CLINICAL STUDY REPORT

A Prospective, open-label clinical study to evaluate the safety and efficacy of Auretics Sugar Management Spray in stabilizing blood glucose levels in Diabetic patients.

Investigation Product	:	Auretics Sugar Management Spray
EC Approval Date	:	14/02/2025
Study Start Date	:	07/03/2025
Study Completion Date	:	19/06/2025
Study Period	:	90 days
CTRI Number	:	CTRI/2025/03/081737

Sponsor Address

Arjun Gupta
C/o Auretics Limited
Plot No. 190, Old Block
Near LIC Colony, Mangal Bazar Road,
Dilshad Garden, Delhi – 110095

Sites Address

Shree Maruthi Hospital, Dept of Medicine Room no.1
Ground floor No 67, link Road, Sheshadripura, Bengaluru,
Karnataka 560020

SPONSOR'S DECLARATION:

I, the undersigned, have read this clinical study report and hereby confirm that the study was conducted in accordance with the Ethics Committee approved protocol and with all the applicable regulatory requirements regarding the obligations of the sponsor and all other pertinent requirements of the ICH Guidelines for Good Clinical Practice.

Protocol Number: ACS/CL/01/2024

Title: A Prospective, open-label clinical study to evaluate the safety and efficacy of Auretics Sugar Management Spray in stabilizing blood glucose levels in Diabetic patients.

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SIGNATURE OF THE SPONSOR REPRESENTATIVE DATE

Name of the sponsor: Arjun Gupta

C/o Auretics Limited

Plot No. 190, Old Block

Near LIC Colony, Mangal Bazar Road,

Dilshad Garden, Delhi – 110095

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INVESTIGATOR'S DECLARATION:

I, the undersigned, have read this clinical study report and hereby confirm that the study was conducted in accordance with Ethics Committee approved protocol and also with all the applicable regulatory requirements regarding the obligations of the Investigator and all other pertinent requirements of the ICH Guidelines for Good Clinical Practice. I further agree and confirm that all associates involved in the study were informed and aware of their study obligations and completion.

Protocol Number: ACS/CL/01/2024

Title: A Prospective, open-label clinical study to evaluate the safety and efficacy of Auretics Sugar Management Spray in stabilizing blood glucose levels in Diabetic patients.

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SIGNATURE OF THE PRINCIPAL INVESTIGATOR DATE

Name of the Principal Investigator: Dr. Vishnu Hayagreev MBBS, MD

Professor of Medicine Director, Shree Maruti Hospital

Director, Amruth Biological and Clinical Services

Study Centre: Shree Maruti Hospital

Contents

1. ABBREVIATIONS:

%	Percent
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AE	Adverse Event
CFR	Code of Federal Regulations
CI	Confidence Interval
Con-med	Concomitant Medications
CRF	Case Report Form
CSR	Clinical Study Report
CTRI	Clinical Trial Registry of India
EC	Ethics Committee
GCP	Good Clinical Practices
ICH	International Council for Harmonization
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
ITT	Intention-to-treat
LAR	Legally Acceptable Representative
mITT	Modified Intention-to-treat
PP	Per Protocol
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SD	Standard Deviation
SOP	Standard Operating Procedure

2. STUDY SYNOPSIS:

Study title	A Prospective, open-label clinical study to evaluate the safety and efficacy of Auretics Sugar Management Spray in stabilizing blood glucose levels in Diabetic patients.
Sample size	24 subjects (both Male and female diabetic detected Patients)
Description of the product	Auretics Sugar Management Spray
Study design	Prospective, open-label, clinical study
Dosage	Spray and rub to the palms and foot in the morning and night before food.
Study Objective	**Primary Objective -** To evaluate the efficacy of Auretics Sugar Management Spray in Stabilizing Blood glucose levels in diabetic patients. **Secondary Objective –** To evaluate the safety and consumer acceptance through feedback questionnaires.
Study Outcomes	**Primary outcome** To evaluate the efficacy of Auretics Sugar Management Spray in stabilizing Blood Sugar in Diabetic patients. Following parameters are evaluated: • Decrease in Blood Sugar Level- Fasting blood sugar (FBS), Post Prandial Blood Sugar (PPBS), Glycated hemoglobin (HbA1c) from Day 0 to Day 90. **Secondary outcome** To evaluate the safety and consumer acceptance of Sugar Rodhi Spray in stabilizing blood glucose levels in Diabetic patients through feedback questionnaires
Inclusion criteria:	• Subjects between the age group of 30-60 years. • Diabetic subjects who are on Anti-diabetic drug. • Subjects consuming coffee in their daily routine.

	• Subjects consuming tea in their daily routine. • Subjects who are hypertensive. • Subjects free from infection, cancerous, concomitant user of other drugs and any other infection which may vary sugar levels. • Subjects who were willing and able to understand and follow the protocol and provide informed consent. • Fasting blood glucose level>110 mg /dl <250 mg/dl • Post prandial blood sugar level >140 mg /dl <350 mg /dl
Exclusion criteria:	• Subjects with diabetes mellitus along with other comorbid conditions. • Pregnant or lactating women • Women of childbearing potential who do not take adequate contraceptive protection. • History of hypersensitivity to the metformin or to drug with similar chemical structure. • History of any severe systemic disease. • Patients with uncontrolled hypertension • History of stroke, cancer, acute illness • Patients suffering from any serious medical or surgical illness.
Study Procedure	After obtaining the Ethics committee approval subjects were asked to visit the site. Informed consent were provided to the subjects, and after obtaining their consent, the subjects were asked about their medical history and the Investigator, or his/her designee conducted a physical examination. Demographics and vital signs were recorded. Safety parameters like Hematology and biochemistry were analysed in visit 1. Also the PPBS, HbA1c, FBS and Urine routine were assessed and based on the inclusion criteria, the subjects were asked to visit the site which was day 0. Once the subjects were found eligible, they were be given the Investigational Product and asked to apply 8 to 10 drops of Auretics Sugar Management Spray before food on their Palm in the

	morning and night and Rub their hands for 5 minutes against each other. Repeat the process the same way on the bottom of your feet for 5 minutes. In Visit 3 (Day 30), Visit 4 (Day 60), and Visit 5 (Day 90) efficacy parameters like blood glucose level were assessed by biochemical tests such as FBS, PPBS and Urine Routine. HbA1C was monitored on Day -3 and on Day 90. They were advised to fill in the feedback questionnaires. The responses obtained was statistically analyzed at the end of the trial to assess the safety and efficacy of the product.

3. ETHICS COMMITTEE:

3.1. Institutional Review Board:

All the study related documents were reviewed by **Pranav Diabetes Center Ethics Committee.** The study was approved on 1st February 2024. The study was conducted in compliance with Part 56 of Title 21 of the Code of Federal Regulations (CFR) and International Conference on Harmonization (ICH) guidelines. The Ethics Committee is registered with DCGI with the registration number **CTRI/2025/03/081737** under provision of rule 122DD of the Drugs & Cosmetics Rules 1945.

3.2. Ethical Conduct of the Study:

This research was conducted in accordance with the clinical research guidelines established by the Supplements and Cosmetics Act, 1940 of India, Supplements and Cosmetics Rules, 1945 of India, Ethical Guidelines for Biomedical Research on Human Participants, 2006 of Indian Council of Medical Research (ICMR) in India, the principles enunciated in the Declaration of Helsinki (Edinburgh, 2000) and the ICH-harmonized tripartite guideline regarding Good Clinical Practice (GCP). Written and oral information about the study in a language understandable by the subject was provided to all subjects. Each subject was informed by the investigator, prior to the screening evaluation, of the purpose of this clinical trial, including possible risks and benefits and documented the informed consent process in the subject's chart. Prior to entry into the study or initiation of any study-related procedures, the subject read, signed and dated the IEC approved informed consent form. Sufficient time was provided for each subject to decide whether to participate in the study and all the questions and clarifications regarding the study were clarified by the investigator. The original signed informed consent form has been retained by the study site and a copy was given to the subject. The form summarized, in non-technical terms, the purpose of the study, the procedures to be carried out, and the potential hazards.

4. STUDY TEAM:

Sponsor	Auretics Limited Plot No. 190, Old Block Near LIC Colony, Mangal Bazar Road, Dilshad Garden, Delhi – 110095
Sponsor's Representative	Arjun Gupta C/o Auretics Limited Plot No. 190, Old Block Near LIC Colony, Mangal Bazar Road, Dilshad Garden, Delhi – 110095
Project Coordinator	Mr Prabhu CM Project Coordinator Amruth Biological and Clinical Services
Principal Investigator	Dr. Vishnu Hayagreev MBBS, MD Professor of Medicine Director, Shree Maruti Hospital Director, Amruth Biological and Clinical Services

5. INTRODUCTION:

Type 2 diabetes mellitus (DM) has become a significant global health issue, attracting increasing attention due to its widespread impact. It is anticipated to remain a major public health challenge, often leading to severe complications. India ranks among the top five countries with the highest prevalence of diabetes. According to the IDF Diabetes Atlas (2021), 10.5% of adults aged 20 to 79 are affected by diabetes, with nearly half of them unaware of their condition. By 2045, IDF projections show that 1 in 8 adults, approximately 783 million, will be living with diabetes, an increase of 46%. Rephrase it differently [1]

The term diabetes describes a group of metabolic disorders characterized and identified by the presence of hyperglycaemia in the absence of treatment. The heterogeneous aetio-pathology includes defects in insulin secretion, insulin action, or both, and disturbances of carbohydrate, fat and protein metabolism. The long-term specific effects of diabetes include retinopathy, nephropathy and neuropathy, among other complications. People with diabetes are also at increased risk of other diseases including heart, peripheral arterial and cerebrovascular disease, obesity, cataracts, erectile dysfunction, and nonalcoholic fatty liver disease. [2]

Types of Diabetes Mellitus [2-3]

There are several types of diabetes. The most common forms include:

1. **Type 2 Diabetes:** Results from insulin resistance and relative insulin deficiency. Strongly associated with obesity, sedentary lifestyle, and genetic predisposition. Accounts for 90-95% of diabetes cases globally.
2. **Prediabetes:** This type is the stage before Type 2 diabetes. Your blood glucose levels are higher than normal but not high enough to be officially diagnosed with Type 2 diabetes.
3. **Type 1 diabetes:** This type is an autoimmune disease in which your immune system attacks and destroys insulin-producing cells in your pancreas for unknown reasons. Type 1 diabetes (previously known as insulin-dependent, juvenile or childhood-onset) is characterized by deficient insulin production.
4. **Gestational diabetes:** Gestational diabetes is hyperglycaemia with blood glucose values above normal but below those diagnostics of diabetes. Gestational diabetes occurs during pregnancy. Women with gestational diabetes are at an increased risk of complications during pregnancy and at delivery. These women and possibly their children are also at increased risk of type 2 diabetes in the future and requires daily administration of insulin. Gestational diabetes is diagnosed through prenatal screening, rather than through reported symptoms. Up to 10% of people who have diabetes have Type 1.

5. Impaired glucose tolerance and impaired fasting glycaemia

Impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG) are intermediate conditions in the transition between normality and diabetes. People with IGT or IFG are at high risk of progressing to type 2 diabetes, although this is not inevitable.

Pathophysiology [4]

Diabetes leads to microvascular and macrovascular complications over time. Diabetes arises due to:

- Impaired glucose metabolism.
- Increased hepatic glucose production.
- Reduced peripheral glucose uptake by muscles and adipose tissue.
- Altered insulin secretion and action.
- Chronic hyperglycemia in diabetes leads to microvascular and macrovascular complications over time.

Signs and symptoms [4]:

Some of the symptoms of type 1 diabetes and type 2 diabetes are:

- Feeling more thirsty than usual.
- Urinating often.
- Losing weight without trying.
- Presence of ketones in the urine. Ketones are a byproduct of the breakdown of muscle and fat that happens when there's not enough available insulin.
- Feeling tired and weak.
- Feeling irritable or having other mood changes.
- Having blurry vision.
- Having slow-healing sores.
- Getting a lot of infections, such as gum, skin and vaginal infections.

Complications of diabetes [4]:

Long-term complications of diabetes develop gradually. The longer you have diabetes — and the less controlled your blood sugar — the higher the risk of complications. Eventually, diabetes complications may be disabling or even life-threatening. In fact, prediabetes can lead to type 2 diabetes. Possible complications include:

- **Heart and blood vessel (cardiovascular) disease -** Diabetes majorly increases the risk of many heart problems. These can include coronary artery disease with chest pain

(angina), heart attack, stroke and narrowing of arteries (atherosclerosis). If you have diabetes, you're more likely to have heart disease or stroke.

- **Nerve damage from diabetes (diabetic neuropathy) -** Too much sugar can injure the walls of the tiny blood vessels (capillaries) that nourish the nerves, especially in the legs. This can cause tingling, numbness, burning or pain that usually begins at the tips of the toes or fingers and gradually spreads upward.

Damage to the nerves related to digestion can cause problems with nausea, vomiting, diarrhea or constipation. For men, it may lead to erectile dysfunction.

- **Kidney damage from diabetes (diabetic nephropathy) -** The kidneys hold millions of tiny blood vessel clusters (glomeruli) that filter waste from the blood. Diabetes can damage this delicate filtering system.
- **Eye damage from diabetes (diabetic retinopathy) -** Diabetes can damage the blood vessels of the eye. This could lead to blindness.
- **Foot damage -** Nerve damage in the feet or poor blood flow to the feet increases the risk of many foot complications.
- **Skin and mouth conditions -** Diabetes may leave you more prone to skin problems, including bacterial and fungal infections.
- **Hearing impairment -** Hearing problems are more common in people with diabetes.
- **Alzheimer's disease -** Type 2 diabetes may increase the risk of dementia, such as Alzheimer's disease.
- **Depression related to diabetes -** Depression symptoms are common in people with type 1 and type 2 diabetes.

Prevention [4]:

Eat healthy foods.

Get more physical activity.

Lose excess pounds. But don't try to lose weight during pregnancy.

Treatment [2]:

Some people with type 2 diabetes will need to take medicines to help manage their blood sugar levels. These can include insulin injections or other medicines. Some examples include:

- metformin
- sulfonylureas
- sodium-glucose co-transporters type 2 (SGLT-2) inhibitors.

Along with medicines to lower blood sugar, people with diabetes often need medications to lower their blood pressure and statins to reduce the risk of complications.

Additional medical care may be needed to treat the effects of diabetes:

- foot care to treat ulcers
- screening and treatment for kidney disease
- eye exams to screen for retinopathy (which causes blindness).

In Ayurveda diabetes is called as **Prameha [6]:** Ayurveda has three basic principles Hetu, Linga, and Ausadha that call Trisutra, and most important is Linga. In ayurvedic text, prameha is characterized by excessive urination (both in frequency and quantity) and turbidity. The nature of turbidity may vary depending upon the body reaction to the doshas. i.e., Prabhuta avila mutrata. Prameha is considered kapha Pradhan tridoshaja vyadhi. The aggravated kapha along with other doshas is responsible for the clinical manifestation of prameha ‘’prakarsena prabhutam prachuram varam va mehati mutratyagam karoti iti’’.

Types of Prameha in Ayurveda:

In Ayurveda, there are twenty types of prameha:

1) **Kaphaja Prameha –** which includes Ten types – early stage
   Overweight with mild hyperglycaemia. - Polyuria/ glycosuria
2) **Pittaja prameha –** which includes six types – Avute stage
   Loss of weight. - Hyperglycaemia and glycosuria - urinary tract infection
3) **Vataja Prameha –** which includes four types – Chronic stage.
   - Severe hyperglycaemia with glycosuria (Chronic diabetes)
   - Nephropathy neuropathy - Retinopathy – Gangrene
4) **THERAPEUTIC CLASSIFICATION** on body constitution (Charak) –
   - Sthula pramehi (obese diabetic)
   - Krisha prameha (Lean diabetic)
5) **PROGNOSTIC CLASSIFICATION –**
   - SADHYA (manageable) - Apathyanimittaja prameha (NIDDM) - Kaphaja prameha - Sthul prameha
   - YAPYA (palliative) -pittaja prameha
   - ASADHYA (unmanageable) - sahaja prameha - vataja prameha - Krisha prameha

Below is the table of different kinds of Prameha [6-7]**:**

1) KAPHAJA PRAMEHA – 10

S.No.	CHARAKA	SUSHRUTA	VAGBHATA	MADHAVA NIDAN
1	Udakameha (Diabetes Insipidus)	Udakmeha	udakameha	Udakameha
2	Ikshuvalikarasmeha (Glycosuria)	ikshuvalikameha	ikshumeha	Ikshumeha
3	Sandrameha (Phosphaturia)	Sandrameha	sandrameha	Sandrameha
4	Sandraprasadmeha (Belluria)	Surameha	surameha	Surameha
5	Suklameha (Chyluria)	Pisthameha	pisthameha	Pishtameha
6	Sukrameha (spermaturia)	Sukrameha	sukrameha	Sukrameha
7	Sitameha (Renal Glycosuria)	Lavanmeha	Sitameha	Sitameha
8	Siktameha (Lithuria)	Siktameha	Siktameha	Siktameha
9	Saneimeha (Slow micturation)	Saneimeha	saneimeha	Saneimeha
10	Alalmeha (Albuminuria)	Phanmeha	Lalameha	Lalameha

2) PITTAJA PRAMEHA – 6

S.No.	CHARAKA	SUSHRUTA	VAGBHATA	MADHAVA NIDAN
1	Kharmeha (Alkalinuria)	Kharmeha	Kharmeha	Kharmeha
2	Kalameha (melenuria)	Amlameha	Kalameha	Kalameha
3	Nilameha (Indicanuria)	Nilameha	Nilameha	Nilameha

4	Lohitmeha (Haematuria)	Shonitameha	raktameha	Raktameha
5	Manjisthameha (Haemoglob inuria)	Manjisthameha	manjisthameha	Manjisthameha
6	Haridrameha (Biluria)	Haridrameha	haridrameha	Haridrameha

3) VATAJA PRAMEHA – 4

S.No.	CHARAKA	SUSHRUTA	VAGBHATA	MADHAVA NIDAN
1	Vasameha (Lipuria)	Vasameha	vasameha	Vasameha
2	Majjameha (Myelouria)	Majjameha	majjameha	Majjameha
3	Hastimeha (polyuria)	Hastimeha	hastimeha	Hastimeha
4	Madhumeha (Diabetes mellitus)	kshaudrameha	madhumeha	Madhumeha

Chikitsa in Ayurevda for Prameha (Diabetes) [7]:

In ayurveda, treatment management focuses on:

- **Lifestyle Modifications:** Implementing regular physical activity, yoga, and stress management techniques.
- **Dietary Changes:** Adopting a diet that balances the doshas, typically involving the reduction of sweet, oily, and heavy foods.
- **Herbal Remedies:** Utilizing herbs known for their anti-diabetic properties, such as Guduchi (Tinospora cordifolia), Karela (Momordica charantia), and Vijaysar (Pterocarpus marsupium).
- **Panchakarma Therapies:** Detoxification procedures like Vamana (therapeutic emesis) and Virechana (therapeutic purgation) to eliminate doshic imbalances.
- Early diagnosis and a comprehensive treatment approach are crucial in managing Prameha effectively and preventing its progression to more severe forms like Madhumeha.

6. BACKGROUND INFORMATION

Formulation Review:

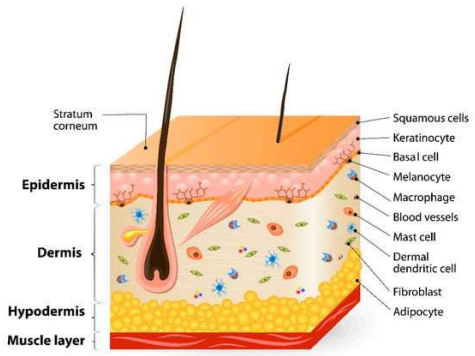
Table. 1: Formulation- Investigational Product- Auretics Sugar Management Spray contains

Sl. No.	Latin Names	Ingredients
1	*Citrullus colocynthis*	Indrayan
2	*Gymnema sylvestre*	Gudmar
3	*Berberis aristate*	Daruhaldi
4	*Swertia chirat*	Chirayita
5	*Azardirachta indica*	Neemboli
6	*Syzygium cumini*	Jamun
7	*Nigella sativa*	Kalonji
8	*Prunus amygdalus*	Badam
9	*Boerhaavia diffusa*	Punarnava
10	*Emblica officinalis*	Amla
11	*Momordica charantia*	Karela
12	*Tinospora cordifolia*	Giloy/guduchi
13	*Aegele marmelos*	Bael
14	*Ziziphus jujuba*	Ber
15	*Picrorhiza kurroa*	Kutki/Katuki
16	*Pterocarpus marsupium*	Vijaysar
17	*Trigonella foenum-graecum*	Methi

Benefits of Auretics Sugar Management Spray:

- Helps reduce increased blood sugar and increase insulin levels after meals.
- Helps lower fasting blood glucose levels by enhancing the insulin activity and sensitivity.
- Helps strengthen pancreas and increases insulin secretion, making the body more responsive to insulin.

Rationale: Our formulation Auretics Sugar Management Spray contains all active natural ingredients. These natural ingredients in common have capacity to lower the blood sugar levels. Also this product is applied through external route that is topical absorption.



TOPICAL ABSORPTION – AN ALTERNATE ROUTE

7 Layers of our Skin:

The Epidermis

1. The Basal Cell Layer
2. The Squamous Cell Layer
3. The Stratum Granulosum & the Stratum Lucidum
4. The Stratum Corneum

The Dermis

5. The Papillary Layer
6. The Reticular Layer

The Subcutis

7. Subcutis Layer

Transdermal drug delivery systems have been explored for diabetes management, offering a non-invasive alternative to injections. These systems deliver medications through the skin to help regulate blood sugar levels. For instance, transdermal insulin patches have been developed to provide controlled, sustained release of insulin, potentially improving patient compliance and glycemic outcomes. [8]

Our product works on these layers and skin and reduce the sugar levels in the blood.

7. STUDY OBJECTIVES

7.1. Primary Objective

To evaluate the efficacy of Auretics Sugar Management Spray in Stabilizing Blood glucose levels in diabetic patients.

7.2. Secondary Objective

To evaluate safety and consumer acceptance through feedback questionnaires.

8. STUDY DESIGN

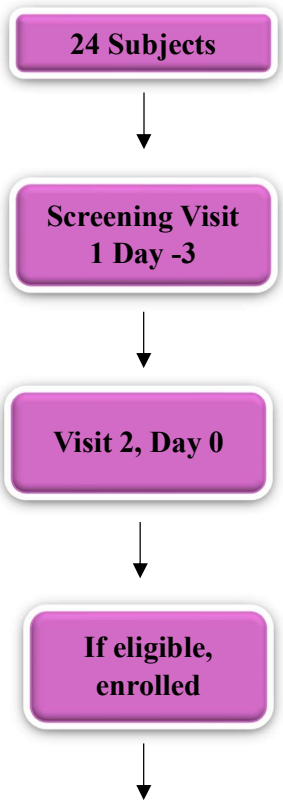
8.1. Design: This was an open label clinical study design.

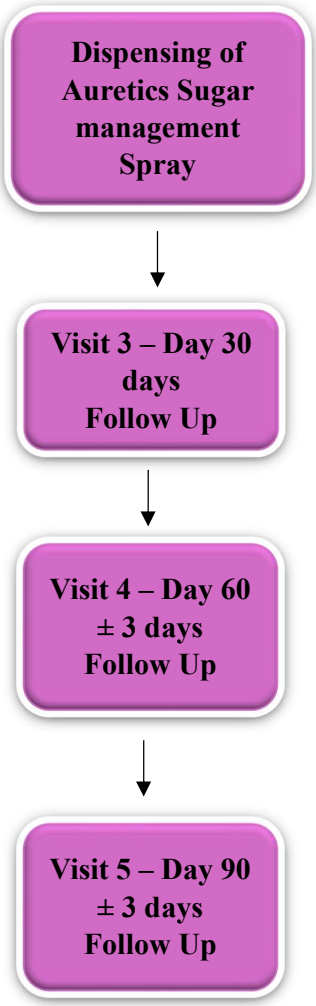
8.2. Number of Subjects: 24 male and female subject.

8.3. Randomization: Non-Randomized Study

8.4. Overall Study Plan: Subjects with Fasting blood glucose level>110 mg /dl <250 mg/dl and Post prandial blood sugar level >140 mg /dl <350 mg /dl are enrolled into the study after evaluating inclusion/exclusion criteria. An informed consent was obtained from the enrolling subjects which was duly approved by institutional ethics committee. All 24 subjects received the investigational product Auretics Sugar Management Spray for a period of 90 days. The subject should take 5-6 drops of the lotion and apply for 5 mins daily in the morning and night before food. The efficacy of Auretics Sugar Management Spray was evaluated with decrease in Blood Sugar Level- Fasting blood sugar (FBS), Post Prandial Blood Sugar (PPBS), Glycated hemoglobin (HbA1c), Urine sugar from Day 0 to Day 90. To evaluate the safety and consumer acceptance of Auretics Sugar Management Spray in stabilizing blood glucose levels in Diabetic patients through feedback questionnaires

8.5. Study Design Chart





Subjects with Type 2 Diabetes Mellitus, aged 30–60 years, with fasting blood glucose levels between 110–250 mg/dL and postprandial levels between 140–350 mg/dL, were enrolled into the study based on inclusion and exclusion criteria. Following the provision of written informed consent, approved by the Institutional Ethics Committee, a total of 24 subjects were enrolled in this 90-day open-label clinical study. All subjects received the investigational product — Auretics Sugar Management Spray — administered topically with 5–6 drops applied to the palms and soles, twice daily before meals. The efficacy of the product was assessed using changes in Fasting Blood Sugar (FBS), Postprandial Blood Sugar (PPBS), Glycated Hemoglobin (HbA1c), and urine routine analysis. Safety and consumer acceptance were evaluated through adverse event monitoring and structured patient feedback questionnaires administered on Day 90.

The study consists of four visits:

Screening Visit 1 (Day -3): Subjects were screened for inclusion and exclusion criteria of the study after obtaining the informed consent. After screening the subjects were assigned with a unique subject number. All subjects were assessed for:

- Demographics which include initials, age, sex, height, weight and BMI.
- Vitals which include heart rate, respiratory rate, pulse, and blood pressure.
- General Physical examination which includes Head, Eyes, Ears, Nose, Throat, Nails, Skin, Teeth, Tongue, Heart, Lungs, Abdomen, Extremities and Musculoskeletal. CNS: Pupils, Motor, Sensory systems, Reflexes.
- Medical history and Previous/Concomitant medications
- Inclusion and Exclusion criteria
- Hematology
- Biochemical tests: LFT, RFT, Lipid profile
- Blood glucose level- RBS, PPBS
- HbA1C
- Urine Routine
- Concomitant Medication

Visit 2, Day 0:

- Vitals which include heart rate, respiratory rate, pulse, and blood pressure.
- Inclusion and Exclusion criteria
- IP dispensing
- Concomitant Medication

Visit 3, Day 30:

- Vitals
- Blood glucose level- RBS, PPBS
- Urine Routine
- ADRs if any, were be recorded, graded and appropriate action taken for both the group.
- Any complaints of the patients are recorded and evaluated
- Concomitant Medication

Visit 4, Day 60 ± 3 days

- Vitals
- Blood glucose level- RBS, PPBS
- Urine Routine
- ADRs if any, were be recorded, graded and appropriate action taken for both the group.
- Any complaints of the patients are recorded and evaluated
- Concomitant Medication

Visit 5, Day 90 ± 3 days

- Vitals
- Blood glucose level- RBS, PPBS
- Hematology
- Biochemical tests: LFT, RFT, Lipid profile
- Urine Routine
- HbA1C
- Feedback questionnaires
- Any complaints of the patients are recorded and evaluated
- Concomitant Medication
- ADRs if any, were be recorded, graded and appropriate action taken for both the group.
- Any complaints of the patients are recorded and evaluated

8.6. Investigational Plan

Activity	Visit 1 (Day -3 days)	Visit 2 (Day 0)	Visit 3 (Day 30)	Visit 4 (Day 60)	Visit 5 (Day 90)
Written Informed Consent	X	-	-	-	-
Demographics	X	-	-	-	-
Physical Examination	X	-	-	-	-
Medical and Medication History	X	-	-	-	-
Vitals	X	X	X	X	X
Hematology	X	-	-	-	X
Inclusion and Exclusion Criteria	X	X	-	-	-

IP dispensing	-	X	-	-	-
Biochemical tests: LFT, RFT, Lipid profile	X	-	-	-	X
Blood glucose level- RBS, PPBS	X	-	X	X	X
HbA1C	X	-	-	-	X
Urine Routine	X		X	X	X
Feedback Questionnaire	-	-	-	-	X
Adverse Event	-	-	X	X	X
Concomitant Medication	X	X	X	X	X

9. SELECTION AND WITHDRAWAL CRITERIA

9.1. Inclusion Criteria

The following were the inclusion criteria that should be met by all subjects included:

1. Subjects between the age group of 30-60 years.
2. Diabetic subjects who were on Anti-diabetic drug.
3. Subjects consuming coffee in their daily routine.
4. Subjects consuming tea in their daily routine.
5. Subjects who were hypertensive.
6. Subjects free from infection, cancerous, concomitant user of other drugs and any other infection which may vary sugar levels.
7. Subjects who were willing and able to understand and follow the protocol and provide informed consent.
8. Fasting blood glucose level>110 mg /dl <250 mg/dl
9. Post prandial blood sugar level >140 mg /dl <350 mg /dl

9.2. Exclusion Criteria

The following were the exclusion criteria. Subjects who possess any of these should not be included in this study:

1. Subjects with diabetes mellitus along with other comorbid conditions.
2. Pregnant or lactating women
3. Women of childbearing potential who did not take adequate contraceptive protection.
4. History of hypersensitivity to the metformin or to drug with similar chemical structure.
5. History of any severe systemic disease.
6. Patients with uncontrolled hypertension
7. History of stroke, cancer, acute illness

9.3. Screen Failures.

Totally 29 patients were screened and there were 5 screen failures in the study.

9.4. Subject Withdrawal

There were two subject withdrawals during the study period, attributed to relocation.

9.5. Statistical Considerations

This section of the clinical trial protocol forms the basis for the Statistical Analysis Plan (SAP) for the study. In the present study, descriptive statistical analysis and frequency procedures were performed using IBM SPSS software. For continuous variables, the data were expressed as Mean ± Standard Deviation (SD), and for categorical variables, results were presented in terms of frequencies and percentages.

Parametric tests were employed for normally distributed data to assess changes from baseline (Visit 2, Day 0) to subsequent visits (Visit 3 – Day 30, Visit 4 – Day 60, and Visit 5 – Day 90). A paired t-test was used to analyze the significance of within-group changes across visits.

Descriptive and inferential statistics along with percentage improvement were presented for all key efficacy parameters including Fasting Blood Sugar (FBS), Postprandial Blood Sugar (PPBS), Glycated Hemoglobin (HbA1c), and Urine Routine findings. In addition, safety and consumer acceptance were evaluated using structured feedback questionnaires on Day 90. A p-value of less than 0.05 was considered statistically significant.

10. EFFICACY EVALUATION

The results of evaluation of all the efficacy variables are described in the result section with appropriate tabular and graphical representation. A brief description of the demographic characteristics of the trial patients are also provided.

10.1. SAFETY EVALUATION

10.1.1. Adverse Event Monitoring:

- The Clinical Investigator or a medical officer was available within the clinical facility until 24 hours post dose during each period. Medically qualified personnel or any specialist was also available on call until the completion of the study. Subjects were monitored throughout the study period for adverse events.
- Subjects were informed to bring to the notice of the doctor or nurse or any other staff any adverse event that may occur during their Study period.

10.1.2. Intensity of Adverse Events:

Mild**:** events require minimal or no treatment and do not interfere with the subject's daily activities.

Moderate**:** events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.

Severe: events interrupt a subject's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually incapacitating.

Life threatening**:** any adverse drug experience that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e., it does not include a reaction that had it occurred in a more severe form, might have caused death. Changes in the severity of an AE should be documented to allow an assessment of the duration of the event at each level of intensity to be performed. Adverse events characterized as intermittent require documentation of onset and duration of each episode.

10.1.3. Causality of Adverse Events:

The Investigator will document his/her opinion of AE relationship to study treatment using the following criteria,

Definitely	The adverse event is clearly related to the vaccine – i.e. an event that follows a reasonable temporal sequence from administration of the vaccine, follows a known or expected response pattern to the suspected vaccine that cannot be explained by concurrent disease or other drugs or chemical.

Probably	The adverse event is probably related to the vaccine- i.e. an event follows a reasonable temporal sequence from administration of the vaccine, is unlikely to be attributed to concurrent disease or other drugs or chemicals.
Possibly	An event that follows a reasonable temporal sequence from administration of the vaccine, but which could also be explained by concurrent disease or other drugs or chemicals.
Unlikely	An event whose time relationship to vaccine administration makes a causal connection improbable, but which could be plausible explained by underlying disease or other drugs or chemicals.
Not Related	An event with an incompatible time relationship and which could be explained by underlying disease or other drugs or chemicals.
Unclassifiable	An event with insufficient information to permit assessment and identification of the cause.

10.1.4. Serious Adverse Events:

Serious Adverse Event (SAE): An SAE is defined as an AE that meets one of the following conditions:

- Death during the period of protocol defined surveillance Life-threatening event (defined as a subject at immediate risk of death at the time of the event)
- An event requiring inpatient hospitalization or prolongation of existing hospitalization during the period of protocol defined surveillance
- Results in congenital anomaly or birth defect
- Results in a persistent or significant disability/incapacity

Any other important medical event that may not result in death, be life threatening, or require hospitalization, may be considered a serious adverse experience when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home,

blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse. All SAEs will be recorded on the appropriate CRF and SAE form followed through resolution by a study clinician reviewed and evaluated by a study clinician. In all case of clinical trial related injury or death, Licensing Authority will also determine the quantum of compensation within three months of receiving of the SAE and Sponsor or his representative concerned will pay the compensation as per the order of Licensing Authority within thirty days of the receipt of such order.

In the entire period of the study, there were no Adverse Events reported. Also there was no protocol deviation observed during the trial.

11. RESULTS:

Table 1: Descriptive statistics – Age (Years)

Age		
N	**Valid**	24
	Missing	0
Mean		45.8333
Median		45.0000
Minimum		35.00
Maximum		60.00

Table 2: Descriptive statistics – Gender

GENDER					
		Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Valid	**F**	16	66.7	66.7	66.7
	M	8	33.3	33.3	100.0
	Total	24	100.0	100.0	

Table 3: Descriptive statistics – Demographics

	Height	**Weight**	**BMI**

N	**Valid**	24	24	24
	Missing	0	0	0
Mean		158.1667	159.7917	69.9167
Median		158.5000	160.0000	70.0000
Minimum		150.00	150.00	59.00
Maximum		166.00	166.00	80.00

Table 4: Medical History

Parameter	Yes	No
Head, Ears, Nose, Throat, n[%]	0 (0.0)	24 (100.0)
Cardiovascular, n[%]	24 (100.0)	0 (0.0)
Respiratory, n[%]	0 (0.0)	24 (100.0)
Endocrine, n[%]	24 (100.0)	0 (0.0)
Gastrointestinal, n[%]	0 (0.0)	24 (100.0)
Hepatobiliary, n[%]	0 (0.0)	24 (100.0)
Genitourinary, n[%]	0 (0.0)	24 (100.0)
Musculoskeletal, n[%]	0 (0.0)	24 (100.0)
Neurological, n[%]	0 (0.0)	24 (100.0)
Psychological, n[%]	0 (0.0)	24 (100.0)
Hematological, n[%]	0 (0.0)	24 (100.0)
Immunological, n[%]	0 (0.0)	24 (100.0)
Dermatological, n[%]	0 (0.0)	24 (100.0)
Allergies, n[%]	0 (0.0)	24 (100.0)
Other, n[%]	0 (0.0)	24 (100.0)

All the included (24) subjects had Blood pressure and was under control. Additionally, as per the inclusion criteria, all subjects were diagnosed as Type 2 Diabetes Mellitus and was under medication Metformin.

Table 5: Physical Examination

Parameter	Normal	Abnormal
General Appearance, n [%]	24 (100.0)	0 (0.0)
Head, Ears, Nose, and Throat, n [%]	24 (100.0)	0 (0.0)
Heart, n [%]	24 (100.0)	0 (0.0)
Lungs, n [%]	24 (100.0)	0 (0.0)

Parameter	Normal	Abnormal
Abdomen, n [%]	24 (100.0)	0 (0.0)
Extremities, n [%]	24 (100.0)	0 (0.0)
Neurological, n [%]	24 (100.0)	0 (0.0)

Table 6: Descriptive Statistics – Inclusion and Exclusion Criteria (Day-0)

Parameter	Yes	No
Inclusion Criteria, n [%]	24 (100.0)	0 (0.0)
Exclusion Criteria, n [%]	0 (0.0)	24 (100.0)

Table 7: Descriptive Statistics – Medication History

Parameter/Statistics	Visit	Treatment group
Yes	Screening	0(0.0)
No	Screening	24 (100.0)

Table 8: Descriptive Statistics – Concomitant Medication

Parameter	Yes	No
Concomitant Medication, n [%]	24 (100.0)	0(0.0)

Note: All the 24 subjects were on anti-hypertensives and on anti-diabetic medication

Table 9: Descriptive statistics for Vital signs

Vitals – Visit 1, Day -3							
		Systolic Blood Pressure (mm/Hg)	Diastolic Blood Pressure (mm/hg)	Heart Rate (beats / min)	Pulse Rate (beats / min)	Respiratory Rate (per/ min)	Temperature (ºF)
N	Valid	24	24	24	24	24	24
	Missing	0	0	0	0	0	0
Mean		130.1667	82.0417	78.5417	78.5417	15.0417	97.9167
Median		130.0000	83.0000	79.5000	79.5000	15.5000	98.0000
Minimum		120.00	68.00	64.00	64.00	12.00	97.30
Maximum		139.00	90.00	90.00	90.00	18.00	98.40

Vitals – Visit 2, Day 0

		Systolic Blood Pressure (mm/Hg)	Diastolic Blood Pressure (mm/hg)	Heart Rate (beats / min)	Pulse Rate (beats / min)	Respiratory Rate (per/ min)	Temperature (°F)
N	Valid	24	24	24	24	24	24
	Missing	0	0	0	0	0	0
Mean		129.2917	83.6250	73.2083	73.2083	15.4167	97.7917
Median		130.0000	84.0000	73.0000	73.0000	15.0000	98.0000
Minimum		120.00	70.00	60.00	60.00	13.00	96.00
Maximum		138.00	90.00	84.00	84.00	17.00	98.40

Vitals – Visit 3, Day 30							
		Systolic Blood Pressure (mm/Hg)	Diastolic Blood Pressure (mm/hg)	Heart Rate (beats / min)	Pulse Rate (beats / min)	Respiratory Rate (per/ min)	Temperature (°F)
N	Valid	24	24	24	24	24	24
	Missing	0	0	0	0	0	0
Mean		121.9167	78.0833	72.9583	72.9583	15.0000	98.0792
Median		120.0000	80.0000	72.0000	72.0000	15.0000	98.0500
Minimum		110.00	60.00	68.00	68.00	13.00	97.30
Maximum		135.00	88.00	90.00	90.00	18.00	98.40

Vitals – Visit 4, Day 60							
		Systolic Blood Pressure (mm/Hg)	Diastolic Blood Pressure (mm/hg)	Heart Rate (beats / min)	Pulse Rate (beats / min)	Respiratory Rate (per/ min)	Temperature (°F)
N	Valid	24	24	24	24	24	24
	Missing	0	0	0	0	0	0
Mean		116.2500	73.7500	71.1250	71.1250	14.9583	97.9333
Median		120.0000	70.0000	71.0000	71.0000	15.0000	98.0000
Minimum		110.00	65.00	68.00	68.00	14.00	96.90
Maximum		120.00	80.00	75.00	75.00	16.00	98.40

Vitals – Visit 4, Day 90							
		Systolic Blood Pressure (mm/Hg)	Diastolic Blood Pressure (mm/Hg)	Heart Rate (beats / min)	Pulse Rate (beats / min)	Respiratory Rate (per/ min)	Temperature (°F)
N	Valid	24	24	24	24	24	24

Missing	0	0	0	0	0	0
Mean	116.2500	74.1667	71.1250	71.1250	15.0000	97.9250
Median	120.0000	72.5000	71.0000	71.0000	15.0000	98.0000
Minimum	110.00	65.00	68.00	68.00	14.00	96.90
Maximum	120.00	80.00	75.00	75.00	16.00	98.40

Table 10: Descriptive statistics for Safety Parameters

Table 10. 1: Descriptive statistics for Safety Parameter – Hematology - Screening Visit 1, Day -3

Hematology - Screening Visit 1, Day -3						
	N		Mean	Median	Minimum	Maximum
	Valid	Missing				
Hemoglobin (gms/dl)	24	0	13.625	13.55	12.6	14.9
RBC Count (Millions/mm)	24	0	4.2996	4.285	3.81	4.86
Platelets	24	0	3.6263	3.61	3.07	4.21
WBC (cells/mm3)	24	0	9666.66	9300	7500	12300
Neutrophills	24	0	57.6667	59.5	45	71
Lymphocytes (%)	24	0	34.9583	34.5	26	42
Eosinophills (%)	24	0	3.9583	4	2	6
Monocytes (%)	24	0	4.4167	4	2	7
Basophills (%)	24	0	1.125	1	0	2
ESR (mm/hr)	24	0	18.3333	20.5	2	29

Table 10. 2: Descriptive statistics for Safety Parameter – Hematology - Visit 3, Day 90

Hematology - Visit 5 - Day 90						
	N		Mean	Median	Minimum	Maximum
	Valid	Missing				
Haemoglobin (gms/dl)	24	0	11.3375	11.4	6.6	13.9
RBC Count (Millions/mm)	24	0	4.3567	4.28	3.75	5.38
Platelets	24	0	2.52	2.55	1.8	3.7
WBC (cells/mm3)	24	0	6230.8333	6085	3960	10550
Neutrophills	24	0	58.0417	57	50	75
Lymphocytes (%)	24	0	37.75	40	20	46
Eosinophills (%)	24	0	2.9583	3	2	5
Monocytes (%)	24	0	1.25	1	0	2
Basophills (%)	24	0	0	0	0	0
ESR (mm/hr)	24	0	16.5833	16.5	7	29

Table 10. 3: Descriptive statistics for Safety Parameter – Biochemistry - Screening Visit 1, Day -3

Biochemistry - Screening Visit 1, Day -3						
	N		Mean	Median	Minimum	Maximum
	Valid	Missing				
Total Cholesterol (mg/dl)	24	0	179.7387	179.405	120	214.42
Triglycerides (mg/dl)	24	0	94.6058	86.24	60.31	144.07
HDL (mg/dl)	24	0	55.1758	54.94	40.34	70
LDL (mg/dl)	24	0	79.0796	76.27	50.38	112.59
Urea (mg/dl)	24	0	32.4992	31.85	14.47	48.08
Creatinine (mg/dl)	24	0	5.0014	1.015	0.64	98
TB Total Bilirubin (mg/dl)	23	1	0.8082	0.812	0.3	1.12
SGOT (U/L)	23	1	32.247	32.31	22.22	41.77
SGPT (U/L)	23	1	25.8513	23.45	10.26	40.89
Albumin (g/dl)	23	1	4.2791	4.21	3.68	4.97
ALP (U/L)	23	1	163.0843	158.95	75.16	279.47
Uric Acid (mg/dl)	23	1	4.6583	4.65	2.7	6.52

Table 10. 4: Descriptive statistics for Safety Parameter – Biochemistry - Visit 3, Day 90

Biochemistry - Visit 5, Day 90						
	N		Mean	Median	Minimum	Maximum
	Valid	Missing				
Total Cholesterol (mg/dl)	24	0	171.8554	162.06	112.44	200
Triglycerides (mg/dl)	24	0	97.9583	103.5	55.05	144.07
HDL (mg/dl)	24	0	53.7733	53.885	40.26	66.15
LDL (mg/dl)	24	0	79.9137	81.44	50.38	112.59
Urea (mg/dl)	24	0	20.0375	21	10.5	33.6
Creatinine (mg/dl)	24	0	0.7788	0.78	0.54	0.92
TB Total Bilirubin (mg/dl)	24	0	0.5583	0.55	0.3	0.8
SGOT (U/L)	24	0	35.0417	34.5	22	53
SGPT (U/L)	24	0	42.5	39	32	88
Albumin (g/dl)	24	0	3.9625	3.9	3.6	4.7
ALP (U/L)	24	0	99.9167	101.5	68	138
Uric Acid (mg/dl)	24	0	4.5583	4.6	2.9	6.1

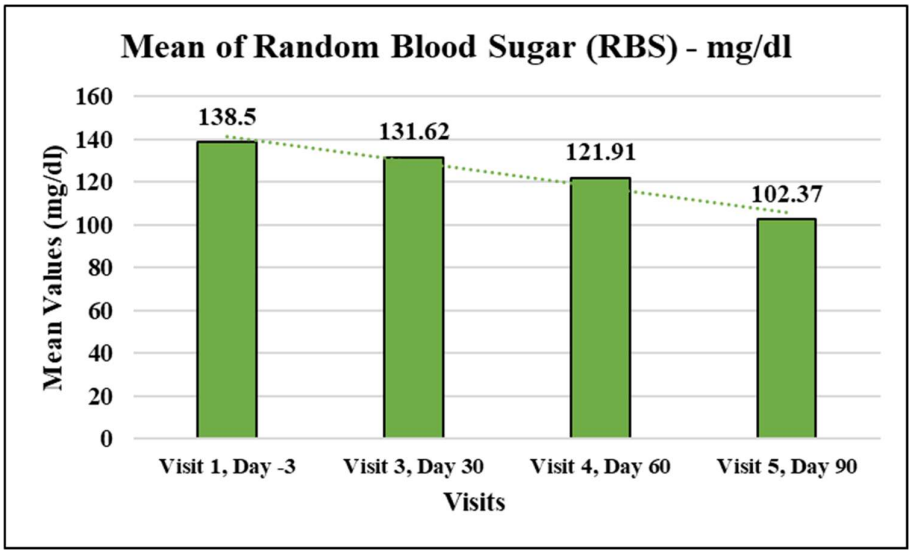
Table 11: Descriptive statistics for Efficacy Parameters

Table 11.1: Comparative Descriptive statistics for Efficacy parameters – Random Blood Sugar (RBS)

Random Blood Sugar (RBS)					
		Visit 1 Day -3	Visit 3 Day 30	Visit 4 Day 60	Visit 5 Day 90
N	Valid	24	24	24	24
	Missing	0	0	0	0
Mean		138.5000	131.6250	121.9167	102.3750
Median		137.5000	130.5000	121.0000	101.5000
Minimum		117.00	111.00	103.00	87.00
Maximum		168.00	160.00	148.00	124.00

Paired Samples Test									
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Visit 1 -Visit 3	6.87500	.74089	.15123	6.56215	7.18785	45.460	23	.000
Pair 2	Visit 1 - Visit 4	16.58333	1.69184	.34535	15.86893	17.29773	48.020	23	.000
Pair 3	Visit 1 - Visit 5	36.12500	3.68679	.75256	34.56821	37.68179	48.003	23	.000

Graph 1: Graphical Representation of Mean scores of Random Blood Sugar (RBS) of each Visits



Graph 1: Graphical Representation of Mean difference – Random Blood Sugar (RBS)

Outcome Measures of Physician assessment:

The efficacy of Auretics Sugar Management Spray in stabilizing blood glucose levels was assessed through serial measurement of Random Blood Sugar (RBS) at four time points: Screening Visit (Day -3), Day 30, Day 60, and Day 90.

A total of 24 subjects were assessed for RBS levels across all four visits. The descriptive statistics showed a consistent and progressive decline in mean blood sugar values throughout the study period, indicating favourable glycemic response to the intervention.

- The mean RBS level reduced from 138.5 mg/dL at baseline (Visit 1, Day -3) to 102.38 mg/dL at the end of the study (Visit 5, Day 90).
- The median RBS dropped from 137.5 mg/dL to 101.5 mg/dL.
- The maximum RBS decreased from 168 mg/dL at baseline to 124 mg/dL at the end of the study.
- The minimum RBS also showed improvement from 117 mg/dL to 87 mg/dL.

A Paired Samples t-test was conducted to analyze the statistical significance of these reductions:

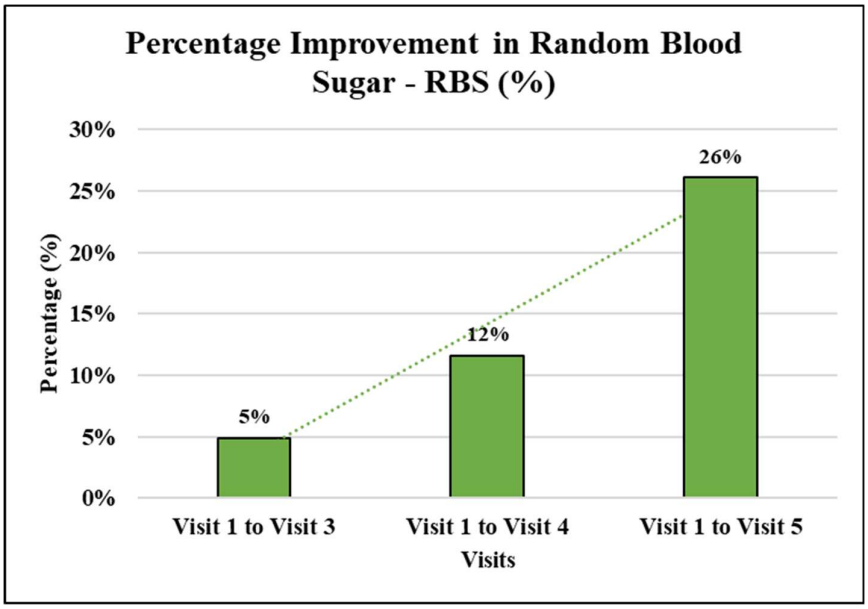
- From Visit 1 to Visit 3 (Day 30), the mean reduction in RBS was 6.88 mg/dL, which was statistically significant ($p < 0.001$).
- From Visit 1 to Visit 4 (Day 60), the RBS reduced by 16.58 mg/dL ($p < 0.001$).
- From Visit 1 to Visit 5 (Day 90), the mean difference was a highly significant reduction of 36.13 mg/dL ($p < 0.001$), indicating a robust and sustained hypoglycemic effect of the study product over the 90-day period.

These statistically significant findings, with consistent improvement across all patients and visits, affirm the clinical efficacy of the investigational product in promoting glycemic control in patients with Type 2 Diabetes Mellitus.

Table 11.2: Physician Assessment - Percentage Improvement

Visits	Percentage Improvement
Visit 1 to Visit 3	5%
Visit 1 to Visit 4	12%
Visit 1 to Visit 5	26%

Graph 2: Graphical Representation of Percentage Improvement of Random Blood Sugar (RBS)



Graph 2: Graphical Representation of Percentage Improvement – Random Blood Sugar (RBS)

The study overall demonstrated 26% improvement in Random Blood Sugar (RBS) from Day 1 (Visit 1) to Day 90 (Visit 5).

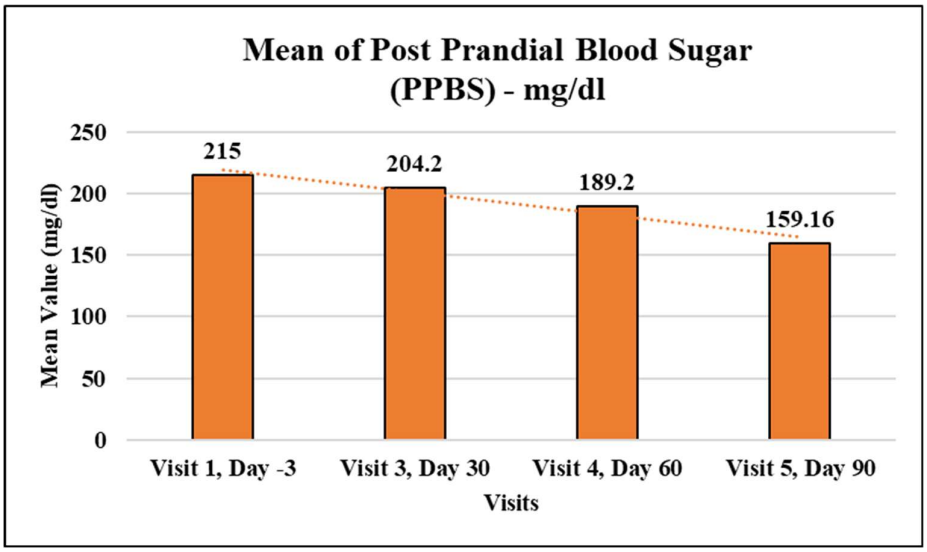
Table 11.3: Comparative Descriptive statistics for Efficacy parameters – Post Prandial Blood Sugar (PPBS)

Post Prandial Blood Sugar (PPBS)					
		Visit 1	Visit 3	Visit 4	Visit 5
N	Valid	24	24	24	24
	Missing	0	0	0	0
Mean		215.0000	204.2083	189.2083	159.1667
Std. Error of Mean		6.16147	5.86626	5.42437	4.54832
Median		207.0000	197.0000	182.5000	153.0000
Std. Deviation		30.18494	28.73867	26.57390	22.28212
Variance		911.130	825.911	706.172	496.493
Minimum		171.00	162.00	150.00	127.00
Maximum		278.00	264.00	245.00	206.00

Paired Samples Test - PPBS				
	Paired Differences	t	df	

		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				Sig. (2-tailed)
					Lower	Upper			
Pair 1	**Visit 1 - Visit**	10.79167	1.47381	.30084	10.16933	11.41400	35.872	23	.000
Pair 2	**Visit 1 - Visit 4**	25.79167	3.62334	.73961	24.26166	27.32167	34.872	23	.000
Pair 3	**Visit 1 - Visit 5**	55.83333	7.91073	1.61477	52.49292	59.17374	34.577	23	.000

Graph 3: Graphical Representation of Mean scores of Post Prandial Blood Sugar (PPBS) of each Visits



Graph 3: Graphical Representation of Mean Scores – Post Prandial Blood Sugar (PPBS)

Outcome Measures of Post Prandial Blood Sugar (PPBS)

The effect of Auretics Sugar Management Spray on postprandial glycemic control was evaluated by assessing Post Prandial Blood Sugar (PPBS) levels at four time points: Visit 1 (Day -3), Visit 3 (Day 30), Visit 4 (Day 60), and Visit 5 (Day 90).

A total of 24 subjects were evaluated at each visit. The results demonstrated a clear and progressive improvement in PPBS values over the 90-day study period:

- The mean PPBS reduced from 215.0 mg/dL at baseline to 159.17 mg/dL by Day 90.
- The median PPBS dropped from 207.0 mg/dL to 153.0 mg/dL, indicating a shift in central tendency.
- The maximum PPBS value decreased from 278 mg/dL to 206 mg/dL, while the minimum improved from 171 mg/dL to 127 mg/dL.

Variability in PPBS readings also reduced, as seen in the standard deviation, which declined from 30.18 at baseline to 22.28 at Day 90, reflecting more stable glycemic control over time.

A Paired Samples t-test was used to determine the statistical significance of these reductions:

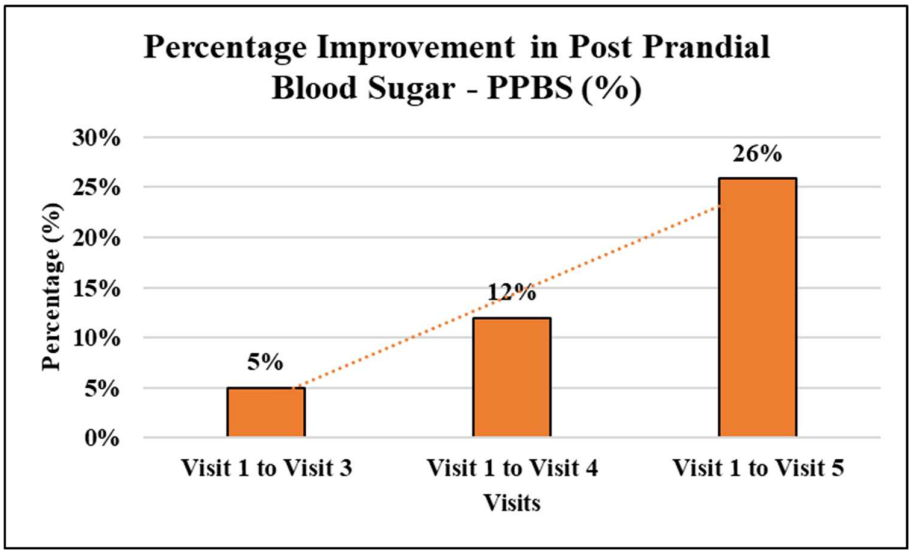
- Between Visit 1 and Visit 3 (Day 30), the mean reduction was 10.79 mg/dL, which was statistically significant ($p < 0.001$).
- Between Visit 1 and Visit 4 (Day 60), the PPBS dropped by 25.79 mg/dL ($p < 0.001$).
- Between Visit 1 and Visit 5 (Day 90), a highly significant reduction of 55.83 mg/dL was observed ($p < 0.001$), indicating substantial improvement in postprandial blood sugar control by the end of the study.

These findings reinforce the clinical utility of the investigational product in reducing postprandial hyperglycemia, a key therapeutic goal in the management of Type 2 Diabetes Mellitus.

Table 11.4: Percentage Improvement in Post Prandial Blood Sugar (PPBS)

Visits	Percentage Improvement
Visit 1 to Visit 3	5%
Visit 1 to Visit 4	12%
Visit 1 to Visit 5	26%

Graph 4 - Percentage Decrease in Post Prandial Blood Sugar (PPBS)



Graph 4: Representation of Efficacy Parameters – Percentage Decrease in Post Prandial Blood Sugar from Day 1 to Day 90

The study overall demonstrated 26% improvement in Post Prandial Blood Sugar (PPBS) from Day 1 (Visit 1) to Day 90 (Visit 5).

Table 11.5: Comparative Descriptive statistics for Efficacy parameters – Post Prandial Blood Sugar (PPBS)

HbA1C			
		Visit 1- Day -3	**Visit 5 - Day 90**
N	**Valid**	24	24
	Missing	0	0
Mean		7.7792	6.1750
Std. Error of Mean		.15522	.11425
Median		7.5500	6.0500
Std. Deviation		.76042	.55970
Variance		.578	.313
Minimum		6.70	5.40
Maximum		9.40	7.40

Paired Samples Test									
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	**Visit 1- Visit 5**	1.60417	.20532	.04191	1.51747	1.69087	38.276	23	.000

Outcome Measures of HbA1C

The long-term glycemic control was assessed through HbA1c measurement at Visit 1 (Day -3) and Visit 5 (Day 90). A total of 24 subjects had valid HbA1c values at both time points, with no missing data.

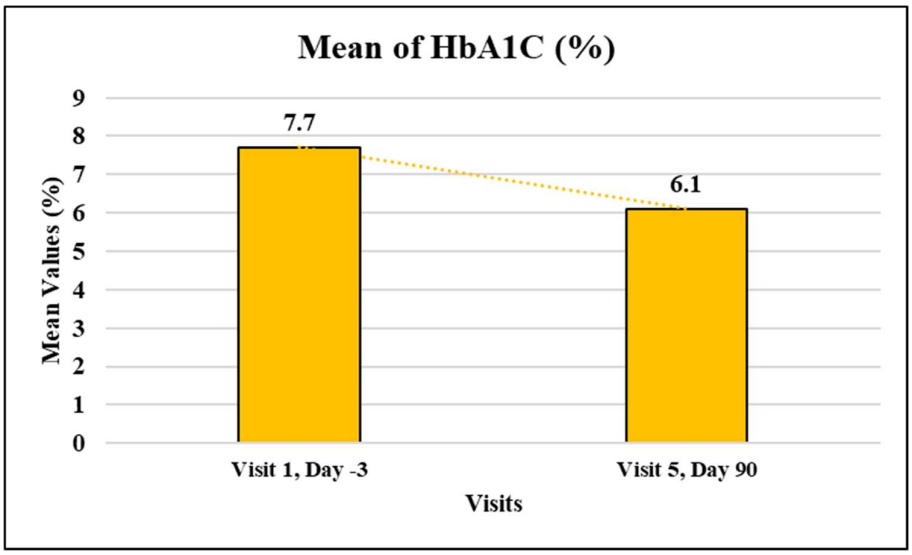
- The mean HbA1c reduced significantly from 7.78% at baseline to 6.18% by Day 90, reflecting improved glycemic control over the study period.
- The median HbA1c declined from 7.55% to 6.05%.
- The maximum HbA1c reduced from 9.40% to 7.40%, and the minimum from 6.70% to 5.40%.

- The variability in HbA1c decreased as well, with the standard deviation reducing from 0.76 to 0.56, indicating tighter glycemic regulation.

Statistical analysis using Paired Samples t-test showed a mean difference of 1.60%, which was highly significant ($p < 0.001$). The confidence interval (95%) ranged from 1.52% to 1.69%, further affirming the robustness of the observed change.

These results strongly support the long-term efficacy of the investigational product in achieving sustained glycemic control in individuals with Type 2 Diabetes Mellitus.

Graph 5: Graphical Representation of Mean scores of HbA1C



Graph 3: Graphical Representation of Mean Scores – HbA1C

Table 11.6: Percentage Improvement in HbA1C

Visits	Percentage Improvement
Visit 1 to Visit 5	21%

The study overall demonstrated 21% improvement in HbA1C from Day 1 (Visit 1) to Day 90 (Visit 5).

Table 11.7: Comparative Descriptive statistics for Efficacy parameters – Urine Routine

Urine Routine Analysis – Screening Visit 1

		Color	Appearance	pH	Specific Gravity	Protein	Sugar	Ketone Bodies	Pus Cells (/hpf)	RBCs (/hpf)
N	Valid	24	24	24	24	24	24	24	24	24
	Missing	0	0	0	0	0	0	0	0	0
Mean		1.4167	1.8333	6.0000	1.0199	1.6250	1.7083	2.0000	1.5417	2.8750
Std. Error of Mean		.10280	.07771	.06730	.00083	.10095	.09478	.00000	.15902	.06896
Median		1.0000	2.0000	6.0000	1.0210	2.0000	2.0000	2.0000	1.0000	3.0000
Std. Deviation		.50361	.38069	.32969	.00407	.49454	.46431	.00000	.77903	.33783
Variance		.254	.145	.109	.000	.245	.216	.000	.607	.114
Minimum		1.00	1.00	5.50	1.02	1.00	1.00	2.00	1.00	2.00
Maximum		2.00	2.00	6.50	1.03	2.00	2.00	2.00	4.00	3.00

Urine Routine Analysis –Visit 3 – Day 30										
		Color	Appearance	pH	Specific Gravity	Protein	Sugar	Ketone Bodies	Pus Cells (/hpf)	RBCs (/hpf)
N	Valid	24	24	24	24	24	24	24	24	24
	Missing	0	0	0	0	0	0	0	0	0
Mean		1.4167	1.8333	6.0000	1.0199	2.0000	2.0000	2.0000	1.5417	2.8750
Median		1.0000	2.0000	6.0000	1.0210	2.0000	2.0000	2.0000	1.0000	3.0000
Minimum		1.00	1.00	5.50	1.02	2.00	2.00	2.00	1.00	2.00
Maximum		2.00	2.00	6.50	1.03	2.00	2.00	2.00	4.00	3.00

Urine Routine Analysis –Visit 4 – Day 60										
		Color	Appearance	pH	Specific Gravity	Protein	Sugar	Ketone Bodies	Pus Cells (/hpf)	RBCs (/hpf)
N	Valid	24	24	24	24	24	24	24	24	24
	Missing	0	0	0	0	0	0	0	0	0
Mean		1.4167	1.8333	6.0000	1.0199	2.0000	2.0000	2.0000	1.5833	2.8750
Std. Error of Mean		.10280	.07771	.06730	.00083	.00000	.00000	.00000	.15830	.06896
Median		1.0000	2.0000	6.0000	1.0210	2.0000	2.0000	2.0000	1.0000	3.0000
Minimum		1.00	1.00	5.50	1.02	2.00	2.00	2.00	1.00	2.00
Maximum		2.00	2.00	6.50	1.03	2.00	2.00	2.00	4.00	3.00

Urine Routine Analysis –Visit 5 – Day 90										
		Color	**Appearance**	**pH**	**Specific Gravity**	**Protein**	**Sugar**	**Ketone Bodies**	**Pus Cells (/hpf)**	**RBCs (/hpf)**
N	**Valid**	24	24	24	24	24	24	24	24	24
	Missing	0	0	0	0	0	0	0	0	0
Mean		1.4167	1.8333	6.0000	1.0199	2.0000	2.0000	2.0000	1.5417	2.8750
Std. Error of Mean		.10280	.07771	.06730	.00083	.00000	.00000	.00000	.15902	.06896
Median		1.0000	2.0000	6.0000	1.0210	2.0000	2.0000	2.0000	1.0000	3.0000
Minimum		1.00	1.00	5.50	1.02	2.00	2.00	2.00	1.00	2.00
Maximum		2.00	2.00	6.50	1.03	2.00	2.00	2.00	4.00	3.00

Outcome Measures of HbA1C

Urine routine examination was performed at baseline (Visit 1 – Screening), and subsequently on Day 30 (Visit 3), Day 60 (Visit 4), and Day 90 (Visit 5) to monitor renal function, systemic health, and any emerging abnormalities throughout the study duration.

Across all four visits, data from all 24 subjects were available for analysis, with no missing values reported. The parameters assessed included color, appearance, pH, specific gravity, protein, sugar, ketone bodies, pus cells, and red blood cells (RBCs).

- Color and appearance remained consistent across visits. The majority of urine samples were recorded as pale yellow to yellow (coded numerically as 1.0 to 2.0), with clear or slightly turbid appearance, showing no significant variation throughout the study.
- Urine pH was stable across all time points, with a mean value of 6.00, indicating no acidic or alkaline shift.
- Specific gravity remained within normal physiological limits (Mean ~1.0199), suggesting maintained renal concentrating ability.
- Protein and sugar levels showed no pathological elevations. All subjects recorded a value of 2.00, representing absence or trace presence (based on coding), consistent from Day 30 onward. While mean protein was 1.63 at screening, this normalized to 2.00 by Day 30 and remained stable, indicating no emerging proteinuria.

- Ketone bodies were consistently reported at a value of 2.00, denoting absence of ketonuria throughout the trial period.
- Pus cells (per high power field) were within normal range, with a mean ranging from 1.54 to 1.58, and no indication of urinary tract infection or inflammation. No progressive increase was observed.
- Red Blood Cells (RBCs) remained stable with a consistent mean of 2.875, median of 3.00, and maximum of 3.00, indicating no signs of microscopic hematuria or renal pathology.

Overall, the urine routine findings across all visits remained within normal limits, with no clinically significant changes or emerging abnormalities. These results support the renal safety and general tolerability of the investigational product over the 90-day administration period.

Table 12: Descriptive statistics of Feedback Questionnaires

Questionnaires	N		Mean	Std. Error of Mean	Median	Minimum	Maximum
	Valid	Missing					
How regularly did you use the product as per instructions?	24	0	1.1667	0.0777	1.0000	1.00	2.00
Did you face any difficulty in applying the spray to palms and soles? 1. No 2. Yes	24	0	1.1667	0.0777	1.0000	1.00	2.00
Was the application process (spraying and rubbing) convenient for you?	24	0	2.6250	0.2540	2.5000	1.00	4.00
How long did it take you each time to complete the application process?	23	1	2.1739	0.1201	2.0000	1.00	3.00

Did you feel any improvement in your blood sugar control during the study?	24	0	3.3333	0.0982	3.0000	3.00	4.00
How would you rate your overall energy/stamina levels over the last 90 days?	24	0	2.7917	0.0846	3.0000	2.00	3.00
Did you observe any reduction in symptoms commonly associated with diabetes (e.g., fatigue, frequent urination, thirst)?	24	0	2.0000	0.0000	2.0000	2.00	2.00
Did you require any changes to your existing diabetes medications during the study?	24	0	2.0000	0.2085	2.0000	1.00	3.00
Did you experience any side effects or discomfort from using the product?_____	24	0	1.0000	0.0000	1.0000	1.00	1.00
Was the smell or texture of the product acceptable to you?	24	0	3.5000	0.1042	3.5000	3.00	4.00
Overall, how satisfied are you with Sug Rodhi Spray?	24	0	2.7917	0.1343	3.0000	2.00	4.00
Would you continue using this product after the study?	24	0	2.3333	0.0982	2.0000	2.00	3.00

Would you recommend this product to other diabetic patients?	24	0	1.7917	0.1200	2.0000	1.00	3.00

A. How regularly did you use the product as per instructions?
1. Always (Morning and Night Daily) 2. Mostly 3. Occasionally 4. Rarely

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	20	83.3	83.3	83.3
	2.00	4	16.7	16.7	100.0
	Total	24	100.0	100.0	

B. Did you face any difficulty in applying the spray to palms and soles? 1. No 2. Yes

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	20	83.3	83.3	83.3
	2.00	4	16.7	16.7	100.0
	Total	24	100.0	100.0	

C. Was the application process (spraying and rubbing) convenient for you?
1. Very convenient 2. Somewhat convenient 3. Neutral 4. Slightly inconvenient 5. Very inconvenient

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	6	25.0	25.0	25.0
	2.00	6	25.0	25.0	50.0
	3.00	3	12.5	12.5	62.5
	4.00	9	37.5	37.5	100.0
	Total	24	100.0	100.0	

D. How long did it take you each time to complete the application process? 1. Less than 5 minutes 2. 5–10 minutes 3. More than 10 minutes

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	2	8.3	8.7	8.7
	2.00	15	62.5	65.2	73.9
	3.00	6	25.0	26.1	100.0
	Total	23	95.8	100.0	
Missing	System	1	4.2		
Total		24	100.0		

E. Did you feel any improvement in your blood sugar control during the study? 1. Significant improvement 2. Moderate improvement 3. Mild improvement 4. No noticeable improvement

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	3.00	16	66.7	66.7	66.7
	4.00	8	33.3	33.3	100.0
	Total	24	100.0	100.0	

F. How would you rate your overall energy/stamina levels over the last 90 days? 1. Much better than before 2. Slightly better 3. No change 4.Worse

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2.00	5	20.8	20.8	20.8
	3.00	19	79.2	79.2	100.0
	Total	24	100.0	100.0	

G. Did you observe any reduction in symptoms commonly associated with diabetes (e.g., fatigue, frequent urination, thirst)?1. Yes – Please specify: _____ 2. No change

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2.00	24	100.0	100.0	100.0

H. Did you require any changes to your existing diabetes medications during the study? 1. Reduced2. Increased 3. No change 4. Not applicable					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	12	50.0	50.0	50.0
	3.00	12	50.0	50.0	100.0
	Total	24	100.0	100.0	

I. Did you experience any side effects or discomfort from using the product? 1. No 2. Yes - Please specify: _____					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	24	100.0	100.0	100.0

J. Was the smell or texture of the product acceptable to you? 1. Very acceptable 2. Acceptable 3. Neutral 4. Unacceptable					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	3.00	12	50.0	50.0	50.0
	4.00	12	50.0	50.0	100.0
	Total	24	100.0	100.0	

K. Overall, how satisfied are you with Sug Rodhi Spray? 1. Very satisfied 2. Satisfied 3. Neutral 4. Dissatisfied 4. Very dissatisfied					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2.00	8	33.3	33.3	33.3
	3.00	13	54.2	54.2	87.5
	4.00	3	12.5	12.5	100.0
	Total	24	100.0	100.0	

L. Would you continue using this product after the study? 1. Definitely 2. Probably 3. Not sure 4. Probably not 5. Definitely not					
		Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Valid	**2.00**	16	66.7	66.7	66.7
	3.00	8	33.3	33.3	100.0
	Total	24	100.0	100.0	

M. Would you recommend this product to other diabetic patients? 1. Yes 2. Maybe 3. No					
		Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Valid	**1.00**	7	29.2	29.2	29.2
	2.00	15	62.5	62.5	91.7
	3.00	2	8.3	8.3	100.0
	Total	24	100.0	100.0	

Outcome Measures of Patient Feedback (Visit 5 – Day 90)

At the end of the 90-day study period, all participants (n=24) completed a structured feedback questionnaire to evaluate their experience with the Sug Rodhi spray, its usability, convenience, subjective benefits, and satisfaction levels.

Compliance and Usability

- 83.3% of patients reported that they used the product regularly as instructed both morning and night (Mean: 1.17 ± 0.08).
- 83.3% of subjects did not face any difficulty in applying the spray to palms and soles.
- Regarding the convenience of the application process, 50% rated it as very or somewhat convenient, while 37.5% found it slightly inconvenient (Mean score: 2.63 ± 0.25).
- Time to apply the spray was mostly manageable, with 65.2% completing the process in 5–10 minutes and 26.1% taking >10 minutes (Mean: 2.17 ± 0.12).

Perceived Efficacy

- 66.7% of subjects reported mild improvement in blood sugar control; no patients reported moderate or significant improvement (Mean: 3.33 ± 0.10).

- None of the participants reported improvement in common diabetes symptoms like fatigue, thirst, or frequent urination, suggesting neutral symptomatic impact in this area.
- Energy/stamina levels were perceived as unchanged by 79.2% of patients (Mean: 2.79 ± 0.08).

Safety and Medication Impact

- No participants experienced any side effects or discomfort, confirming the excellent tolerability of the product.
- Half of the participants (50%) reported a reduction in the dosage or frequency of their existing antidiabetic medications, while the other half noted no change (Mean: 2.00 ± 0.21).

Sensory Acceptance

- 50% rated the smell or texture of the product as “Neutral” and 50% as “Unacceptable” (Mean: 3.5 ± 0.10), suggesting a need for improvement in the organoleptic profile of the formulation.

Overall Satisfaction and Recommendation

- 33.3% were "Satisfied" and 54.2% were "Neutral" in their overall satisfaction, while 12.5% were "Dissatisfied" (Mean: 2.79 ± 0.13).
- When asked about continued use post-study, 66.7% said they would “Probably” continue, and 33.3% were “Not sure” (Mean: 2.33 ± 0.10).
- For recommendation to other diabetic patients, only 29.2% said “Yes” while 62.5% said “Maybe”, and 8.3% said “No” (Mean: 1.79 ± 0.12).

Interpretation:

- Compliance with product use was high.
- Ease of use was moderately acceptable, though a significant proportion found the process slightly inconvenient.
- Safety was excellent, with zero reports of side effects.
- Efficacy perception was modest, with most patients reporting mild benefit and no major improvement in symptoms.
- Taste/smell and texture were identified as key areas for formulation improvement.
- Willingness to recommend and future use intention were cautiously positive, indicating potential with refinement and education.

12. DISCUSSION

Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and impaired glucose metabolism, leading to elevated blood glucose levels. If left unmanaged, it may lead to systemic complications affecting cardiovascular, renal, neurological, and visual health. Effective glycemic control remains the cornerstone in the management of T2DM, and complementary approaches using lifestyle and integrative therapies are gaining attention globally.

In Ayurveda, diabetes is classified under *Prameha*, particularly *Madhumeha*, which involves deranged *Kapha* and *Medas* affecting *Mutravaha srotas*. The pathology is deeply rooted in metabolic imbalance, accumulation of *Ama*, and impaired *Agni*, resulting in symptoms such as frequent urination, fatigue, excessive thirst, and sluggish metabolism. Ayurvedic treatment focuses on correcting metabolism, enhancing tissue nourishment, and pacifying aggravated doshas.

Sug Rodhi is a proprietary Ayurvedic spray formulation developed as a transdermal supportive therapy for individuals with Type 2 Diabetes. It is composed of scientifically validated herbs known for their antioxidant, microcirculatory, rejuvenative, and blood sugar modulating actions.

The formulation is intended to:

- Support peripheral circulation and lymphatic detoxification
- Assist glycemic control via percutaneous herbal delivery
- Enhance energy levels and metabolism
- Complement oral antidiabetic therapies without systemic side effects

The formulation embodies the Ayurvedic principles of *Snehana* (unctuous absorption), *Swedana* (micro-sweating), and *Doshahara* (detoxification and dosha pacification), offering a novel and holistic approach to diabetes support.

This clinical study was conducted at Shree Maruthi Hospital, Bengaluru, India, under the supervision of Dr.Vishnu Hayagreev, as the Principal Investigator, after obtaining approval from the Institutional Ethics Committee. A total of 24 subjects aged between 30 to 60 years, with clinically diagnosed Type 2 Diabetes Mellitus, were enrolled in the study after obtaining written informed consent. The recruitment period started on 10th March 2025 and concluded 21st March 2025, with the last follow-up completed on 19th June 2025.

Demographic Characteristics and Baseline Measurements: The demographic and baseline health parameters, including age, gender, height, weight, and BMI, along with vital signs, were

recorded during the screening visit (Visit 1). All subjects had elevated HbA1c and blood glucose levels, fulfilling the inclusion criteria. No major abnormalities were observed in baseline physical examination or laboratory parameters.

Efficacy Parameters: The efficacy of the Sug Rodhi spray was evaluated using both objective and subjective endpoints across a 90-day intervention period. These included:

Random Blood Sugar (RBS): showed a statistically significant mean reduction of 36.13 mg/dL from baseline ($p < 0.001$).

Post Prandial Blood Sugar (PPBS) showed a 55.83 mg/dL reduction from baseline to Day 90 ($p < 0.001$), amounting to a 21% improvement.

HbA1c levels showed a mean reduction of 1.60%, from 7.78% to 6.18%, indicating a robust long-term glycemic control ($p < 0.001$).

Urine routine parameters including pH, specific gravity, proteins, and sugars remained normal throughout the study, confirming no renal stress or glycosuria progression.

Patient Feedback Questionnaire (Table 12) assessed compliance, ease of use, and perceived benefit. While 83% of patients complied with regular use and 66% perceived mild improvement, the product was generally well tolerated with zero side effects.

Safety Parameters: Throughout the study, no adverse events, side effects, or serious medical incidents were reported. Vital signs remained within normal limits during each visit, and physical examination findings did not reveal any drug-related anomalies. Additionally, there were no dropouts, medication interactions, or abnormalities in urine or systemic parameters.

13. CONCLUSION

This prospective, open-label clinical evaluation assessed the safety, efficacy, and user experience of *Sug Rodhi Spray*, a topical Ayurvedic formulation, in 24 adult subjects diagnosed with Type 2 Diabetes Mellitus. Over a 90-day period, multiple clinical, biochemical, and patient-reported outcomes were systematically evaluated.

Glycemic Control

One of the primary endpoints of the study was the improvement in glycemic parameters. Notable and statistically significant reductions were observed across all major markers:

- Random Blood Sugar (RBS) reduced from a mean of 138.5 mg/dL at baseline to 102.38 mg/dL at Day 90 - a 26% reduction ($p < 0.001$), indicating consistent and robust glycemic stabilization.
- Post Prandial Blood Sugar (PPBS) decreased from 215.0 mg/dL to 159.17 mg/dL by Day 90 - a 26% decline ($p < 0.001$), demonstrating postprandial glycemic control.

- HbA1c, a long-term glycemic marker, showed a significant improvement from 7.78% at baseline to 6.18% at Day 90 - a 1.6% absolute reduction ($p < 0.001$), confirming sustained glycemic benefit of the intervention.

These outcomes reflect clinically meaningful glycemic improvements without adjunct changes in anti-diabetic medication in 50% of subjects.

Safety and Tolerability

Across all visits, no adverse events, side effects, or discomfort were reported by any of the 24 participants, highlighting the excellent safety and tolerability of the formulation. Vital signs, hematological, biochemical, and urine parameters remained within physiological norms throughout the study. Specifically:

- Renal and hepatic markers showed no signs of toxicity.
- No abnormal findings were observed in physical exams or systemic evaluations.
- Urine routine reports remained stable, indicating preserved renal function and systemic homeostasis.

These results validate the renal, hepatic, and systemic safety of *Sug Rodhi Spray* with consistent use over 90 days.

Patient Feedback and Experience

Patient-reported outcomes collected on Day 90 provided insight into product usability, satisfaction, and perceived benefits:

- Compliance was high, with 83.3% of subjects adhering strictly to the dosing schedule.
- Convenience of use was moderately acceptable, while 50% found it convenient, 37.5% rated the process as slightly inconvenient.
- Efficacy perception was modest: 66.7% reported mild improvement in blood sugar control; however, no improvement was observed in diabetes-associated symptoms (e.g., fatigue, frequent urination).
- Satisfaction levels were generally neutral to positive, with 33.3% “Satisfied” and 54.2% “Neutral”.
- No participant reported any side effects, confirming its dermatological tolerability.
- Future use intent was encouraging, with 66.7% expressing willingness to continue the product post-study, and 91.7% open to recommending it (conditionally) to other diabetic patients.

Overall Interpretation

The clinical findings strongly support the utility of *Sug Rodhi Spray* as a safe and moderately effective adjunct in glycemic management for patients with Type 2 Diabetes Mellitus. Over 90 days of use, the formulation:

- Significantly improved RBS, PPBS, and HbA1c
- Maintained safety across all vital, hematological, and biochemical markers
- Was well-tolerated with no reported side effects
- Showed high compliance and neutral-to-positive patient satisfaction
- Did not cause adverse effects on renal, hepatic, cardiovascular, or dermatological systems

These outcomes demonstrate both glycemic efficacy and systemic safety of *Sug Rodhi Spray* as a non-invasive, topical, herbal intervention. Further large-scale, placebo-controlled trials are warranted to validate its clinical benefits and optimize user acceptability through sensory enhancements.

14. CONFIDENTIALITY AND PUBLICATION:

You agree that all information communicated to you by Sponsor is the exclusive property of Sponsor. And you will ensure that the same shall be kept strictly confidential by you or any other person connected with the work and shall not be disclosed, either orally or in written form, by you or such person to any third party without the prior written consent of Sponsor. You shall communicate the results of the work promptly to Sponsor. We agree that you shall have the right to publish or permit the publication of any information or material relating to or arising out of the work after prior submission to us provided that if we shall request you will delay publication for a maximum of six months to enable us to protect our rights in such information or material. Any proposed publication or presentation (e.g., manuscript, abstract or poster) for submission to a journal or scientific meeting should be sent to the Site Monitor prior to submission, together with confirmation that any other author(s) has seen and agreed the proposed publication/presentation. The publication policy was at the discretion of the Sponsor. If published the subject's identity will not be revealed**.**

15. LIST OF REFERENCES:

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16. APPENDICES:

16.1. Ethics Committee approval

PRANAV DIABETES CENTER ETHICS COMMITTEE

ECR/1217/Inst/KA/2019/RR-22

14 FEB 2025 **PDCEC/DIAB-06/14 FEB 25**

To,
Dr Vishnu Hayagreev
Principal Investigator
Shree Maruti Hospital
#67, Link Road, Jai Bheema Nagar
Sheshadripuram, Bengaluru-560020

Subject: Ethics Committee Approval

Dear **Dr Vishnu Hayagreev**

The Pranav Diabetes Center Ethics Committee Bangalore has reviewed and discussed your application to conduct the clinical study entitled

Protocol Title: A prospective,Open Label,clinical Study to evaluate the safety and efficacy of Auretics Sugar Management Spray,in stabilizing blood glucose levels in Diabetic patients.
Study Protocol No: ACS/CL/01/2024 Version 1.0 Dated 28 Dec 2024

The following documents were reviewed:

1. Study Protocol No: ACS/CL/01/2024 Version 1.0 Dated 28 Dec 2024
2. Investigator Undertaking.
3. CV, MRC and GCP Certificate of the investigator.
4. English_PIS_ICF Version 1.0 Dated 28 Dec 2024

The following members of the Ethics Committee were present at the meeting held on 10 Feb 2025 at 18:00 hrs. The discussion and decision-making process were facilitated through conference call with all quorum members on skype.

Sl. No.	NAME	ROLE	QUALIFICATION
1.	Dr. Shivaraja Shetty	Chair person	MBBS, MD Bio Chemistry
2.	Mrs. Rutuja Joshi	Member Secretary	B.Sc. & P G Diploma in Dietetics & Clinical Nutrition
3.	Dr Rajeshwari K G	Basic Medical Scientist	MBBS, (MD -Pathology& Microbiology)

Page 1 of 2

Office Address: #57/1 Nanda Complex, Ramamurthy Nagar Main Road, Banaswadi, Bangalore-560043,Karnataka,

PRANAV DIABETES CENTER ETHICS COMMITTEE

ECR/1217/Inst/KA/2019/RR-22

4.	Dr Roopa R	Clinician	MBBS, DOMS
5.	Mrs. Geetha Giriraj	Legal Expert	B.Com, B.L., M.L.
6.	Mrs. Sandhya S	Lay Person	P.U.C
7.	Mr. B .Vincent Jayaseelan.	Social Scientist	M.Div., M. Th. M A Public Administration.

PDCEC is functioning in accordance with ICH GCP Guidelines, Ethical guidelines for biomedical research in human subjects by ICMR, New Delhi and as per the requirement laid down in the Indian GCP and in accordance to The New Drugs and Clinical Trial Rules 2019.

We, hereby confirm that PDCEC who have participated in the decision making process don't have any Conflict of interest In the study and the EC is located within the 50km radius from the study site. We approve the study to be conducted in its presented form.

This approval is in effective for twelve months from the above approval date. PDCEC expects to be informed about the study, any changes in the protocol and asks to be provided a copy of the final report.

RUTUJA ANIRUDDHA JOSHI
Digitally signed by RUTUJA ANIRUDDHA JOSHI
Date: 2025.02.14 19:08:38 +05'30'

Yours Sincerely,
Member Secretary

Office Address: *#57/1 Nanda Complex, Ramamurthy Nagar Main Road, Banaswadi, Bangalore-560043,Karnataka,*

16.2. Clinical Trial Registry – India Trial Registration Details

FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI No	**CTRI/2025/03/081737** [Registered on: 06/03/2025] **Trial Registered Prospectively**
Acknowledgement Number	REF/2025/02/100532
Last Modified On:	01/03/2025
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Ayurveda Nutraceutical
Study Design	Single Arm Study
Public Title of Study Clarification(s) with Reply Modification(s)	Clinical trial on blood glucose level in diabetic patients.
Scientific Title of Study	A Prospective, open-label clinical study to evaluate the safety and efficacy of Auretics Sugar Management Spray in stabilizing blood glucose levels in Diabetic patients.
Trial Acronym	NIL
Secondary IDs if Any	Secondary ID: NIL; Identifier: NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study) Clarification(s) with Reply Modification(s)	**Name**: Dr Vishnu Hayagreev **Designation**: Principal Investigator **Affliation**: Shree Maruthi Hospital **Address**: Shree Maruthi Hospital Dept.of Medicine Room No 1, Ground Floor No 67 Link Road, Sheshadripuram Bengaluru Bangalore KARNATAKA 560020 India **Phone**: 9448144151 **Fax**: **Email**: amruthvishnu@gmail.com
Details Contact Person Scientific Query	**Name**: Arjun Gupta **Designation**: Director **Affliation**: Auretics Limited **Address**: Plot No 190,Old Block Near LIC Colony, Mangal Bazar Road, Dilshad Garden New Delhi DELHI 110095 India **Phone**: 9999112999 **Fax**: **Email**: arjun@auretics.com
Details Contact Person Public Query	**Name**: Arjun Gupta **Designation**: Director **Affliation**: Auretics Limited

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Source of Monetary or Material Support	Auretics Limited Plot No 190, Old Block, Near LIC Colony, Mangal Bazar Road, Dilshad Garden, New Delhi 110095	
Primary Sponsor	**Name**	Auretics Limited
	Address	Plot No 190, Old Block, Near LIC Colony, Mangal Bazar Road, Dilshad Garden, New Delhi 110095
	Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor	Name	Address
	NIL	NIL

Countries of Recruitment	India

Sites of Study
Clarification(s) with Reply
Modification(s)

No of Sites = **1**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Vishnu Hayagreev	Shree Maruti Hospital	Shree Maruthi Hospital Dept. of Medicine, Room No 1 Ground Floor #67 Link Road, Sheshadripuram, Bengaluru 560020 Bangalore KARNATAKA	9448144151 amruthvishnu@gmail.com

Details of Ethics Committee

No of Ethics Committees= **1**

Name of Committee	Ethics Committee registered with DHR /CDSCO or not	Ethics Committee Registration No.	Approval Status	Date of Approval	Approval Document	Is IEC?
Pranav Diabetic Center Ethics Committee	Yes	ECR/1217/Inst/KA/2019/RR-20	Approved	14/02/2025	Approval File	No

Regulatory Clearance Status from DCGI

Status	Date	Aproval Document
Not Applicable	No Date Specified	No File Uploaded

Health Condition / Problems Studied

Health Type	Condition
Patients	**(1) ICD-10 Condition:**E089||Diabetes mellitus due to underlying condition without complications. **Ayurveda Condition:** MADHUMEHAH/KSHAUDRAMEHAH,

Intervention / Comparator Agent

sno	Intervention/Comparator	Type	Drug-Type	Procedure Name	Details
1	Intervention Arm	Drug	Other than Classical		(1) Medicine Name: Sug Rodhi, Reference: NA, Route: Topical, Dosage Form: Taila, Dose: 10(ml), Frequency: tds, Bhaishajya Kal: Muhurmuhu, Duration: 3 Months, anupAna/sahapAna: No, Additional Information: -none

Inclusion Criteria

Age From	30.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1. Subject Between 30 years to 60 years of both genders. 2. Diabetic subjects on anti diabetic medication. 3. Subject who are hypertensive 4. Subject free from infection, cancer and other diseases 5. Subject willing to give written Informed Consent 6.FAsting Blood Glucose level between 110 mg/dl to 250 mg/dl 7.Post Parandial Blood Sugar level between 140 mg/dl to 350 mg/dl

Exclusion Criteria

Details	1.Subjects with diabetes mellitus along with other comorbid conditions. 2.Pregnant or lactating women 3. Women of childbearing potential who do not take adequate contraceptive protection 4.History of hypersensitivity to the metformin or to drug with similar chemical structure 5.History of any severe systemic disease 6.Patients with uncontrolled hypertension 7.History of stroke, cancer, acute illness

Method of Generating Random Sequence

Not Applicable

Method of Concealment

Not Applicable

Blinding/Masking

Not Applicable

Primary Outcome
Clarification(s) with Reply
Modification(s)

Outcome	TimePoints
Primary out Come: 1.To evaluate the efficacy of Auretics Sugar Management Spray in stabilizing Blood Sugar in Diabetic patients. 2. Decrease in Blood Sugar Level- Fasting blood sugar (FBS), Post Prandial Blood Sugar (PPBS) Glycated hemoglobin (HbA1c) and Urine Sugar from Day 0 to Day 90	Evaluation from baseline to day 30, day 60 and day 90

Secondary Outcome

Outcome	TimePoints
Secondary Outcome: To evaluate the safety and consumer acceptance of Auretics Sugar Management Spray in stabilizing blood glucose levels in Diabetic patients through feedback questionnaires	Baseline and Day 90

Target Sample Size	**Total Sample Size=**"24" **Sample Size from India=**"24" **Final Enrollment numbers achieved (Total)=** "Applicable only for Completed/Terminated trials" **Final Enrollment numbers achieved (India)=**"Applicable only for Completed/Terminated trials"
Phase of Trial Clarification(s) with Reply Modification(s)	Phase 3
Date of First Enrollment (India)	17/03/2025
Date of Study Completion (India)	Applicable only for Completed/Terminated trials
Date of First Enrollment (Global)	If country of recruitment is only India, global date would be not applicable.
Date of Study Completion (Global)	Applicable only for Completed/Terminated trials
Estimated Duration of Trial	**Years=**"0" **Months=**"6" **Days=**"0"
Recruitment Status of Trial (Global)	If country of recruitment is only India, global status would be not applicable.
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	N/A
Individual Participant Data (IPD) Sharing Statement	**Will individual participant data (IPD) be shared publicly (including data dictionaries)?** **Response** - NO
Result Disclosure	**Do you wish to upload results?** **Response** - Summary results have not yet been disclosed
Brief Summary	Type 2 diabetes mellitus (DM) has become a significant global health issue, attracting increasing attention due to its widespread impact. It is anticipated to remain a major public health challenge, often leading to severe complications. India ranks among the top five countries with the highest prevalence of diabetes. In Ayurveda diabetes is called as Prameha. There are twenty types of prameha: 1) Kaphaja Prameha – which includes Ten types – early stage Overweight with mild hyperglycaemia. - Polyuria/ glycosuria 2) Pittaja prameha – which includes six types – Acute stage Loss of weight. - Hyperglycaemia and glycosuria - urinary tract infection 3) Vataja Prameha – which includes four types – Chronic stage. • Severe hyperglycaemia with glycosuria (Chronic diabetes) • Nephropathy neuropathy - Retinopathy – Gangrene Auretics Sugar Management Spray helps reduce increased blood sugar and increase insulin levels after meals, helps lower fasting blood glucose levels by enhancing the insulin activity and sensitivity and helps strengthen pancreas and increases insulin secretion, making the body more responsive to insulin. Our formulation Auretics Sugar Management Spray contains all active natural ingredients. These natural ingredients in common have capacity to lower the blood sugar levels. Also this product is applied through external route that is topical absorption. Transdermal drug delivery systems have been explored for diabetes management, offering a non- invasive alternative to injections. These systems deliver medications through the skin to help regulate blood sugar levels.