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Research on Antidiabetic Sublingual Tablet

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Abstract: *Concrete is a widely used construction material for various types of structure due to its structural stability and strength. The ordinary Portland cement is one of the main ingredients used for the production of concrete and has no alternative in the civil construction industry. Sustainable energy and cost saving can result when industrial by-products are used as a partial replacement of cement. Wollastonite increases the performance of products like polymers, plastics, paints and coatings, construction materials, friction devices, ceramic, etc. It also been employed for metallurgical applications. Wollastonite powder is used in numerous mixtures which can be replaced at from 0% to 18% through weight of cement in concrete and constant percentage of jute fiber. After curing period of 28 days, it is checked for its compressive strength, flexural strength test and durability test are taken. These are in comparison with a normal mixture which is 0% of wollastonite powder and constant percentage of jute fiber determine the best combination of replacing the material.*

Keywords: Wollastonite Powder, OPC, Concrete, Compressive Strength, Flexural Strength

I. INTRODUCTION

DIABETES

Diabetes mellitus, commonly referred to as diabetes, is a condition in which the body either does not produce enough insulin or cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar levels, and high blood sugar can lead to issues in various parts of the body.

Diabetes mellitus is a metabolic disorder characterized by abnormally high blood sugar levels. The primary subtypes of diabetes mellitus are type 1 and type 2, which typically arise from impaired insulin secretion or action.

T1DM is characterized by the destruction of beta cells in the pancreas, typically secondary to an autoimmune process. The result is the absolute destruction of beta cells, and consequentially, insulin is absent or extremely low.

T2DM involves a more insidious onset where an imbalance between insulin levels and insulin sensitivity causes a functional deficit of insulin. Insulin resistance is multifactorial but commonly develops from obesity and aging.

1.1 TYPES OF DIABETES MELLITUS

Type 1 diabetes often develops in children and is also referred to as juvenile-onset diabetes mellitus or insulin-dependent diabetes mellitus. In this condition, the pancreas produces little to no insulin, requiring lifelong insulin injections. Type 2 diabetes, which is more common, usually occurs in people over 40 and is called adult onset diabetes mellitus. It is also called non-insulin-dependent diabetes mellitus. In Type 2, your pancreas makes insulin, but your body does not use it properly. The high blood sugar level often can be controlled by following a diet and/or taking medication, although some patients must take insulin. Type 2 diabetes mellitus is defined by insulin resistance, often accompanied by a relative decrease in insulin secretion. The body's tissues do not respond properly to insulin, likely due to issues with the insulin receptor, although the exact defects remain unclear. Cases of diabetes linked to a known defect are classified separately. Type 2 diabetes is the most prevalent form of the disease.

In the early stage of type 2 diabetes, the primary issue is decreased insulin sensitivity. During this phase, hyperglycemia can be reversed through various treatments and medications that enhance insulin sensitivity or decrease glucose production in the liver.

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1.2 SYMPTOMS

Diabetes symptoms vary depending on how much your blood sugar is elevated. Some people, especially those with prediabetes or type 2 diabetes, may not experience symptoms initially. In type 1 diabetes, symptoms tend to come on quickly and be more severe.

The following are the symptoms of diabetes mellitus

- Frequent urination
- Blurred vision
- Weight loss
- Weakness
- Excessive thirst
- Slower rate in healing of sores
- Increased Fatigue
- Numbness And Tingling Especially In Your Feet And Hands
- Slow Healing Sores
- Red, Swollen ,Tender Gums
- Skin Itchy Irritability

1.3 CAUSES

- Genetics play a role in increasing the likelihood of developing diabetes, and it often runs in families.
- Obesity: Excess weight and abdominal fat can cause insulin resistance, which is a major trigger for type 2 diabetes.
- Physical inactivity: Insufficient physical activity can increase the likelihood of developing type 2 diabetes.
- High blood pressure: Elevated blood pressure is another risk factor for developing diabetes.
- HIV/AIDS: Chronic inflammation from HIV and the use of HAART medications can raise the risk of developing diabetes.
- Autoimmune disease: Autoimmune disorders can contribute to the development of diabetes.
- Hormonal imbalances: Disruptions in hormone levels can lead to the development of diabetes.

II. LITARATURE REVIEW

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Content: Concentrated pomegranate juice improves lipid profiles in diabetic patients with hyperlipidemia.

2. Tang S, Fang C, Liu Y, Tang L, Xu Y. Anti-obesity and Anti-diabetic Effect of Ursolic Acid against Streptozotocin/High Fat Induced Obese in Diabetic Rats. J Oleo Sci. 2022 Feb 3;71(2):289-300. doi: 10.5650/jos.ess21258. Epub 2022 Jan 14. PMID: 35034940. formulation and evaluation of pomegranate peel antidiabetic sublingual tablet

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3. Abdul-Ghani MA, Tripathy D, DeFronzo RA. Contributions of β-cell dysfunction and insulin resistance to the pathogenesis of impaired glucose tolerance and impaired fasting glucose. Diabetes care 2006;29:1130–9 Content : Lack of first phase insulin secretion during oral glucose tolerance test [OGTT] in Type 2 Diabetes Mellitus (DM) is attributed to glucose toxicity.

Early postprandial Insulin secretion: Its relation to Insulin sensitivity

4. Harakeh S, Almuhayawi M, Jaouni SA, Almasaudi S, Hassan S, Amri TA, Azhar N, AbdAllah E, Ali S, El-Shitany N, Mousa SA. Antidiabetic effects of novel ellagic acid nano formulation: Insulin-secreting and anti-apoptosis effects. Saudi J Biol Sci. 2020 Dec;27(12):3474-3480. doi: 10.1016/j.sjbs.2020.09.060. Epub 2020 Oct 9. PMID: 33304158; PMCID: PMC7715050. formulation and evaluation of antidiabetic sublingual tablet

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Content: Antioxidants are one of the effective treatment lines in managing type 2 diabetes (type2diabetic) and its complications.

5. Guo, Y.; Baldelli, A.; Singh, A.; Fathordoobady, F.; Kitts, D.; Pratap-Singh, Production of high loading insulin nanoparticles suitable for oral delivery by spray drying and freeze drying techniques. Sci. Rep. 2022, 12, 9949. [Google Scholar] [CrossRe]

Content :Insulin nanoparticles (NPs) with high loading content have found diverse applications in different dosage forms.

III. POMEGRANATE PEEL

Punica granatum Linn., commonly known as pomegranate, belongs to the Punicaceae family. According to Unani literature, pomegranate—particularly its flowers and peel—has traditionally been used for the management of diabetes mellitus. Recent studies have shown that various parts of the pomegranate, especially the peel and fruit, exhibit hypoglycemic activity. These parts possess functional properties such as anti-diabetic, antioxidant, and anti-inflammatory effects.

Pomegranate peel, a highly nutritive byproduct of the fruit, is widely recognized for its medicinal value in managing diabetes. It is a rich source of bioactive compounds, including flavonoids, polyphenols, ellagitannins, and other components such as gallic acid, ellagic acid, punicalagin, punicalin, luteolin, quercetin, kaempferol, and various glycosides like pedunculagin. It also contains essential minerals such as calcium, phosphorus, nitrogen, potassium, magnesium, and sodium, along with a composite of polysaccharides.

Phenolic compounds in pomegranate, such as oleanolic acid, ursolic acid, and gallic acid, contribute to its anti-diabetic properties. Pomegranate peel has been shown to increase α-amylase activity, reduce blood insulin levels, and modulate serum glucose levels. Its phenolic content helps reduce glucose absorption in the gut and affects glycemic control through multiple mechanisms.

3.1 MECHANISM OF ACTION

One of the primary mechanisms through which pomegranate fractions help manage type 2 diabetes is by reducing oxidative stress and lipid peroxidation.

This effect mitigates the harmful impact of reactive oxygen species (ROS), ,proinflammatory cytokines, and radiation. Pomegranate also enhances the activity of certain antioxidant enzymes, exhibits metal-chelating properties, reduces resistin formation, and modulates key transcription factors such as nuclear factor κB (NFκB) and peroxisome proliferator-activated receptor γ.

3.2 PARTS POMEGRANATE

Table- 1 Plant Description

Part of plant	Chemical constituent	Pharmacological Activity
Fruit	Polyphenols,ellagitannins,vitamin c, pottasium organic acid	Anti diabetic , Anti malaria , Anti fungal, Anti bacterial
Leaves	Tannins, flavanoids,anthacyanin and poly phenols	Anti inflammantory, Anti cancer, Anti angiagenesis
Stem	Polyphenol,flavanoid punicalagin	Anti Diabetics, Anti tumor, Anti fungal
Root	Punicalagins, ellagic acids, punicic acid ,tannins, gallic acid,	Anti oxidant, Anti tumor,
Peel	Gallic acid,ellagic acid, tannins ,anthacyannins	Antiinflammatory, cardioprotective,. Antidaibetes

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3.3 SUBLUNGAL

Punicalagin, a major polyphenol found in pomegranate, has been shown to enhance insulin secretion from a β-cell tumor line, an effect comparable to the activity of the enzyme paraoxonase 1 (PON1). Additionally, both punicic acid and pomegranate peel extract significantly reduce fasting blood glucose levels.

Several bioactive compounds present in pomegranate—such as punicalagin, ellagic acid, gallic acid, oleanolic acid, ursolic acid, and uallic acid—have been recognized for their potent anti-diabetic properties.

Sublingual drug delivery involves administering medication under the tongue, allowing the drug to be directly absorbed into the bloodstream through the floor of the mouth and the underside of the tongue. The primary mechanism for drug retention in the oral mucosa is passive diffusion into the lipoidal layer. Drug absorption through the sublingual route is three to ten times more efficient than oral administration, with only hypodermic injection providing faster absorption. Typically, the small amount of saliva present in the oral cavity is sufficient to disintegrate the tablet and facilitate drug release.

This method of drug delivery offers several advantages over both enteral and parenteral routes, including a rich blood supply, rapid onset of action, improved bioavailability, and greater patient compliance and ease of self-administration. Over time, numerous pharmaceutical products utilizing oral mucosal drug delivery have been developed and introduced to the market.

If a material can efficiently decompose in saliva, it may be suitable for sublingual administration. Vaporizers and powders can also utilize this delivery method.

However, several factors—such as pH, molecular weight, and lipid solubility— play a crucial role in determining its feasibility. Even if a drug is adequately soluble, it may still diffuse too slowly through the mucosa to be effective. Despite this, many medications show significantly improved performance when administered sublingually, and this route is generally considered safer than drug delivery through the nasal mucosa.

3.4 Plant Material Collection

Pomegranate fruits were first collected, then peeled and dried using a simple process. The fruits were washed thoroughly with filtered water and air-dried at room temperature for about ten minutes. The peel was carefully removed using a knife and subsequently dried material was then passed through sieves numbered 44, 60 to separate it into different particle size fractions for further preformulation studies.

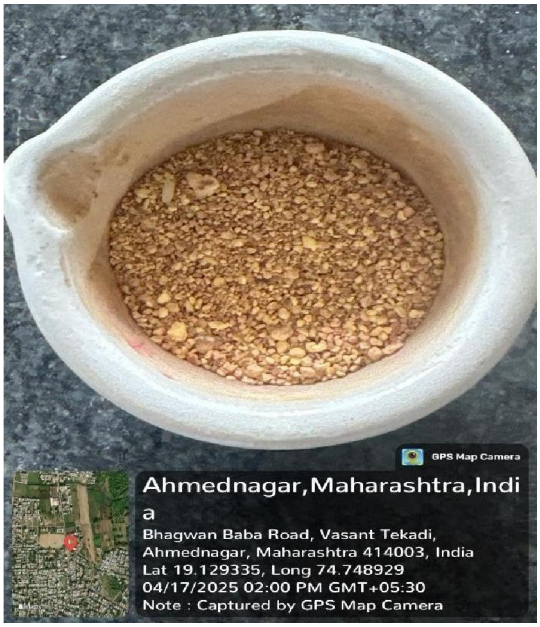

Fig 1 : Dried powder of Pomegranate peel

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IV. INGREDIENTS

1) Pomegranate

Fig 2 : Pomegranate Synonym- Punica Granatum, Anar

Biological source- It is the riped fruit of plant Punica granatum belonging to punicaceae family.
Family- Punicaceae

Chemical constituents –
Punica granatum peel contain tannins, flavonoids, pectin, 3-estrogen compounds luetolin, quercitin & kemferol. Antioxidant & antidiabetic activity shown by the peel extract stimulation of beta-cells, protection of pancreas, increase the no of beta- cells & subsequent release of insulin it also reduce the blood sugar through regeneration of beta-cells pomegranate also contain other compounds with anti- diabetic actions including punicalagin, punicalin, gallic acid, ellagic acid, oleanolic acid, ursolic acid and uallic acid.

2. Sodium starch glycolate:
Sodium starch glycolate is a superdisintegrant used to promote the rapid disintegration and dissolution of immediate-release (IR) solid dosage forms. It is the sodium salt of carboxymethyl ether of starch. Superdisintegrants are substances that facilitate faster disintegration in smaller quantities compared to conventional disintegrants. Sodium starch glycolate is a naturally derived material that can be used in tablet and capsule formulations as a disintegrant, binder, and diluent. It rapidly absorbs water, causing the particles to swell, which leads to quick disintegration of tablets and granules.

3. STARCH
Synonym: Amylum.
Biological Source: Starch consists of polysaccharide granules obtained from the grains of maize (Zea mays Linn); rice (Orzya sativa Linn); or wheat (Triticum aestivum Linn); belonging to family Gramineae or from the tubers of potato (Solanum tuberosum Linn.).
Family: Solanaceae.
Chemical Constituents:
Starch contains chemically two different polysaccharides, such as amylose (β- amylose) and amylopectin (α- amylose), in the proportion of 1:2.
Binder: Starch can act as a binder to hold the active pharmaceutical ingredients and other excipients together. This is crucial for sublingual tablet, as they need to dissolve or disintegrate rapidly in the saliva under tongue.

4. ACACIA
Synonym : Gum acacia, gum Arabic, acacia
Biological source: Indian gum is the dried gummy exudation obtained from the stem and branches of Acacia Arabica belonging to family :Leguminosae.

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Family- Leguminosae
Thickening Agent: Acacia gum can contribute to the viscosity of the tablet. Formulation, providing a suitable consistency for processing and ensuring uniform distribution of the API and other excipients.

5. Menthol powder Synonyms- Mint
Biological source- It is the dried leaves obtained from the plant Mentha Piperita.
Family- Lamiaceae
Flavouring: Mint powder can add a refreshing flavor to sublingual tablets, enhancing the overall taste experience for the patient.
Cooling Sensation: Mint powder can impart a cooling sensation in the mouth, which can be soothing for some patients, especially if the tablet is intended to relieve symptoms like sore throat or mouth irritation.

6. Microcrystalline cellulose (MCC)
Microcrystalline cellulose (MCC) adds bulk to tablet formulations without significantly increasing overall weight, making it ideal for producing tablets of suitable size and shape for sublingual administration. Additionally, MCC enhances the flow properties of the tablet blend during manufacturing, ensuring uniform ingredient distribution and consistent tablet weight.

4.1 FORMULATION TABLE :

Sr. No.	EXCIPIENT	QUANTITY TAKEN	USES
1.	Pomegranate	10 gm	API
2.	Sodium starch glycolate	0.6 gm	Super disintigrant
3.	Starch paste	q.s	Binder
4.	Acacia	0.8 gm	Thickening agent
5.	Menthol	0.4 gm	Cooling agent
6.	Microcrystalline cellulose (MCC)	1 gm	Diluent

Fig 3 : INGREDIENTS

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4.2 Procedure

Accurately weighed quantity of API and all excipient(sodium starch glycolate ,menthol, microcrysalline cellulose) and mix with mortar and pestle as per formula.

↓

In the above mixture a solution of binder (starch paste) was added to make a lump mass.

↓

This lump mass was screened using sieve with the suitable equipment and forms granules.

↓

Then these granules ware dried in hot air oven at 60 .

↓

After drying the granules ware screened through a sieve to get uniform sized granules

↓

These granules mixed with lubricant in it and also preservative .

↓

Compresed this into a punching machine to gate proper shape and size of the tablet .

Fig. Compress Tablet

V. EVALUATION PARAMETER

5.1 PRE- FORMULATION STUDIES:

Bulk Density:- Weighed quantity of tablet blend was transferred into 100ml measuring cylinder without tapping during transfer. The volume occupied by drug was measured. Bulk density was calculated and found 0.44gm/ml

$$\text{Bulk Density} = \frac{Weight\ of\ granules}{Bulk\ volume\ of\ granules}$$

= 23/52

= 0.44gm/ml

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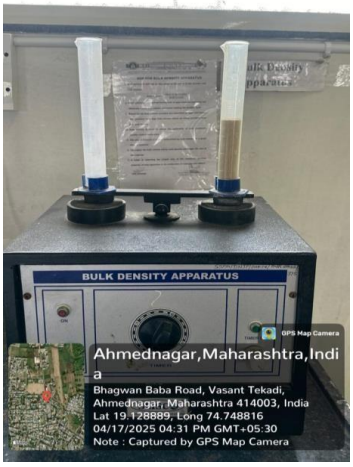

Fig 5: Bulk Density

Tapped Density:- Weighed accurate quantity of powder sample was into a graduated cylinder. Volume occupied by the drug was noted down. Then cylinder was subjected to 100, 200 & 300 taps in tap density apparatus.
The experiment was performed in triplicate and tapped density was calculated and was found 0.52kg/m3

$$\text{Tapped Density} = \frac{Weight\ of\ gra}{Volume\ of\ granules\ c}$$

$$= 23/44 = 0.52 \text{ gm/ml}$$

Fig 6: Tapped Density

Carr's Index:- The compressibility index and Hauser"s ratio was measured and found within the range of 15-20 %

$$\text{Carr"s Index} = \frac{Tapped\ density - Bulk}{Tapped\ densit}$$

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$= \frac{52 \times 0.44}{0.52} \times 100$

$= 15.38\ \%$

Hausners Ratio:- Hausners Ratio was calculated and was within the specified limit and found within the range of 1.10-1.18

Hausner"s Ratio= $\frac{Tapped\ density}{Bluk\ density}$

$= 0.52/0.44$

$= 1.18$

Angle of Repose:- Weighed quantity of the powder sample was passed through a funnel kept at a height 2cm from the base. The powder was passed till it forms a heap and touches the tip of the funnel. The angle of repose was calculated and found within the range and having good flow property

Angle of repose= $\boldsymbol{\tan \theta}$ = h/r

D1=8.4cm, D2=8.4cm, D3=8cm, D4=7.8cm

Radius= $diametr/2$ = 4.2cm

R2= 4.2cm

R3 = 4 cm

R4= 3.9 cm

Average of radius = $\boldsymbol{R1+R2+R3+R4\ /4 = 4.2+4.2+4+3.9\ /\ 4 =}$ 4.07 cm

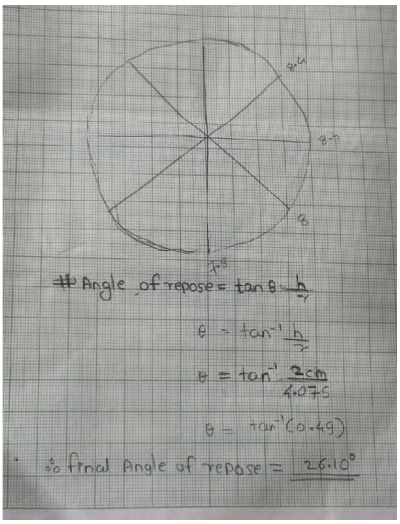

Fig 7 : angle of repose

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Angle of repose is 26.10°

5.2 Post-formulation studies-

Hardness Test

Tablets require certain amount of strength or hardness, to with stand mechanical shocks of handling in manufacture, packaging and shipping. The most widely used apparatus to measure tablets hardness (strength) is the pifzer hardness tester.

The hardness test of the sublingual tablets was found to be 3.4 kg/cm 2 using hardness tester apparatus. The hardness was measured by using hardness tester.

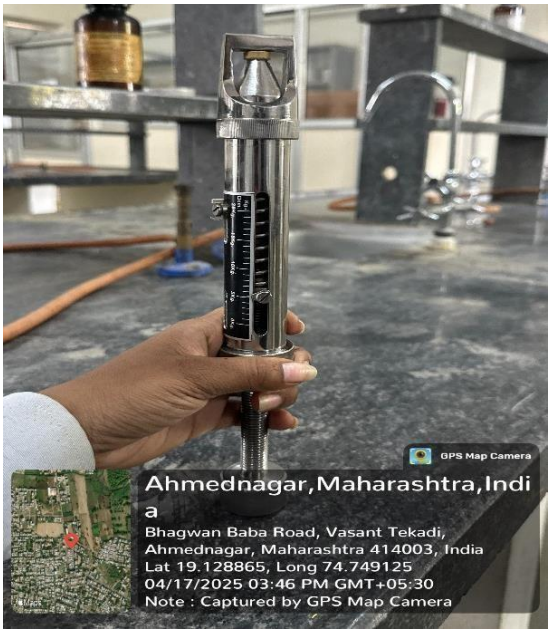

Fig 8 : Hardness Test

Friability Test :-

Friability can be evaluated by means of Roche friability test apparatus.Friability is related to the ability of tablets to withstand both shocks and abrasion without crumbling during manufacturing, packing, transportation and consumer handling. Friability can be evaluated by means of Roche friability test apparatus.

compressed tablets that loose less than 0.5% to 1.0% in weight generally considered as acceptable.

$$formula = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

1 tablet =0.2%
2 tablet =0.2%
3 tablet =0.7%
4 tablet =0.5%

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Fig 9: Friability Test

Disintegration Test :- In vitro disintegration time was measured using disintegration apparatus. The sublingual tablets was dissolve excellent in disintegration time period (75sec).

In vitro disintegration time was measured using USP disintegration test apparatus for DT test randomly one tablets were selected from each batch and test was performed in 900 ml distilled water 35°c to 37°c temperature .

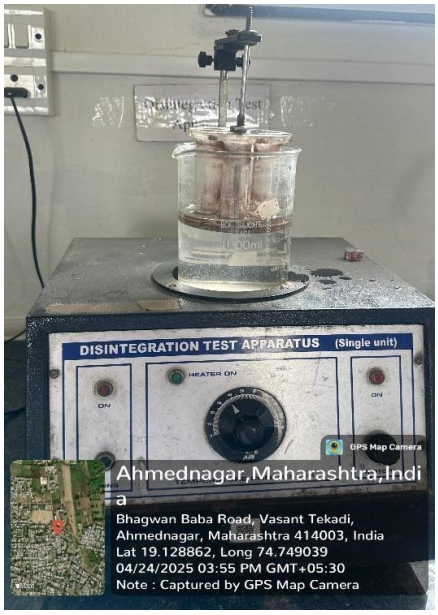

Fig 10: Disintegration Test

Thickness Test:- To determine the uniformity and physical dimension of tablets thickness is measured by Micrometer screw gauge for randomly selected 10 tablets from formuation.

The thikkness test of the sublingual tablets was found to be 3.1mm.

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Fig 11: Thickness Test

VI. RESULT

Sr.no	Test	Observation	conclusion
1	Angle of repose	29.03°	Good
2	Bulk density	0.44gm/ml	-
3	Tapped density	0.52gm/ml	-
4	Carrs index	15.38%	Good
5	Hausner ratio	1.18	Excellent

Table 7- Post compression study-

Sr.No	Parameter	Result
1	General Apperance Colour - Odour - Size – Shape-	Yellowish Characteristics Length=1 cm Width= 0.4 cm Circular
2	Average weight	400 mg
3	Hardness test	3.4kg/cm^2
4	Friability test	0.5 to 1 %
5	Disintegration test	75 sec.
6	Thickness test	3.1mm

VII. FUTURE PROSPECTS

Overall, the future prospects of sublingual antidiabetic tablets are promising, with potential advancements in drug formulation, delivery technology, and personalized medicine offering opportunities to enhance efficacy, safety, and patient adherence in diabetes management. Different agents can be used in the formulation , long term studies , preclinical studies and clinical trials can also be possible in this work yields encouraging results.

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n the wake of the sustained advancement of pharmaceutical techniques and innovative drug administration system, numerous delivery methods have been explored researchers. This formulation can also be incorporated in different suitable dosage forms such as buccal tablet, fast dissolving tablet, etc.

VIII. CONCLUSION

The formulation approach adopted in this study proved to be both suitable and practical for achieving the desired objective of managing diabetes. The excipients used were inexpensive, readily available, and mostly water-soluble, contributing to improved patient acceptability. The present work involved the development of sublingual tablets containing phenolic compounds, glycosides, and saponins—phytoconstituents known for their antidiabetic activity. This formulation offers a cost-effective solution with enhanced patient compliance and therapeutic efficacy.

The study indicated that excipients such as microcrystalline cellulose, aloe vera, mint, sodium starch glycolate, acacia, and starch paste were ideal for formulating sublingual tablets. Sublingual tablets offer several advantages, particularly for children and elderly patients, as they enable rapid absorption into the systemic circulation within a short time. Among the various formulations, batch F3 was found to be the most effective, demonstrating optimal disintegration time and satisfactory hardness, making it the preferred choice.

Thus, it can be concluded that the growing demand for herbal formulations is steadily increasing due to their safety and effectiveness. A key advantage of this formulation is its rapid onset of action through absorption into the bloodstream, bypassing first-pass metabolism and thereby enhancing therapeutic efficacy.

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