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AN ORGANOLEPTICALLY ENHANCED SALACIA PLANT EXTRACT AND A PROCESS THEREOF (MINORA)

Field of the Invention

The present invention relates to clinically safe and non-toxic plant extracts useful for the management of diabetes and their related disorders. More particularly, the present invention relates to easily oral administrable bioactive *Salacia oblonga* extracts with an improved efficacy for the management of diabetes and related disorders. The invention also discloses bioactive Salacia extracts with improved organoleptic properties. The invention further discloses oral administrable bioactive salacia extracts, which can be safely given to both children and adults having blood glucose intolerance.

Also, the invention discloses a process for the preparation of bioactive salacia extracts that are non-toxic, clinically viable, have a better and improved taste appeal and those, which may be effectively used for the management of early and mid diabetes and related disorders.

Background of the Invention

Diabetes mellitus, commonly referred to as diabetes, is a medical condition associated with abnormally high levels of glucose (or sugar) in the blood (hyperglycaemia). Normally, blood glucose levels are tightly controlled by insulin, a chemical signalling substance (hormone) that is produced by a gland near the stomach called the pancreas.

Insulin helps lower the blood glucose level and stimulates the body to make use of glucose. When the amount of glucose in the blood increases, for example, after eating food, insulin is released from the pancreas to normalise the glucose level. However, in patients with diabetes mellitus, the elevated glucose levels will not be normalized easily as compared to healthy individuals. This causes abnormally high levels of blood glucose, which ultimately leads to the presence of glucose in the urine (glucosuria).

The disease can be divided into two major subclasses: insulin-dependent diabetes mellitus (IDDM), also known as type I diabetes, and non-insulin-dependent diabetes mellitus (NIDDM), also known as type II diabetes. IDDM results from insulin deficiency caused by cell-mediated autoimmune destruction of pancreatic beta cells, and generally develops in the young. IDDM accounts for approximately 10-15% of the diabetic population worldwide. In contrast, NIDDM results from a variable combination of insulin resistance and insulin deficiency, which generally noticed in
adults above 35 years. However, NIDDM can be noticed at a younger age too. NIDDM accounts for over 85% of the diabetic population worldwide.

The secondary complications of the diabetes mellitus disease involves, Diabetic Neuropathy, Diabetic Diarrhea, Urinary retention, Gustatory Swelling, Papillary Reflexes, Cardiac Autonomic Disturbances, Collagen Disturbances, thickening of capillary basement membrane, increase in vessel wall matrix and cellular proliferation resulting in vascular complications like lumen narrowing, early atherosclerosis, sclerosis of glomerular capillaries, retinopathy, neuropathy and peripheral vascular insufficiency. Of these disorders Diabetic Neuropathy is the most common and affects patients at earlier stages. As such, there is no drug available for the curing of these diabetes or its complications.

Diabetes is a lifestyle disease and can be controlled / managed though not completely cured. There are many well-known therapies for the management of diabetes. Firstly, it may be managed with a carbohydrate-based, low-fat diet. The carbohydrates in such a diet inevitably put large amounts of glucose in the bloodstream. The patients therefore need to be administered insulin daily. The drawback associated with this therapy is that the right dosage of insulin needs to be administered every time. A greater than required insulin dosage can reduce the glucose level too much such that it may become risky for the patient. A skilled administrator is therefore a must in following such a therapy. The complications' attached to such a form of therapy, makes it tedious and less patient compliant

The second method of managing diabetes is by using chemical drugs. Based upon the kinds of diabetes prevalent, the drugs available for treatment can be grouped under the following heads:

i. Pancreatic stimulators: - This class of drugs helps to stimulate the pancreas, leading to increased secretion of insulin. This addresses the diabetes caused by inadequate insulin secretion. Common examples of this category are sulphonylureas and meglitinides.

ii. Insulin sensitizers: -This category of drugs improves the cell's sensitivity to the presence of insulin, thereby improving the uptake of glucose into the cells,
leading to better blood sugar control. The common examples for this category are the biguanides, thiazolidinediones.

iii. Alpha-glucosidase inhibitors: - Acarbose and meglitol are the commonly known alpha-glucosidase inhibitors. These drugs help the body to lower blood glucose levels by blocking the breakdown of starch and oligosaccharides in the intestine. They also slow the breakdown of some sugars. Their action slows the rise in blood glucose levels (post-prandial) after a meal. They should be taken with the first bite of a meal.

iv. Insulin: - As explained earlier, insulin is exogenously supplemented in the case of people suffering from both type I and type II diabetes.

The available synthetic drugs however suffer from concomitant side effects caused due to long duration of usage. It is indicated that cardiovascular mortality is higher in patients with oral hypoglycemic than in those who are treated without them. Sulphonylurcas cause hypoglycemia as a side effect. Biguanides cause lactic acidosis. Oral hypoglycemic drugs also cause GIT irritation, weight gain, hypertension, etc. On continuous and constant exertion, the diabetic person is also liable for pancreatic fatigue. In addition, many of these available drugs lead to drug resistance in patients with long durations of use. Acarbose and meglitol are known to cause gas and diarrhea.

Added to these are the long-term complications of diabetes, which are still more damaging. These are caused by spikes in blood sugar in patients during the day. Increased blood sugar even for short periods leads to glycosylation of hemoglobin. Glycosylated hemoglobin causes long-term irreversible damages to eyes, kidneys, nerves and blood vessels.

The drugs listed above have different mechanisms of action to lower blood glucose levels. They are therefore often prescribed in the form of a combination therapy. More over combination therapy suits best, when one single drug does not seem to show the desired effects. Many combinations are known and used. For example, a biguanide and a sulfonylurea may be used together. Adding a drug from a different category of diabetes therapy is definitely more effective than switching from one single pill to another. Yet the disadvantages associated, with combinatorial effect of taking more than one drug each of which has individual side effect attached to it, cannot be avoided.
Besides, taking more than one drug at a time makes the therapy more costly and less patient compliant.

The ayurvedic and ancient Indian literature refers to the usefulness of many plant extracts in the treatment of diabetes mellitus. The use of traditional medicines, mainly derived from plant sources, has been a major part in the management of many chronic ailments including diabetes. Physicians in India who practice Ayurveda, Unani, and Siddha have long used extracts of leaves, flowers, fruits, seeds, wood, bark, roots, or even whole plants of more than a hundred Indian medicinal plants for the treatment of diabetes.

One of the plants actively used in Ayurveda for the treatment of diabetes is Salacia. *Salacia Oblonga*, commonly called "Ponkoranti", is a large, straggling, woody shrub found in southern India and Sri Lanka. It can also be traced in the evergreen forests of Western Ghats. Salacia belongs to the family Celastraceae. The roots and stems of this plant are used for the treatment of diabetes. Salacia has also proven effective against the increasing problem of other life-stage diseases like hypertension. It has also been found effective in lowering triglyceride and LDL cholesterol levels. Salacia oblonga is known to exhibit alpha glucosidase activity. It contains two potent α-Glucosidase inhibitors: Salicinol and Kotalanol. Methanol extracts from the roots of Salacia oblonga exhibit an inhibitory effect on the increase of serum glucose levels in sucrose- and maltose-loaded rats. Salacia oblonga has also been found to show inhibitory activity on Aldose Reductase, which is related to such chronic diabetic complications as peripheral neuropathy, retinopathy, and cataracts.

The Applicant has carried studies for amalgam of 15 (fifteen) different traditional Indian medicinal plants' including Salacia and the same is disclosed in the WO publication bearing the number WO/2006/061676. The studies included isolating the actives from Salacia, characterizing the extract, combining with other plant extracts and studying their activity for management of diabetes. In addition, currently studies were carried on Salacia plant with an objective focused towards enhancing the organoleptic properties of Salacia extract. Further, the instant invention provides a process for preparation of organoleptically enhanced Salacia extract which can be used for management of not only diabetes but also all the diabetic related disorders.
Yet it is well known that in Ayurveda, each herb has properties of curbing many disorders and this property is attributed to the composite nature of the herbal preparation. Therefore, any single component of the extract of herb has failed in offering clinically significant results for a particular disorder. Comprehensive studies on the components of the herb that are responsible for certain indications need to be undertaken to obtain effective medications from this therapy. Also, not necessarily all the ayurvedic extracts are non-toxic.

**Prior Art of the Invention:**

The related art of interest describes various processes for obtaining *Salacia* extract, but none discloses the present invention. There is a need for an effective process in obtaining an organoleptically improved salacia plant extract which is not only safe but also used for management of diabetes and its related disorders. The related art will be discussed in the order of perceived relevance to the present invention.

US Patent 6,376,682 relates to compound extracted from salacia oblonga having the characteristic of specifically inhibiting the activity of alpha-glucosidase (an enzyme that breaks down disaccharides, etc.) at the intestinal level. It does not reflect on the additional, insulin mimetic and insulin sensitization activities of found in a well-extracted salacia extract.

US Patent 5,691,386 relates to a compound extracted from a woody climbing plant belonging to the Cestaceae family and inhibits the activity of alpha-glucosidase, and further to an antidiabetic and dieting agent containing the compound and a method for producing such a compound. It does not mention any insulin mimetic activity attached to salacia extract. Similarly no insulin sensitization activity of salacia is disclosed in the patent as well.

US Patent Application 20020041904 states a compound which is extracted from *Salacia oblonga* or *Salacia prinoides* and contains a compound having an alpha-glucosidase inhibiting effect. It however does not state the insulin mimetic and insulin sensitization activities of salacia. The invention therefore discloses an extract with acting with a single mode of action.

A Chinese Patent application number CN1742763 entitled "Use of Wucenglong extract in preparing health-care product and medicines". This citation is disclosing the
preparation of salacia extraction but the citation is no where in relation to the instant invention as it is not able to arrive at the product and the process to obtain the organoleptically improved salacia extract which is as disclosed in the application of instant invention.

A Japanese Patent bearing the publication number **JP2001149038** entitled "Salacia Food Material and Method for producing the same and food containing the food material". This citation discloses the fact that there have been efforts to increase the flavor of Salacia in combination with food stuffs. However, the aforementioned citation is no where related to the application of instant invention wherein it specifies the usage of organoleptic agents to increase the organoleptic characteristics like color, odor and taste of the Salacia Extract.

A Japanese Patent bearing the publication number **JP2006042623** entitled "Bread And Health Food Containing Salacia Reticulata". This citation is aimed at obtaining the Salacia extract and establishing its activity as antidiabetic, anti obesity, anti oxidant, anti tumor and liver protection activities. However, this document provides no motivation for a person of average skill to arrive at the aspects of the application of instant invention. Hence the citation is no where related to the application of instant invention.

A Japanese Patent bearing the publication number **JP2006160710** entitled “Composition for Preventing/Treating Diabetes and Health Food Containing the Active Ingredient Thereof”. This citation discusses about the anti-diabetic activity of *Salacia* extract. However, the same is no where in relation to the application of instant invention, wherein it utilizes a novel and inventive process to obtain a organoleptically improved or enhanced salacia extract.

A Japanese patent bearing the publication number **JP 11152218** entitled "Anticarious Agent". The above citation discloses the method of extracting actives from Salacia. However, the citation does not disclose the step of decolorizing or deodorizing as disclosed in the instant invention. Further the citation has aimed at incorporating the Salacia extract in combination with anticarious agent and the same has been used as a dentifrice a mouth wash etc which is no where related to the application of instant invention.
The need of the hour therefore is a mono-therapy, which even though exhibits the combinatorial effect of two or more different categories of anti-diabetes drugs, is potentially devoid of any side effects associated with them. The salacia extract so prepared by making use of the instant invention laid down hereunder has been very surprisingly found to display three modes of action. It not just shows enhanced alpha glucosidase activity but also works equivalent to any well-known insulin sensitizer drugs. Furthermore, the extract has additional insulin mimetic activity and free radical scavenging abilities. It is thus capable of managing blood sugar in diabetes mellitus patients and also lends itself for long-term use without any side effects and without developing resistance. It is therefore the main objective of the invention to provide a safe and efficacious plant extract, which acts upon diabetes by at least three different mechanisms.

None of the above patents, taken either singly or in combination, is seen to describe the instant invention as claimed. Thus, obtaining organoleptically enhanced Salacia plant extract using the process of instant invention will therefore helps in addressing the problems associated with the prior art. The novelty of the process of instant invention resides not in a single step. It is the sequence of steps involved which are unique and which has resulted in arriving at organoleptically enhanced Salacia plant extract for management of diabetes and its related disorders. Accordingly, the product of the instant invention has been named as "Minora".

Objects of the Present Invention

The principal object of the present invention is to prepare a Salacia plant extract having enhanced organoleptic properties.

Yet another object of the present invention is to develop a process for obtaining organoleptically enhanced Salacia plant extract.

Still another object of the present invention is to study the activity of the Salacia plant extract for its anti-diabetic, its related disorders and free radical scavenging activity.

Still another object of the present invention is to develop a safe, non-toxic and adverse effects free Salacia plant extract.

Still another object of the present invention is to provide salacia plant extract capable of treating diabetes in more than one mode of action.
Still another object of the present invention is to provide salacia plant extract which is easily and safely administrable to children and adults.

Statement of the Invention

Accordingly, the present invention provides an organoleptically enhanced salacia plant extract for management of diabetes and related disorders; a method of treating diabetes and/or related disorders in a subject in need thereof, said method comprising step of administering pharmaceutically acceptable amount of organoleptically improved salacia plant extract, optionally along with pharmaceutically acceptable additives, to the subject; and a process for enhancing organoleptic and anti diabetic properties of a salacia plant extract, said process comprising steps of (a) size-reducing plant parts to obtain powder; (b) extracting the powder with a solvent and/or combination of solvents by heating at temperature ranging from 25°C to 100°C to obtain a mixture; (c) clarifying the mixture to arrive at clear liquid; (d) concentrating the clear liquid to achieve a concentrated extract; (e) solubilizing the concentrated extract in a solvent and re-concentrating it to obtain further concentrated extract; and (f) treating the further concentrated extract with an organoleptic agent (s) followed by drying the treated extract to obtain organoleptically enhanced salacia plant extract.

Brief Description of the Accompanying Drawings

Figure 1: is a bar graph showing Insulin Mimetic Activity of Treated Salacia Water Extract in 3T3 L1 Cell Lines.

Figure 2: is a bar graph showing Insulin Mimetic Activity of Treated Salacia Alcohol Extract in 3T3 L1 Cell Lines.

Figure 3: is a bar graph showing the percent insulin Mimetic Activity of Untreated Salacia extract as Determined by 3T3 L1 glucose Uptake Assay

Figure 4: is a bar graph showing Insulin Sensitization Activity of Treated Salacia Water Extract in 3T3 L1 Cell Lines.

Figure 5: is a bar diagram showing is a bar graph showing Insulin Sensitization Activity of Treated Salacia Ethanol Extract in 3T3 L1 Cell Lines.

Figure 6: is a bar diagram showing percent insulin sensitization activity of salacia water extract in comparison to insulin
Figure 7: is a bar graph showing the alpha glucosidase inhibition potential of salacia water extract.

**Figure 8**: is a bar diagram showing free radical scavenging ability of salacia plant extracts

**Figure 9**: is a bar diagram showing total polyphenol estimation of salacia water extract

Figure 10: is a bar graph showing percentage variation of Fasting Blood Glucose (FBG) level over 5 week period in various groups of animals.

**Figure 11**: is a bar diagram showing percentage variation in postprandial glucose (PPG) over 5 periods.

**Figure 12**: Percent alpha-glucosidase inhibition of various Salacia extract in comparison to acarbose

**Figure 13**: Percent insulin sensitization activity of different Salacia concentration 334 µg as determined by 3T3-L1 glucose uptake assay

**Detailed description of the present invention**

The present invention is in relation to an organoleptically enhanced *salacia* plant extract for management of diabetes and related disorders.

In another embodiment of the present invention, wherein the organoleptic agents are decolorizing and deodorizing agents.

In yet another embodiment of the present invention, wherein the extract is treated with said organoleptic agents at a ratio ranging from 0.5: 10 to 10: 0.5.

In still another embodiment of the present invention, wherein the extract is treated with organoleptic agents preferably at a ratio of about 1: 0.25.

The present invention is in relation to a method of treating diabetes and/or related disorders in a subject in need thereof, said method comprising step of administering pharmaceutically acceptable amount of organoleptically improved salacia plant extract, optionally along with pharmaceutically acceptable additives, to the subject.

In another embodiment of the present invention, wherein the subject is an animal or human being.
In yet another embodiment of the present invention, wherein the organoleptically improved salacia plant extract is having insulin mimetic activity, insulin sensitizing activity, and alpha glucosidase activity.

In still another embodiment of the present invention, wherein the organoleptically improved salacia plant extract is administered at dosage ranging between 20 to 300 mg/kg body weight.

In still another embodiment of the present invention, wherein the organoleptically improved salacia plant extract is administered preferably at dose of about 50mg/kg body weight.


In still another embodiment of the present invention, wherein the additives are selected from a group comprising granulating agents, binding agents, lubricating agents, disintegrating agents, sweetening agents, coloring agents, flavoring agents, coating agents, plasticizers, preservatives, suspending agents, emulsifying agents and spheronization agents.

In still another embodiment of the present invention, wherein the organoleptically improved salacia extract is formulated into dosage forms selected from a group comprising tablet, troches, lozenges, aqueous or oily suspensions, dispersible powders or granules, emulsion in hard or soft gel capsules, syrups, elixirs, phyotceuticals and neutraceuticals.

In still another embodiment of the present invention, wherein the organoleptically improved salacia plant extract is non-toxic and free of adverse effects.

In still another embodiment of the present invention, wherein the organoleptically improved salacia plant extract can be administered to subjects in combination with agents selected from a group comprising synthetic anti-diabetic drugs, anti-diabetic plant extracts and food stuffs.
The present invention is in relation to a process for enhancing organoleptic and anti-diabetic properties of a *salacia* plant extract, said process comprising steps of (a) size-reducing plant parts to obtain powder; (b) extracting the powder with a solvent and/or combination of solvents by heating at temperature ranging from 25° to 100° C to obtain a mixture; (c) clarifying the mixture to arrive at clear liquid; (d) concentrating the clear liquid to achieve a concentrated extract; (e) solubilizing the concentrated extract in a solvent and re-concentrating it to obtain further concentrated extract; and (f) treating the further concentrated extract with an organoleptic agent(s) followed by drying the treated extract to obtain organoleptically enhanced *salacia* plant extract.

In another embodiment of the present invention, wherein the size reduction is done either manually or mechanically to achieve powder particle size ranging from 50 # to 200 # and piccrably of 100 mesh size.

In yet another embodiment of the present invention, wherein the parts of plant are selected from a group comprising root, shoot, leaf and seeds or the whole plant.

In still another embodiment of the present invention, wherein the solvent used for extraction could be aqueous, organic and/or combinations thereof.

In still another embodiment of the present invention, wherein said solvents and/or combination of solvents are selected from a group comprising water, buffer, cell media, dilute acid, dilute bases, methanol, ethanol, n-propanol, isopropanol, 2-butanol. and tertbutanol.

In still another embodiment of the present invention, wherein the powder is extracted with a solvent at a ratio ranging from 1:3 to 1:50.

In still another embodiment of the present invention, wherein the powder is extracted with a solvent preferably at a ratio of about 1:10.

In still another embodiment of the present invention, wherein the extraction of powder with solvent and/or combination of solvents is brought about by stirring for a time period ranging from 2-3 hours.

In still another embodiment of the present invention, wherein the extraction of powder with solvent and/or combination of solvents is brought about by stirring preferably for a time period of about 2.5 hours.

In still another embodiment of the present invention, wherein the extraction of powder with solvent and/or combination of solvents is brought about by heating preferably at specific temperatures of about 80° C.
In still another embodiment of the present invention, wherein said clarification is achieved by filtration or centrifugation.

In still another embodiment of the present invention, wherein said concentration method is selected from a group comprising soxhlation, rotary evaporation, distillation, centrifugal vacuum evaporation and lyophilisation.

In still another embodiment of the present invention, wherein said solubilization of concentrated extract is carried out in a solvent selected from a group comprising ethyl acetate, diethyl ether, hexane, dichloromethane, butyl alcohol, ether, acetone and/or combination thereof.

In still another embodiment of the present invention, wherein said organoleptic agents for decolorizing and deodorizing agents.

In still another embodiment of the present invention, wherein the decolorizing agents are selected from a group comprising carbon, activated carbon, resins, chemicals like hydrogen peroxide, acetone peroxide, benzoyl peroxide, sulfites like sodium metabisulfite, ammonium persulfate, sodium hydrosulfite, sodium sulfite and sulfur dioxide.

In still another embodiment of the present invention, wherein said deodorizing agents are selected from a group comprising activated carbon and hydrogen peroxide.

In still another embodiment of the present invention, wherein said treated extract is dried at a temperature ranging from 35° to 65° C.

In still another embodiment of the present invention, wherein said treated extract is preferably dried at a temperature of about 50° C.

In still another embodiment of the present invention, wherein the extract is treated with said organoleptic agents at a ratio ranging from 0.5: 10 to 10: 0.5.

In still another embodiment of the present invention, wherein the extract is treated with said organoleptic agents preferably at a ratio of about 1: 0.25.

The present invention provides a plant extract with ant diabetic activity. In particular, the invention provides a salacia plant extract with ant diabetic activity. Also, the invention provides Salacia extract with improved ant diabetic activity and free radical scavenging ability. Further, the invention provides a non-toxic Salacia plant extract with anti diabetic activity. Furthermore, the invention provides a non-toxic salacia plant extract capable of treating diabetes in more than one mode of action. Therefore, the invention provides a non-toxic salacia extract with a better efficacy in the treatment of
diabetes mellitus. Still, the invention provides a salacia plant extract which has improved organoleptic properties and which is easily and safely administrable to children and adults. Still further, the invention provides a salacia plant extract, which is non-toxic, patient compliant, shows better efficacy and effectively in the treatment of diabetes and exhibits improved organoleptic properties. The invention provides also the method of preparation of a non-toxic, patient compliant, improved and effective salacia plant extract. The crux of the invention lies in the preparation of an extract by a procedure, which enhances both its activity and organoleptic appeal.

It will be readily understood that the components of the present invention, as generally described herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description of the embodiments of the system and method of the present invention is not intended to limit the scope of the invention, as claimed, but is merely representative of the presently preferred embodiments of the invention.

The instant invention herewith states in greater details an extraction procedure for the improvement of basic therapeutic activity of any given plant extract and its organoleptic appeal. It discloses unique procedures for preparation of improved plant extracts with increased efficacy. The plant extracts so produced by making use of the procedures laid down hereunder act in unprecedented modes of action towards the treatment of diabetes. Plant material suitable for preparation of the plant extract for inclusion of the therapeutic composition of the invention is derived from a potential plant administered to a person suffering from diabetes, which results in the lowering of the blood glucose level of the patient. Administration of the composition to the patient both prevented and treated incidences of clinical diabetes.

In accordance with a further embodiment of the present invention, the potential plant is a member of the family Celastraceae. In another embodiment of the invention, the potential plant is a member of the genus Salacia. It will be readily apparent to one skilled in art that other extracts capable of potential positive anti-diabetic properties could be isolated using similar techniques from other known Salacia species and also from a wide range of plants i.e., potential plants. The potential plants include all species of the family Celastraceae, including terrestrial, aquatic or other plants that can be subjected to standard extraction procedures such as those described herein in order to
generate an extract that can be tested for its therapeutic abilities, including but not limited to Salacia oblonga, S. zeylanica, S. chimensis, S. prinoides. The present invention is directed to a herbal medicinal composition comprising the foregoing plant extracts that can be administered to a person suffering from diabetes which results in the lowering of the blood glucose level of the patient.

Salacia is a large, straggling, woody shrub with dichotomous branching. It has a smooth bark, which is greenish grey, thin and white inside. The leaves are opposite, elliptic-oblong, base acute, apex abruptly acuminate having toothed margin with minute rounded teeth. It has leathery, hairless, shiny, lateral nerves about seven pairs. The flowers in the shrub are bisexual and are found in clusters of 2-8 in leaf axils. They are greenish white to greenish yellow in colour. The fruit is in the form of a drupe; it is globose, tubercular and pinkish orange when ripe. The seeds are 1-4 in number and shaped like almond. As used herein, "extract" refers to a concentrated preparation of the essential constituents of the medicinal plant. Typically, an extract is prepared by drying and powderizing the plant. Optionally, the plant, the dried plant or the powderized plant may be boiled in solution. The extract as used herein may be used in liquid form, or it may be mixed with other liquid or solid medicinal herbal extracts. Alternatively, this medicinal herbal extiaict may be obtained by further precipitating solid extracts from the liquid form.

As used herein, "anti-diabetic" or "hypoglycemic" compound or composition generally refers to an agent that lowers blood glucose levels. If blood glucose level is decreased by at least about 100 mg/dl, then the compound is considered to be a hypoglycemic agent. The hypoglycemic or anti-diabetic effect can be measured by a variety of methods including, but not limited to, measuring the blood glucose levels, the rate of insulin binding to its receptor, the level of insulin secretion from pancreatic beta cells, and inhibition of glucohydrolase activity.

As used herein the term, "related disorders" means disorders related to diabetes mellitus, which include but are not limited to Diabetic Neuropathy, Diabetic Diarrhea, Urinary retention, Gustatory Swelling, Papillary Reflexes, Cardiac Autonomic Disturbances, Collagen Disturbances, thickening of capillary basement membrane, increase in vessel wall matrix and cellular proliferation resulting in vascular
complications like lumen narrowing, early atherosclerosis, sclerosis of glomerular capillaries, retinopathy, neuropathy and peripheral vascular insufficiency.

As used herein the term, "potential plants" includes plants from which anti-diabetic extracts can be extracted out. The term comprises of plants like Momordica sp., Salacia, Eugenia, Coccimia, Cinammentum sp, Gymnema sp, Ptcrocarpus sp. Azadiricta sp., Trigonella sp, Cymopsis sp.

As used herein the term, "treated extract" refers to the dried extract produced after treatment of the concentrated extract with deodourizing/decolorizing agents.

As used herein the term "herbal composition" means an extract containing different compounds from the same plant or from different plants in various combinations.

In one embodiment of the invention, there is provided a process for obtaining a plant extract possessing hypoglycemic properties, the process comprising (a) obtaining plant material from one or more plants (b) obtaining an extract from the plant material by contacting the plant material with an aqueous, an ethanolic or an organic solvent, or a combination thereof, thereby providing one or more plant extracts (c) treating the extract with food grade decolorizing agents to obtain an organoleptically improved product (d) analyzing the plant extracts for free radical scavenging potential, Intestinal alpha-glucosidase inhibition potential, insulin mimetic activity and insulin sensitizing activity, in-vitro screening of Salacia root extracts for glucose uptake and the in-vivo efficacy studies.

**Extraction of the plant material by solvent extraction process:**

The plant material employed in the extraction process can be the entire potential plant, or it can be one or more distinct tissues from the plant for example, leaves, seeds, roots, stems, flowers, or various combinations thereof but preferably the root of the plant. The plant material may also be treated prior to extraction, for example, by drying, freezing, lyophilizing, or some combination thereof. If desired, the plant material can be fragmented and/or homogenized by some means such that a greater surface area is presented to the solvent. For example, the plant material can be crushed or sliced mechanically, using a grinder or other device to fragment the plant parts into small pieces or particles, or the plant material can be frozen liquid nitrogen and then crushed or fragmented into smaller pieces.
The solvent used for the extraction process can be aqueous, alcoholic or organic, or a combination thereof. In one embodiment of the present invention, plant material is extracted with an aqueous solvent. Examples of suitable solvents include but are not limited to water, buffers, cell media, dilute acids or bases and the like.

In an alternate embodiment of the invention, the plant material is extracted with an alcoholic solvent. Examples of suitable alcoholic solvents include, but are not limited to methanol, ethanol, n-propanol, iso-propanol, 2-butanol, ter-butanol, and combinations thereof.

Various extraction processes are known in the art and can be employed in the methods of the present invention. The extract is generally produced by contacting the solid plant material with a solvent with adequate mixing and for a period of time sufficient to ensure adequate exposure of the solid plant material to the solvent such that inhibitory activity present in the plant material can be taken up by the solvent.

The solvent extraction process may be selected from direct and successive extraction types such as extraction from plant parts in soxhlet apparatus or in flasks at room temperature or at higher temperature with polar and/or non-polar solvent(s). Regardless of the number of extraction processes, each extraction process typically is conducted over a period of time between about 6 hours to 24 hours at room temperature. Adequate contact of the solvent with the plant material can be encouraged by shaking the suspension.

The liquid fraction is then separated from the solid (insoluble) matter resulting in the generation of two fractions: a liquid fraction and a solid fraction, which is the potential extract. Separation of the liquid and solid fractions can be achieved by one or more standard processes known to those skilled in art.

The potential extracts obtained thereof may be concentrated and solubilised in an appropriate solvent preferably ethyl acetate. Examples of various other organic solvents include but are not limited to, di-ethyl ether, hexane, heptane, dichloromethane, ethyl acetate, butyl alcohol, ether, acetone and the combinations thereof.

The purified extracts or partially purified extracts are concentrated by solvent removal from the original extract and/or fractionated extract, and/or purified extract. The techniques of solvent removal are known to those skilled in the art and include, but are
not limited to rotary evaporation, distillation (normal and reduced pressure), centrifugal vacuum evaporation (speed vac), and lyophilisation.

The extract referred to herein can be produced by any of the two procedures stated hereunder. The procedures laid down herewith are general procedures alterable with variations known in the art to one skilled in the art. These may not in any way be treated as restrictive to the instant invention. Accordingly, the product obtained by the process of instant invention has been named as "Minora".

The technology of the instant Application is further elaborated with the help of following examples. However, the examples should not be construed to limit the scope of the invention.

Example: 1
Extraction: Procedure A

1. Raw material is cut or pulverized to an approximate 30# size.

2. The pulverized powder is contacted to an aqueous solvent in a ratio ranging from 1:5 to 1:50 (powder:solvent).

3. The mixture prepared in step 2 is stirred continuously for 2-3 hours at a temperature of 70°C - 95°C.

4 a). Resulting mixture obtained from step 3 is filtered and the filtrate is collected.

4 b). Alternatively, resulting mixture obtained from step 3 is centrifuged (3000 - 4000rpm) and the supernatant is collected.

5. The filtrate / supernatant obtained in step 4 is concentrated, by known procedures such as distillation, or by using roto-evaporator.

6. The concentrated extract so obtained from step 5 is treated with a bleaching agent (ketones) in the ratio ranging from 0.5 : 10 to 10 : 0.5 (extract:bleaching agent).

7. The treated extract obtained from step 6 is dried, in particular at a temperature ranging from 55°C to 60°C and stored.
Optionally, the treated extract obtained from step 6 may be freeze dried to obtain the final product, which has been named as "Minora".

Example: 2
Procedure B

1. Raw material is cut or pulverized to an approximate 30# size.

2. The pulverized powder is added to alcoholic solvent in a ratio ranging from 1:3 to 1:50 (powder:solvent).

3. The mixture prepared in step 2 is stirred continuously for 2-3 hours at a temperature of 30°C to 45°C.

4. Resulting mixture obtained from step 3 is filtered and the filtrate is collected.

5. Alternatively, resulting mixture obtained from step 3 is centrifuged (3000 - 4000rpm) and the supernatant is collected.

6. The filtrate / supernatant obtained in step 4 or 5 is concentrated, for example by soxhalation, fermentation or rotoevaporator.

7. The concentrated extract so obtained from step 6 is treated with a bleaching agent (ketones) in the ratio ranging from 0.5:10 to 10:0.5 (extract:bleaching agent)

8. The treated extract obtained from step 7 is dried at a temperature ranging from "55°C to 60°C".

Optionally, the treated extract obtained from step 7 is freeze dried to obtain the final product, which has been named as "Minora". Thus prepared dried extract is stored in airtight food grade plastic bins and the same is taken through several in-vitro cells free and cell based bioassay to validate the extract efficacy.

Modifications of the type, which are required to scale up the procedures and such as are standard in the industry, are included with in the realm and scope of the invention laid down. Similarly, modifications as would be readily apparent to those skilled in the art fall within the scope of the invention.

By making use of the processes stated above with variations known to a person skilled in the art, salacia plant extract can be extracted using varied solvents, solubilizers and
concentration procedures. Illustrative experiments using a few of the commonly known solvents and solubilizers are stated hereunder. The same are merely illustrative and should not in any way be treated restrictive to the invention.

Example: 3

Experiment No. 1

1. Dry salacia roots were cut and pulverized to a 30# size by means of a pulverizer.

2. Approximately 1 kg of pulverized powder is added to 10 lts of de-ionized water.

3. The mixture prepared in step 2 is stirred continuously for 2-3 hours at a temperature of 80°C.

4. Resulting mixture obtained from step 3 is filtered and the filtrate is collected at 45°C under reduced pressure.

5. The filtrate obtained in step 4 is concentrated, by soxhalation or water based extraction.

6. The concentrated extract so obtained from step 5 is treated with H₂O₂ in the ratio of 1: 0.25.

7. The treated extract obtained from step 6 is dried, in particular oven dried.

Example: 4

Experiment No. 2

1. Dry salacia roots were cut and pulverized to a 30# size by means of a pulverizer.

2. Approximately 1 kg of pulverized powder is added to 5 liters of ethanol.

3. The mixture prepared in step 2 is stirred continuously for 2-3 hours at a temperature of 40°C.

4. Resulting mixture obtained from step 3 is filtered and the filtrate is collected at 45°C under reduced pressure.

5. The filtrate obtained in step 4 is concentrated, by soxhalation or water based extraction.
6. The concentrated extract so obtained from step 5 is treated with $H_2O_2$ in the ratio of 1 : 0.25.

7. The treated extract obtained from step 6 is dried, in particular oven dried.

**Example: 5**

**Determination of improved organoleptic properties of salacia extract (Minora)**

A 15-member panel of judges for comparing the organoleptic properties of the extracts so produced by making use of the invention was constituted. Properties like, taste, flavor, color and overall acceptability were characterized. A grading system from 1 - 5 was generated wherein 1 meant poor and 5 meant excellent. A mean of readings generated by the judges was taken. Results obtained for two of the batches are laid down hereunder as table 1.

<table>
<thead>
<tr>
<th>Experiment No.</th>
<th>Colour</th>
<th>Taste / Mouth feel</th>
<th>Flavour</th>
<th>Overall Acceptability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.8</td>
<td>2.6</td>
<td>2.9</td>
<td>2.8</td>
</tr>
<tr>
<td>2</td>
<td>3.1</td>
<td>2.5</td>
<td>2.5</td>
<td>2.8</td>
</tr>
</tbody>
</table>

**Table 1: Experiments showing improved organoleptic properties in treated salacia extract**

**Example: 6**

**Tests to determine the anti-diabetic efficacy of salacia extract**

**Tii-vitro screening** of Salacia water extract and salacia 70% ethanol root extract for glucose uptake

Insulin-stimulated glucose uptake in adipose tissue and striated muscle is critical for reducing postprandial blood glucose concentration and the dysregulation of this process is one of the hallmarks of Type -II Diabetes mellitus (Non Insulin dependent). Oral therapies for Diabetes mellitus have emerged out of this interest and are widely used still today. But rather than acting by mimicking insulin, these drugs acts either by stimulating insulin release [Sulphonylurcase], potentiating insulin action (thiazolidinedione) or lowering hepatic glucose production (biguanides). Various amounts of Salacia aqueous and alcoholic extracts (0.034µg to 33.4µg) are tested for insulin mimetic and sensitization effects with / without insulin.
Insulin mimetic activity shown by salacia extracts

Radio labeled glucose is used to measure the changes in the level of glucose uptake activity of the adipocyte cells in response to treatment with samples in the presence or absence of insulin. The assay is performed in a 96-well microtiter plate format and the counts per minute are measured using a radioactive counter. The count per minute can be measured on a microtiter plate by radioactive counter.

Insulin mimetic activity was tested in both 3T3-1 adipocyte cells and C2C12 myocyte cells. Three different concentrations of salacia extract were used. Both aqueous extracts and alcoholic extracts were tested. Both extracts showed insulin mimetic activity in varying concentration. The results obtained are stated in table and shown in figures 1,2.

Table 2: Glucose Uptake studies using 3T3L-1 adipocyte cells for salacia aqueous extract

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Concentration in µg</th>
<th>Fold Stimulation (wrt 5nM insulin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>33.3</td>
<td>3.29</td>
</tr>
<tr>
<td>2.</td>
<td>3.3</td>
<td>1.87</td>
</tr>
<tr>
<td>3.</td>
<td>0.33</td>
<td>2.25</td>
</tr>
</tbody>
</table>

Table 3: Glucose Uptake studies using 3T3L-1 adipocyte cells for salacia 70% alcoholic extract

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Concentration in µg</th>
<th>Fold Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>0.33</td>
<td>3.03</td>
</tr>
<tr>
<td>2.</td>
<td>3.3</td>
<td>1.73</td>
</tr>
<tr>
<td>3.</td>
<td>33</td>
<td>2.06</td>
</tr>
</tbody>
</table>

Table 4: Glucose Uptake studies using C2C12 cells for salacia aqueous extract

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Concentration in µg</th>
<th>Fold Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Interestingly, it was also found during the conduction of assays that the treated salacia extracts alone showed insulin mimetic activity. The untreated salacia extract showed insignificant insulin mimetic activity. The results shown by the untreated salacia extract are depicted in figure 3.

**Table 5: Glucose Uptake studies using C2C12 cells for salacia 70% alcoholic extract**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Concentration in µg</th>
<th>Fold Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>0.33</td>
<td>1.02</td>
</tr>
<tr>
<td>2.</td>
<td>3.3</td>
<td>0.79</td>
</tr>
<tr>
<td>3.</td>
<td>33</td>
<td>1.64</td>
</tr>
</tbody>
</table>

Insulin sensitization activity shown by Salacia extract

Insulin sensitization activity was tested in both 3T3-L1 adipocyte cells and C2C12 myoblast cells. Three different concentrations of salacia extract were used. Both aqueous extracts and alcoholic extracts were tested. Both extracts showed insulin-sensitizing activity in all concentrations. The results obtained are stated in table and shown in figures 4, 5.

**Table 6: Glucose Uptake studies using 3T3-L1 adipocyte cells for salacia aqueous extract showing insulin sensitization activity**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Concentration in µg + 10nmM insulin</th>
<th>Fold Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>0.33</td>
<td>1.84</td>
</tr>
<tr>
<td>2.</td>
<td>3.3</td>
<td>1.74</td>
</tr>
<tr>
<td>3.</td>
<td>33</td>
<td>3.3</td>
</tr>
</tbody>
</table>
Table 7: Glucose Uptake studies using 3T3L-1 adipocyte cells for salacia 70% alcoholic extract showing insulin sensitization activity

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Concentration in µg + 10nM insulin</th>
<th>Fold Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>0.33</td>
<td>2.11</td>
</tr>
<tr>
<td>2.</td>
<td>3.3</td>
<td>2.54</td>
</tr>
<tr>
<td>3.</td>
<td>33</td>
<td>2.09</td>
</tr>
</tbody>
</table>

Table 8: Glucose Uptake studies using C2C12 cells for salacia aqueous extract showing insulin sensitization activity

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Concentration in µg + 5nM insulin</th>
<th>Fold Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>0.33</td>
<td>1.02</td>
</tr>
<tr>
<td>2.</td>
<td>3.3</td>
<td>1.26</td>
</tr>
<tr>
<td>3.</td>
<td>33</td>
<td>0.86</td>
</tr>
</tbody>
</table>

Table 9: Glucose Uptake studies using C2C12 cells for salacia 70% alcoholic extract

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Concentration in µg + 5 nmM insulin</th>
<th>Fold Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>0.33</td>
<td>1.61</td>
</tr>
<tr>
<td>2.</td>
<td>3.3</td>
<td>2.02</td>
</tr>
<tr>
<td>3.</td>
<td>33</td>
<td>1.42</td>
</tr>
</tbody>
</table>

The amount that showed best insulin mimetic and sensitization activity in 3T3L-1 adipocyte cells and C2C12 myocyte cells for glucose uptake was around 0.334µg. The cited, enhanced insulin mimetic activity can be clearly deciphered by means of a bar graph, Figure 6 which compares salacia extract with insulin.
The method followed for screening is as follows:

Preadipocytes (3T3-L1) and premyocytes (C2C12) are cultured in DMEM containing 10%FCS, 4mM Glutamine, 2% NaHCO3 and antimycotic, in an atmosphere of 5% CO2 at 37°C, separately. Myoblasts are cultured up to 80% confluency and the cells are sub-cultured at three-day intervals. 20,000 of preadipocytes and myocytes are seeded separately in each well of a 96 well plate and differentiated for 48 hours in DMEM:F12(1:1), 0.5mMIBMX, 0.25mM Dexamethasone and lug Insulin for 48hrs followed by incubation with 1ug of Insulin for 8hours. The ability of the plant extract to induce glucose uptake is tested in two different ways 1) glucose uptake in presence of insulin (extract + insulin) and 2) glucose uptake in absence of insulin (extract alone). Therefore incubate in duplicate (one set to evaluate glucose uptake in presence of insulin i.e. extract + insulin and other set without insulin i.e. extract alone) with different concentration of extracts (300μg/well, 30μg/well, 3μg/well and 0.3μg/well) in triplicates for 18 hours at 370 C and 5%CO2 100μl of DMEM. The medium is then removed and the cells are incubated with KRH buffer (100 microliters) at 37°C and 5% CO2 for 10 minutes. Cells are incubated with insulin. For standard insulin response incubate cells with 5nN, 10 nN, 25 nN, 50 nN and 100nN in KRH buffer in triplicate. To one set of wells to be treated with extract +insulin, 5nN of insulin in KRH buffer is added and in other set of well treated with extract alone, 100μl of KRH buffer is added for 15 minutes at 37°C and 5%CO2. Glucose uptake reaction is initiated by adding 0.1 mM 2-deoxy glucose containing 2-deoxy [3H] glucose (final concentration 12.2 kkl/ml) and incubated for 1 hour at 37°C and 5%CO2. assay is terminated by adding 40 μM Cytochalasin B. The cells are washed three times with ice-cold KRH buffer (100μl). KRH buffer is removed and 20 μl 1% Triton X is added to each well to lyse the cells and incubate for 10 min at 37°C and 5%CO2 200μl of Aqualite is added per well and the supernatant is transferred back to the plates and counted on a micro-titer plate radioactive counter. The results obtained for insulin mimetic and sensitization potential of Salacia 70% ethanol root extract and water extracts are depicted in figure 1 to figure 6 using differentiated adipocyte and myocytes. All the observed values of glucose uptake activity are blank corrected using the control (cells alone background value). These values are normalized with MTrf cell viability assay values for the corresponding extracts. The degree of insulin mimetic/sensitization activity of each
sample concentration is calculated as a percentage of that observed using 10nM insulin alone.

Example: 7

Tests to confirm the Intestinal $\alpha$-glucosidase inhibition potential of Salacia extracts

The inhibition of degradation of oligosaccharides (carbohydrates having 2 to 10 glucose residues connected by 1-4 or 1-6 $\alpha$-D-glycosidic linkage) into monosaccharides by alpha-gliicohydrolasc-catalyzed enzymatic reactions was tested for Salacia water root extract using Calorimetric - para-nitro-phenyl (pNP) release method using pNP-$\alpha$-D-glucoside. The Salacia water extract showed greater $\alpha$-glucosidase inhibition potential (IC50 value of 5.145 $\mu$g/ml) relative to the commercially available $\alpha$-glucosidase inhibitor, acarbose (IC50 value of 146.55$\mu$g/ml) for 0.2 $\alpha$-glucosidase enzyme units at standard enzymatic reaction conditions. The same has been depicted in figure 7.

Example: 8

Free radical scavenging potential of the Salacia water extracts

There are several intriguing human studies show that administration of antioxidants plays a role in the reduced metabolic effects of insulin. In humans, the diabetogenic process appears to be caused by immune destruction of the beta cells; part of this process is apparently mediated by white cell production of active oxygen species. It has been shown that scavengers of oxygen radicals are effective in preventing diabetes in these animal models. Not only are oxygen radicals involved in the cause of diabetes, they also appear to play a role in some of the complications seen in long-term treatment of diabetes. Oberley et.al Free radicals and diabetes, Free Radic Biol Med. 1988; 5(2): 113-24. Free radical reactions and non-enzymatic glycosylation may play important roles not only in the development of diabetes but also in its complications. Hayakawa et al, Free radicals and diabetes mellitus, Nippon Ronen Igakkai Zasshi. 1990 Mar; 27(2): 149-54.

In the present invention the isolated extracts were used to estimate its free radical scavenging potency relative to ascorbic acid by using Calorimetric-DPPH method (Polterait O. (1997) Anti Oxidants and free-radical Scavengers of Natural origin Current Org. Chem. 1. 415-440). The Salacia water extract isolated from the roots of
the plant showed nearly 16% of free radical scavenging potency equivalent to that of ascorbic acid. The result is represented as a bar graph in figure 8.

Example: 9

Estimation of total polyphenols and its hypoglycemic effects

Several studies show that apple polyphenols have a positive effect on diabetes and insulin resistance in animals and humans. In 2004, scientists at the National Institutes of Health in the U.S. gave this same apple polyphenol to mice. Two weeks of treatment “significantly decreased blood glucose levels” in diabetic mice. Whole body fat mass was also "significantly reduced." An Asian study in diabetic human volunteers showed that even weak polyphenols in apple juice produced "avoidance of sharp peaks" in blood glucose levels. The polyphenols polymers have anti-oxidant effects, which provides synergistic benefits to persons with various forms of diabetes.

In the current invention, the total polyphenol content of the Salacia water extract was estimated relative to gallic acid using Calorimetric - Singleton method (Singleton, V.L. and Ropssi, J.A. Jr (1965). The Salacia water extract showed 21 ± 2.25 % total phenol content equivalent to gallic acid clearly indicative of the potential beneficial effects the extracts possess with respect to the management of diabetes and its medicative properties. The results are represented in the form of bar graph in figure 9.

Example: 10

Use of the extract as a therapeutic composition

The present invention envisages the method of treating diabetes and other related diseases thereof by administering an effective amount of the therapeutic composition comprising the single plant extract or the screened plant extracts purified there from in combination. The therapeutic compositions of the invention can be administered alone or in combination with one or more standard anti-diabetic therapeutics. The present invention also contemplates the administration of sub-optimal doses of the therapeutic composition, for example, chemotherapeutic drug(s), in combination with the therapeutic composition.

Thus, in one embodiment of the present invention, in order to prepare a therapeutic combination, one or more plant extracts is first selected and then the efficacy of the extract(s) in controlling diabetes and maintaining glucose homeostasis is determined.
using standard techniques as one of those outlined above. The efficacy of the one or more plant extract alone is then compared to the efficacy of the one or more plant extract in combination with varying amounts of another component i.e., another plant extract. The invention also contemplates the combination the plant extract with another synthetic inhibitor. A combination that demonstrates therapeutic index in comparison to the individual properties is considered to be an effective combination.

For compositions comprising two or more plant extracts, various ratios of the constituent plant extracts are contemplated. By a way of example, for a composition comprising two plant extracts, for example, extract A and extract B, the ratio of extract A to extract B can vary anywhere between 1:99 and 99:1. By "anywhere between 99:1 and 1:99" it is meant that the ratio of the two extracts can be defined by any ratio within this ratio can be between 98:2 and about 1:99 between about 98:2 and 2:98, between 97:3 and 1:99, between 97:3 and 2:98, between 97:3 and 3:97, etc. The present invention contemplates the ratio of the two extracts is between about 90:10 and 90:10, 80:20 and 20:80, 70:30 and 30:70, 60:40 and 40:60 or 50:50. Analogous ratios are contemplated for compositions comprising more than two or more plant extracts.

The formulations of the present invention contain at least an effective amount of the therapeutic composition. The effective amount is considered to be that amount of the composition, in weight percent of the overall formulation, which must be present in order to produce the desired therapeutic effect. As would be apparent to one skilled in art, the effective amount may vary, depending upon, for example the disease to be treated and the form of administration. In general the therapeutic composition will be present in an amount ranging from about 1% to 100% by weight of the formulation, 10% to about 90% by weight of the formulation, 20% to about 80% by weight of the formulation, 30% to 70% by weight of the formulation, from about 40% to 60% by weight of the formulation and about 50% by weight of the formulation.

The present invention contemplates the use of the therapeutic compositions at various stages in the disease development and progression, including in the treatment of early stage, or advanced and/or aggressive stage of hyperglycemia, diabetes or related disorders. The administration of the therapeutic composition comprising the isolated and screened extracts to mammal having an early stage of the disorder can help to attenuate the progression of the disease.
The dosage of the therapeutic composition to be administered is not subject to defined limits, but will usually be an effective amount. However, it will be understood that the actual amount of the composition to be administered will be determined by a physician, in the light of the relevant circumstances, including the exact condition to be treated, the chosen route of administration, the actual composition administered, the age, the weight, and the response of the individual patient and the severity of the patient's symptoms. The dosage ranges are not intended to limit the scope of the invention in any way.

The therapeutic compositions comprising the plant extract are not limited to only those for humans but also include those for various animals, in particular, other mammals. Therefore, the food compositions include foods for animals such as cats, dogs, and the like pets, and the medical compositions include those for animals other than humans.

Example: 11

Modes of administration:

For administration to a mammal, the therapeutic composition can be formulated as a pharmaceutical or naturopathic formulation such as phytoceuticals or nutraceuticals, for oral, topical, rectal or parenteral administration or for administration by inhalation or spray. The phytoceutical or naturopathic formulation may comprise the one or more plant extracts in dosage unit formulations containing the conventional non-toxic physiologically acceptable carriers, adjuvants and vehicles.

The pharmaceutical or naturopathic formulations may be in a form suitable for oral use, for example, as tablets, troches, lozenges, aqueous or oily suspensions, dispersible powders or granules, emulsion hard or soft capsules, or syrups or elixirs. The therapeutic compositions of the invention may be formulated as phytoceuticals, or nutraceuticals. Phytoceuticals may optionally comprise other plant-derived components and can therefore be delivered by such non-limiting vehicles as teas, tonics, juices or syrups. Nutraceuticals contemplated by the present invention may provide nutritional and/or supplemental benefits and therefore be delivered, for example as foods, dietary supplements, extracts, beverages or the like. Phytoceutical and nutraceuticals can be administered in accordance with conventional treatment programs and/or may be a part of the dietary or supplemental program.
Formulations intended for oral use may be prepared according to methods known in art for the manufacture of pharmaceutical compositions and may contain one or more agents selected from the group of flavoring agents, coloring agents and preserving agents in order to provide palatable preparations.

Tablets contain the active ingredient in admixture with suitable non-toxic physiologically acceptable excipients including, for example, inert diluents, such as calcium carbonate, lactose, calcium phosphate or sodium phosphate; granulating and disintegrating agents, such as corn starch, or alginic acid, binding agents, such as starch, gelatine or acacia, and lubricating agents, such as magnesium stearate, stearic acid or talc. The tablets can be uncoated, or they may be coated by known techniques in order to delay disintegration and absorption in the gastrointestinal tract and thereby provide a sustained action over a longer period.

Various additives or carriers can be incorporated into the orally delivered pharmaceutical naturopathic formulations or the invention. Optional additives of the present composition include, without limitation, phospholipids, such as phosphatidyl glycerol, phosphotidyl inositol, phosphotidyl serine, phosphotidyl choline, phosphotidyl ethanolamine as well as phosphatidic acids, ceramide, cerebrosides, sphingomyelins and cardiolipins.

Pharmaceutical or naturopathic formulations for oral use may also be presented as hard gelatin capsules wherein the active ingredient is mixed with an inert diluent, for example, calcium carbonate, calcium phosphate or kaolin, or as soft gelatin capsules wherein the active ingredient is mixed with water or an oil based medium such as peanut oil, liquid paraffin or olive oil.

Oily suspensions may be formulated by suspending the plant extract(s) in a vegetable oil, for example, arachis oil, olive oil, sesame oil or coconut oil, or in a mineral oil such as liquid paraffin. The oily suspensions may contain a thickening agent, for example beeswax, hard paraffin or cetyl alcohol. Flavoring agents may be added to provide palatable oral preparations. These formulations can be preserved by the addition of an anti-oxidant such as ascorbic acid.

Dispersible powders and granules suitable for preparation suitable for an aqueous suspension by the addition of water provide the active ingredient in admixture with
dispersing or wetting agent, suspending agent and one or more preservatives. Suitable dispersing or wetting agents and suspending agents, sweetening, flavoring and coloring agents may also be present.

In another aspect of the invention, the extract produced by the invention can be used in combination with other known extracts from different plant sources. Also, the instant invention can be prepared and used in combination with other therapeutic agents such as well known drugs selected from the groups consisting of sulfonylurea, a biguanide, a thiazolidinedione, a P3-adrenergic receptor agonist, an alpha-glycosidase inhibitor, insulin and mixtures thereof. The common yet delimiting examples of such drugs are biguanide such as metformin or buformin; a sulfonylurea such as acetohexamide, chlorpropamide, tolazamide, tolbutamide, glyburide, glypizide or glyclazide; a thiazolidinedione such as troglitazone; an a-glycosidase inhibitor such as acarbose or miglitol, or a P3-adrenergic receptor agonist such as CL-3 l6, 243, etc; or mixtures thereof. In a further aspect of the invention there is provided a comestible, that is to say, a foodstuff comprising at least an extract of the invention, typically in dried form, such as in a lyophilized form. The skilled addressee will appreciate that such comestibles may contain more than one extract of the invention and may be used. Such foodstuffs may be used in a prophylactic manner and may contain further extracts having a similar function to the first added extract or further added extracts may be added that have a dilTcienl prophylactic function. Thus a foodstuff could either comprise extracts that provide for a comestible having a single functional aspect, or a comestible may have a multi-functional prophylactic effect against two or more disease types. It is thought that a multi-functional role could be assigned to pharmaceutical formulations comprising two or more extracts possessing dissimilar therapeutic or prophylactic properties designed either for prophylaxis or for the treatment of more than one disease(s) in a mammal, particularly in a human.

The type of foodstuff or comestible to which at least an extract of the invention may be added includes any processed food such as confectionaries, baked products including breads such as loafs, and flat breads such as pitta bread, naan bread and the like, cakes, snack foods such as museli bars, compressed dried fruit bars, biscuits, dairy products such as yoghurts, milk and milk-based products such as custards, cream, cheese, butter and crmc fraichc. simulated dairy food product such as Elmlea products, fruits and
vegetable juices, aerated drinks, such as carbonated soft drinks and non-aerated drinks such as squashes, soya milk, rice milk and coconut milk and the like, pastas, noodles, vegetables, seed and nut oils, fruited oils such as sunflower oil, rapeseed oil, olive oil, walnut, hazelnut, and sesame seed oil and the like, and frozen confectionaries such as ice cream, iced yoghurts and the like.

The present water and ethanol based plant extracts can also be used for the management of diabetic related disorders, which are general, or local diseases directly or indirectly caused by diabetes. Specific examples thereof are diabetic acidosis, diabetic xanthoma, diabetic myatrophy, diabetic ketosis, diabetic coma, diabetic stomach disorders, diabetic gangrene, diabetic ulcer, diabetic diarrhea, diabetic microangiopathy, diabetic uterosclerosis, diabetic cardiomyopathy, diabetic neuropathy, diabetic nephropathy, diabetic blister, diabetic cataract, diabetic dermatitis, diabetic scleredema, diabetic retinopathy, diabetic necrobiosis lipoidica, diabetic blood flow obstructions, etc.

The invention will now be exemplified with reference to the following Examples section. It is to be understood that the examples are not to be construed as limiting the scope of the invention in any way.

The present invention relates to mixtures, which can be isolated from Salacia bark (Celastraccae family) for the management of an important clinical problem like diabetes. The following examples set forth and present the effects of Salacia species on both pre-existing diabetes conditions, as well as the preventative effects of Salacia species against the onset of or contracting diabetes. These examples are not intended to be limiting in any way, but are merely illustrative of the beneficial, advantageous, and remedial effects of Salacia species on diabetes.

Example: 12

**In-vivo efficacy screening using Sprague dawley rats**

In-vivo efficacy screening of Salacia root water extract was done using Sprague dawley rats and the procedure undertaken is as follows:

Sprague dawley rats weighing ~250g with a variation of ± 20% of the mean weight are selected for In-vivo efficacy screening of Salacia root water extract. The identification is undertaken by the cage tag and the corresponding picric acid color body markings.

The number of animals selected in a group is five and kept in an experimental room
after veterinary examination. The route of administration is oral gavage. The rats are fed with 5% glucose water for two days before STZ injection to avoid death due to hypoglycemic shock. Rats are fasted for 12 hours and injected intraperitoneally with 45mg/kg-body weight of streptozotocin. Blood collection is undertaken with CO2 anesthesia and FBG analysis before STZ injection is performed which serves as the normal baseline (60-120mg/dl) for the animals. Citrate buffer (Ph of 4.5) is used as the vehicle, STZ is a photo, temperature and Ph sensitive chemical; hence the animals are injected with in 45 minutes of the dose formulation. Animals initially become hypoglycemic for the first 3 days because of the insulin surge into the blood stream. Gradually from day 4 animals attain hyperglycemia. On the 6th blood collected by retro orbital (ROP) plexus method in heparin as the anti-coagulant, under CO2 anesthesia and analyzed for postprandial glucose levels. Animals are fasted for 12 hours on Day 7 after STZ injection. Day 8 blood collected in heparin as the anti-coagulant, under CO2 anesthesia and analyzed for FBG. Animals that have the range of FBG beyond 250 mg/dl are considered for the study.

**Example: 13**

**Screening of Salacia root water extract at 50, 125 and 200 mg/kg-body weight.**

Selection, randomization and grouping of the animals into different treatment groups with the FBG range of 250 mg/dl is undertaken as above. The dosing formulations are prepared freshly each day 0.5% CMC was used as the vehicle. The test article Salacia root water extract, is administered by oral gavage to each rat daily, for 35 consecutive days. The animals were dosed at approximately the same time each day where possible using a stainless steel intubation needle fitted onto a suitably graduated glass syringe. The dosage volume administered to individual rat was adjusted according to its most recently recorded body weights. Treatment in this manner continued once a day, seven days a week, for a total period of 35 days. Vehicle control group animals are treated with the vehicle only at the same dosage volume i.e. 10 ml/kg body weight. The Groups include: G1-Vehicle control, G2-Diabetic control, G-3 Diabetic animals treated with Pioglitazone (Standard anti-diabetic drug) 20mg/kg-body weight. G-4 Salacia water root extract 50 mg/kg-body weight, G-5 Salacia water root extract 125 mg/kg-body weight, G-6 Salacia water root extract 200 mg/kg-body weight. Throughout the study, all cages were checked early on each working day and again in the afternoon and evening to look for dead or moribund animals to allow necropsy examination to be
carried out during the working hours of that day. All rats that will be killed in extremes, or found dead in the cage were subjected to detailed necropsy examination. All signs of ill health, together with any behavioral changes or reaction to treatment are recorded for individual animals. Dated and signed records of appearance, change and disappearance of clinical signs are maintained in clinical history sheets for individual animals. The parameters that are observed or included in the study were postprandial glucose, fasting blood glucose (FBG), body weight and feed consumption. Blood collection by ROP on week 1, 2 & 5 for the above said parameters. The animals selected for the study are treated with the extract at 3 different dose levels for 35 days. Necropsy Examination: On completion of 35 days of treatment period, all surviving rats will be sacrificed by exsanguinations under CO2 anesthesia. Complete necropsies were carried out on all animals including those, which died during the study.

The fasting blood glucose lowering potential of Salacia water root extract at different concentrations are illustrated in figure 10. The diabetic control rat group showed 240% increase in their fasting blood glucose levels compared to the baseline values of the same group at the start of the study. While the groups treated with pioglitazone, Salacia water root extract at 50, 125 and 200mpk (milligram per kg body weight) did not show any significant percent change from their baseline values. The results have been represented in Table No. 10

<table>
<thead>
<tr>
<th>Groups</th>
<th>Week 1 (% change from Base line)</th>
<th>Week 2 (% change from Base line)</th>
<th>Week 5 (% change from Base line)</th>
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<td>87.78</td>
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<td>G3</td>
<td>-30.99</td>
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<tr>
<td>G6</td>
<td>-3.53</td>
<td>13.44</td>
<td>-6.92</td>
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</table>
The postprandial blood glucose lowering potential of Salacia root water extracts at different concentrations are illustrated in **figure 11**. The diabetic control rat group showed over 240% increase in their postprandial blood glucose levels compared to the baseline values of the same group at the start of the study. While the groups treated with pioglitazone, Salacia root water extract at 50, 125 and 200mpk (milligram per kg body weight) did not show any significant percent change from their baseline values. The results have been represented in Table No. 11

<table>
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<td>-7.83</td>
</tr>
<tr>
<td>G5</td>
<td>-0.93</td>
</tr>
<tr>
<td>G6</td>
<td>7.87</td>
</tr>
</tbody>
</table>

While the invention has been described in connection with specific and preferred embodiments thereof, it is capable of further modifications without departing from the spirit and scope of the invention. This application is intended to cover all variations, uses, or adaptations of the invention, following, in general, the principles of the invention and including such departures from the present disclosure as come within known or customary practice within the art to which the invention pertains, or as are obvious to persons skilled in the art, at the time the departure is made. It should be appreciated that the scope of this invention is not limited to the detailed description of the invention hereinabove, which is intended merely to be illustrative, but rather comprehends the subject matter defined by the claims. Although the present invention has been described in considerable detail with reference to certain preferred versions thereof, other versions are possible. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred versions contained herein.
Example: 14

Comparative data on Salacia extracts

The details regarding the comparative data of different Salacia extracts in comparison with acarbose are provided in figure 12, and the data regarding insulin sensitization activity for different Salacia extracts are shown in figure 13. The three extracts compared were Salacia 0 which is an ethanol extract, Salacia 1 is a water extract, Salacia 2 is an ethyl extract. Of the three extracts, Salacia 1 and Salacia 0, extracts showed potential α-glucosidase inhibition activity at the concentration of 60 and 80 µg per ml while only Salacia 1 (145 %) showed some amount of insulin sensitization activity in case of 3T3-L1 based glucose uptake assay.

Example: 15

Acute Oral toxicity Study of Anti diabetic Salacia Extract

Acute oral toxicity study of Ant diabetic Extract - AGT028Ro08(00) in Sprague Dawley rats was performed in compliance with the OECD Guidelines for Testing of Chemicals, Section 4, No. 423 - Acute Oral Toxicity - Acute Toxic Class Method, adopted 17 December, 2001. The method uses pre-defined doses and the results allow a substance to be ranked and classified according to the Globally Harmonised System (Gl IS) for classification of chemicals which cause acute toxicity.

In the present study, single oral administration of Antidiabetic Extract - AGT028Ro08(00), suspended in 0.5% aqueous solution of carboxymethyl cellulose (CMC), was made to groups of three female Sprague Dawley rats in step-wise manner to assess its acute toxicity. Following the starting dose of 2000 mg/kg, which was also repeated in the second step of the test, Antidiabetic Extract - AGT028Ro08(00) did not cause death of any of the treated females. Also, no abnormal clinical signs were observed in the six female rats.

In next step of the study Antidiabetic Extract - AGT028Ro08(00) was further tested at the dose of 5000 mg/kg, on three female rats in stepwise manner. The test article did not cause death of any of the female rats treated at 5000 mg/kg after dosing and also did not induce any signs of evident toxicity.
Antidiabetic Extract - AGT028Ro08(00), at the dose levels of 2000 mg/kg and 5000 mg/kg body weight, did not adversely affect body weight gain by treated rats during the 14 day observation period, post-treatment. The test article did not induce any gross pathological alterations in the tissues / organs of the treated rats as was evident during the terminal necropsy. Based on these results, and according to the "Globally Harmonised System (GHS) for classification of chemicals which cause acute toxicity, OECD series on testing and assessment, Number 33 ; Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures [i:NV/JM/MONO(2001)6]", the test article Antidiabetic Extract - AGT028Ro08(00) has to be classified as GHS Category 5 or Unclassified for the obligatory labeling requirement for oral toxicity. This category indicates that following acute oral exposure to Antidiabetic Extract - AGT028Ro08(00) in female rats, the LD50 value is expected to exceed 5000 mg/kg. This category indicates that following acute oral exposure to Antidiabetic Extract - AGT028Ro08(00) in female rats, the LD50 value is expected to exceed 5000 mg/kg.

Subacute oral toxicity test

Repeated Dose 28-day Oral Toxicity Study of Antidiabetic Extract - AGT028Ro08(00) in Sprague Dawley rats was performed in compliance with the OECD Guidelines for Testing of Chemicals (No. 407, Section 4 : Health Effects) on conduct of "Repeated Dose 28-day Oral Toxicity Study in Rodents" (Adopted : 27 July 1995), and “Requirements and Guidelines for Permission to Import and / or Manufacture of New Drugs for Sale or to Undertake Clinical Trials", under Schedule Y of The Drugs and Cosmetics Rules, 2005, Government of India. The study protocol was also based upon the respective ICH and WHO test guidelines. Based upon the findings of a 7 day dose range finding study, groups of six male and six female Sprague Dawley rats were administered Antidiabetic Extract - AGT028Ro08(00) by oral gavage daily at the doses of 100 mg/kg, 300 mg/kg and 1000 mg/kg body weight for 28 days and were then sacrificed to evaluate its toxicity.
Concurrent control group receiving the vehicle (0.5% CMC in water) only at 10 ml/kg was also maintained. Additionally, satellite groups of six rats per sex receiving the vehicle at 10 ml/kg, and the test article at 1000 mg/kg levels were further observed for a period of 14 days following 28 day exposure, for assessment of reversibility, persistence or delayed occurrence of toxicity.

The rats were examined daily for signs of toxicity and mortality, and were subjected to detailed clinical examination before initiation of the experiment and weekly thereafter during the exposure period and reversal period. In the fourth week of exposure they were additionally examined for assessment of sensory reactivity, assessment of grip strength and motor activity. Body weight and food consumption were recorded weekly. Laboratory investigations were performed on blood and urine at termination of the study. All animals were sacrificed terminally and were subjected to a detailed necropsy and weights of certain organs were recorded. Histopathological evaluation was performed on all protocol-listed tissues in all rats from the control and high dose level groups, and any tissues with gross abnormalities. Following results were obtained under the experimental conditions described in the Materials and Methods section of this report.

Conclusion:

**Antidiabetic Extract - AGT028Ro08(00)**, following daily oral administration at the levels of 100 mg/kg, 300 mg/kg and 1000 mg/kg, to groups of six Sprague Dawley rats per sex for 28 days caused:

* no mortality in male and female rats, at and up to the dose of 1000 mg/kg ;
* no incidence of any remarkable abnormal clinical signs in either sex, at and up to the dose of 1000 mg/kg ;
* no neurotoxicity, at and up to the dose of 1000 mg/kg ;
* no remarkable effect on the body weights of male and female rats, at and up to the dose of 1000 mg/kg ;
* no effect on the average daily food consumption by the male and female rats treated at and up to the dose of 1000 mg/kg ;
* no effect on the absolute and relative organ weights of male and female rats, at and up to the dose of 1000 mg/kg ;

* no effect on the haematological parameters of male and female rats treated at and up to the dose of 1000 mg/kg;
* no effect on biochemical parameters of male and female rats treated at and up to the dose of 1000 mg/kg;
* no effect on the urinalysis parameters of male and female rats treated at and up to the dose of 1000 mg/kg;
* no remarkable gross pathological and histo-pathological alterations in the tissues of male and female rats treated at and up to the dose level of 1000 mg/kg.

Results of the study indicated that the test article Antidiabetic Extract - AGT028Ro08(00) had no effect on general health and growth, on behavioural, neurological, haematological, clinical chemistry and urinalysis parameters, and on organ weights and gross and microscopic appearance of the tissues / organs of the rats treated at and up to the dose level of 1000 mg/kg body weight.

Based on the findings of this study, the no observed effect level (NOEL) of Antidiabetic Extract - AGT028Ro08(00) in rats, following oral administration for 28 days was found to be more than 1000 mg/kg body weight.

AMES study

Mutagenicity Study of Antidiabetic Extract - AGT028Ro08(00) by Salmonella typhimurium Reverse Mutation Assay was carried out following the OECD Guidelines for Testing of Chemicals (No. 471, Section 4 : Health Effects) on conduct of "Bacterial Reverse Mutation Test" , adopted 21 July 1997 and as per mutually agreed protocol.

Antidiabetic Extract - AGT028Ro08(00) was evaluated in the Ames / Salmonella Plate Incorporation Assay to determine its ability to induce reverse mutation at selected histidine loci in five tester strains of Salmonella typhimurium viz. TA 1535, TA 97a, TA 98, TA 100 and TA 102 in the presence and absence of metabolic activation system (S9). Based upon the preliminary tests conducted to assess the solubility / precipitation and cytotoxicity of Antidiabetic Extract - AGT028Ro08(00) the tester strains were exposed to the test article in triplicate cultures at the doses of 5000 µg, 1500 µg, 500 µg, 150 µg and 50 µg/plate, both with and without metabolic activation system (S9).

Liver S9, induced in Sprague Dawley rats by phenobarbitone with β-naphthoflavone, was used for this purpose.

Dimethyl sulphoxide was used as a vehicle. The exposed bacteria were plated onto minimal glucose agar medium supplemented with L-histidine. The plates were
incubated at 370°C for 48 hours after which the histidine revertant colonies were counted and their frequency was compared with that in the vehicle control group. Results of this test indicated that the frequencies of histidine revertant colonies at all concentrations of Antidiabetic Extract - AGT028Ro08(00) in strains TA 1535, TA 97a, TA 98, TA 100 and TA 102, with and without the presence of a metabolic activation system, were comparable to those observed in the vehicle control groups, and this observation was confirmed by repetition of the experiments. Plate counts for the spontaneous histidine revertant colonies in the vehicle control groups were found to be within the frequency ranges expected from the laboratory historical control data at INTOX. They also compared well with the range reported in the literature. Concurrent positive controls demonstrated sensitivity of the assay with and without metabolic activation. It is concluded that, under the conditions of this study, AGT028Ro08(00) is non-mutagenic in Salmonella typhirminum strains TA 1535, TA 97a, TA 98, TA 100 and TA 102.

Conclusion:
Mutagenicity Study of Antidiabetic Extract - AGT028Ro08(00) by Salmonella typhirminum Reverse Mutation Assay was carried out following the OECD Guidelines for Testing of Chemicals (No. 471, Section 4 : Health Effects) on conduct of "Bacterial Reverse Mutation Test", adopted 21 July 1997.

It is concluded that, under the conditions of this study, Antidiabetic Extract - AGT028Ro08(00) is non-mutagenic in Salmonella typhimurium strains TA 1535, TA 97a, TA 98, TA 100 and TA 102.
We Claim:

1) An organoleptically enhanced *salacia* plant extract for management of diabetes and related disorders.

2) The organoleptic extract as claimed in claim 1, wherein the organoleptic agents are decolorizing and deodorizing agents.

3) The organoleptic extract as claimed in claim 1, wherein the extract is treated with said organoleptic agents at a ratio ranging from 0.5: 10 to 10: 0.5.

4) The organoleptic extract as claimed in claim 1, wherein the extract is treated with organoleptic agents preferably at a ratio of about 1: 0.25.

5) A method of treating diabetes and/or related disorders in a subject in need thereof, said method comprising step of administering pharmaceutically acceptable amount of organoleptically improved salacia plant extract, optionally along with pharmaceutically acceptable additives, to the subject.

6) The method of treating as claimed in claim 5, wherein the subject is an animal or human being.

7) The method of treating as claimed in claim 5, wherein the organoleptically improved salacia plant extract is having insulin mimetic activity, insulin sensitizing activity, and alpha glucosidase activity.

8) The method of treating as claimed in claim 5, wherein the organoleptically improved salacia plant extract is administered at dosage ranging between 20 to 300 mg/kg body weight.

9) The method of treating as claimed in claim 5, wherein the organoleptically improved salacia plant extract is administered preferably at dose of about 50 mg/kg body weight.

1) The method of treating as claimed in claim 5, wherein the additives are selected from a group comprising granulating agents, binding agents, lubricating agents, disintegrating agents, sweetening agents, coloring agents, flavoring agents, coating agents, plasticizers, preservatives, suspending agents, emulsifying agents and spherization agents.

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12) The method of treating as claimed in claim 5, wherein the organoleptically improved salacia extract is formulated into dosage forms selected from a group comprising tablet, troches, lozenges, aqueous or oily suspensions, dispersible powders or granules, emulsion in hard or soft gel capsules, syrups, elixirs, phyotccuticals and neutraccuticals.

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13) The method of treating as claimed in claim 5, wherein the organoleptically improved salacia plant extract is non-toxic and free of adverse effects.

14) The method of treating as claimed in claim 5, wherein the organoleptically improved salacia plant extract can be administered to subjects in combination with agents selected from a group comprising synthetic anti-diabetic drugs, anti-diabetic plant extracts and food stuffs.

15) A process for enhancing organoleptic and anti diabetic properties of a salacia plant extract, said process comprising steps of (a) size-reducing plant parts to obtain powder; (b) extracting the powder with a solvent and/ or combination of solvents by heating at temperature ranging from 25$^0$ to 100$^0$ C to obtain a mixture; (c) clarifying the mixture to arrive at clear liquid; (d) concentrating the clear liquid to achieve a concentrated extract; (e) solubilizing the concentrated extract in a solvent and re-concentrating it to obtain further concentrated extract; and (f) treating the further concentrated extract with an organoleptic agent (s) followed by drying the treated extract to obtain organoleptically enhanced salacia plant extract.

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16) The process as claimed in claim 15, wherein the size reduction is done either manually or mechanically to achieve powder particle size ranging from 50 # to 200 # and preferably of 100 mesh size.

25

17) The process as claimed in claim 15, wherein the parts of plant are selected from a group comprising root, shoot, leaf and seeds or the whole plant.

30

18) The process as claimed in claim 15, wherein the solvent used for extraction could be aqueous, organic and/or combinations thereof.
19) The process as claimed in claim 15, wherein said solvents and/or combination of solvents are selected from a group comprising water, buffer, cell media, dilute acid, dilute bases, methanol, ethanol, n-propanol, isopropanol, 2-butanol, and terbutanol.

20) The process as claimed in claim 15, wherein the powder is extracted with a solvent at a ratio ranging from 1:3 to 1:50.

21) The process as claimed in claim 15, wherein the powder is extracted with a solvent preferably at a ratio of about 1:10.

22) The process as claimed in claim 15, wherein the extraction of powder with solvent and/or combination of solvents is brought about by stirring for a time period ranging from 2-3 hours.

23) The process as claimed in claim 15, wherein the extraction of powder with solvent and/or combination of solvents is brought about by stirring preferably for a time period of about 2.5 hours.

24) The process as claimed in claim 15, wherein the extraction of powder with solvent and/or combination of solvents is brought about by heating preferably at specific temperatures of about 80°C.

25) The process as claimed in claim 15, wherein said clarification is achieved by filtration or centrifugation.

26) The process as claimed in claim 15, wherein said concentration method is selected from a group comprising soxhlation, rotary evaporation, distillation, centrifugal vacuum evaporation and lyophilisation.

27) The process as claimed in claim 15, wherein said solubilization of concentrated extract is carried out in a solvent selected from a group comprising ethyl acetate, diethyl ether, hexane, dichloromethane, butyl alcohol, ether, acetone and/or combination thereof.

28) The process as claimed in claim 15, wherein said organoleptic agents are decolorizing and deodorizing agents.

29) The process as claimed in claim 15, wherein the decolorizing agents are selected from a group comprising carbon, activated carbon, resins, chemicals like hydrogen peroxide, acetone peroxide, benzoyl peroxide, sulfites like sodium metabisulfite, ammonium persulfate, sodium hydrosulfite, sodium sulfite and sulfur dioxide.
30) The process as claimed in claim 15, wherein said deodorizing agents are selected from a group comprising activated carbon and hydrogen peroxide.

31) The process as claimed in claim 15, wherein said treated extract is dried at a temperature ranging from 35° to 65° C.

32) The process as claimed in claim 15, wherein said treated extract is preferably dried at a temperature of about 50° C.

33) The process as claimed in claim 15, wherein the extract is treated with said organoleptic agents at a ratio ranging from 0.5: 10 to 10: 0.5.

34) The process as claimed in claim 15, wherein the extract is treated with said organoleptic agents preferably at a ratio of about 1: 0.25.
Figure 3
Figure 4
Figure 5
Figure 6
Figure 7

IC\textsubscript{50} (\textmu g/ml) for \alpha-glucosidase inhibition

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<th>Samples</th>
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<tr>
<td>Acarbose</td>
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<td>Salacia water extract</td>
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07/13
Figure: 8
Figure 9
Percentage variation in FBG over 5 week period

Figure 10
Figure 11
Figure: 12
Figure: 13
INTERNATIONAL SEARCH REPORT

International application No. PCT/IN2007/000263

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.
A61K 36/37 (2006.01) A61P 3/10 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

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

WPIDS, CA, Medline, Pubmed. SALACIA, DIABETES, EXTRACT, CELASTRACEA, INSULIN,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Relevant to claim No.</th>
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[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

'A' document defining the general state of the art which is not considered to be of particular relevance

'E' earlier application or patent but published on or after the international filing date

'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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'P' document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search 22 October 2007

Date of mailing of the international search report 07 DEC 2007

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Form PCT/ISA/210 (second sheet) (April 2007)
### DOCUMENTS CONSIDERED TO BE RELEVANT

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This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX