of the invention compared to 100g of inulin (chicory root) and 100g of polydextrose.
DETAILED DESCRIPTION OF THE INVENTION

In describing and claiming the present invention, the following terminology will be used in accordance with the definitions set forth below.

The singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a solvent" includes reference to one or more of such solvents, and reference to "the excipient" includes reference to one or more of such excipients.

As used herein, "formulation" and "composition" can be used interchangeably and refer to a combination of elements that is presented together for a given purpose. Such terms are well known to those of ordinary skill in the art.

As used herein, "pulverize" refers to a process of physically acting on plant tissue in a manner that ruptures plant cells and allows for the release of intracellular material therefrom.

As used herein, "fruit extract" and "vegetable extract" refer to positive health benefit imparting extracts obtained from various commonly known botanical organisms classified as "fruits" or "vegetables".

As used herein, "admixture" refers to fruit or vegetable extracts optionally combined with additional GRAS (generally regarded as safe) ingredients.

As used herein, "functional food" refers to a food where a new ingredient(s) or more of an existing ingredient(s) has been added to a food and the new product has a new function related to health-promotion or disease prevention in that it lowers the risk of disease, protects against disease or lessens the severity of symptoms of disease. The general category of functional foods includes processed food or foods fortified with health-promoting additives, like "vitamin-enriched" products.

As used herein, "functional beverage" refers to a drink product that is non-alcoholic, ready to drink and includes in its formulation non-traditional ingredients so as to provide specific health benefits that go beyond general nutrition. Examples of functional beverages include sports and performance drinks, energy drinks, ready to drink (RTD) teas, enhanced fruit drinks, soy beverages and enhanced water.
As used herein, "nutraceutical" refers to natural health products of a specified dose for diagnosing disease, treating disease or lowering the risk of getting disease by restoring or correcting function or maintaining/promoting health.

As used herein, "pharmaceutical" refers to drugs containing an active medicinal ingredient, which may or may not be from a natural source. Pharmaceuticals include natural ingredients that have been transformed by a chemical process and newly synthesized chemical compounds or compositions.

As used herein, "excipients" refers to one or more agents that can be combined with a fruit and/or vegetable extract in order to provide specifically desired physical or chemical properties, such as improved stability, flow, texture, etc. Various materials are known as excipients in both the pharmaceutical and food industries.

As used herein, "carrier", "inert carrier", and "pharmaceutically acceptable carrier" can be used interchangeable and refer to an inert carrier which can be combined with a fruit and/or vegetable extract in order to provide a desired formulation form. Those of ordinary skill in the art will recognize a number of carriers that are well known for making specific dosage forms, such as liquids, tablets, capsules, powders, granules, food substances, etc.

As used herein, "solvent", "co-solvent" refer to substances in which the fruits and/or vegetables are dissolved or suspended to effect processing and making of the extracts of the invention. Solvent includes water and additionally can include chemicals to adjust various characteristics such as, the salinity or polarity and the pH.

As used herein, "an effective amount" refers to an amount of the specified constituent that is effective in attaining the purpose for which the constituent is provided. For example, an effective amount of a carrier would be an amount suitable for accepting a fruit and/or vegetable extract and then providing a specified formulation, such as a tablet, granule, powder, etc.

Concentrations, amounts, solubilities, and other numerical data can 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.
For example, a concentration range of 1 to 5 should be interpreted to include not only the explicitly recited limits of 1 and 5, but also to include individual values such as 2, 3.6, 4.2, and sub-ranges such as 1-2.5, 1.8-3.2, 2.6-4.9, etc. This interpretation should apply regardless of the breadth of the range or the characteristic being described, and also applies to open-ended ranges reciting only one end point, such as "greater than 25" or "less than 10."

The present invention provides fruit and/or vegetable extract formulations containing certain desirable properties and methods for the making thereof. The formulations are generally prepared in a manner that preserves and/or enhances the natural color, odor, taste and other organoleptic properties of the fresh fruit or vegetable. Additionally, the formulations are typically prepared so as to contain mostly, if not all, natural ingredients. Further, the formulations are typically soluble in both hot and cold water.

In one aspect, the present invention provides a banana extract in the form of a liquid solution and having at least one or more, if not all, of the following characteristics less than about 10 calories per 100g liquid extract composition, about 0g sugar per 100g liquid extract composition, less than about 0.1g fat per 100g liquid extract composition, more than about 20mg calcium per 100g extract composition, and more than about 150mg potassium per 100g extract composition.

In another aspect, the present invention provides a banana extract in the form of a dough and having at least one or more, if not all, of the following characteristics less than about 80 calories per 100g dough extract composition, about 0g sugar per 100g dough extract composition, less than about 5g fat per 100g extract composition, more than about 6.5g fiber per 100g dough extract composition, more than about 2.5g protein per 100g dough extract composition, more than about 190IU Vitamin A per 100g dough extract composition, more than about 160mg calcium per 100g dough extract composition, more than about 0.75mg iron per 100g dough extract composition, and more than about 150mg potassium per 100g dough extract composition.

In another aspect, the present invention provides a banana extract in the form of a partially lyophilized powder and having at least one or more, if not all, of the following characteristics less than about 0.5g sugar per 100g extract composition, more than about 15g fiber per 100g extract composition, more than about 12g protein per 100g extract composition, more than about 400IU Vitamin A per 100g extract composition, more than about 3mg pantothenic acid per 100g extract composition, more than about 72mg calcium per 100g extract composition, more than
about 3mg iron per 100g extract composition, more than about 200mg magnesium per 100g extract composition, more than about 2500mg potassium per 100g extract composition, more than about 2mg Vitamin B6 per 100g extract composition, more than about 250mg phosphorus per 100g extract composition, more than about 4mg niacin per 100g extract composition, more than about 0.5mg riboflavin per 100g extract composition, more than about 300mcg folic acid per 100g extract composition, more than about 2mg zinc per 100g extract composition, more than about 4mg manganese per 100g extract composition, and more than about 0.9mg copper per 100g extract composition.

In another aspect, the present invention provides a fruit and/or vegetable extract in the form of a powder and having at least one or more, if not all, of the following characteristics less than about 0.5g sugar per 100g extract composition, about 5-50g fiber per 100g extract composition, about 6-30g protein per 100g extract composition, about 200-5000IU Vitamin A per 100g extract composition, about 2-20mg pantothenic acid per 100g extract composition, about 50-1000mg calcium per 100g extract composition, about 2-20mg iron per 100g extract composition, about 100-500mg magnesium per 100g extract composition, about 1000-7000mg potassium per 100g extract composition, about 2-5mg Vitamin B6 per 100g extract composition, about 150-1000mg phosphorus per 100g extract composition, about 2-20mg niacin per 100g extract composition, about 0.5-10mg riboflavin per 100g extract composition, about 300-700mcg folic acid per 100g extract composition, about 2-5mg zinc per 100g extract composition, about 4-10mg manganese per 100g extract composition, about 0.5-3mg copper per 100g extract composition, about 0.1-2mg thiamin per 100g extract composition, about 0.1-6mcg Vitamin B12 per 100g extract composition, and about 5-1000mg Vitamin C per 100g extract composition.

Potassium is known to have a number of desirable positive health benefits including lowering the risk of or treating hypertension and cardiovascular diseases. Accordingly, it is desirable to provide a fruit and/or vegetable extract with high potassium content. While the present extraction method is capable of obtaining an extract with high potassium content, its purpose is not to target and extract potassium only, but rather to provide an extract that includes many beneficial nutrients naturally existing in fruits and vegetables. In accordance with the present invention, such an extract can be obtained using the processes described herein, and can in some aspects, be used to prepare a fruit or vegetable product that has the visual, taste, and organoleptic characteristics recited herein.
Accordingly, in one aspect of the present invention, a fruit and/or vegetable extract having a potassium content of about 7000mg potassium per 100g of extract, can be obtained using the methods recited herein. In another aspect the potassium content can be from about 1000mg to about 2500mg per 100g total extract. In yet other aspects the potassium content can be from about 2000mg to about 4000mg per 100g total extract or from about 3500mg to about 7000mg per 100g total extract. Alternatively, the potassium content of the extract can be recited by total potassium content provided by an extract when used to prepare a single serving of a food or beverage item. In one aspect, the amount can be sufficient to provide a single serving of a food or beverage item with at least about 875mg to about 1750mg potassium (i.e. about 25%-50% of the recommended daily value of potassium). In another aspect, the amount of potassium can be at least about 1750mg to about 2625mg (i.e. about 50%-75% of the recommended daily value of potassium). In yet another aspect, the amount of potassium can be at least about 2625mg to about 3500mg (i.e. about 75%-100% of the recommended daily value of potassium).

The methods of the present invention are ones that allow the production of fruit and/or vegetable extract formulations having one or more of the characteristics as recited herein. Generally, the first step is select and provide very ripe fruits or vegetables. For example, in one aspect of the invention Stage 12 ripe bananas are selected and provided. Stage 12 bananas are characterized as having turned black and would normally be discarded. Selecting very ripe fruits or vegetables provides for a starting material that is low in carbohydrate and high in sugar.

The methods of the present invention use cold water and temperature conditions during the preparation of the extracts to yield formulations having one or more of the characteristics as recited herein.

Once the fruits or vegetables have been selected they can be reduced in size prior to adding water. Those of ordinary skill in the art will recognize a variety of mechanisms for reducing the fruit or vegetable size, such as by chopping, cutting, crushing, tearing, slicing, etc., any of which may be suitably used. While the temperature of the cold water can vary, in some aspects, it is less than about 60°C. In another aspect, the water temperature can be from about 0°C to about 25°C. In another aspect, the water temperature can be from about 25°C to about 35°C. In yet another aspect, the water temperature can be from about 35°C to about 45°C. Additionally, the amount of water with which the fruit or vegetable is mixed can vary. In one aspect the quantity
of fruit or vegetable is mixed with an amount of water, which is sufficient to provide a ratio of fruit or vegetable mass to water of from about 1:1 to about 1:2 (w/w). In another aspect, the ratio can be from about 1:2 to about 1:5. In yet another aspect, the ratio can be about 1:5 to about 1:10.

Once the appropriate mixture ratio of fruit or vegetable is obtained, the fruit or vegetable mass of the mixture is then pulverized in order to rupture the cells of the fruit or vegetable mass, and the mixture is maintained for an amount of time sufficient to release intracellular material from the fruit or vegetable mass into the water and create an aqueous extract component and a particulate component. Any method of pulverizing which physically ruptures the fruit or vegetable cells, such as homogenizing, milling, grinding, chopping, blending, cutting, tearing, mashing, etc., can be used. A number of specific devices that can be suitably used to pulverize the fruit or vegetable mass will be recognized by those of ordinary skill in the art, such as homogenizers, colloidal mills, stone mills, ball mills or tangential fluid energy mills. In accordance with the present method, the fruit or vegetable mass and water mixture can be subjected to various degrees of pulverization. In one aspect, at least about 50% of the non-aqueous fruit or vegetable cells are ruptured. In another aspect, at least about 75% of the non-aqueous fruit or vegetable cells can be ruptured. In a further aspect, at least about 90% of the non-aqueous fruit or vegetable cells can be ruptured.

Once the aqueous extract component has received a desired amount of intracellular material, large fruit particulates can be removed or separated from the extract (see e.g. Figures 5-8), and the aqueous extract component can be collected for further processing.

In particular processing includes fermenting to remove carbohydrates and sugars. Fermentation: Fermentation is conducted at a low pH — at or below 7. Fermentation is conducted with a high water content (over 75%) to facilitate mass transfer and proper operation of the yeast. Post-fermentation the process can include a filtering step to remove yeast remnants.

Alternatively, fermentation can be performed using immobilized yeast to reduce yeast content, taste and smell in the final product. Yeast can be immobilized on magnetic particles and separated from the fermentation slurry using magnets. Alternatively, the yeast can be physically separated from the fermentation using a filter between two bioreactor compartments. Both aerobic and anaerobic fermentation may occur to produce the final product. Ingredients such as
ascorbic acid or alcohol may be added to the admixture before, during or after fermentation to prevent bacterial growth.

Secondary Fermentation of carbohydrate component of the starting material can be performed by introducing alpha and branch amylases to mainly the carbohydrate component (over 80% carbohydrates) of the separated components in high heat (over 60°C) followed by using immobilized or regular yeast diluted by water. Any starch is broken down into sugars without significant impact to the target vitamins. Sugar is broken down into alcohol, CO₂ or other ingredients and the remaining non-starch carbohydrates are processed and optionally reintroduced to the final target product.

The present invention relates to converting fruits and/or vegetables to an extract composition that can be formulated as a dosage form that allows for both optimally controlled and reproducible dosing of essential nutrients and therefore patient compliance with treatment or supplement regimens and successful patient treatment.

For example, the banana has effective levels of beneficial components but at low concentration, thereby requiring the ingestions of multiple bananas, as many as 8, to achieve a therapeutically effective outcome. However, this dose, taken on a daily basis is considered to have adverse effects due to the high caloric intake. Therefore, the utility of this invention is the described process for converting bananas into a "core" substance that can be used for formulating a wide variety of dosage forms (solid, liquid, pastes, tablets, capsules, powders, to name a few), a new composition of matter which is the "core" therapeutic agent derived from the banana, and novel use of the banana and core for the treatment of human and animal health disorders and improve human health.

The "core" component cited in this patent refers to potassium complexed or otherwise rendered relatively insoluble by it's association with banana components, in particular pectin but also including other anionic components whereby potassium is the counter ion. The invention also extends the "core" beyond the banana, to any potassium ion delivery system or composition of matter that involves the use of a natural complexation reaction as seen with potassium and pectin and other charged polymers, natural or non-natural. Besides bananas, other sources of natural polymers such as pectin are fruits such as apples, pears, cherries, and in particular but not
exclusively their skins and pulp and extracts thereof, which therefore are also included as
potential sources of the core.

The invention includes fruit and vegetable extracts comprising the core or supplementing the
core. Fruits and vegetables rich in potassium that can be used to produce extracts of the
invention include banana, plantain, kale, onion, celery, raisin, prune, avocado, potato, fig,
cantaloupe, mango, papaya, tomato, lima bean, cucumber, orange and other citrus fruits, garlic,
strawberry, artichoke, beet, almonds, kiwi, apricot, coconut, date, and sweet potato. Additional
ingredients, fruits and vegetables included for use in producing extracts of the invention
comprising the core or supplementing the core include bitter melon, citrulline, broccoli, glutamic
acid, guava, cocoa, flavonols, hawthorn, resveratrol, acai, pomegranate, goji and cherries. All of
these ingredients and extracts thereof can be used alone or in combination with each other and
additional "GRAS" (generally recognized as safe) ingredients for food, beverages and cosmetics.
Other supplements that can be added to the core to give additional health benefits are potassium
to supplement the naturally occurring levels as well as compounds known or expected to have
synergistic effects with the core such as Vitamin D, Vitamin C, resveratrol, flavonol, and/or
hawthorn.

The present invention is directed to nutraceutical compositions relating to a new and useful
tablet, food, drink, or other beneficial preparations in the form of banana-based admixtures
which may be in conjunction with other fruit components.

The present invention will provide a natural way to address various ailments such as
hypertension and diseases related to water and electrolyte balance, cardiovascular diseases, and
as a supplement to patients taking antihypertensives such as diuretics.

This invention describes a manipulation methodology of the banana, its many uses and the
process used to achieve the desired results. Such method equally can be applied to other fruits
and vegetables.

The invention also describes incorporation and manipulation of GRAS ingredients and
pharmaceutical ingredients with fruit and vegetable extracts including the banana.

The invention is directed to isolating, concentrating and otherwise fractionating sugars, pectins
and other ingredients from the banana and other fruits and vegetables, enabling the admixture to
be significantly concentrated in the essential elements and/or nutrients of the invention, resulting
in more useful and compliant administration of banana and other fruits and vegetable components that have significant health benefits for the treatment of human health disorders. Additionally, the invention includes introducing ingredients for co-administration, into the banana admixture that act synergistically to address a wide range of health, beauty and other lifestyle concerns.

The invention includes a range of delivery mechanisms of the core, that depend on the type of health concern being addressed and the manner in which it is being delivered to the end-user. Examples of processes useful for all or part of the methods of producing the extracts of the invention include:

1. Extracting the sugar and starch from the banana

   One example of this process is as follows:

   blending the banana into a pulp with water;

   using enzymes such as pectinases or whole organisms such as yeast, or chemical acid or base treatment in combination with heating to break down or otherwise allow for the pectin to be more easily extracted into aqueous solution;

   optionally adding and mixing in preservatives or antioxidants such as sulfur dioxide or citric acid;

   pressing, centrifuging or filtering the treated pulp to recover the pectin containing solution out of the pulp and isolating the soluble material;

   extraction the soluble materials from the pulp by further diluting and mixing with water and repeating the isolation of soluble material step;

   optionally concentrating the soluble material derived from the pulp using reverse-osmosis to achieve a more concentrated solution;

   treating the concentrate with an acid (e.g., hydrochloric, sulfuric) to lower the pH of the concentrate to a range of pH 2 - 5 at ambient or sub-ambient temperature;

   precipitating the desired soluble fraction by treating with calcium ion or alcohol solution;
isolating the precipitate using centrifugation or filtration;
washing the precipitate with alcohol;
drying the precipitate as an intermediate, which should be highly enriched in pectin;
conversing the intermediate to the Core by dissolving the intermediate at neutral pH in a potassium containing buffer such as potassium citrate while controlling or adjusting the amount of potassium to reflect the level desired for a particular dosage form and potency;
concentrating the intermediate using reverse osmosis or evaporation;
optionally drying to a stable core using spray drying, lyophilization or oven drying;
determining the final potassium level as a control of potency and optionally adding additional potassium; and
optionally adding Vitamin D3 or other agents to enhance the therapeutic efficacy of the material.

2. Another example of processing the banana to make the core is

blending the banana into a pulp using water with a potassium phosphate or other potassium containing buffer at a pH above 4;
isolating the soluble fraction using centrifugation or filtration with washing with water; and
drying the soluble fraction using spray drying, lyophilization or other method.

3. Other examples of processing steps that can be included in the methods of the invention include:

using dried or fresh banana as a starting material;
suspending dried banana in water and adjusting pH to 2.0 with a mineral acid such as hydrochloric, sulfuric or phosphoric acid;
heating the acidified banana and banana pulp and titrating the solution to a pH of between 2 - 4 during heating to assure hydrolysis of the pectin occurs;
isolating the soluble pectin using filtration, centrifugation or sedimentation;
concentrating the isolated soluble pectin;
precipitating the pectin using alcohol addition;
recovering the isolated purified pectin using filtration, centrifugation or sedimentation and adjusting the level of potassium ion to that physiologically relevant level;
spray drying, drying by heating or lyophilization of the pectin.

4. Fractionating banana and banana pulp using a combination of aqueous and organic solvents, salts and buffers to control pH.

5. Use of temperature to control solubility of banana components, in combination with changes in pH and ionic strength of banana pulp.

6. Fractionation of banana pulp using highly pressurized carbon dioxide as a solvent, also known as supercritical carbon dioxide for fluid extraction.

7. Supercritical fluid extraction with carbon dioxide in combinations of CO₂ between 100% - 0% with at least one other fluid component whereby the other component is an organic solvent, water, or alcohol, and in combinations with buffers and salts and controlled pH and variations of ambient temperature.

8. Extraction using citric acid followed by ethanol precipitation to produce pectin with a high galacturonic acid (greater than 5%) content followed by neutralization using potassium citrate.

9. Extraction using calcium containing buffer to render pectin insoluble with concentration and drying to result in the core.

10. Selective extraction or removal of sugars and carbohydrates from banana, thereby resulting in non-extractable solids such as pectin, dietary fiber and other materials that have little caloric value.

11. Selectively removing of sugars and carbohydrates from banana using enzymatic agents (amylases in particular) and fermentation using microbes such as yeast (Saccharomyces cerevisiae) or other GRAS microbial agents.

12. Selective removal of sugars from ripe bananas in particular using S. cerevisiae and other natural microbial agents.
In a preferred embodiment of the invention, pectin is a major ingredient of the core and is extracted by pH whereby the pectin, which normally carries a negative charge at neutral pH, will become uncharged at low pH. Thus, lowering the pH below 3 of a pectin containing solution will cause a concentrated solution to precipitate at low temperature and in the presence of alcohol.

An optimal method is to reduce the pH and temperature of an aqueous solution containing the pectin, derived by aqueous extractions, using a strong acid such as HCl, citric, phosphoric or sulfuric acid, to recover high levels of pectin (up to 35 weight% depending on the raw material). Acid precipitated pectin that has undergone mild heating, thereby hydrolyzing ester groups to the carboxylic acid, will contain high levels of galacturonic acid as well as methylated galactose and neutral sugars which were mainly arabinose and galactose. This pectin is in an uncharged state and prior to use as the core will need to be titrated to a neutral pH using KOH, so that the potassium salt form of the pectin is achieved.

Due to the polymeric nature of pectin the potassium pectinate form when hydrated has sustained release characteristics and the potassium will ion-exchange, primarily with sodium ion but also with other cations in the digestive tract and potassium will be absorbed by the body over an extended period of time.

In one embodiment, the present invention admixture will contain multiple banana's worth of potassium complexed to the pectin derived from banana, naturally occurring in significant quantities in the banana. With the possible addition of other ingredients, it shall be possible to provide a statistically significant reduction of blood pressure from 5 - 20% or at least 3mm. Use of the invention will allow for elimination or reduction of conventional pharmaceutical compositions used to treat hypertension such as ACE inhibitors and diuretics shall reduce the side effects for users.

The potassium in the banana is naturally found and is a safer method of delivering potassium than current methods. Potassium is a critical but dangerous substance if ingested in high qualities. A majority of the human population ingests insufficient potassium in their diet (recommended dose is about 2 - 4 g per day). The maximum potassium used in our hypertension
admixture is what is recommended as the daily requirement for the target patient population but not to exceed between 2,000 - 4,000 mg/day, the recommended level for an adult. Additionally, the potassium is in a slow release form, meaning that it will be released over a period of time within the human body and will therefore generate maximum benefit without dose dumping.

An embodiment of the invention includes compositions for and methods of treating high blood pressure (hypertension) and for lowering risk of atherosclerosis and for lowering the risk of stroke by administering the core of the invention comprising potassium.

An embodiment of the invention includes compositions for and methods of treating kidney stones and osteoporosis by administering the core of the invention comprising potassium. Also included is the composition of the invention whereby calcium loss from the body is reduced or minimized, i.e. the core composition suppresses calcium excretion in the urine.

In an embodiment of the invention the composition includes Vitamin D. This composition of the invention improves hypertension and lowers the risk of osteoporosis. Vitamin D deficiency is relevant when levels are below 50ng/ml in patients and restoring levels to more than 50ng/ml is expected to reduce blood pressure. Vitamin D deficiency has been shown to predict hypertension. Supplementation with Vitamin D of between 400-5,000 IU per day is safe for most adults and Vitamin D supplementation has been shown in some studies to reduce systolic and diastolic blood pressure in patients with high blood pressure.

In an embodiment of the invention the composition includes fructooligosaccharides, a compound called a *pfbiotic* because it nourishes *probiotic* (friendly) bacteria in the colon. In another embodiment of the invention the composition includes short chain fatty acids (SCFAs) extracted from green bananas. These compositions of the invention improve absorption of nutrients, including calcium, in the digestive systems of mammals. These compositions of the invention can be used to decrease the risk of colon cancer and to treat Crohn’s disease.

In an embodiment of the invention the composition includes pro-vitamin A carotenoids. These compositions of the invention can be used to decrease the risk of chronic disease, including certain cancers, cardiovascular disease, and diabetes.
In one embodiment of the invention the composition includes extracts of cabbage and root vegetables, alone or in combination with extracts of bananas, can be used to decrease the risk of kidney cancer. These compositions of the invention can further be supplemented with antioxidants, including phenolic compounds, and or sulfur compounds.

In an embodiment of the invention the composition includes tryptophan. The tryptophan can be present in amount of at least about 10.6 mg per dose or serving of the nutraceutical composition, and can be supplemented for higher concentrations. In addition, the compositions can include Vitamin B₆. The compositions also can include iron. These compositions of the invention can be used to enhance mood, for example when treating depression. These compositions of the invention can also be used as a sedative or to relieve the symptoms of stress, for example when treating anxiety disorders. In addition, these compositions of the invention can be used for treating anemia, hypoglycemia and immune disorders.

In another embodiment of the invention the composition includes fiber. Other embodiments of the invention can additionally include pectin and/or resistant starch. These compositions can be used to improve laxation (smooth bowel movements). These compositions can also be used to treat constipation and diarrhea. Further, these compositions can be used to reduce the risk of coronary heart disease and of type 2 diabetes. The concentration of fiber in the nutraceutical admixture of the invention can be up to about 20-35 grams of soluble dietary fiber per day. For a children's formulation the dosage will be adjusted to an amount equal to or greater than their age plus 5 grams per day.

In another embodiment of the invention the composition includes antacid. Other embodiments of the invention can include protease inhibitors. These compositions can be used to treat heartburn, i.e. acid reflux, and to treat ulcers.

In an embodiment of the invention the composition includes antioxidants. The antioxidants can include polyphenols, vitamins A, C and E and carotenoids. These compositions can be used to reduce the risk of developing age-related macular degeneration (ARMD). These compositions can also be used to reduce the risk of coronary heart disease and to reduce inflammation in autoimmune diseases.
In an embodiment of the invention the composition includes vitamins C, Al, B6, B12, potassium and magnesium. These compositions can be used to treat the symptoms of nicotine withdrawal, i.e. as an aid to help people give up smoking.

Compositions comprising the core of the invention can be used to decrease the risk of developing certain cancers including leukemia, colorectal cancer and kidney cancer.

Compositions comprising the core of the invention can be used to treat nausea, including "morning sickness" experienced during pregnancy. In addition, compositions of the invention can be used to stabilize body temperature including fluctuations caused by changes in hormone levels, for example during pregnancy or menopause.

In another embodiment of the invention the composition includes an extract of banana peel. These compositions can be used to reduce itching and swelling, e.g. as caused by mosquito bites.

A key benefit of this invention are processes and dosage forms that will enable the effective manipulation of the banana, leading to a new set of "banana-extract" products with greater potency then the native fruit and therefore easier to ingest, store and otherwise use, thereby enhancing patient compliance and therapeutic potential.

Additional ingredients that can be combined with the fruit and/or vegetable extracts of the invention include:

1. Chymotrypsin for use in treating Asthma, bronchitis, lung diseases, sinusitis, inflammation;
2. Alpha-lipoic for use in treating or aiding Acid: type 2 diabetes, dementia, eye problems, chronic fatigue syndrome (CFS), HIV/AIDS, cancer, Lyme disease, Wilson's disease, heart disease, peripheral arterial disease, claudication, aging skin and wrinkles, Amanita mushroom poisoning;
3. Acai for use in treating or aiding Arthritis, high cholesterol, and improving general health;
5. N-acetyl Glucosamine for use in treating Osteoarthritis, and inflammatory bowel diseases including ulcerative colitis and Crohn's disease;
6. Lactobacillus for use in treating diarrhea, Bacterial vaginal infections, Irritable bowel
syndrome (IBS), ulcerative colitis, urinary tract infections (UTIs), general digestion problems, yeast infections, high cholesterol, Lyme disease, hives, fever blisters, canker sores, acne, cancer, stimulating the immune system;

7. Adenosine for use in treating irregular heart beat, Pain, shingles, lung cancer, immune system;

8. Alpha-Glyceryl Phosphatidylcholine for use in treating Alzheimer's disease, vascular dementia, ischemic dementia, multi-infarct dementia, stroke, transient ischemic attack (TIA), improving memory and cognitive function, and learning;

9. Alpha-ketoglutarate for use in treating Kidney disease, intestinal and stomach disorders, bacterial infections, yeast infections, improving athletic performance, improving protein usage in hemodialysis patients, and cataracts;

10. Alpha-linolenic Acid for use in treating heart disease, atherosclerosis, High blood pressure, Rheumatoid arthritis (RA), multiple sclerosis, lung infections in children, lupus, diabetes, high cholesterol, kidney disease, Crohn's disease, migraines, depression, skin diseases, lowering the risk of colds;

11. L-arginine for use in treating Congestive heart failure, angina pectoris, erectile dysfunction, Bladder inflammation, inflammation of the digestive tract, Male infertility, lowering the risk of contracting the common cold, migraine headache, decreased mental function in the elderly, improving athletic performance, breast cancer when used in combination with chemotherapy, wound healing, female sexual problems, sickle cell disease, improving healing of diabetic foot ulcers, and improving the immune system in people with head and neck cancer;

12. Ginseng for use in treating Thinking and memory deficiencies, Diabetes, erectile dysfunction, Depression, anemia, fluid retention, stomach inflammation and other digestive problems, chronic fatigue syndrome (CFS), fibromyalgia, breast cancer, ovarian cancer, lung cancer, liver cancer, skin cancer, fever, bronchitis, cancer, common cold, influenza;

13. Beta-sitosterol for use in treating High cholesterol, benign prostatic hyperplasia, Burns, prostate infections, sexual dysfunction, lowering the risk of colon cancer, rheumatoid arthritis, psoriasis, allergies, cervical cancer, fibromyalgia, systemic lupus erythematosus (SLE), asthma, baldness, migraines, chronic fatigue syndrome, menopause;
14. Bifidobacteria for use in treating colitis, diarrhea, Irritable bowel syndrome (IBS),
Ulcerative colitis, Common cold and flu (influenza); diarrhea caused by antibiotics; liver
problems; high cholesterol; lactose intolerance; mastitis; mumps; cancer; stomach
problems; replacing bacteria removed by diarrhea; chemotherapy; Lyme disease;
lowering the risk of infections after exposure to radiation, aging, antibiotics;
15. Brewer's Yeast for use in treating Premenstrual syndrome, Diarrhea, common cold, the
flu (influenza), loss of appetite, acne, boils, and diabetes;
16. Bromelain for use in treating osteoarthritis, Knee pain, severe burns, inflammation,
reducing swelling after surgery or injury, improving antibiotic absorption, hayfever,
lowering the risk of cancer, shortening of labor, making it easier to get rid of fats,
ulcerative colitis;
17. Casein Peptides for use in treating High blood pressure, high cholesterol, anxiety, fatigue,
epilepsy, intestinal disorders, lowering the risk of cancer, and reducing stress;
18. Calcium for use in treating heartburn, lowering bone loss, osteoporosis, premenstrual
syndrome, lowering the risk of colorectal cancer, High blood pressure, Pre-eclampsia,
High cholesterol, stroke, Reducing weight and body fat while dieting, lowering the risk of
or lessening the intensity of seizures, lowering the risk of falls, metabolic syndrome,
cancer, pregnancy-related leg cramps, diabetes, Lyme disease;
19. Cocoa for use in treating High blood pressure, high cholesterol; heart disease; intestinal
diseases; diarrhea; asthma; bronchitis; lung congestion; liver, bladder and kidney
ailments; diabetes; and lowering the risk of heart disease, wrinkles, and stretch marks
during pregnancy;
20. Chondroitin Sulfate for use in treating reduce hip and knee joint pain due to a type of
arthritis known as osteoarthritis, Heart disease, osteoporosis (weak bones), high
cholesterol;
21. Calcium Magnesium Inositol Hexaphosphate for use in treating lowering the risk of
kidney stones, Treating and lowering the risk of cancer, lowering the risk of heart
attacks;
22. Capsaicin for use in treating the pain of arthritis, shingles, and nerve pain in people with
diabetes, colic, cramps, toothache, blood clots, fever, nausea, high cholesterol, heart
disease, muscle spasms, laryngitis, Back pain, stomach ulcers, heartburn, irritable bowel
syndrome, migraine headache, allergic rhinitis, perennial rhinitis, nasal polyps, muscle spasms, laryngitis, swallowing dysfunction;

23. Cassia Cinnamon for use in treating Loss of appetite, muscle and stomach spasms, bloating, intestinal gas, vomiting, diarrhea, common cold, impotence, bed wetting, menstrual complaints, chest pain, high blood pressure, kidney problems, cancer;


25. Cranberry for use in treating urinary tract infections, Skin healing, pleurisy, cancer, chronic fatigue syndrome (CFS), reducing urine odor;

26. Curcumin for use in treating Upset stomach, Jaundice, hepatitis, diarrhea, fibromyalgia, liver and gallbladder problems, headache, menstrual problems, pain, ringworm, bruising, eye infections, skin problems, rheumatoid arthritis (RA), cancer;

27. Dehydroepiandrosterone for use in treating or lowering the risk of heart disease, breast cancer, lessening the signs of aging, and diabetes; and treatment of Alzheimer's disease and Parkinson's disease, Schizophrenia, achieve an erection, lupus, Osteoporosis, Heart disease, breast cancer, diabetes, weight loss, metabolic syndrome, depression, aging, HIV/AIDS, Parkinson's disease, Addison's disease, chronic fatigue syndrome (CFS), menopausal symptoms such as hot flashes, and improving growth and maturation in girls with hormone deficiency;

28. Dha (docosahexaenoic Acid) for use in treating coronary artery disease, AMD (age-related macular degeneration), Psoriasis, depression, dementia, improving vision, high cholesterol, improving infant development, reducing aggressive behavior in people under stressful situations, improving night vision in children with dyslexia, improving movement disorders in children;

29. Black Psyllium for use in treating Constipation, high cholesterol, Cancer, diarrhea, irritable bowel syndrome (IBS);

30. Guar Gum for use in treating Diarrhea, Constipation, Irritable bowel syndrome (IBS), High cholesterol, Diabetes, atherosclerosis;
31. Larch Arabinogalactan for use in treating common cold, flu, liver disease, high cholesterol, earache (otitis media), HIV/AIDS, cancer treatment, dietary fiber supplementation, stimulating the immune system, inflammation;

32. Rice Bran for use in treating High cholesterol, kidney stones, Allergic skin rash (atopic dermatitis), stomach cancer, Diabetes, high blood pressure, alcoholism, weight loss, AIDS, strengthening the immune system, increasing energy, enhancing athletic performance, improving liver function, lowering the risk of heart and blood vessel disease;

33. EGCG for use in treating cholesterol, kidney disease, heart disease, kidney stones, tooth decay, Genital warts, orthostatic hypotension, lowering the risk of bladder, esophageal, ovarian, and pancreatic cancers, Parkinson's disease, Decreasing high levels of fat in the blood (hyperlipidemia), Weight loss, high blood pressure, lowering the risk of heart disease, lowering the risk of stroke, osteoporosis, type 2 diabetes, skin cancer, breast cancer, lung cancer, stomach cancer, dental cavities, gingivitis, kidney stones, prostate cancer, diarrhea, chronic fatigue syndrome (CFS);

34. Ellagic Acid for use in treating or lowering the risk of cancer, treating viral infections, and treating bacterial infections;

35. Epa (eicosapentaenoic Acid) for use in treating depression, wound healing, borderline personality disorder, Reducing the risk of heart attack, stroke, and other cardiovascular problems in people with heart disease, Psoriasis, Prostate cancer, attention deficit-hyperactivity disorder (ADHD), menstrual disorders, schizophrenia, Alzheimer's disease, lung diseases, lupus;

36. Chrysin for use in treating Anxiety, inflammation, gout, HIV infection/AIDS, impotence, baldness, or lowering the risk of cancer;

37. Diosmin for use in treating hemorrhoids, leg ulcers caused by poor circulation, Varicose veins, bleeding (hemorrhage) in the eye, bleeding gums, and lessening or lowering the risk of damage to the liver;

38. Hesperidin for use in treating hemorrhoids, leg ulcers caused by poor circulation, Varicose veins;

39. Quercetin for use in treating prostate pain and swelling (inflammation), Hardening of the arteries (atherosclerosis), heart disease, high cholesterol, high blood pressure, diabetes,
cataracts, hayfever (allergic rhinitis), stomach and intestinal ulcers, kidney transplants, schizophrenia, inflammation, asthma, gout, viral infections, chronic fatigue syndrome (CFS), increasing exercise endurance, lowering the risk of cancer;

40. Rutin for use in treating Osteoarthritis, Blood vessel disease, varicose veins, lowering the risk of mouth ulcers associated with cancer treatments, bleeding, and hemorrhoids;

41. Folic Acid for use in treating Kidney problems, Lowering homocysteine levels in people with kidney disease, Reducing harmful effects of a medicine called methotrexate, Decreasing the risk of certain birth defects when taken by pregnant women, colorectal cancer, pancreatic cancer, breast cancer, Depression, vitiligo, gum disease, lowering the risk of re-blockage of blood vessels after angioplasty, liver disease, alcoholism, Alzheimer's disease, memory and thinking function in older people, lowering the risk of pregnancy loss, lowering the risk of cervical cancer, infertility, lung cancer, restless leg syndrome, age-related hearing loss, sickle cell disease, cancer due to a disease called ulcerative colitis, osteoporosis (brittle bones);

42. Genistein for use in treating reduce cholesterol, Hot flashes, osteoporosis, breast cancer, diabetic nerve problems, diabetes type 2, lowering the risk of thyroid cancer, endometrial cancer, lung cancer, prostate cancer, improving memory, reducing breast pain, weight loss, asthma, high blood pressure, premenstrual syndrome (PMS);

43. Ginger for use in treating motion sickness and seasickness, joint pain, Nausea and vomiting following surgery, dizziness, Rheumatoid arthritis, osteoarthritis, loss of appetite, colds, flu, migraine headache, lessening nausea caused by chemotherapy;

44. Ginkgo for use in treating Alzheimer's disease, Raynaud's syndrome, Vertigo and dizziness, Premenstrual syndrome (PMS), glaucoma and eye damage caused by diabetes, age-related macular degeneration (AMD), anxiety, attention deficit-hyperactivity disorder (ADHD), blood clots, heart disease, stroke, high cholesterol, "hardening" of the arteries (atherosclerosis), colorectal cancer, ovarian cancer, hearing loss, schizophrenia, Coughs, asthma, bronchitis, urinary problems, cognitive problems related to Lyme disease, digestion disorders, chronic fatigue syndrome (CFS), scabies, and skin sores;

45. Ginseng, American for use in treating type 2 diabetes, lowering the risk of respiratory tract infections such as the common cold or influenza in adults, Stress, anemia, insomnia, gastritis, impotence, fever, attention deficit-hyperactivity disorder (ADHD), HIV/AIDS,
fibromyalgia, breast cancer;

46. Glutathione for use in treating lung diseases by inhaling (breathing in) glutathione, use as an injection into the veins to treat infertility in men, Parkinson's disease, diabetes, anemia in people on hemodialysis, or clogging of the arteries (atherosclerosis). When taken by mouth for cataracts, glaucoma, lessening the signs of aging, treating or lowering the risk of alcoholism, asthma, cancer, heart disease, high cholesterol levels, liver problems, AIDS, chronic fatigue syndrome, memory loss, Alzheimer's disease, osteoarthritis, or Parkinson's disease;

47. Goji Berry for use in treating Diabetes, high blood pressure, fever, malaria, cancer, blood circulation problems, sexual problems (impotence), dizziness, ringing in the ears (tinnitus);

48. Grape seed extract for use in treating Circulation problems, lowering the risk of heart disease, treating varicose veins, hemorrhoids, constipation, cough, attention deficit-hyperactivity disorder (ADHD), chronic fatigue syndrome (CFS), diarrhea, heavy menstrual bleeding (periods), age-related macular degeneration (ARMD), canker sores, poor night vision, liver damage, high cholesterol levels;

49. Guarana for use in treating Malaria, diarrhea, fever, headaches, heart problems, improvement of exercise endurance, improvement of short-term, high-intensity performance and power, increased mental alertness, increasing blood pressure in people who have low blood pressure, chronic fatigue syndrome (CFS), joint pain, fluid retention, weight loss;

50. Hawthorn for use in treating heart failure, Decreased heart function, blood circulation problems, heart disease, abnormal heartbeat rhythms (arrhythmias), high blood pressure, low blood pressure, high cholesterol, muscle spasms, anxiety, sedation;

51. Hyaluronic Acid for use in treating Osteoarthritis, Sores in the mouth, Healing skin wounds and burns, and lessening the signs of aging;

52. Kava for use in treating anxiety, Stress, insomnia, restlessness, social anxiety, attention deficit-hyperactivity disorder (ADHD), epilepsy, psychosis, depression, chronic fatigue syndrome (CFS), headaches, colds, respiratory tract infections, tuberculosis, rheumatism, chronic bladder infections, sexually transmitted diseases, menstrual problems, lowering the risk of cancer;
53. L-carnitine for use in treating heart disease and heart failure, Eating disorders, fatigue, diabetes, high cholesterol, blood disorders, circulatory problems in the legs, leg ulcers, attention deficit-hyperactivity disorder (ADHD), Lyme disease, autism, Rett syndrome;

54. Lactoferrin for use in treating Hepatitis C, Helicobacter pylori infection (an ulcer-causing bacterial infection), stimulating the immune system, lessening damage related to aging, promoting healthy bacteria in the intestine, regulating iron metabolism, fighting bacteria and viruses (antibacterial and antiviral agent), use as an antioxidant;

55. Lycopene for use in treating diabetes, Prostate cancer, breast cancer, bladder cancer, ovarian cancer, pancreatic cancer, lung cancer, colorectal cancer, oral leukoplakia, heart disease, eye disease (age related maculopathy), exercise-induced asthma, human papilloma virus (HPV) infection, cataracts, and lessening or lowering the risk of hardening of the arteries (atherosclerosis);

56. Magnesium for use in treating magnesium deficiency, laxative for constipation, Dyspepsia, pre-eclampsia, Cluster headaches, Migraine headaches, Asthma attacks, Premenstrual syndrome (PMS), osteoporosis, lowering the risk of type 2 diabetes in overweight, middle-aged women, Pregnancy-related leg cramps, Irregular heartbeat (arrhythmia), Diseases of heart valves (mitral valve prolapse), High cholesterol, Chest pain due to artery disease, Kidney stones, Fibromyalgia pain, Metabolic syndrome, Chronic fatigue syndrome (CFS), stroke, Chronic obstructive pulmonary disease (COPD), Attention deficit-hyperactivity disorder (ADHD), hayfever, anxiety, restless leg syndrome, high blood pressure (hypertension), Lyme disease, multiple sclerosis (MS), premature labor

57. Manganese for use in treating osteoporosis, Anemia, premenstrual syndrome (PMS), arthritis (osteoarthritis);

58. Mangosteen for use in treating Dysentery, diarrhea, urinary tract infections (UTI), gonorrhea, thrush, tuberculosis, eczema, menstrual disorders;

59. Melatonin for use in treating sleep disorders, improving the effectiveness of certain cancer medications used to fight tumors in the breast, lung, kidney, liver, pancreas, stomach, colon, prostate, and decreasing some side effects of cancer treatment, Cluster headaches, Ringing in the ears (tinnitus), chronic fatigue syndrome (CFS), osteoporosis, irritable bowel syndrome (IBS), epilepsy, birth control, fibromyalgia, aging, menopausal
symptoms, sleep problems associated with attention deficit-hyperactivity disorder (ADHD), insomnia caused by medications used for high blood pressure (beta-blockers), headache characterized by sudden sharp pain (idiopathic stabbing headache), migraine;

60. Niacin for use in treating High cholesterol, Heart disease, including hardening of the arteries (atherosclerosis), Diarrhea, Diabetes, types 1 and 2, cataracts, Osteoarthritis, Alzheimer's disease, Migraine headache, dizziness, depression, motion sickness, alcohol dependence, improving orgasm, acne, attention deficit-hyperactivity disorder (ADHD);

61. Octacosanol for use in treating amyotrophic lateral sclerosis (Lou Gehrig's disease, ALS), improving strength, stamina, and reaction times; herpes infections; skin diseases; Parkinson's disease; high cholesterol levels; hardening of the arteries (atherosclerosis);

62. Onion for use in treating Asthma, diabetes, upset stomach, fever, colds, cough, bronchitis, high blood pressure (hypertension), lowering the risk of infection, swelling (inflammation) of the mouth and throat, wounds, loss of appetite, lessening or lowering the risk of hardening of the arteries (atherosclerosis);

63. Papain for use in treating Herpes zoster (shingles), Sore throat and throat swelling (pharyngitis), Digestion problems, diarrhea, hayfever, runny nose, psoriasis, cancer, treating infected wounds, sores, ulcers, intestinal worms;

64. Papaya for use in treating Stomach and intestine problems, parasite infections;

65. Pectin for use in treating High cholesterol, Diarrhea, reducing the risk of colon cancer, diabetes, infection, mouth and throat sores, reducing damage from radiation, lessening or lowering the risk of heavy metal toxicity, prostate cancer, heartburn;

66. Phosphatidylcholine for use in treating Anxiety, hepatitis B, eczema, gallbladder disease, manic-depressive illness, circulation disorders of the arms and legs, weight loss, decrease fat, high cholesterol, premenstrual syndrome (PMS), memory loss, Alzheimer's disease, depressed immunity, lessening the signs of aging;

67. Phosphatidylserine for use in treating Alzheimer's disease, Depression, exercise-induced stress, improving athletic performance, improving thinking ability, attention deficit-hyperactivity disorder (ADHD);

68. Pomegranate for use in treating High cholesterol (hyperlipidemia), heart disease, intestinal worm infestations, high blood pressure (hypertension), hardening of the arteries (atherosclerosis), obesity and weight loss, gum disease, fungal mouth infections, diarrhea,
dysentery, sore throat, hemorrhoids, prostate cancer;

69. Potassium for use in treating High blood potassium, stroke, Insulin resistance, heart attack, menopausal symptoms, fatigue and mood swings in early menopause, infant colic, allergies, headaches, acne, alcoholism, Alzheimer's disease, arthritis, blurred vision, cancer, chronic fatigue syndrome, colitis, confusion, constipation, skin problems, fluid retention, fever, gout, insomnia, irritability, Meniere's disease, muscle weakness, muscular dystrophy, stress, myasthenia gravis;

70. Fructo-oligosaccharides for use in treating diarrhea, Promoting growth of bacteria in the gut, high cholesterol levels, and constipation;

71. Prickly Pear Cactus for use in treating Diabetes, Hangover, High blood cholesterol, obesity, colitis, diarrhea, enlarged prostate, and treating infections caused by viruses;

72. Saccharomyces Boulardii for use in treating diarrhea, Acne, lessening or lowering the risk of yeast overgrowth in the digestive tract of patients with cystic fibrosis, urinary Indigestion, diarrhea, improving blood circulation, spleen and stomach problems hives, fever blisters, canker sores, irritable bowel syndrome (IBS), Crohn's disease, ulcerative colitis, lactose intolerance;

73. Pycnogenol for use in treating Circulation problems, Varicose veins, endurance in athletes, High blood pressure, Asthma, Aging, allergies, heart disease, lowering the risk of stroke, muscle soreness, pelvic pain in women, pain in late pregnancy, diabetes, leg cramps, circulation problems in diabetes, osteoarthritis, erectile dysfunction (impotence), menopausal symptoms;

74. Red Yeast for use in treating High cholesterol, Indigestion, diarrhea, improving blood circulation, spleen and stomach problems;

75. Resveratrol for use in treating Hardening of the arteries (atherosclerosis), high cholesterol, and lowering the risk of cancer;

76. SAMe for use in treating osteoarthritis, Depression, Fibromyalgia, Heart disease, anxiety, bursitis, tendonitis, chronic low back pain, improving intelligence, premenstrual syndrome (PMS), premenstrual dysphoric disorder (PMDD), attention deficit-hyperactivity disorder (ADHD), chronic fatigue syndrome (CFS), alcohol-related liver disease, multiple sclerosis, spinal cord injury, seizures, migraine headache;

77. Saffron for use in treating Depression, Premenstrual syndrome (PMS), Asthma, insomnia,
cancer, hardening of the arteries due to fatty plaques, cough, stomach gas, premature ejaculation, baldness, pain;

78. Saw Palmetto for use in treating the symptoms of enlarged prostate, Treating nonbacterial prostatitis/chronic pelvic pain syndrome, increasing breast size, hair growth, colds and coughs, sore throat, asthma, chronic bronchitis, prostate cancer, and migraine headache;

79. Selenium for use in treating or lowering the risk of heart disease, skin cancers, lung cancer, prostate cancer, rheumatoid arthritis, HIV/AIDS; hardening of the arteries (atherosclerosis); arthritis (osteoarthritis); rheumatoid arthritis; macular degeneration (eye disease); hayfever; gray hair; mood disorders; chemotherapy side effects, swelling after surgery, abnormal pap smears; infertility; cataracts; chronic fatigue syndrome (CFS); bird flu; lowering the risk of miscarriage; protecting against colorectal cancer, esophageal cancer, gastric cancer, and lowering the overall cancer risk;

80. Tamarind for use in treating Constipation, fever, liver and gallbladder disorders, dry eyes;

81. Tomato for use in treating or lowering the risk of bladder cancer, breast cancer, Diabetes, Heart disease, cataracts, arthritis, asthma, cervical cancer, colorectal cancer, gastric cancer, lung cancer, ovarian cancer, pancreatic cancer, high blood pressure, prostate cancer, the common cold, chills, and digestive disorders;

82. L-tryptophan for use in treating Depression, anxiety, seasonal affective disorder, attention deficit-hyperactivity disorder (ADHD), treating sleep disorders;

83. Vitamin A for use in treating Breast cancer, cataracts, Lung cancer, ovarian cancer, cervical cancer, esophageal cancer, pancreatic cancer, colorectal cancer, gastric cancer, promoting good vision, age-related macular degeneration (AMD), glaucoma, lowering the risk of and speeding recovery from infections, improving immune function, skin conditions other than acne, relieving hayfever symptoms;

84. Vitamin B1 for use in treating Cataracts, Kidney disease, Poor appetite, ulcerative colitis (UC), chronic diarrhea, stomach problems, brain conditions, AIDS, heart disease, alcoholism, stress, aging, canker sores, improving athletic performance, lowering the risk of cervical cancer;

85. Vitamin B5 for use in treating Skin problems, alcoholism, allergies, attention deficit-hyperactivity disorder (ADHD), rheumatoid arthritis, osteoarthritis, hair loss, asthma, heart problems, carpal tunnel syndrome, lung disorders, colitis, conjunctivitis,
86. Vitamin B6 for use in treating sideroblastic anemia, Reducing elevated blood levels of homocysteine, a substance thought to be involved in heart disease, Upset stomach and vomiting in pregnancy, Premenstrual syndrome (PMS), Kidney stones, Reducing lung cancer risk in men who smoke, lowering the risk of reblockage of blood vessels after angioplasty, boosting the immune system, muscle cramps, eye problems, kidney problems, night leg cramps, arthritis, allergies, asthma, attention deficit-hyperactivity disorder (ADHD), Lyme disease;

87. Para-aminobenzoic Acid (paba) for use in treating Female infertility, arthritis, anemia, constipation, headaches, lessening hair loss, darkening gray hair, and various skin conditions such as vitiligo, pemphigus, dermatomyositis, morphea, Peyronie's disease;

88. Vitamin B12 for use in treating or lowering the risk of re-blockage of blood vessels after heart artery dilation (balloon angioplasty), shaky-leg syndrome, allergies, aging, fatigue or tiredness, eczema, chronic fatigue syndrome (CFS), Alzheimer's disease, diabetes, heart disease, Lyme disease, immune system problems, memory problems, multiple sclerosis, breast cancer, high cholesterol, lung cancer, lowering the risk of cervical cancer, psoriasis;

89. Vitamin B2 for use in treating migraine headaches, cataracts, Acne, muscle cramps, boosting the immune system, aging, maintaining healthy skin and hair, canker sores, memory loss including Alzheimer's disease, lactic acidosis (a serious blood-acid imbalance) in people with acquired immunodeficiency syndrome (AIDS), lowering the risk of cervical cancer;

90. Vitamin B7 for use in treating Hair loss, diabetes, diabetic nerve pain, brittle fingernails and toenails;

91. Inositol for use in treating polycystic ovary syndrome, Psoriasis, Problems metabolizing fat, high cholesterol, inability to sleep, attention deficit-hyperactivity disorder (ADHD), cancer, hair growth;

92. Para-aminobenzoic Acid (paba) for use in treating Female infertility, arthritis, anemia,
constipation, headaches, lessening hair loss, darkening gray hair, and various skin conditions such as vitiligo, pemphigus, dermatomyositis, morphea, Peyronie's disease;

93. Vitamin C for use in treating or reducing the risk of certain cancers of the mouth and breast, common cold, High blood pressure, gallbladder disease, Reducing the risk of bone and cartilage loss, atherosclerosis, ulcers in the stomach, AMD (age-related macular degeneration), Wounds, pressure sores, gout, tuberculosis, dental cavities, constipation, acne, allergies (hayfever), cystic fibrosis, infertility, diabetes, heart disease, attention deficit-hyperactivity disorder (ADHD), lowering cholesterol, kidney disease, liver disease, esophageal cancer, gastric cancer, mental stress, Lyme disease, chronic fatigue syndrome (CFS), treating and protecting against sun-damaged skin when vitamin C is put on the skin;

94. Vitamin D for use in treating osteomalacia, Psoriasis, osteoporosis, Reducing the risk of multiple sclerosis (MS), rheumatoid arthritis, hyperparathyroidism, Cancer, Weight loss, Cardiovascular disease, high cholesterol, a blood cell disease called myelodysplasia syndrome, a muscle disease called proximal myopathy, colorectal cancer, warts, gum disease, bronchitis, asthma, breathing disorders, diabetes, metabolic syndrome, premenstrual syndrome (PMS);

95. Vitamin E for use in treating bladder cancer, Alzheimer's disease, rheumatoid arthritis, pre-eclampsia, Premenstrual syndrome (PMS), lowering the risk of Parkinson's disease, glomerulosclerosis, Beta-thalassemia, AMD (age-related macular degeneration), Allergies, asthma, skin disorders, cloudy vision in older people (cataracts), diabetes, esophageal cancer, gastric cancer, chronic fatigue syndrome (CFS), oral cancer, skin cancer, epilepsy, menstrual disorders, high blood fat levels, liver disease, stroke, leg cramps, common cold;

96. Vitamin K for use in treating Osteoporosis, heart disease, spider veins, bruises, scars, stretch marks, burns, swelling;

97. Whey Protein for use in Improving of athletic performance, an alternative to milk for people with lactose intolerance, lowering the risk of allergies in infants, asthma, high cholesterol, cancer, obesity; and

98. Zinc for use in Decreasing the length of time the common cold lasts, Acne, Osteoporosis, AMD (age-related macular degeneration), stomach ulcers, lowering the risk of muscle
cramps, Attention deficit-hyperactivity disorder (ADHD), Alzheimer's disease, wrinkled skin, Crohn's disease, ulcerative colitis, diabetes, treating the common cold when used as a nose spray, asthma, Down syndrome, recurrent ear infections, male sexual problems, lowering the risk of cancer.

The following fruits and vegetables can be used for the sugar removal and extract preparation process of the invention: Apple, Apricots, Cantaloupe, Grapefruit, Pineapple, Strawberries, Raspberries, Blueberries, Blackberries, Watermelon, Cactus pear, Carambola, Cherimoya, Date, Feijoa, Fig, Orange, Clementine, Grape, Plum, Kiwi, Kumquat, Loquat, Lychee, Mango, Mangosteen, Monster deliciosa, Papaya, Passion fruit, Pepino, Persimmon, Physalis, Pomelo, Cherry, Pomegranate, Rambutan, Peach, Pear, Tamarind, Quince, Cranberry, Coconut, Goji berry, Nectarine, Black currant, Red currant, Gooseberry, Pumpkin, Beet, and Carrot and combinations thereof.

EXAMPLES

EXAMPLE 1: Method of processing bananas to isolate the desirable components.

1. Homogenize the fruit in an excess of purified water until the material is fully in suspension.
2. Sieve the homogenate to remove large pieces of material.
3. Adjust the pH of the homogenate to pH 6.0 - 6.4, which is within the optimum pH for α-Amylase activity from a microbial source such as B. subtilis. Also, the addition of between 50 - 70 ppm of calcium ion is recommended to maintain stability of the enzyme during high temperature digestion.
4. Add enzyme so that between 0.2 - 0.5U of activity is present per gram dry weight of banana homogenate.
5. Raise temperature to 50 - 70°C and monitor reaction by the liquefaction of the homogenate. During processing pasteurization of the material is also an option, with thermal cycling between 70° - 90°C.
6. The digestion is completed with the homogenate completely liquefied and the level of simple sugars does not increase.
7. After starch digestion it is desired to remove as much simple sugars as possible.
a) Simple sugars can be removed by dilution of the homogenate and then subjecting the homogenate to tangential flow filtration (TFF) using a nano-filtration membrane. 

b) An alternative method to produce banana extract with lower sugar is to directly remove sugar using the TFF step above prior to amylase digestion. This can be applied to very ripe bananas that have a high sugar content.

c) Another process for removing simple sugars is to extract the banana homogenate with an excess of ethanol. The simple sugars partitioned into the ethanol while the other starch components remained in the insoluble phase. The insoluble phase was then removed and recovered, dried and used as product. The application of amylase and ethanol extraction removed as much as 60% of the original starch content.

8. The potency of the material is defined by the level of potassium and therefore some adjustments to the process will be needed during the TFF operation of step 7 to ensure that potassium is not depleted from the product (e.g., adding potassium as part of a buffer or, at the drug product stage, using potassium bicarbonate for a rapid dissolving tablet or as an excipient).

The intention of the process is to maintain the same level of potassium in the final product as was seen on a dry weight basis in the raw materials.

9. The final step in processing the material can be spray drying to remove water and render the product in a state suitable for storage and blending.

All chemicals and product contact materials used in the process need to be food grade or better.

The use of potassium containing buffers is acceptable while the use of sodium containing chemicals and buffers should be avoided.

**EXAMPLE 2: Method of processing banana to isolate the desirable components as well as remove undesirable components.**

1. Homogenize the fruit in an excess of purified water until the material is fully in suspension.
2. Sieve the homogenate to remove large pieces of material. Further homogenize the large pieces, sieve and combine with homogenate.
3. Adjust the pH of the homogenate to pH 6.0 - 6.4, which is within the optimum pH for α-Amylase and other amylase activity from a microbial source such as B. subtilis or other amylase source, be it natural, recombinant, mammalian or other microbial sources or sources as well as in combination with other enzymes such as pectinases. Also, the addition of between 50 - 70 ppm
of calcium ion is recommended to maintain stability of the some amylase enzymes during high
temperature digestion.
4. Add enzyme so that between 0.2 - 0.5U of activity is present per gram dry weight of banana
homogenate. Enzyme levels can vary from trace levels to higher levels.
5. Raise temperature to 50 - 70°C and monitor reaction by the liquefaction of the homogenate.
During processing pasteurization of the material is also on option, with thermal cycling between
70°C - 90°C.
6. The digestion is completed when the homogenate is completely liquefied and the level of
simple sugars does not increase.
7. After starch digestion it is desired to remove as much simple sugars as possible.
   a) Simple sugars can be removed by addition of Saccharomyces cerevisiae and other
      Saccharomyces sp. and/or Lactobacillus acidophilus and other Lactobacillus sp. as well
      as other microbes that can utilize carbohydrates and sugars as nutritional substrates after
      the amylase treated banana homogenate has cooled to room temperature. In this case the
      homogenate is incubated at a temperature between 5 - 90°C in a sanitary container with
      an air lock or other device to prevent microbial contamination of the homogenate.
   b) A preferred embodiment is to conduct the above fermentation with the homogenate
      being stirred and with the addition of air sparging to accelerate the digestion of the
      carbohydrates and sugars. Fermentation and removal of the sugars and carbohydrates are
      indicated when carbon dioxide is no longer evolving from the homogenate.
   c) Removal of carbohydrates and sugars from the banana homogenate can also be
      facilitated using the above fermentation technology with membranes to separate the small
      molecular weight sugars from the large molecular entities. Membranes are those used for
      nanofiltration and dialysis and salt removal.
   d) Additionally, centrifugation can be used to remove and otherwise separate high
      molecular weight constituents from other constituents in combination with membranes
      and pressure, by controlling a combination of centrifugal force, hydrostatic pressure and
      trans-membrane pressure.
8. A subsequent step in processing the material is lyophilization to remove all accessible water
   while retaining other components or the use of spray drying to remove water and render the
   product in a dry state suitable for storage and blending. Additionally, water can be removed by
heating the material in an oven, boiling with and without application of partial pressure or vacuum, rotoevaporation, spin-drying under vacuum at high speed, distillation and evaporation using other means. The use of potassium containing buffers is acceptable while the use of sodium containing chemicals and buffers should be avoided.

EXAMPLE 3: Process for the fractionation of fruit derived products using supercritical fluid chromatography.

This invention pertains to the large scale processing of fruit derived products to remove objectionable agents. A process stream comprising of a process fruit that is subjected to enzymatic treatment(s), fermentation, and phase separation between solids and liquid supernatant is disclosed. Said process allows for the preparation of a fruit derived product that is low in sugars and carbohydrates while retaining in the solid and liquid phases nutritionally useful components found in the fruit. Additionally, said process allows for the removal of objectionable flavor components derived during the fermentation process through selective fractionation of the product into a multi-component process stream, whereby the objectionable components are discarded. The treatment process is comprised of chromatography unit operations whereby the sample is applied to a chromatographic column (a stationary phase) and treated in the column using a mobile phase comprised of carbon dioxide, water, solvents, buffer and/or mixtures of liquids and buffers. The stationary phase is comprised of silica, polymeric, inorganic materials and/or other solids and supports that facilitate the fractionation by being the stationary phase. The process is optimized such that process conditions allow for the objectionable agents to be retained on the chromatographic system while the desired products are not retained on the system and pass directly through the system. Conditions are then changed to optimize the removal of all other retained product related materials such that said material is recovered. This binary chromatographic system can be comprised of any number of stationary phases such as normal, reversed, ion-exchange, hydrophobic and other phases and modes of chromatography.

EXAMPLE 4: Process and system for a compartmentalized fermentation in a tank that allows for isolation of the fermenting microbes such as yeast, bacteria, and other food processing microbes.
The intended use of the system is to allow for use of microbial processing type unit operations remotely from the primary process stream, whereby the microbial operations are contained in an isolated tank separated from the product tank by a membrane. Said membrane is selected based on the ability of the membrane to retain microbes in the isolation tank while allow for the liquid portion of the product stream to perfuse through the microbial tank. The isolation tank segregates the process stream solid from the microbes, facilitating recovery of the process stream and allowing for the microbe to perform as a biostat in a continuous flow operation. The membrane can be composed of smooth sheets, hollow fibers, pleated sheets, and operates in a preferred mode of tangential flow filtration.
What is claimed is:

1. A composition comprising a fruit or vegetable extract wherein said extract comprises more than about 2500mg potassium.
2. The composition of claim 1, wherein said extract is formulated in a dosage form selected from the group consisting of caplets, capsules, tablets, powders, flakes, immediate release form, rapid release form, sustained release form, controlled release form and dissolving forms.
3. The composition of claim 1, wherein said extract is formulated as a slow release oral dosage forms or device.
4. The composition of claim 1, wherein said extract is formulated as drinks.
5. The composition of claim 4, wherein said drinks are alcoholic beverages or non-alcoholic beverages.
6. The composition of claim 1, wherein said extract is formulated an edible product.
7. The composition of claim 6, wherein said edible product is selected from the group consisting of chocolate, cereal, bars, and yoghurt.
8. The composition of claim 1, wherein said extract is formulated as a product that is applied to the skin.
9. The composition of claim 1, wherein said extract is formulated as a product that is smelled, absorbed through the olfactory senses or both.
10. The composition of claim 1, wherein said extract is formulated as a product applied to hair.
11. The composition of claim 1, wherein said extract is formulated as a product applied to nails.
12. The composition of claim 1, wherein said extract is formulated as a product applied within body cavities.
13. The composition of claim 12, wherein said product is a suppository.
14. The composition of claim 1, wherein said extract is formulated as a product applied to the eyes or its surroundings.
15. The composition of claim 1, wherein said extract is formulated as a cream, ointment, mask or skin patch.
16. The composition of claim 1, wherein said extract is formulated as a soap or shampoo.
17. The composition of claim 1, wherein said extract is formulated as an injectable or intravenous product.
18. The composition of claim 1, wherein said fruit is Stage 12 bananas, non-desiccated bananas, partially desiccated bananas or completely desiccated bananas.
19. The composition of claim 1, wherein said extract further comprises more than about 15g fiber.
20. The composition of claim 1, wherein said extract further comprises less than about 0.5g sugar.
21. The composition of claim 1, wherein said extract further comprises anti-oxidants.
22. The composition of claim 21, wherein said extract further comprises more than about 15g fiber and less than about 0.5g sugar.
23. The composition of claim 1, further comprising GRAS ingredients, pharmaceutical ingredients or combinations thereof.
24. The composition of claim 1, wherein said extract is from banana peel.
25. The composition of claim 1, wherein said extract is from plantain, kale, onion, celery, raisin, prune, avocado, potato, fig, cantaloupe, mango, papaya, tomato, lima bean, cucumber, garlic, strawberry, artichoke, beet, almonds, kiwi, apricot, coconut, date, and/or sweet potato.
26. The composition of claim 1, wherein the product is produced by the removal of sugars and carbohydrates.
27. The composition of claim 26 wherein said sugars and carbohydrates are removed using GRAS enzymes, microbial agents or by selective extraction with solvents, co-solvents, and water.
28. A method of treating a health condition comprising administering the composition of claim 1 to a mammal in need thereof.
29. The method of claim 28, wherein said health condition is selected from the group consisting of hypertension, stroke, nervous system disorders, kidney disorders, osteoporosis, anemia, nausea, stress, anxiety, depression, mood disorders, menopause, morning sickness, pregnancy-related temperature disorders, heartburn, ulcers, cancer, constipation, diarrhea, macular degeneration, Crohn's disease, cardiovascular disease,
diabetes, obesity, nicotine withdrawal, mosquito bites, autoimmune diseases, inflammation, HIV infection, and metabolic syndromes.

30. A method of making the composition of claim 1, comprising: (a) combining said fruit or vegetable with water to create a slurry, (b) pulverizing the fruit or vegetable slurry, (c) optionally, contacting said fruit or vegetable slurry with an enzyme, (d) incubating said fruit or vegetable slurry with a microorganism, (e) separating the solids component of the slurry from the liquid supernatant, (f) optionally drying the solids component.

31. The method claim 30, comprising freezing said fruit or vegetable prior to step (a).

32. The method of claim 30, further comprising extracting ingredients prior to at least step (f) wherein extracting comprises fractionating or precipitating said ingredients using a solvent, supercritical fluid, acids or bases.

33. The composition of claim 1, further comprising Vitamin D.

34. The composition of claim 1, further comprising resveratrol.

35. The composition of claim 1, further comprising potassium.

36. The composition of claim 33, further comprising potassium.

37. The composition of claim 1, further comprising flavonol.

38. The composition of claim 1, further comprising hawthorn.

39. The composition of claim 1, further comprising bitter melon, citrulline, broccoli, glutamic acid, guava, cocoa, acai, pomegranate, goji and/or cherries.

40. A method of making the composition of claim 35, comprising measuring the concentration of potassium in said extract and adjusting the potassium concentration to be within a desired range for allowing for uniform dosing of a patient.
Process 1: Removal of yeast with pre-treating target material

1. Eliminate sugar
2. Precipitate for filtering
3. Filter yeast and bacteria
4. Separate liquid from target
5. Dry the target
6. Is the target product dried or in dough format?
7. Dried Fruit powder
8. Separated alcohol from water (optional)
9. Water and Alcohol
10. Solids
11. Supernatant
12. Recycle
13. Yes
14. No
15. Out

FIGURE 1
Process 1 (details):
Centrifuge removal of yeast and TFF to clean up the target material

FIGURE 2
Process 2: Removal of yeast without pre-treating prior to filtering

1. Eliminate sugar
2. Filter yeast and bacteria
3. Pre-treat for liquid separation (optional)
4. Separate liquid from target
   - Dried? Yes → Dry the target
   - Dried? No → Separate alcohol from water (optional)
     - Water and Alcohol
     - Dried Fruit powder
5. Is the target product dried or in dough format?
6. Recycle Yes → Water
7. No → Alcohol
8. For sale

Out
Process 3: Pre-removal of large particles and TFF of yeast
Process 4: Removal of yeast with pre-treating target material

1. Is the target product dried or in dough format?
   - Yes: Dry the target
   - No: Separate liquid from target

2. Separate liquid from target
   - Yes: Filter yeast and bacteria
   - No: Separate alcohol from water (optional)

3. Filter yeast and bacteria
   - Yes: Separate fiber and all other material
   - No: Prewash for filtering

4. Separate fiber and all other material
   - Yes: Starch conversion and sugar removal (optional)
   - No: Remove sugar

5. Remove sugar
   - Yes: Separate Carbohydrates from target
   - No: Sugar + Rest of fruit

6. Separate Carbohydrates from target
   - Yes: "big" particles
   - No: Sugars + Rest of fruit

7. Out

Dried: Fruit powder
Water and Alcohol
Alcohol
Water
Recycle
No
Out
Fiber
Solids
"big" particles
Process 4 (details): Pre-removal of large particles and centrifuge removal of yeast!

1. Lyophilize
2. Is the target product dried or in dough format?
   - Yes: Dried fruit powder
   - No: Reverse Osmosis

3. Reverse Osmosis
   - Yes: Water and Alcohol
   - No: Distiller

4. Distiller
   - Yes: Water
   - No: Wash

5. Wash
   - Yes: Bioreactor
   - No: Centrifuge

6. Centrifuge
   - Yes: Removes Big particles
   - No: Removes Yeast (optional)

7. Bioreactor
   - Yes: "big" particles
   - No: Wash (particles to separate residual sugar)

8. Wash
   - Yes: Rest of fruit
   - No: Out

9. Out

- Process flowchart detailing the steps for pre-removal of large particles and yeast removal using various processing techniques such as lyophilization, reverse osmosis, distillation, washing, centrifugation, and bioreactors.
**LIQUID SOLUTION VERSION 3.0-LAL 5/3/11 SUPER**

**BANANA LOGIX INC**  
**ATTN: LALIT LODHA**  
**519 HARRISON AVE**  
**BOSTON, MA 02118**

**LAB SAMPLE #**  
**AI07513**

**SAMPLE RECEIVED** May 04, 2011

<table>
<thead>
<tr>
<th>Serving Per Container</th>
<th>100.0 g</th>
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<tr>
<td>3.5 oz (100 g)</td>
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<table>
<thead>
<tr>
<th>VARIED</th>
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</thead>
<tbody>
<tr>
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</tbody>
</table>

<table>
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<th>Daily Value (42 g)</th>
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<td>Fat</td>
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<tr>
<td>Protein</td>
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<tr>
<td>Moisture</td>
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<td>Ash</td>
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<tr>
<td>Dietary Fiber</td>
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<td>0 %</td>
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<tr>
<td>Sugars</td>
<td>0 g</td>
<td>0 %</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>0 mg</td>
<td>0 %</td>
</tr>
<tr>
<td>Saturated Fat</td>
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<td>0 %</td>
</tr>
<tr>
<td>Monounsaturated Fat</td>
<td>N/A</td>
<td>0 %</td>
</tr>
<tr>
<td>Polyunsaturated Fat</td>
<td>N/A</td>
<td>0 %</td>
</tr>
<tr>
<td>Trans Fat</td>
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<tr>
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<td>Vitamin C</td>
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<tr>
<td>Calcium</td>
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</tr>
<tr>
<td>Potassium</td>
<td>170 mg</td>
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</tr>
</tbody>
</table>

**END OF REPORT**

**Managing Director**

200 Express Street • Plainview, NY 11803 • 516-576-1400 • 800-CERT-LAB • Fax 516-576-1410 • www.certified-laboratories.com
## Nutrition Facts

**Serving Size** 3.5 oz (100 g)  
**Servings per Container** VARIED

### Amount Per Serving

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Amount</th>
<th>% Daily Value ^ *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Calories From Fat</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Total Fat</td>
<td>0g</td>
<td>0 %</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>0g</td>
<td>0 %</td>
</tr>
<tr>
<td>Trans Fat</td>
<td>0g</td>
<td>0 %</td>
</tr>
<tr>
<td>Cholesterol</td>
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<td>0 %</td>
</tr>
<tr>
<td>Sodium</td>
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<tr>
<td>Total Carbohydrate</td>
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</tr>
<tr>
<td>Dietary Fiber</td>
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</tr>
<tr>
<td>Sugars</td>
<td>0g</td>
<td>0 %</td>
</tr>
<tr>
<td>Protein</td>
<td>0g</td>
<td>0 %</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>0 %</td>
<td></td>
</tr>
<tr>
<td>Vitamin C</td>
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<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>2 %</td>
<td></td>
</tr>
<tr>
<td>Iron</td>
<td>2 %</td>
<td></td>
</tr>
</tbody>
</table>

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.*

### Calories per gram:

- Fat: 9
- Carbohydrate: 4
- Protein: 4

---

Certified Laboratories, Inc.  
10/17  
REPORT DATE: 5/18/2011  
LAB SAMPLE # Al07513  
LIQUID SOLUTION VERSION 3.0-LAL 5/3/11 SUPER
# BANANA LOGIX INC

**ATTN: LALIT LODHA**

519 HARRISON AVE

BOSTON, MA 02118

**LAB SAMPLE #**

AJ07515

**REPORT DATE:** 5/18/2011

**DOUGH VERSION 3.0-LAL 5/3/11 BASE**

**SAMPLE RECEIVED:** May 04, 2011

<table>
<thead>
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<th>Servings Per Container</th>
<th>VARIED</th>
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<tr>
<td>Serving Size For Calculation</td>
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<tr>
<td>Reference Value</td>
<td>N/A (INGREDIENT)</td>
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<tr>
<td>Household Measure</td>
<td>3.5 oz (100 g)</td>
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<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Per 100 g</th>
<th>Per Serving</th>
<th>Daily Value (DV)</th>
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<tbody>
<tr>
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<tr>
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<td>Moisture</td>
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</tr>
<tr>
<td>Ash</td>
<td>0.45 g</td>
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<tr>
<td>Total Carbohydrates</td>
<td>14.82 g</td>
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<td>Dietary Fiber</td>
<td>7.1 g</td>
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<td>Sugars</td>
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<td>0 %</td>
</tr>
<tr>
<td>Saturated Fat</td>
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<td>0 %</td>
</tr>
<tr>
<td>Monounsaturated Fat</td>
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<td>0 %</td>
</tr>
<tr>
<td>Polyunsaturated Fat</td>
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<tr>
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<td>194 I.U.</td>
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<td>Vitamin C</td>
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<tr>
<td>Calcium</td>
<td>180 mg</td>
<td>180 mg</td>
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</tr>
<tr>
<td>Potassium</td>
<td>160 mg</td>
<td>160 mg</td>
<td>5 %</td>
</tr>
</tbody>
</table>

END OF REPORT

Managing Director

200 Express Street • Plainview, NY 11803 • 516-576-1400 • 800-CERT-LAB • Fax 516-576-1410 • www.certified-laboratories.com
**Nutrition Facts**

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<thead>
<tr>
<th>Serving Size</th>
<th>3.5 oz (100 g)</th>
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<tbody>
<tr>
<td>Servings per Container</td>
<td>VARIED</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Amount Per Serving</th>
<th>Calories 80</th>
<th>Calories From Fat 5</th>
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</thead>
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<td>% Daily Value</td>
<td></td>
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<tr>
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<td></td>
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<tr>
<td>Total Fat</td>
<td>0 g</td>
<td>0 %</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>0 g</td>
<td>0 %</td>
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<tr>
<td>Trans Fat</td>
<td>0 g</td>
<td>0 %</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>0 mg</td>
<td>0 %</td>
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<tr>
<td>Sodium</td>
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<td>0 %</td>
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<td></td>
</tr>
</tbody>
</table>

| Vitamin A | 4 % | Vitamin C | 0 % |
| Calcium   | 20 %| Iron      | 4 % |

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.*

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<td>Total Carbohydrate</td>
<td>300g</td>
<td>375g</td>
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<tr>
<td>Dietary Fiber</td>
<td>25g</td>
<td>30g</td>
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</table>

**Calories per gram:**
- Fat 9
- Carbohydrate 4
- Protein 4
# Certificate of Analysis

**Sample ID:** 11CR-1108736-26737  
**Description/Method/Result:** Partially Lyophilized Banana  
**Collection Date:** 7/17/2011  
**Analysis Date:** 7/21/2011

<table>
<thead>
<tr>
<th>Sample</th>
<th>Method</th>
<th>Result</th>
<th>Description/Method</th>
<th>Result</th>
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<td>Moisture</td>
<td>AOAC 950.46</td>
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<td>Trans Fat</td>
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<tr>
<td>Vitamin B6 Pyridoxine Hydrochloride Elisa</td>
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<td>Vitamin A WRE 054</td>
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<td>Phosphorus AOAC 965.17</td>
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<td>Niacin (B3) Elisa</td>
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<td>Iodine Ion Selective Electrode</td>
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<tr>
<td>Calcium EPA 6020 (modified)</td>
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<td>mg/100g</td>
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<td>Selenium EPA 6020 (modified)</td>
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<td>Chromium EPA 6020 (modified)</td>
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<td>Fat - Acid Hydrolysis AOAC 945.44</td>
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<td>Vitamin B12 Elisa</td>
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<td>Total Vitamin D AOAC 995.05</td>
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<tr>
<td>Riboflavin (B2) AOAC 970.65</td>
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<td>Pantothenic Acid - B5 Elisa</td>
<td>3.844</td>
<td>3.844</td>
<td>mg/100g</td>
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<tr>
<td>Iron WRE 063</td>
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<td>mg/100g</td>
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<tr>
<td>Folic Acid (B9) Elisa</td>
<td>323.18</td>
<td>323.18</td>
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<td>Cholesterol AOAC 976.26</td>
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<td>kcal</td>
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<td>Zinc WRE 063</td>
<td>2.5</td>
<td>2.5</td>
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<td>Potassium EPA 6020 (modified)</td>
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<td>Manganese EPA 6020 (modified)</td>
<td>4.31</td>
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<tr>
<td>Copper EPA 6020 (modified)</td>
<td>1.09</td>
<td>1.09</td>
<td>mg/100g</td>
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</tbody>
</table>
CERTIFICATE OF ANALYSIS
BananaLogix, Inc.
Contact: Lalit Lodha
519 Harrison Avenue Suite D216
Boston, MA 02118
Phone: 617-438-6726
Fax: 617-249-0132

TRADE SECRET / CONFIDENTIAL COMMERCIAL INFORMATION

Note: Samples also outsourced to Aquatic Research (Seattle, WA) for Ca and Medallion Lab (Minnesota) for B Vitamins

Authorized Analyst Melanie Carwin

UNLESS OTHERWISE NOTED, ALL SAMPLES WERE RECEIVED IN ACCEPTABLE CONDITION.
THE RESULT(S) IN THIS REPORT RELATE ONLY TO THE PORTION OF THE SAMPLE(S) TESTED.
THIS REPORT DOES NOT CONSTITUTE A RELEASE OF PRODUCT FOR CONSUMPTION.
THIS REPORT SHALL NOT BE REPRODUCED EXCEPT IN FULL, WITHOUT WRITTEN APPROVAL OF THE LABORATORY.
# Nutrition Comparison

<table>
<thead>
<tr>
<th></th>
<th>Banana Extract (100 g)</th>
<th>Banana (100 g)</th>
<th>Dehydrated Banana (100 g)</th>
<th>DV</th>
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<tbody>
<tr>
<td>Calories</td>
<td>251</td>
<td>89</td>
<td>346</td>
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<td>Fat (g)</td>
<td>0.96</td>
<td>0.33</td>
<td>1.81</td>
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<td>Carbohydrates (g)</td>
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<td>22.84</td>
<td>88.28</td>
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<td>Dietary Fiber (g)</td>
<td>17.26</td>
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<td>9.9</td>
<td>25</td>
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<tr>
<td>Sugar (g)</td>
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<tr>
<td>Protein (g)</td>
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<tr>
<td>Vitamin A (IU)</td>
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<td>248</td>
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<td>Vitamin C (mg)</td>
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<tr>
<td>Pantothenic Acid (mg)</td>
<td>3.844</td>
<td>0.334</td>
<td>0.44</td>
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<tr>
<td>Calcium (mg)</td>
<td>72</td>
<td>5</td>
<td>22</td>
<td>1000</td>
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<tr>
<td>Iron (mg)</td>
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<tr>
<td>Magnesium (mg)</td>
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<td>Potassium (mg)</td>
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## Nutrition Comparison

<table>
<thead>
<tr>
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<th>Banana Extract (100 g)</th>
<th>Banana (100 g)</th>
<th>Dehydrated Banana (100 g)</th>
<th>DV</th>
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<tbody>
<tr>
<td>Water (g)</td>
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<td>Thiamin (B1) (mg)</td>
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<tr>
<td>Phosphorus (mg)</td>
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<td>1000</td>
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<tr>
<td>Niacin (B3) (mg)</td>
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<td>Ash (g)</td>
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<td>Riboflavin (B2) (mg)</td>
<td>0.840</td>
<td>0.073</td>
<td>0.240</td>
<td>1.7</td>
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<tr>
<td>Folic Acid (B9) (mcg)</td>
<td>323.18</td>
<td>0.0</td>
<td>0.0</td>
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</tr>
<tr>
<td>Zinc (mg)</td>
<td>2.5</td>
<td>0.15</td>
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<td>Manganese (mg)</td>
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<td>Copper (mg)</td>
<td>1.09</td>
<td>0.078</td>
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## Comparison to Other Soluble Fiber Ingredients

<table>
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<tr>
<th></th>
<th>Banana Extract (100 g)</th>
<th>Inulin (Chicory Root) 100 g</th>
<th>Polydextrose (100 g)</th>
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<tr>
<td>Calories</td>
<td>251</td>
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<td>100</td>
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<tr>
<td>Fat (g)</td>
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<td>Carbohydrates (g)</td>
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<tr>
<td>Vitamin C (mg)</td>
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