

A nano botanical composition with maximum bioavailability for treatment of diabetes

Abstract

The present invention relates to a topical pharmaceutical Nanocomposition (with maximum bioavailability) for treatment of diabetes mellitus. The composition for treating diabetes, preferably formed of gel or cream, contains Vitamin B3 (Niacinamide), Galega Officinalis, Berberis Vulgaris or extract of them. In particular the composition is applied on reflexological points of a human body to cause the release of insulin from the patient's pancreas and to enhance the treatment of diabetes. Observed results showed excellent results for both types of diabetes with no adverse or side effects.

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Background of the invention

Diabetes mellitus, referred to as diabetes, is a chronic condition in which a person has elevated blood glucose levels that result from defects in the body's ability to produce and/or use insulin. There are two main types of diabetes. One of them is type 1 diabetes usually strikes children and young adults, and may be genetic, and/or environmental. The other one is Type 2 diabetes accounts for 90-95% of diabetes cases and is linked to obesity and physical inactivity.

Diabetes is a serious health problem that can lead the patient to several physiological complications. According to World Health Organization, at least 171 million people have a medical condition of diabetes, or 2.8% of the whole world population. Diabetes occurrence is increasing quickly, and it is estimated that by 2030, this number will be approximately 366 million people.

Diabetes is generally time-consuming for patients because of the need to consistently obtain reliable diagnostic information, follow prescribed therapy, and manage lifestyle on a daily basis. Diagnostic information is typically obtained from a blood sample with a device and is then measured with a handheld blood glucose meter. Interstitial glucose levels may be obtained from a continuous glucose sensor worn on the body.

Patients with diabetes and their healthcare professionals interact with a variety of medical devices and systems to help manage the disease. Currently, the clinical mostly use for the treatment of diabetes drugs to control blood sugar level, medications to control diabetes. Drug therapy is used to replace the function of the pancreas. This can be very time-consuming for patients.

There are more than dozens kinds of therapy methods for treating diabetes. Scientific studies and clinical tests have shown that acupuncture can help diabetic patients. The treatment for diabetes focuses on regulating the circulation of blood and energy and balancing the organ systems to improve pancreatic function and address internal heat and the depletion of fluids.

Using compositions including hypoglycemic extracts are known for treatment of diabetes. Such as *Berberis Vulgaris*¹ and *Galega Officinalis*^{2,3} are known to be hypoglycemic anti-diabetic ingredients and their extracts are used orally to treat diabetes but not as one formula containing all of them together formed as a cream or a gel. It relates to the field of therapeutic natural products, particularly to

plant extracts effective in treating and preventing diabetes and/or conditions associated therewith.

Maximum bioavailability

The herbal composition if used as an oral formulation its bioavailability will be poor compared to a topical (external) form on abdominal pancreatic area, rectum, sublingual, ears, penis, umbilicus, hands and feet and though sublingual and rectum suppository forms do give good bioavailability it was found that this cream with its Nano particle size did give maximum bioavailability effect.

Objects of the invention

Primary object of the present invention is to provide a composition to repair pancreatic function, and reduce the blood sugar for treating diabetes. Another object of the present invention is to provide a process for the preparation of the herbal composition for treating diabetes; the said process comprises herbal mix or more pharmaceutically acceptable additives/carriers.

Summary of the invention

The present invention relates to a topical pharmaceutical composition for treatment of diabetes mellitus. The composition for treating diabetes, preferably formed of gel or cream, contains vitamin B3, *Galega officinalis*, *Berberis Vulgaris* or extract of them.

Detailed description of the invention

Present invention relates to the use of a composition which can be formed as a cream or a gel that capable of improves metabolism which leads to blood sugar reduction. Said composition is used directly to the targeted zone deep within the cell where they can perform to their maximum potential bioavailability. Said pharmaceutical composition may be in the form of gel, ointment, cream, spray or lotion. In general, the composition according to the first aspect of this invention may be formulated in the form of usual preparations. The preparations may additionally contain one or more of filler, extender, and binder, moistening agent, disintegrator, surface active agent and lubricant.

Niacinamide or niacin,⁴ formed of Vitamin B3, has many biological activities such as that it is hypoglycemic, hypolipidemic, vasodilator, hepatoprotective, Anti-anginal and cancer-preventive which means it is a strong candidate for treating diabetes, high cholesterol, triglycerides, heart disorders, poor blood circulation and hence it prevents diabetes

complications in eyes, heart, kidneys, sex dysfunction and diabetic foot. *Galega officinalis* is known to be hypoglycemic and has also diuretic properties. Phytochemical databases show that *Berberis vulgaris* to be hypoglycemic, anti-diabetic and hypolipidemic.

Examples of pre-clinical results

The following examples are set forth to assist in understanding the invention but are not intended to, and should not be construed to; limit in any way the invention as defined by the claims which follow. Significant lowering of blood glucose was manifest within 30 minutes and persisted for at least 24 hours. The effect was dose dependent, and session-period dependent. For 10-30 minutes 3 times daily to treat type 1 and 2 of diabetes together with consequences resulting from diabetes in eyes, heart, kidney, feet, blood circulation and nervous system for 3-6 month course (Table 1).

Table 1 Effect of Nano Cream on Diabetes (for both types of Diabetes)

Case	Age	Diabetes type	Treatment time	HbA1C	
				Before	After
1	72	2	9 months	9.9	5.8
2	69	2	3 months	12.6	6.6
3	70	2	4 months	11.2	7.1
4	55	2	2 weeks	NA	NA
5	67	2	1 week	NA	NA
6	50	2	6 months	11	5.5
7	22	1	6 months	10	6
8	25	1	14 years	11	5
9	28	1	3 months	NA	NA
10	59	2	2 weeks	NA	NA

Case 1

The first patient was a 72 year old female with poorly controlled non-insulin- dependent diabetes, hypertension, and hypercholesterolemia. She was on insulin and metformin for more than 10 years. She started using composition 9 months ago. Her blood sugar was improved and HbA1c was dropped from 9.9 before treatment to 7.8, 6.6 and 5.8 during 9 months after commencement of treatment. The patient eventually stopped insulin and metformin gradually. To date her HbA1c remains below 6 on diet alone. She used Mansour device with Mansour's gel cream once and her glucose reading dropped from 195 to 83 within 30 minutes only.

Case 2

The second patient was a 69 year old male with a long history of non-insulin dependent diabetes and hypertension. Diabetic neuropathy had affected his feet and he could not feel the shoe rubbing. A small superficial ulcer developed on his foot which became infected and he used Mansour's foot cream for his diabetic ulcer and he avoided amputation and foot ulcer was cured. He used Mansour's Nano Gel Cream on reflexological points in his feet, acupuncture points in his hands and inside his umbilica for 3 months and his HbA1C dropped from 12.6 to 7.8 and he reduced amount of insulin. His condition rapidly improves after that and. in one day his blood sugar dropped from 292 postprandial to 190 at bed time then his fasting blood sugar

was 88 next morning and he quit insulin within one week only. HbA1c dropped from 7.8 to 6.6 after treatment.

Case 3

A 70 year old female was diagnosed with hypertension, and Type 2 diabetes 8 years ago and her sugar was not controlled by oral medications hence her doctor asked her to switch to insulin together with metformin. She started to use composition 4 months ago and she could reduce her HbA1C from 11.2 to 7.1 and she quit insulin.

Case 4

A 55 year old male with hypertension, hypercholesterolemia, hypothyroidism, and type 2 diabetes (NIDDM) was treated with the composition on his hands for 2 weeks only. His blood sugar dropped from 450 to 122 during 2 week- treatment and he is still using the cream 3 times on his umbilica.

Case 5

A 67 years old male doctor diagnosed with hypertension and type2 diabetes (NIDDM) was treated with the composition on his hands for 1 week only. His blood sugar dropped from 195 to 125 during 1 week treatment and he is still the cream 3 times on his umbilica daily.

Case 6

A 50 year old female with type-2 diabetes (NIDDM) and hypercholesterolemia, was treated with composition on her hands, foot and umbilica for 6 months during which she quit insulin. Her HbA1C dropped from 11 to 5.5 and she is still using the cream.

Case 7

A 22 year old male with type-1 diabetes (IDDM) was treated with composition on his hands, foot and umbilica for 6 months during which he quit insulin. His HbA1C dropped from 10 to 6 and he is still using the cream and his c-peptide blood test increased from 0.6 to 2.5 within the first 3 months which means a regeneration of pancreatic beta cells and big increase in their numbers to produce enough insulin.

Case 8

A 25 year old male with type 1 diabetes (IDDM) suffering from the age of 12. He started to use composition on preventive basis. His c-peptide increased from 0.5 to 2.6, and his sugar HbA1C became normal within 3 months.

Case 9

A 28 year old female university student with type 1 diabetes (IDDM) started to use composition on preventive basis. Her c-peptide increased from 0.3 to 2.8 within 3-month course.

Case 10

A 59 year old female with type 2 diabetes (NIDDM), hypertension, was treated with composition on feet and umbilica together with HVPC- electrostatic acupuncture therapy device for 1 week and her blood sugar dropped from 285 to 122.

Safety and toxicity study

Toxicity study performed on mice in the animal house showed that the composition is free of adverse effects especially on liver, kidneys, lipid and other body organs.

Conclusion

This patented botanical nano cream is expected to help millions of diabetics of both types worldwide. Double blind is still needed to give more reliable results.

Acknowledgement

None.

Conflict of interest

The author declares no conflict of interest.

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