

## LITERARY, ANALYTICAL AND OBSERVATIONAL CLINICAL EVALUATION OF 500 MG DM CAPSULE, IN DIABETES MELLITUS (MADHUMEHA)

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### ABSTRACT

Diabetes Mellitus has been recognized as a significant health disorder since ancient times, affecting populations across various civilizations. Diabetes Mellitus is a complex metabolic disorder characterized by persistent hyperglycemia resulting from deficient insulin secretion, insulin resistance, or both. Its global prevalence has risen sharply in recent decades, primarily due to sedentary lifestyles and unhealthy dietary habits. In Ayurvedic literature, this condition closely corresponds to *Madhumeha*, a subtype of *Prameha*, which arises from the vitiation of *Kapha dosha*, dysfunction of *Medo dhatu*, and impairment of *Agni*. These pathophysiological changes disrupt normal metabolic processes, leading to the manifestation and progression of the disease. Understanding *Madhumeha* through the lens of Ayurveda offers a holistic framework for its prevention and management. According to the latest data from the International Diabetes Federation (IDF), approximately 72.9 million individuals in India are currently living with Diabetes Mellitus. In classical Ayurvedic texts, this condition is described as *Madhumeha*, a subtype of *Vataja Prameha*,

characterized by the excessive elimination of sweet-tasting urine. *Madhumeha* is considered a chronic metabolic disorder arising from *dosha* imbalance—particularly *Vata*—along with *Medo dhatu* dysfunction and impaired *Agni*, aligning closely with the clinical features of type 2 Diabetes Mellitus. The present study was conducted on 130 patients presenting with chief

complaints such as generalized body ache, sweet taste in the mouth, burning sensation in the soles, excessive hunger (*Ati-bubhuksha*), excessive thirst (*Ati-trishna*), increased psychological stress, and frequent micturition (*Prabhuta-mutrata*). Based on clinical evaluation, physical findings, and relevant biochemical investigations, the condition was diagnosed as *Madhumeha* (Type 2 Diabetes Mellitus), a chronic metabolic disorder described in Ayurveda under the broader classification of *Prameha*. The treatment protocol included the administration of 500 mg of DM Capsule twice daily, in conjunction with prescribed dietary modifications and lifestyle interventions. Patients were monitored through regular follow-up visits at seven-day intervals over a period of two months (60 days). Notable clinical improvements were observed after the first month of treatment, indicating a significant therapeutic response. The therapeutic intervention comprised the administration of 500 mg DM Capsule twice daily, alongside individualized dietary regulation and lifestyle modification. Patients were assessed at regular intervals of seven days over a total duration of 60 days. Significant clinical improvement was observed by the end of the first month, suggesting a positive therapeutic response to the integrative management approach. The study administered a total daily dose of 1 gram of DM Capsule powder (500 mg taken twice daily on an empty stomach, before breakfast and dinner) over a period of 60 consecutive days. The treatment resulted in a statistically significant improvement in glycemic control among diabetic patients ( $P < 0.005$ ).

## INTRODUCTION

Ancient Indian physicians identified Diabetes Mellitus as *Madhumeha* (Type 2 Diabetes Mellitus), so named because the urine of affected individuals was observed to attract ants. *Madhumeha* is classified as a *Vataja* subtype of *Prameha*, a disease extensively described in Ayurvedic literature. Recognized as *Mahagada* in Ayurveda.<sup>[1]</sup> This chronic disorder has been afflicting humanity since antiquity, with its prevalence and associated complications rising steadily. It is a complex syndrome encompassing clinical conditions such as obesity, prediabetes, diabetes, and metabolic syndrome.<sup>[2]</sup> Classical Ayurvedic texts describe the cardinal symptom of *Prameha* as “*Prabhootavila Mutrata*”, meaning the excretion of large volumes of turbid urine<sup>[3]</sup> which corresponds closely to the polyuria observed in modern Diabetes Mellitus. Epidemiological data indicate a growing global burden of diabetes, with approximately 424.9 million adults affected worldwide as of 2017.<sup>[4]</sup> India follows this global trend, currently ranking second among countries with the highest number of diabetic patients.<sup>[5]</sup>

Diabetes Mellitus refers to a group of metabolic disorders characterized by chronic hyperglycemia, resulting from defects in insulin secretion, insulin action, or both. The sustained elevation of blood glucose levels manifests clinically as polyuria (frequent urination), polydipsia (increased thirst), and polyphagia (increased hunger). If left untreated, Diabetes Mellitus can lead to a wide range of complications, including diabetic ketoacidosis, hyperosmolar non-ketotic coma, cardiovascular diseases, cerebrovascular accidents (stroke), diabetic nephropathy (kidney failure), diabetic foot ulcers, retinopathy, cataracts, and glaucoma.<sup>[6]</sup>

*Prameha* is classified as a *Tridoshaja Vyadhi* of *Santarpanajanya* origin, primarily resulting from over-nourishment and indulgence in *Prameh-otpadaka Ahara* and *Vihara* (dietary and lifestyle factors that promote the disease). According to *Acharya Sushruta*, excessive consumption of such causative factors leads to the vitiation of immature (*Aparipakva*) *Vata*, *Pitta*, and *Kapha* doshas, which then associate with *Medo Dhatu* (adipose tissue). These vitiated doshas and dhatus subsequently flow through the *Mutravaha Srotas* and localize in the *Basti* (urinary bladder), initiating the pathogenesis of *Prameha*.<sup>[7]</sup>

According to Ayurvedic literature, *Madhumeha* (Type 2 Diabetes Mellitus), classified under *Vataja Prameha*, is considered *Asadhya* (incurable) due to its chronic and degenerative nature. However, with timely and appropriate intervention, its progression can be effectively managed. The Ayurvedic approach to management includes a comprehensive treatment protocol comprising *Shamana Chikitsa* (palliative therapy through anti-diabetic formulations), *Shodhana Chikitsa* (purificatory procedures such as *Panchakarma*), and strict adherence to *Pathya Ahara-Vihara* (regulated diet and lifestyle modifications).<sup>[8]</sup>

The herbal ingredients used in the formulation of DM Capsule are well-established in classical Ayurvedic literature for their anti-diabetic properties. These herbs have been traditionally utilized for centuries in the management of *Madhumeha* (Type 2 Diabetes Mellitus). This study focuses on the DM Capsule, detailing its therapeutic application, method of preparation, and pharmacological characteristics relevant to the treatment of *Madhumeha*.

The preparation of the **500 mg DM Capsule** follows a standardized and repeated pharmaceutical process to ensure consistency and therapeutic efficacy. This formulation may be regarded as a classical example of *potentization* of anti-diabetic herbs, as referenced in

Ayurvedic texts and *Nighantus* such as *Bhavaprakasha Nighantu*. The constituent herbs are known to strengthen pancreatic  $\beta$ -cells and enhance cellular uptake of blood glucose. Additionally, the formulation exhibits properties of *Hypoglycaemic*, *Balya* (strength-promoting), and *Rasayana* (rejuvenative) drugs, showing beneficial effects not only in diabetic individuals but also in healthy volunteers.

## AIMS AND OBJECTIVE

The present work was undertaken with the following aims and objectives.

1. Conceptual and hypothetical evaluation of **Madhumeha (Diabetes mellitus, type-2), a form of Vataja Prameha**.
2. Pharmaceutical, Analytical and Clinical evaluation of an *Ayurvedic* compound “**500 mg DM Capsule**” in the management of **Madhumeha (Diabetes mellitus, type-2), a form of Vataja Prameha** and acting as a compound of Hypoglycaemic, Balya & Rasayana Drugs.

## MATERIAL AND METHODS

**Selection of Cases:** Patients with **Madhumeha (Diabetes mellitus, type-2), Vataja Prameha**, Loss of Energy (fatigue), body ache, sweet taste of mouth, burning sensation at sole, excessive hunger, excessive thirst, excessive mental stress and increased frequency of micturition, selected randomly from OPD of P.G Department of Rasa Shastra at Shri Krishna Govt Ayurvedic College Kurukshetra and its action as Vajikarak Balya & Rasayana.

### Age Group

130 Individual from the age group of 35 to 55 Years were taken for **Madhumeha (Diabetes mellitus, type-2), Vataja Prameha**, Loss of Energy (fatigue), body ache, sweet taste of mouth, burning sensation at sole, excessive hunger, excessive thirst, excessive mental stress and increased frequency of micturition.

### Selection of healthy volunteers

The observational clinical intervention took place from July 2024 to September 2024 at OPD of P.G Department of Rasa Shastra at Shri Krishna Govt Ayurvedic College Kurukshetra. The trial design involved the enrolment of volunteers aged between 25 to 60 Years without consideration of their religious affiliation, income level, or occupation. Initially, a total of 130 volunteers were screened for primary eligibility, but 20 individuals were subsequently excluded for various reasons.

Ultimately, **110 volunteers** were selected for the this trial and were randomly assigned to one particular group: that receiving **500 mg DM Capsule** for the **Madhumeha (Diabetes mellitus, type-2), Vataja Prameha**, Loss of Energy (fatigue), **Body Ache**, Sweet Taste of mouth, Burning Sensation at sole, Excessive Hunger, Excessive Thirst, Excessive Mental Stress and Increased frequency of micturition. Eligibility for participation in the study was determined by specific inclusion and exclusion criteria.

### **Inclusion criteria**

Male / female, married or unmarried patients suffering from **Madhumeha (Diabetes mellitus, type-2), Vataja Prameha**, Loss of Energy (fatigue), **Body Ache**, Sweet Taste of mouth, Burning Sensation at sole, Excessive Hunger, Excessive Thirst, Excessive Mental Stress and Increased frequency of Micturition.

Inclusion criteria involved clinically assessed healthy Male / female, married or unmarried patients aged between 25 to 50 Years, irrespective of their religious beliefs and income status.

These participants were required to be free from chronic, organic, or severe diseases and should not be taking any supplements or vitamins.

### **Exclusion criteria**

1. Age below 25 years and above 60 years.
2. Patients suffering from chronic, organic, or severe diseases and should not be taking any supplements or vitamins, carcinoma, acquired immunodeficiency syndrome, tuberculosis, congenital abnormalities of genital organs, other disease like phimosis, ulceration, hydrocele, spinal cord lesions, etc.

### **Investigations**

- Routine haematological investigations: Haemoglobin %, Total Leucocyte count, Differential Leucocyte count, Erythrocyte Sedimentation Rate.
- Biochemical investigations : Fasting Blood Sugar, Post Prandial Blood Sugar, lipid profile, blood urea, serum creatinine.
- Urine for routine sugar and microscopic examination.

**Assessment criteria:** Effect of the therapy will be assessed on the basis of improved status in **Madhumeha (Diabetes mellitus, type-2), Vataja Prameha**, Loss of Energy (fatigue), body ache, sweet taste of mouth, burning sensation at sole, excessive hunger, excessive thirst, excessive mental stress and increased frequency of micturition.

### DRUG DOSE DURATION

General contents of **500 mg DM Capsule** are mentioned below.

**Table 1: Ingredients of 500 mg DM Capsule.**

	Hindi or Sanskrit Name of Herb	Latin or English Name	Morpho-logical Part Used	Part Used	Each Capsules Contains	Reference Book Name
A.	Ama Haldi	Curcuma amada	Root	Powder	50 Mg	BPN
B.	Giloy	Tinospora cordifolius	Stem	Powder	50 Mg	BPN
C.	Safed Musli	Asparagus adscendens	Root	Powder	25 Mg	BPN
D.	Methi	Trigonella Foenum-graecum	Seed	Powder	50 Mg	BPN
E.	Neem	Azadirachta Indica	Leaves	Powder	50 Mg	BPN
F.	Karela	Momordica charantia	Fruit	Powder	50 Mg	BPN
G.	Jamun	Eugenia Jambolana	Seed	Powder	50 Mg	BPN
H.	Bilav Patr	Aegle Marmelos	Fruit	Powder	50 Mg	BPN
I.	Gudmar	Jymnema sylvetris	Leaves	Powder	50 Mg	BPN
	Minerals (Bhasma, Pishti etc.):					
J.	Shudh Shilajeet	Asphaltum Punjabinum	Ext		75 Mg	Rasa Ratan Samuchaya

**500 mg DM Capsule** is an Ayurvedic Patent Medicine Duly Approved by AYUSH department of Haryana and prepared in the R n' D Lab of NUTRILEY HEALTHCARE PRIVATE LIMITED Unit: Plot No. 16, Moja Patan, Near Arya Nagar, Hisar-125001 (Haryana) (INDIA) and marketed by same.

### Properties of herbs which formulate DM Capsule are said as below

Herb	Key Properties	Role in Managing Diabetes (Madhumeha)
<b>Ama Haldi</b> ( <i>Curcuma amada</i> )	Anti-inflammatory, antioxidant	Helps reduce insulin resistance and inflammation linked with diabetes.
<b>Giloy</b> ( <i>Tinospora cordifolia</i> )	Immunomodulator, anti-hyperglycemic	Enhances glucose metabolism, strengthens immunity, and reduces blood sugar levels.
<b>Safed Musli</b> ( <i>Chlorophytum borivilianum</i> )	Adaptogen, rejuvenative	Tones the body, reduces fatigue in diabetics, and improves strength and stamina.
<b>Methi (Fenugreek)</b> ( <i>Trigonella foenum-graecum</i> )	Hypoglycemic, rich in soluble fiber	Lowers blood sugar by slowing carbohydrate digestion and improving insulin sensitivity.
<b>Neem</b> ( <i>Azadirachta</i> )	Bitter, anti-diabetic,	Helps lower blood sugar, detoxifies the blood,



<i>indica</i> )	blood purifier	and enhances pancreatic function.
<b>Karela (Bitter gourd)</b> ( <i>Momordica charantia</i> )	Insulin-like peptides, hypoglycemic	Contains charantin and polypeptide-p which act like insulin and reduce blood glucose levels.
<b>Jamun (Java plum)</b> ( <i>Syzygium cumini</i> )	Astringent, hypoglycemic	Seeds especially reduce blood sugar and improve insulin sensitivity.
<b>Bilva Patra</b> ( <i>Aegle marmelos</i> )	Digestive, anti-diabetic	Helps regulate metabolism and lowers sugar levels naturally.
<b>Gudmar</b> ( <i>Gymnema sylvestre</i> )	Sugar destroyer, hypoglycemic	Reduces sugar absorption in the intestine and regenerates pancreatic beta cells.
<b>Shuddh Shilajeet</b> ( <i>Asphaltum</i> )	Rasayana, rejuvenator	Improves cellular glucose uptake, enhances stamina, and supports kidney function in diabetics.

### Treatment Plan

The following oral medicines were administrated for 15 days

1. **500 mg DM Capsule** with luke warm water twice a day before meal in morning and evening.
2. **No Sugar in meal**
3. **No Processed food, Fruits and rice in diet**
4. **Morning end event Vigorous walk or exercise twice a day for 30 minutes.**

After 15 days the following treatment schedule was followed:

1. **500 mg DM Capsule** with luke warm water twice a day before meal in morning and evening.
2. **No Sugar in meal**
3. **No Processed food, Fruits and rice in diet**
4. **Morning end event Vigorous walk or exercise twice a day for 30 minutes.**

After 30 days the following treatment schedule was followed

1. **500 mg DM Capsule** with luke warm water twice a day before meal in morning and evening.
2. **No Sugar in meal**
3. **No Processed food, Fruits and rice in diet**
4. **Morning end event Vigorous walk or exercise twice a day for 30 minutes.**
5. **No rice in diet**
6. **Vigorous walk or exercise twice a day for 45 minutes**

After 45 days the following treatment schedule was followed

1. **500 mg DM Capsule** with luke warm water twice a day before meal in morning and evening.
2. **No Sugar in meal**
3. **No Processed food, Fruits and rice in diet**
4. **Morning end event Vigorous walk or exercise twice a day for 30 minutes.**

In addition to the prescribed medication, patients were advised to engage in a daily outdoor walk for 45 minutes, avoid *Divaswapna* (daytime sleeping), and incorporate a protein-rich diet in breakfast and other meals. During the first follow-up on the 15th day, patients reported noticeable relief in presenting symptoms, with a 25–30% improvement observed in body ache, sleep quality, thirst, hunger, and reduced frequency of micturition. By the second follow-up on the 30th day, symptomatic relief had further improved, with 35–45% reduction in the aforementioned complaints. At the third follow-up (45th day), patients reported feeling lighter and more energetic in their daily routines, along with reduced mental stress and burning sensation in the feet—amounting to an overall improvement of 45–55%. On the final follow-up (60th day), following minor adjustments in medication, none of the earlier symptoms reappeared. Patients continued to feel energetic, with urinary frequency reduced to 0–1 times at night and 4–6 times during the day. Overall, a therapeutic improvement of approximately 60–75% was recorded.

At the baseline, the patient's biochemical parameters were as follows: Serum Creatinine – 0.9 mg/dL, Serum Cholesterol – 159 mg/dL, Serum Triglycerides – 191 mg/dL, VLDL – 15 mg/dL, HDL – 26 mg/dL, SGOT (AST) – 115 U/L, and SGPT (ALT) – 200 U/L. Following the administration of the therapeutic regimen, post-treatment investigations revealed notable improvements: Total Bilirubin – 0.8 mg/dL, Total Proteins – 7.0 g/dL, Alkaline Phosphatase – 218.7 IU/L, with SGOT and SGPT levels reduced to 57 U/L and 66 U/L respectively. Additionally, there was a marked improvement in subjective symptoms and clinical signs, accompanied by a significant reduction in both Fasting and Postprandial Blood Sugar levels, indicating positive hepatic response and glycemic control.

### Statistical analysis

The data collected from the two treatment groups at different intervals during the study were statistically analyzed using the paired Student's *t*-test to assess intra-group changes over time.



## RESULT

"Initially, all subjects were thoroughly examined in the OPD, and relevant biochemical investigations were conducted. Only those who met all inclusion criteria were enrolled in the study. During the screening phase, fasting blood glucose levels, renal function parameters (serum urea and creatinine), hepatic enzymes (ALT and AST), hematological values, and stool examinations were within normal limits, which was a prerequisite for inclusion. Clinical evaluation of the DM capsule's efficacy was carried out with respect to symptoms such as body ache, sweet taste in the mouth, burning sensation in the soles, excessive hunger, excessive thirst, heightened mental stress, and increased frequency of micturition."

The study demonstrated a statistically significant improvement ( $P < 0.001$ ) in several clinical symptoms. Notably, there was a 75.0% improvement in the habit of alcohol consumption and a 61.4% reduction in the sweet taste sensation in the mouth. Additionally, symptoms such as burning sensation in the soles, excessive hunger, excessive thirst, excessive mental stress, and increased frequency of micturition showed improvement ranging from 50.4% to 55.4%."

- The study revealed a significant ( $P < 0.001$ ) improvement in Fasting Blood Sugar.
- The study revealed a significant ( $P < 0.001$ ) improvement in Post Prandial blood Sugar.
- The study revealed a significant ( $P < 0.001$ ) improvement in overall associated signs and symptoms like body ache, sweet taste of mouth, burning sensation at sole, excessive hunger, excessive thirst, excessive mental stress and increased frequency of micturition.

This clinical improvement was accompanied by a significant reduction in fasting blood sugar, postprandial blood sugar, lipid profile parameters, blood urea, and serum creatinine levels following a 60-day regimen of **DM capsules**, administered at a dosage of 1–2 capsules twice daily, taken before meals in the morning and evening."

The overall health status of the subjects was confirmed through comprehensive evaluation of hematological and biochemical parameters. These assessments included fasting blood glucose, serum urea, creatinine, liver enzymes (ALT and AST), hemoglobin percentage (Hb%), total red blood cell (RBC) count, total and differential white blood cell (WBC) counts, RBC and WBC morphology, as well as erythrocyte sedimentation rate (ESR)."

### Treatment efficacy

During the course of the study, 20 subjects discontinued their participation at different stages due to various reasons. Consequently, their data were not included in the final analysis of treatment efficacy to ensure the accuracy and integrity of the results."

The administration of the **DM capsule** resulted in a marked increase in overall strength and vitality (Bala) among the subjects. According to Ayurvedic principles, the capsule first mobilizes the Kapha-related doshas from the affected sites (sthanas). It then acts locally to provide nourishing (Bruhana), strengthening (Balya), and aphrodisiac (Vajikarak) effects, thereby contributing to the restoration of physiological balance and improved health outcomes."

The medicine is believed to penetrate the minute channels (srotas) and eliminate the accumulated doshas. The Sneha (medicated oil or fat) reaches deep into these srotas, aiding in the relief of symptoms such as body ache, sweet taste in the mouth, burning sensation in the soles, excessive hunger, excessive thirst, mental stress, and increased frequency of micturition. Regular administration of the DM capsule was found to provide these therapeutic benefits effectively.

Regular use of the DM capsule facilitates the liquefaction and removal of doshas from the affected sites without causing tissue damage. This process ultimately enhances the efficiency of pancreatic beta cells and strengthens the muscles, improving glucose absorption. Rooted in Ayurveda, the ancient Indian system of medicine, the ingredients of the DM capsule are well-established in classical Ayurvedic texts such as the *Bhav Prakash Nighantu* and the *Ayurvedic Pharmacopeia of India*, reflecting their enduring significance in managing a wide range of health conditions.

### DISCUSSION

Madhumeha (Type 2 Diabetes Mellitus) is primarily a Vata-Kapha predominant tridoshaja disorder. It is broadly classified into Sahaja (congenital or type 1) and Apathyanimittaja (acquired or type 2) types. Various classical Ayurvedic texts describe additional subtypes such as Krisha, Dhatukshayajanya, and Apatarpanjanya, which correspond to Sahaja Madhumeha, whereas Sthula, Avaranjanya, and Santarpanjanya types align with Apathyanimittaja Madhumeha. The patients in this study were diagnosed with Apathyanimittaja Madhumeha (type 2 diabetes), necessitating therapeutic interventions targeting the key pathological

components including meda dhatu (adipose tissue), kleda (bodily moisture), kapha dosha, and meda dhatvagni (metabolic fire of fat tissue). Therefore, drugs possessing deepana (appetizer), pachana (digestive), lekhana (scraping), vata-kaphahara (pacifying Vata and Kapha), and medohara (anti-lipogenic) properties are essential for effective management.

The *Bhav Prakash Nighantu* lists several herbs and mineral preparations under the *Prameha Chikitsa Adhyaya*<sup>[8]</sup> which are recognized for their potent anti-diabetic properties<sup>[9]</sup> The efficacy of this formulation likely results from the synergistic effects of its diverse ingredients. It balances the three doshas—Vata, Pitta, and Kapha—due to the presence of classical Ayurvedic components such as Praval Pishti, Ras Sindoor, Mukta Pishti, Abhrak Bhasma, Swarna Bhasma, Rajat Bhasma, Loha Bhasma, Naga Bhasma, Vanga Bhasma, along with herbs like Vasa, Haldi, Ikshu, Kadali, Kamal, Chameli, Shatavari, and Chandan. Among these, Trivanga Bhasma, an Ayurvedic preparation comprising Lead, Zinc, and Tin, is well documented for its anti-diabetic effects both in classical texts and contemporary research.<sup>[10,11]</sup> Similarly, Guduchi (*Tinospora cordifolia*) has been extensively studied and confirmed to exhibit significant anti-diabetic and hypoglycemic activities.<sup>[12,15]</sup>

Furthermore, the combination of herbs such as Ama Haldi (*Curcuma amada*), Giloy (*Tinospora cordifolia*), Safed Musli (*Chlorophytum borivillianum*), Methi (*Trigonella foenum-graecum*), Neem (*Azadirachta indica*), Karela (*Momordica charantia*), Jamun (*Syzygium cumini*), Bilva Patra (*Aegle marmelos*), Gudmar (*Gymnema sylvestre*), and Shuddh Shilajeet (Asphaltum) of **DM Capsule** collectively contribute to the antihyperglycemic activity of the formulation. These ingredients of the DM capsule, provide a comprehensive approach to managing Diabetes mellitus through their well-established anti-diabetic and hypoglycemic properties.

## CONCLUSION

Madhumeha (Type 2 Diabetes Mellitus) is a complex, multifactorial condition often referred to as a silent killer, necessitating early intervention to prevent serious complications. Based on the findings of this study, it can be concluded that effective management of Madhumeha can be achieved through the appropriate administration of the **DM capsule**, combined with adherence to recommended dietary guidelines and lifestyle modifications. **DM capsule** demonstrated significant efficacy, with elevated blood glucose levels reducing to the pre-diabetic range **within 15 days** of treatment initiation, and reaching normal levels by 30 days.

Future research involving a larger population is warranted to further validate the therapeutic potential of the **DM capsule** in the management of Madhumeha.

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