

Mini Review: Natural ingredients for diabetes which are approved by Korean FDA.

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Abstracts

Diabetes mellitus is a condition in which a person has a high blood sugar/glucose level. This is because the body does not produce enough insulin, or because the body cells do not properly respond to the insulin that is produced. Herbal treatment for diabetes has been a part of traditional medicine for thousands of years. The natural herbs for diabetes treatment focus on lowering blood sugar, reducing the damaging effects of the disease and maintaining of a safe, healthy level of blood glucose. Many diabetic patients seeking an alternative treatment to traditional drugs turn to natural herbs for help. This review article provides very useful information of officially-approved antidiabetic natural ingredients [Table 1] by KFDA, thereby providing consumers with a wise decision when they purchase the effective nutraceuticals for diabetes. Therefore, medicinal herbs may be used to prevent and treat diabetes reliably and safely when the government approves the ingredients or products officially.

Keywords: Diabetes, Medicinal herbs, Nutraceuticals, KFDA, Ingredients

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Diabetes is a chronic metabolic disorder of carbohydrates, proteins, and fat due to absolute or relative deficiency of insulin secretion with/without varying degree of insulin resistance [1, 2]. It may also be defined as a disease where the body either produces little insulin/ceases to produce insulin or becomes progressively resistant to its action [3].

Despite of tremendous advancement of medications, many diabetic patients try other means to cure and/or to control diabetes and do get satisfactory results. Among such other means, herbal cure for diabetes is one of the most popular means to deal with diabetes. Herbs from China, India and several countries have been used in place of medication to manage diabetes.

Natural herbs to lower blood sugar typically affect glucose levels in different ways. Although the exact mechanisms and active ingredients are sometimes unknown, many of the herbs contain flavanoids that prevent beta cell damage [4]. Other features of blood sugar lowering herbs may include hypoglycemic agents such as charantin, polypeptide, allyl propyl disulphide and diallyl disulphide oxide. Hundreds of plant species have been studied for their potential blood glucose lowering properties. The better studied botanicals with hypoglycemic activity include *Momordica charantia* (bitter melon), *Trigonella foenum-gracum* (fenugreek), *Gymnema sylvestre* (gurmar),

Panax quinquefolius (ginseng), *Opuntia streptacanthia* (nopal cactus), *Aloe barbadensis* (aloe), *Vaccinium myrtillus* (bilberry), *Silybum marianum* (milk thistle), *Allium sativum* and *Allium cepa* (garlic and onions) and *Pterocarpus marsupium* (Vijayasar).

Most countries regulate and control the use, application, claim, and other parts of medicinal anti-diabetic herbs. In America, conventional foods, functional foods, foods for special dietary use, medical food and dietary supplements are approved, while Japan approves foods for specified health use. Even though herbs have unbelievable anti-diabetic effects, FDA forbids any herb to claim that its active ingredient can cure diabetes. Like other countries, the Korean government (KFDA) regulates and controls on all procedures including approval, production, products, claim and the manufacture of all medical herbs, imported or native herbs.

There are three types of functional levels such as Functions I, II and III approved by Korean FDA [Table 2]. According to classification, levels can be claimed on the label of the box or elsewhere. However, claims should not include name of the disease like diabetes, which is somewhat restricted and strongly controlled by KFDA. Function I indicates that the ingredient has an effect on lowering glucose level as confirmed with several clinical stud-

ies. Function II suggests that the ingredient may be helpful in lowering glucose level also based on some

clinical studies. Function III means that the ingredient may be helpful in lowering glucose level but not based on clinical studies. Due to high cost of the conventional medication for diabetes, developing countries are trying to find out alternative solutions from the natural ingredi-

ents. Several botanical supplements have been studied as potential therapeutic agents in the management of diabetes and its related complications. This article will briefly review what is known about the efficacy of approved herbs or their ingredients with hypoglycemic activity which is currently used in Korea.

Table 1. Approved ingredients as hypoglycemic agents by Korean FDA (KFDA)

Ingredients	Function	Daily Dose	Active Ingredient
Banaba alcohol extract	II	50~100mg	Corosolic acid
Pinitol	III	1200mg	Pinitol (over 95%)
Extracted complex of Rhodiola rosea and Cinnamomum cassia	III	900mg	Salidroside (1.5%), Cinnamic acid (0.2%)
Guava extract	II	123.5mg	Strictinin, Isostrictinin as total polyphenol (17%)
Non-fat Seeds alcohol extract from Oenothera biennis (Evening primrose)	II	200~300mg	Polypenol (60-70%) and Petan-O-galloyl-beta-D-glucose (2-2.8%)
Pine needle essence	II	1350mg	3-carene (12%), limonene (8%) and terpinolene (17.5%)
Soybean fermented extract	II	900mg	
Nopal extract	II	4300mg	
Powder of lyophilized silkworms	II	2700mg	Whole extracts
Mixed Extracts of Fructus Aurantii and Mulberry Leaves	II	2800mg	
Peptide complex from small beans	III	4500mg	
Hydrolyzed Concentrates of ginseng	II	960mg	
Tagatose	II	5000~7500mg	D-tagatose
<i>Dioscorea batatas</i> DECNE (Yam extract)	III	900mg	Whole extracts

Table 2. Three types of Functional Grade from Korean FDA (KFDA)

Types of Function	Contents
Function I	This ingredient is helpful.
Function II	This ingredient can be helpful.
Function III	This ingredient can be helpful but requires clinical studies

Ingredients approved by Korean fda (KFDA)

Yam extract

The herb, wild yam is considered as one of the most versatile of herbs used to treat hormone-related conditions. Wild yam extract is derived from the root and is often used as a PMS (premenstrual syndrome) remedy today; many patients are using it and have reported relief from menopausal symptoms [5]. The additional benefits of wild yam extract include its anti-inflammatory and muscle relaxing properties. However, no reports have so far been available regarding its anti-diabetic property. Yam alcohol extract was approved by KFDA in 2011. However, KFDA claimed that the extract effectively regulates blood sugar level with a dose of 900mg/day, but hu-

man studies still remain insufficient. Its functional grade remains III, the lowest grade. It may be listed as an anti-diabetic ingredient but it has not been fully proven.

Tagatose

Tagatose is a functional sugar. Since it is metabolized differently from sucrose, tagatose has a minimal effect on blood glucose and at the insulin level. Tagatose is sweet like sugar. However, its calorie value is 1.5 calories per gram since less than 20% of ingested tagatose is absorbed in the small intestine [6]. It was approved as a food additive by the FDA in 2003. In preliminary studies in humans, tagatose has shown a low postprandial blood glucose and insulin response. It has recently been documented that oral d-tagatose attenuates the rise in plasma glucose during an oral glucose tolerance test in subjects with type II diabetes [7].

KFDA approved its Functional grade as II and daily intake amounts 5~7.5gram/day as D-tagatose. However, KFDA warned that gastric disorder is associated with high intake of D-tagatose. In 2004, Australia and New Zealand issued a warning that people suffering from fructose malabsorption should not eat tagatose.

Hydrolyzed Concentrates of ginseng: Korean Ginseng contains thirteen different ginsenosides. One of them, Panaxans helps to lower blood sugar. The polysaccharide enhances immune system and its antioxidant property is to protect the body from illness, disease and stress.

Ginseng and its saponins have been studied in alloxan-treated, genetically diabetic, and normal mice [8] and revealing its hypoglycemic effect. Ginseng saponins also stimulate the production of insulin. In elderly patients with hyperglycemia, the saponins reduced serum glucose [9]. Ginseng saponins are typically provided in tablets of 50 mg each, with a dose of 1-2 tablets each time, two to three times per day.

KFDA approved ginseng saponins as grade II and the suggested daily intake is 960mg/day as hydrolyzed concentrates of ginseng. However, patients are to be careful when it is taken with other prescribed medicines such as antidiabetic agents and anticoagulants.

Peptide complex from small black soybeans (*Rhynchosia Nulubilis*)

1. Beans, particularly black beans, are a rich source of antioxidants. Beans with colored seed coats have higher levels of flavonoids, and thus higher antioxidant level. This antioxidant protects and keeps the skin healthy, and also an exerts anti-aging effect.

The small black beans' powder showed to be hypoglycemic with a corresponding effect on insulin sensitivity in Streptozotocin (STZ)-induced diabetic rats [10]. Recently, there are one clinical study about the effect of black soy peptide supplement on glucose control in subjects with prediabetes (impaired fasting glucose or impaired glucose tolerance) and newly diagnosed with type II diabetes mellitus [11].

Subjects with fasting glucose (≥ 110 mg/dL) who consumed black soy peptides for 12 weeks showed lower fasting glucose levels and had a significant reduction in 2-hour postload glucose compared with baseline levels. KFDA approved this ingredient as Function III grade. Recommended daily dose is 4.5 gram peptide complex from small black soybeans.

Mixed extracts of *Fructus aurantii* and Mullberry leaves (*Morus alba*)

Mullberry leaves are commonly used as oriental medicine in Korea. Mullberry (*Morus alba*), a herb contains an active ingredient DNJ (1-deoxynojirimycin) which helps in controlling blood sugar level by inhibiting carbohydrate digestion and absorption [12, 13]. *Fructus aurantii* or *Fructus aurantii* immaturus, called bitter orange is bitter and pungent in flavor. There is no scientific data about anti-diabetic effect of *Fructus aurantii* when its extract is used alone.

However, combined extract of *Fructus aurantii* and mullberry leaves showed blood sugar lowering effect in Streptozotocin-induced type II diabetes model [14] and in type II diabetic Otsuka Long-Evans Tokushima Fatty (OLETF) rats [15], respectively. Prevention of diabetes-related cardiovascular complications by using a mixture of the same herbal extracts has also been claimed. Based on scientific evidence KFDA recommended extracts of these herbal combination as Function II grade at a dose of 2.8 gm/day.

Powder of lyophilized silkworm

Silkworm powder has inhibitory effects on glucose absorption [16] in human intestinal epithelial cells. Silkworm powder inhibits α -glucosidase activation and glucose transporter (SGLT1) expression. These results suggest that silkworm powder can be used as a natural functional food for the prevention and alleviation of type-II diabetes mellitus [17,18].

KFDA approved lyophilized silkworm powder as Function II grade and recommended intake amounts 2.7gram/day. as powder of lyophilized silkworm. However, KFDA warned that this is not applied for diabetic treatment or prevention and you need to consult your physician prior to use before taking this.

Nopal *Opuntia streptacantha* Lemaire (*nopal cactus*) extract

Opuntia streptacantha Lemaire, also referred to as nopal/prickly pear cactus, is a member of the family cacti commonly used as food and medicinal plant in Central and South America. Both the sap and the leaves of the cactus, *Opuntia streptacantha* Lemaire have been studied for their blood glucose lowering properties in animal models or subjects with type II diabetes [19].

The use of *Opuntia streptacantha* Lemaire as a treatment for diabetes has been tested in subjects with type II diabetes. [20]. Studies have not been well designed and the mechanism of blood glucose lowering action of the herb has not been suggested. Since nopal is a good source of fiber and pectin, it is believed to act primarily by decreasing glucose absorption in the gastrointestinal tract [21]. A recent study with adult-onset diabetics in Mexico showed that nopal has hypoglycemic effect on the obese. simultaneously lowers serum levels of low-density cholesterol and triglycerides [21].

KFDA approved the grade of Napol as Function II. 4.3gram/day as water-soluble fiber of Nopal extract has been recommended. However, pregnant or lactating women and children should not go for it.

Extracts of fermented soybean

This product is an aqueous extract of fermented bean (*Glycine max.*) with *Aspergillus oryzae*. It is standardized

with IC₅₀ 0.018~0.1mg/ml as high maximal inhibitory concentration of Tris (2-Amino-2-(hydroxymethyl)-1,3-propanediol) and alpha-Glucosidase. This Tris functions as alpha-Glucose inhibitor, which inhibits glucose absorption. Study with extract of fermented soybean confirmed that blood glucose level and HbA_{1C} are decreased for a longer period of time [22].KFDA approved this preparation as Function II and its intake of 900mg/day as extracts of fermented soybean has been recommended.

Pine tree essence

Pine needle (*Pinus densiflora* Sieb. et Zucc.) extract is being used for many, many years for treating multiple ailments in Asia Pacific region. The extract is a composite mixture of a number of organic compounds. Three primary components standardized by KFDA are 3-carene (12%), limonene (8%) and terpinolene (17.5%), respectively. This product is prepared by steaming needles of *Pinus densiflora* with a distiller. Consistent results of controlling blood glucose levels in streptozotocin-induced diabetic rats are evident [23] but no clinical studies have so far been recorded .

KFDA approved the preparation as Function II grade and the distilled concentrates of pine needles of 1350mg/day has been recommended. . However, persons having bronchial asthma, chronic cough or inflammation of airways are strictly restricted from using this preparation

Non-fat Seeds alcohol extract from *Oenothera biennis* (Evening primrose)

Evening primrose oil found in the plant's seeds is rich in the essential fatty acid gamma-linolenic acid (GLA). Essential fatty acids -- such as omega-6, found in EPO, and omega-3, found in fish oil are used as building blocks for a number of molecules in the body.

Evening primrose extract has inhibitory efficacy on α -amylase and α -glucosidase. One of Japanese pharmaceuticals performed a trial on the efficacy of tablet containing evening primrose extract for 12 weeks on 44 male subjects After taking the tablets for 12 weeks, fasting blood glucose levels were significantly lowered and HbA_{1c} value was also decreased [24].

KFDA regulated the polyphenol (60-70%) and Petan-O-galloyl-beta-D-glucose (2-2.8%) as core ingredients. This extract inhibits the intestinal enzyme alpha-glucosidase. When alpha-glucosidase is inhibited, carbohydrate absorption is slowed down, thereby reducing the rise in blood sugar following a meal. KFDA approved the preparation as Function II grade standardized and recommended the dosage as whole extract of 200-300mg/day

Guava leaf (*Psidium Gujava*) extract

This extract is prepared by hot water and core ingredient, 17% of total polyphenol (strictinin, isostrictinin) is ap-

proved by KFDA. Deguchi et al. [25] demonstrated that Guava leaf hot water extract inhibits in vitro activities of maltase, sucrase, and alpha-amylase in a dose-dependent manner. Recently, Shen et al.[26] have reported that long-term feeding of guava leaf extract in diabetic rats significantly reduced blood glucose and increased levels of plasma insulin.. A crossover clinical trial involving 20 hospitalized patients with T2DM was conducted to compare the potentiality of Guava Leaf Tea and voglibose (Basen®;Takeda Chemical Industries, Ltd., Tokyo, Japan) to reduce postprandial blood glucose elevation [27]. The recommended dose is 123.5mg/day with polyphenol and approved as Function II grade.

Mixture of *Rhodiola rosea* and Cinnamon bark

Kwon et al [28] reported that *Rhodiola* spp. Inhibits activity of alpha-amylase, alpha-glucosidase and angiotensin converting enzyme (ACE), indicating that *Rhodiola* spp. can manage type II diabetes as well as hypertension.. Cinnamon has been used medicinally for a long time. A study was conducted with 60 men and women with Type II diabetes. The participants took either 1.0, 3.0, or 6.0 gm/day of cassia cinnamon or a placebo for 40 days. Blood glucose levels of the patients dropped between 18% and 29%. However, dosage of 1.0 gram/day did not show any significant effect.

The results suggest that the inclusion of cinnamon in the diet of people with type II diabetes reduces risk factors associated with diabetes and cardiovascular diseases [29]. This formulation mixture consists of 88.9% of *Rhodiola rosea* extract and 11.1% of Cinnamon Bark extract. The key ingredients are 1.5% of salidroside and 0.2% of cinnamic acid, respectively. KFDA approved that this mixture has a mild effect in controlling fasting blood sugar but lack of scientific data made the mixture as function III grade. The recommended dose of the mixture for its safe use is 900mg/day.

Pinitol

Pinitol is a sweet crystalline compound that is extracted from the heartwood of sugar pine. D-pinitol (3-O-methylchiroinositol), an active principle of the traditional antidiabetic plant, *Bougainvillea spectabilis*, is claimed to exert insulin-like effects. The antidiabetic effects were studied in streptozotocin (STZ)-induced diabetic Wistar rats [30], in 15 human with type II diabetes [31] and in obese subjects with soybean-derived pinitol supplementation [32]. Results of the studies suggest that pinitol supplementation may be useful in controlling postprandial increase in blood glucose. KFDA approved pinitol as Function III grade with dosage of 1200mg/ day.

Banaba alcohol extract

Park and Lee [4] have reviewed antidiabetic efficacy of banaba. Corosolic acid, one of the primary components of banaba extract which induces GLUT4 (Glucose Trans-

porter) translocation in diabetic mice [33]. The hypoglycemic effects in several human studies were shown with standard extract of *L. speciosa* leaves [34], with banaba tablet containing banaba extract on mild type II diabetic patients [35], with banaba extract on diabetic patients with one-year clinical study [36] and with corosolic acid [37].

KFDA approved blood glucose lowering effects of banaba alcohol extract as function II grade with a restricted dose of 50-100 mg/day corosolic acid. However, KFDA has also suggested that this ingredient should not be used in the prevention of diabetes.

Conclusion

Diabetes mellitus, a disorder of carbohydrate metabolism characterized by hyperglycemia has increasingly become a growing concern in the world. Diabetes develops when there is a defect in the secretion of insulin or a defect in the action of insulin or both [38]. Uncontrolled high blood glucose levels can cause long-term damage to both large and small blood vessels and nerves, leading to unavoidable organ failure. To prevent possible damage to various organs, most diabetic patients remain on several antidiabetic medications. Unfortunately, various adverse effects such as heart failure, hypoglycemia, kidney failure and weight gain are reported following chronic use of prescribed medicines. Due to various reported side effects, many scientists have been seeking the substitution of antidiabetic drugs to natural remedies which have hypoglycemic potency [39, 40]. In the review article, Park and Lee [4] has emphasized banaba as one of powerful natural ingredients having hypoglycemic potency. Several hundreds of medicinal plants species have efficacy for reducing blood sugar level, Herbs are used to manage Type I and Type II diabetes and their complications. The above-mentioned plants and ingredients approved by KFDA have been considered for their possible hypoglycaemic actions. Further scientific investigations on KFDA recommended herbal ingredients can provide appropriate information on trustful guidelines to consumers in choosing herbal nutraceuticals for diabetes.

The beauty of herbs is that they don't cause any serious health problems. Patients need to get a professional medical opinion before using a particular herbal antidiabetic treatment. However, appropriate diet and physical exercise along with herbal medication is a healthy combination for diabetic patients.

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