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Research Article

Formulation And Evaluation of Polyherbal Antidiabetic Tablet

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ABSTRACT

The Present Investigation was aimed to formulate and evaluate Polyherbal antidiabetic tablet. The crude drugs used in this study were Fenungreek, Jamun, Gurmar for the effective formulation, and the prepared granules was evaluated for pre-compression parameter. Then the formulated tablet was evaluated for the post compression studies. The tablet was evaluated for official and non-official tests. The tablet shows instantaneous drug release due to compressed tablet. So, novel antidiabetic formulation ensuring quality, safety and efficacy was developed using traditional herbs

INTRODUCTION

According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drug or a mixture of drugs, with or without diluents. Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. They vary in shape and differ greatly in size and weight, depending on number of medicinal substances and the intended mode of administration.[1]

Use of Tablet formulation-

1. Appropriate for any patient of different ages
2. The most natural and easiest route of administration
3. Economical and safe to the patient
4. No nursing is required, which means the patient can take it with no help

Advantages of tablets:

1. Tablets are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.
2. They are easiest and cheapest to package and strip
3. Low in cost
4. Lighter and compact

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5. Having greatest chemical and microbial stability over all oral dosage

Disadvantages of tablets:

1. Difficult to swallow in case of children and unconscious patients.
2. Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.
3. Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet that will still provide adequate or full drug bioavailability.
4. Bitter testing drugs, drug with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.
5. Irritant effects on the GI mucosa by some solids. [2,3]

Types of tablets-

1. Conventional tablets
2. Chewable tablets
3. Effervescent tablets
4. Sublingual and buccal tablets
5. Extended-release tablets
6. Disintegrating tablets
7. Coated tablet [4]

Diabetes mellitus-

Diabetes mellitus (DM) is defined by serious higher glucose levels occurring due to abnormalities in the production of insulin, or insulin resistance also some individuals can have both responses. Diabetes affects roughly 29.1 million people each year and is the 7th largest death in US obtained to report CDC. It will be one of the primary causes of mortality in 2030, according to the WHO, with a death rate doubling between 2005 and 2030. Diabetes can be diagnosed by the signs and symptoms with elevated blood glucose levels and weight loss. The most recommended methods to detect diabetes mellitus is based upon the level of glucose in blood.

- Fasting plasma glucose: 126 mg/dl
- Random plasma glucose: 200 mg/dl
- Oral glucose tolerance test: > 200 mg/dl

Diabetes is the third leading disease to cause death in the most developed countries and it is considered to be a major health problem. [4,6]

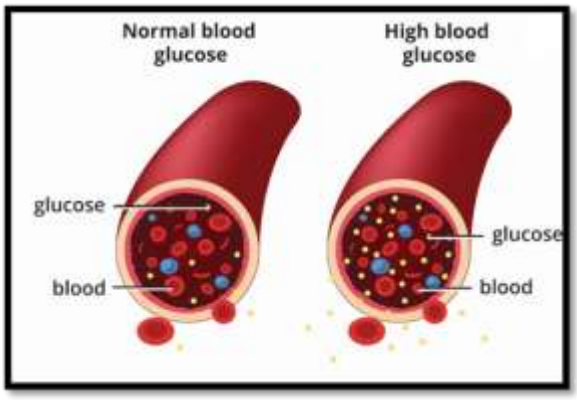


Fig.No.01 Glucose level In Blood

Chronic hyperglycemia of diabetes is associated with long term damage, Dysfunction and failure of various organ specially the eyes, Kidney, nerves, heart and blood vessels. Diabetic mellitus is occurring due to alteration of metabolism of carbohydrate, lipid and proteins. In this preparation of tablet, we were selected three herbal drugs such as Fenungreek, Jamun and Gurmar. [7]

Types of Diabetic mellitus:

1. **Type 1:** Insulin dependent diabetic mellitus
2. **Type 2:** Non-Insulin dependent Diabetic mellitus
3. Gestational Diabetic mellitus

1. **Type 1**:

About 5 % of total diabetic patients come under the category of type 1. This type of diabetic mellitus is occurred due to autoimmune disease of beta cell. Due to the destruction of beta cells of pancreas the circulation of insulin in blood is not regulated. They are occurring in between the age of 30 years. In that the beta cells fail to respond to normal stimuli. This is an auto immune type system and limits or completely eliminates the production and secretion of insulin.

2. **Type 2:**

About 90 to 95 % of the patients belong to this group. This type of diabetic mellitus is not depended on the insulin. Obesity is the major cause of this type of diabetic mellitus. In that the beta cell count are decrease. This type of diabetic is occurring in age onward 40 years.

3. **Gestational diabetic mellitus:**

Gestational diabetes mellitus is defined as "a kind of glucose intolerance that develops in the second and third trimesters of pregnancy, resulting in hyperglycemia of varying severity" It affects 4 % of all pregnant women and retrieves back to normal glucose after the delivery. [8,9]

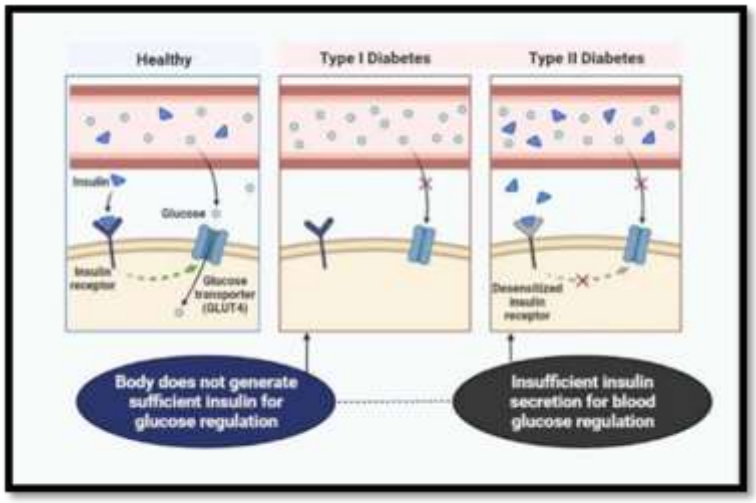


Fig. No. 02 Types of Diabetes

Symptoms of diabetes mellitus:

1. Feeling more thirsty than usual
2. Urinating often
3. Losing weight without trying
4. Presence of ketones in the urine
5. Feeling tired and weak
6. Having blurry vision
7. Having slow healing sores [10]

Antidiabetic Herbs-

1. **Fenungreek [*Trigonella Foenum Gracum*]**

Biological source of fenugreek is the dried seeds of the plant Trigonella foenum-graecum belonging to family Fabaceae. Fenugreek seeds, commonly used in India and other countries as a condiment, are an excellent source of dietary fiber and hence, area advantageous in the context of diabetes. The soluble dietary fiber (sdf) fraction of fenugreek seeds has been shown to reduce post-prandial elevation in blood glucose level of type-2 diabetic rats by delaying the digestion.

Mechanism of action:

fenugreek seeds act as an antidiabetic agent may be achieved via activating of insulin synthesis and its releasing from the pancreatic β-cells. Moreover, a clinical study showed that the antidiabetic effect of fenugreek was through increasing of insulin sensitivity of sucrose. During studies on the effect of fenugreek seeds and leaves on blood glucose and serum insulin responses in diabetic subjects observed a significant reduction in serum cholesterol levels after fenugreek seed therapy for 3 weeks. [11,12]

Fig. No.03 ***Trigonella Foenum Gracum***

2. Gurmar ***[Gymnema sylvestre]***

The biological source of gurmar is dried leaves of *Gymnema sylvestre.* plant *Gymnema sylvestre* belonging to the family Asclepiadaceae, and widely distributed in India, Malaysia, Srilanka, Australia, Indonesia, Japan, Vietnam, tropical Africa and the southwestern region of the People's Republic of China. The plant is commonly known as Periploca of the woods (English); Gurmar (Hindi); Meshashringi, madhunashini (Sanskrit); Kavali, kalikardori (Marathi). G. Sylvester leaves have been found to cause hypoglycemia in laboratory animals and shown a use of Sylvester leaves in herbal medicine to treat diabetes mellitus in adults. When leaf extract of plant, administered to a diabetic patient, there is stimulation of the pancreas by virtue of which there is an increase in insulin release. These compounds have also been found to increase fecal excretion of cholesterol.

Mechanism of action:

It promotes regeneration of islet cells, it increases secretion of insulin, it causes inhibition of glucose absorption from intestine, it increases utilization of glucose as it increases the activities of enzymes responsible for utilization of glucose by insulin-dependent pathways, an increase in phosphorylase activity, decrease in gluconeogenic enzymes and sorbitol dehydrogenase. [13,14]

Fig.No.04 ***Gymnema Sylvestre***

3. Jamun[***Syzygium cumini]***

Biological source of jamun is dried seeds of plant *Syzygium cumini* belonging to Myrtaceae family. The Jamun tree is a tropical evergreen blooming plant. It has been used for a long time in Indian and other traditional medicines across the world. Jamun contains many active phytochemicals, including alkaloids, anthraquinones, catechins, cardiac glycosides, flavonoids, glycosides, steroids, phenols, tannins, and saponins. Jamun includes an essential glycoside called Jambolin, which inhibits starch from being converted into sugar and so aids in blood sugar regulation. Jamun may help lower blood sugar levels by reducing free radicals and improving the function of pancreatic

beta-cells. It may also reduce the activity of alpha-amylase, which is elevated in diabetes.

Mechanism of action:

Insulin Secretion: Jamun's seeds, leaves, and fruits contain compounds that stimulate insulin release from pancreatic β-cells. Insulin Sensitization: Jamun's polyphenols, flavonoids, and anthocyanins enhance insulin sensitivity by activating insulin receptors and glucose transporters.

Glucose Uptake: Jamun's compounds increase glucose uptake in muscles and adipose tissue, reducing blood glucose levels. Glycogen Synthesis: Jamun's extracts stimulate glycogen synthesis in the liver, reducing blood glucose levels. [15,16]

Fig.No.05 *Syzygium cumini*

MATERIALS AND METHODS:

Materials:

- **Drugs-** Fenungreek, Gurmar, Jamun.
- **Excipients-** Lactose, Starch, Talc, Magnesium stearate.

Apparatus:

1. Beaker
2. Measuring cylinder
3. Dropper
4. Glass rod
5. Mortar and Pestle
6. Filter paper
7. Funnel

Method:

For the preparation of tablet, we are going to use Wet granulation technique. Wet granulation is a method of tablet manufacturing where powders are mixed with a liquid binder to form granules, which are then dried and compressed into tablets. It's a widely used technique, especially when powders have poor flow or compressibility. [17]

Formulation of tablet:

1. The herbal antidiabetic tablet was prepared by using wet granulation method.
2. In this method the solvent is used for the preparation of damp mass.
3. All the ingredient were weighed and triturated by using mortar and pestle and this mass was passed through sieve no.8 individually.
4. In the next step the herbal drugs and starch (half quantity) are mixed with sufficient quantity of water along with small amount of gelatine to form dump mass i.e. coherent mass.
5. The mass was passed through sieve no.16 to form granules and the granules were dried at 500C-600C for 15 min in hot air oven.
6. In that dried granules, remaining quantity of starch, Talc, Magnesium stearate, Lactose were added mixed with spatula.
7. At the last prepared granules were passed for compression by single punching machine. [18]

FORMULATION TABLE:

Table no. 01 Formulation table of polyherbal antidiabetic tablet

Sr. No.	Ingredients	Quantity (mg)	Uses
1.	Fenungreek	150 mg	API
2.	Gurmar	100 mg	API
3.	Jamun	50 mg	API
4.	Lactose	135 mg	Diluent
5.	Starch	50 mg	Binder, Glidant, Disintegrant
6.	Talc	7 mg	Anti-adherent
7.	Magnesium stearate	8 mg	Lubricant

EVALUATION TESTS OF TABLET:

1. **Preformulation study**
a. Angle of repose
b. Bulk density
c. Tapped density
d. Hausner's ratio
e. Carr's index
2. **General appearance**
b. Size & shape
c. Organoleptic properties
3. **Hardness test**
4. **Weight variation**
5. **Friability test**
6. **Content uniformity test**
7. **Dissolution test**
8. **Disintegration test**

1. PREFORMULATION STUDY:

a. Angle of repose:

Angle of repose is were used to check the flowability of the granules in hopper before compression of tablet. Fixed funnel method is used to check the angle of repose. At the specific height the funnel was fixed on the graph paper which is placed horizontally at surface. Then the granules were passed to the funnel until the apex of the pile touched to the tip of the funnel. Radius was measured by using scale and determined the angle of repose by using following formula.[19]

$$\emptyset = \tan^{-1}(h/r)$$

Where, $\emptyset$ - Angle of Repose
h – Height of pile
r – Radius of pile

According to IP and USP-

Table no.02: Relationship between the angle of repose and flow prop

Angle of Repose (degrees)	Expected Flow
25-30	Excellent
31-35	Good
36-40	Fair - aid not needed
41-45	Passable - may hang up
46-55	Poor - must agitate or vibrate
56-65	Very Poor
>66	Very, Very Poor

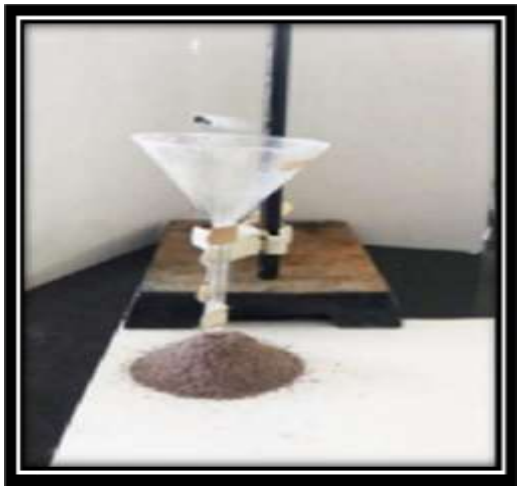


Fig.No.06 Angle of repose

b. Bulk Density:

A known amount of granules was transferred into a 25ml of measuring cylinder, carefully level the powder without compacting and measure the bulk volume.[20] The units for bulk density are typically mass per unit volume (g/cm³)) or (kg/m³).

Bulk Density = weight of powder / Bulk Volume

c. Tapped Density:

Tapped density is the ratio of weight of powder to the Tapped volume. It was determined by tapping a measuring cylinder containing fixed quantity of powder for the specific period of time. [21] The tapped density was calculated by using following formula**.** The unit of tapped density is (g/mL) or (g/cm^3).

Tapped Density = Weight of Powder / Tapped Volume

d. Hausner's Ratio:

It was determined after the measuring of Tapped density and bulk density. It is the densitification of the herbal powder mixture which may result from the vibration of the feed hopper which was calculated by using below formula, The unit of the Hausner ratio is dimensionless, meaning it doesn't have any units.[22]

Hausner's Ratio = Tapped Density / Bulk Density

e. Carr's Index:

Carr's index was used to check the compressibility and flow of the granules from hopper. It is expressed in percentage. Carr's index was calculated by using following formula**.** [23]

Carr' s Index = Bulk Volume – Tapped volume / Bulk volume × 100

2. General Appearance:

1. The general appearance of a tablet, its identity, and general elegance is essential for consumer acceptance, for control of lot-to-lot uniformity and tablet-to-tablet uniformity.
2. The control of general appearance involves the measurement of size, shape, color, presence or absence of odor, taste etc.

a) Size & Shape:

1. It can be dimensionally described & controlled.
2. The unit of the Hausner ratio is dimensionless, meaning it doesn't have any units.
3. The thickness of a tablet is only variables
4. Tablet thickness can be measured by micrometer or by another device.

Fig no.07.Vernier Caliper

Organoleptic properties:

1. Color distribution must be uniform with no mottling.
2. For visual color comparison compare the color of sample against standard color.
3. A tablet level of flaws such s chip, cracks, contamination from foreign solid substances (hair, drops of oil, dirt), surface texture (smooth vs rough) and appearance (shining vs dull) may have zero defect.
4. The presence of odor could be characteristic of the drug (Vitamin), added ingredients (flavoring agent) or the dosage form (film-coated tablet have a characteristic odor). [24]

1. Hardness:

The Hardness of the Tablet is also called as Tablet Crushing strength. Harness test is used to check

the hardness of the prepared tablet.[18] Tablet hardness test could be defined as a tablet strength test which reflect overall tablet strength and it is measured by applying pressure to the tablet diameter. In this test we can measured the force which is required for the breaking of the tablet. Monsanto tablet hardness tester is used to check the hardness of the tablet. The hardness is express in Kg/cm The accepted hardness range for tablets, as per IP (Indian Pharmacopoeia) and USP (United States Pharmacopeia), is generally between 4 to 10 kg/cm2. [25]

Fig.No.08 Monsanto hardness tester

2. Weight Variation:

It is also called Uniformity of weight. In this evaluation test twenty tablet were weighed separately and then average weight was determined. The percentage deviation was calculated and check for weight variation as per IP. By randomly selecting and weighing 20 tablets, the average weight was determined by weighing machine. Individually, each tablet was also weighed. In each case deviation from the average weight was calculated and expressed as percentage. Not more than two of the tablets from the sample size deviate from the average weight by a greater percentage and none of the tablets deviate by more than double that percentage.[26]

Table no.03 Standard values for uniformity of weight

Average weight of Tablet(mg)/IP/USP	Maximum percentage of Deviation allowed(%)
80 or less	10
80-250	7.5
More than 250	5

3. Friability Test:

The friability test is used to check the combined effect of abrasion and stock. This test is used to check the tablet is suitable for transportation or not for that purpose Roche Friabilator is used it is laboratory friability tester. In that the pre weighed antidiabetic tablet sample is placed in the friabilator which consist of plastic chamber that operate 100 rotations for 4 min means 25 rpm. The tablets are then dusted and reweighed. Conventional compressed tablet that loses less than that 0.5-1.0 % of their weight are generally acceptable. According to USP and IP standards, acceptable tablet friability is generally considered to be a weight loss of not more than 1.0%

Fig.No.09 Friabilator

4. Content uniformity test:

For each individual lot, 10 units were sampled. Measurements were done by the individual manufacturer. The assay methods used were IR and UV absorption. The mean and SD of drug content, formulation weight and concentration of active ingredient (w/w%) were calculated for each group of 10 units in a single lot. UV spectrophotometer is used for the analysis. Units were weighed and assayed in succession. The concentration of the active ingredient was

calculated by dividing drug content by formulation weight that included the weight of coating. [27]

5. Dissolution Test:

Dissolution is the process by which a solid solute enters in the solution. It may be defined as the amount of drug substance that goes into solution per unit time. The disintegration test simply identified the time required for the tablet to break up under the condition of test and all the particles are passed through mesh no.10 screen. The rate of drug absorption of acidic drug is high in GIT. So, for that purpose, the rate of dissolution is determined. It is important to point out that quick initial release of a drug from its matrix system may be undesirable therapeutically.

Table No.04 Parameter used in release

Sr. No.	Parameters	Observations
1.	Speed of paddle	100 rpm
2.	Temperature	37 ± 0.5
3.	Sampling time	2hrs
4.	Volume drawn	10ml
5.	Dilution factor	10
6.	Volume of dissolution medium	900ml
7.	Spectrophotometric analysis	UV-Visible at 260 nm

Fig.No.10 Dissolution apparatus

6. Disintegration Test:

Glass of plastic tube [80-100 mm] long with an internal diameter [28 mm] and external diameter [30-31 mm] fitted at the lower end with a disc of rust proof wire gauge. Six tablets were placed in the tube, the tube was raised and lowered in such a manner that the complete up and down movement was repeated [28 to 32] per min. The tablets were disintegrated when no particle remains above the gauge, which readily pass through mesh (10 mesh screen). [28]

Fig.No.11 Disintegrator

RESULT AND CONCLUSION-

Preformulation studies-

Sr.no.	Parameter	Observation
1.	Angle of Repose	26.87°
2.	Bulk density	0.41g/cm³
3.	Tapped density	0.47g/cm
4.	Hausner's Ratio	1.24
5.	Carr's Index	15.33%

Post Formulation studies-

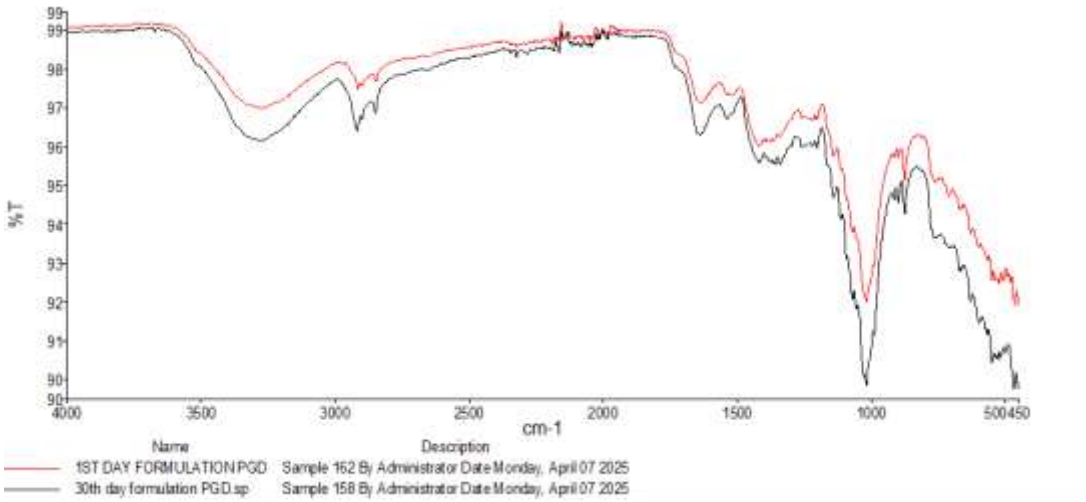
Sr. No.	Parameter	Observation
1.	Shape	Oval
2.	Color	Brownish
3.	Strength (mg)	300
4.	Odor	Pungent
5.	Thickness(cm)	0.9
6.	Hardness (kg/cm2)	4.5
7.	Friability (%)	0.9

8.	Weight variation (mg)	316.5
9.	Disintegration (min)	10

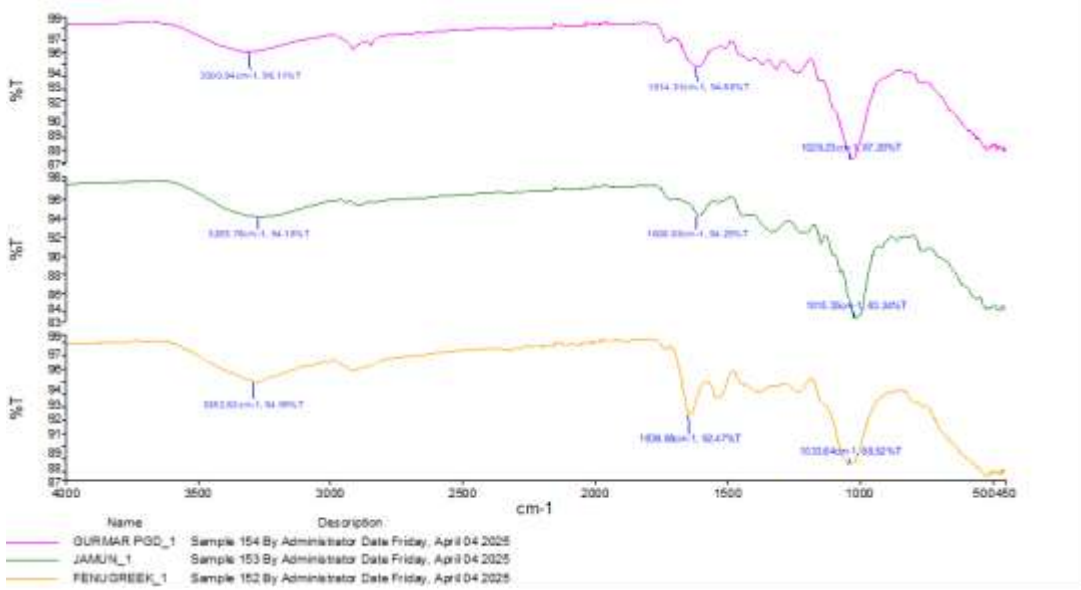
IR Spectroscopy-

Sample Name	Best Hit	Correlation	Pass / Fail
30th day formulation PGD	C:\pel_data\spectra\1ST DAY FORMULATION PGD.sp	0.99557	**Pass**

Sample Name	Pass / Fail
C:\pel_data\spectra\1ST DAY FORMULATION PGD.sp	**Pass**

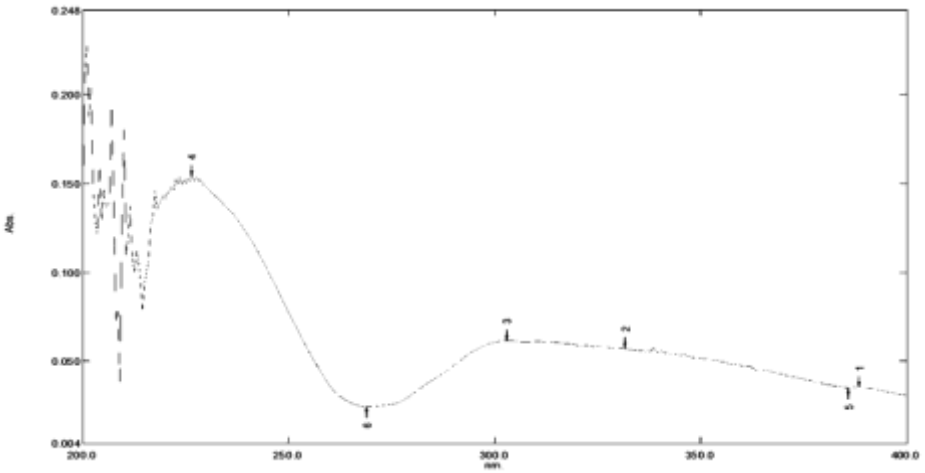


Graph no. 01 IR graph of stability study



Graph no. 02 IR graph of Gurmar, Jamun and Fenungreek

UV Spectrometry-



Graph no.03 lmax of Antidiabetic tablet by UV

CONCLUSION

It was concluded that the herbal antidiabetic tablet which are prepared from natural sources they show fewer side effect as compared to tablet which are prepared from synthetic compound**.** Text provides information on the method of preparation and evaluation tests for tablet.

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