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Formulation And Evaluation Of Herbal Antidiabetic Tablet

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ABSTRACT
The research work is "To focus on the formulation and evolution of the herbal Anti diabetic tablet containing insulin, neem and aloe vera for potential therapeutic application. The tablets were prepared using the suitable excipients by wet granulation method. Preformation study such as bulk density, tapped density and angle of repose were carried out to evaluate the flow properties of the powder blend. The prepared tablets were evaluated for various parameter including hardness, friability disintegration time and dissolution time. The result indicate that all the evaluation parameters were within the acceptable limits as per the standard guidelines. The formulated tablets showed the satisfactory physical characteristics and their suitability for the studies". The study conclude that the formulated herbal tablet possesses promising antidiabetic potential and can be considered as a safe and alternative for diabetes management.

Keywords: Introduction, Diabetic, Antidiabetic drug.

INTRODUCTION

Diabetes mellitus is the most common endocrine disorder that affects more than 100 million people worldwide (6%). It is caused by deficiency or ineffective production of insulin by the pancreas which results in an increase or decrease in concentration of glucose in the blood. Glucose is an important source of energy for the body. In people with diabetes, either the body does not produce enough insulin or cannot use Insulin effectively. This leads to high blood sugar levels, a condition known as hyper glycemia.[1]

Types of diabetes:
Type 1 Diabetes Mellitus
Type 2 Diabetes Mellitus

Type 1 Diabetes mellitus (T1DM):

T1DM is an autoimmune disease that leads to the destruction of pancreatic β-cells in the islets of Langerhans, resulting in absolute insulin deficiency. Insulin deficiency leads to decreased glucose uptake by tissues, increased gluconeogenesis, glycogenolysis, and lipolysis culminating in hyper glycemia, ketogenesis, and potentially diabetic ketoacidosis (DKA). Type 1 diabetes happen when the body stops making insulin.

Type 2 Diabetes Mellitus (T1DM):

T2DM results from a combination of Insulin resistance and relative insulin deficiency. It is primarily associated with obesity, physical inactivity, and genetic predisposition. Initially, the pancreatic β-cells compensate by increasing Insulin secretion. Over time, beta cell ensues, characterized by impaired insulin synthesis and secretion, possibly due to glucotoxicity, lipo-toxicity, oxidative stress, and amyloid deposition. Type 2 diabetes happens when the body still makes insulin but cannot use it properly.

Causes of diabetes mellitus:

- Genetic defects of beta cell function
- Genetic defects in insulin action
- Disease of exocrine Pancreas

Types of tablets:

(A) Tablets ingested orally

1.Compressed tablet

2.Multicompressed tablet

3.Repeat action tablet

4.Delayed release tablet

5.Sugar coated

6.Film coated tablet

7.Chewble tablet

(B) Tablet used in oral cavity

1.Buccal tablet

2. Sublingual tablet

3.Lozenges

4.Dental cone

(C) Tablet administered by another route

(D)Tablets used to preparation

MATERIALS AND METHODS

Materials: The materials are used in the preparation of herbal antidiabetic tablet included Aloe vera extract, Neem extract and Insulin leaves extract as active ingredient. Excipient such as magnesium stearate, talc, microcrystalline cellulose, gum tragacanth and starch are used for the preparation of tablet. Distilled water is used throughout the study.

Instrument: The instruments used in the study of a antidiabetic tablet digital weighing balance for measuring the material and mixing mortar and pestle, standard sieves (10, 16, 14, 20, 80) for particle size separation, hot air oven for drying of granules, tablet compression machine for tablet formation, friability machine for friability testing, vernier caliper for thickness measurement, and pH meter for pH determination.

Preparation of tablet: Seven different batches of tablet were prepared using wet granulation technique. The composition of single table is given in table No. 1. Calculated amount which was required to prepared 250 mg of antidiabetic tablet uniformly. The Necessary materials were accurately weighed and were passed through sieve number 60 to ensure uniformity of particle size. The powdered materials were uniformly mixed to obtain a homogenous blend. A separate binder solution was prepared and added in drops to powder along with continuous mixing until a damp mass was formed. The mixture was then passed through sieve number 10 for granulation and further at room temperature. The dried granules were passed through sieve number 16 for uniform size distribution. Dried granules were added lubricants like magnesium stearates & talc & mixed gently. The granules were ultimately compressed into tablets using a tablet compression machine. The compressed tablets of each batch were stored in air tight container at room temperature for further study. The wet granulation method used to enhance the flow properties and compressibility of the formulation.

Table 1: Formula used to prepare tablet (mg)

INGREDIENTS	BatchF1	BatchF2	BatchF3	BatchF4	BatchF5	BatchF6	BatchF7
Insulin (API)	150	------	-------	75	-------	75	70
Neem (API)	------	150	--------	75	75	-----	70
Aloe vera (API)	------	------	150	------	75	75	50
Microcrystalline cellulose (Diluent)	50	50	50	60	60	60	30
Starch/PVP (Binder)	22.5	22.5	22.5	20	20	20	15
Gum Tragacanth (Disintegrant)	12.5	12.5	12.5	10	10	10	10
Talc (Glidant)	7.5	7.5	7.5	5	5	5	3
Magnesium stearate (Lubricant)	7.5	7.5	7.5	5	5	5	2

Weight of each tablet equal 250 mg

Evaluation of granules: Granules were evaluated for all pre-compression parameters like angle of repose, tapped density, bulk density, Carr's index and Hausner's ratio. The evaluation was done using all the methods.

Angle of repose- By using funnel method, angle pf repose determined. In a funnel accurately blend powder was taken.

$\theta = \tan^{-1} h/r$

Where h= height of the powder cone formed, r= radius of the powder cone formed

h=1.6, r=2.8

$\theta = \tan^{-1} h/r$

$\theta = \tan^{-1} 1.6/2.8$

$\theta = \tan^{-1}(0.572)$

$\theta = 30^{o}$

Bulk density- By pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight.

Bulk density= Mass of powder/Bulk volume of powder

Bulk density= 5/10, = 0.5g/ml OR g/cm^3

Tapped density-The cylinder was tapped on to a hard surface from the height of 10 cm at two second interval. Tapping was continued, "until no further change in volume was noted".

Tapped density= Mass of powder/Tapped volume of powder

Tapped density= 5/5, = $1g/cm^3$

Carr's index- Tapped density- Bulk density/Tapped density

Carr's index= (1-0.5)/1X100

= 0.5X100, =50

Hausner's ratio= Tapped density/Bulk density

Hausner's ratio= 1/0.5

=2

Properties	Batch F1	Batch F2	Batch F3	Batch F4	Batch F5	Batch F6	Batch F6	Standard
Bulk density(g/cm^3)	0.51±0.03	0.57±0.01	1.8±0.07	0.29±0.02	2.4±0.01	0.46±0.04	0.41±0.07	0.57
Tapped density(g/cm^3)	0.6±0.01	1±0.01	2.8±0.01	0.44±0.03	1.6±0.06	0.5±0.06	0.6±0.04	0.62
Carr's index	16±2	50±3	35±4	34±7	-50±6	20±4	33±4	20
Hausner's ratio	1.2±0.2	2±0.6	1.5±0.3	1.5±0.4	0.6±0.6	1.2±0.4	1.5±0.7	1.7
Angle of repose(degrees)	28±0.7	30±0.6	54±0.1	38±0.4	41±0.5	27±0.3	31±0.1	33

Table No. Precompression Properties of Granules

Evaluation of Tablets:

Physical characteristics: The prepared tablets were evaluated for general physical characteristics and were found to be uniform in color with a characteristic herbal odor. The surfaces of the tablets were fairly smooth with no visible cracks or defects. The tablets showed uniformity in weight, and the average weight was found to be within acceptable limits, indicating good consistency of the formulation.

Weight variations: Twenty tablets were selected and weight individually by using the digital weighing balance. The average weight of tablets was calculated and then the weight of each individual tablet is compared with the average weight of tablet for the determination of weight variations.

$$\%\text{Weight variation} = \frac{\text{Individual weight} - \text{Average weight}}{\text{Average weight}} X\ 100$$

Average weight of tablet= 250mg

One tablet= 260mg

% Deviation= 260-250/250x100

=10/250X100

= 4%

Friability: Friability test of all batches was done by using the Roche Friabilator. Friability test is generally performed to check the tendency of tablet to break under the mechanical stress and the tablet are subjected to rotation and the weight loss is calculated.

$$\%\ Friability = \frac{W_1 - W_2}{W_1} X\ 100$$

Five tablets are taken and placed into the friabilator and rotated at the 25 rpm for 5 mins.

Initial weight of tablets= 2.50gm

Final weight of tablets= 2.41gm

% Friability= 2.50-2.41/2.50X100

= 0.09/2.50x100

= 3.6%

Hardness test: Hardness test is used to determine the measurement of mechanical strength of tablet. It is expressed in the kg/cm² and determined using hardness tester.

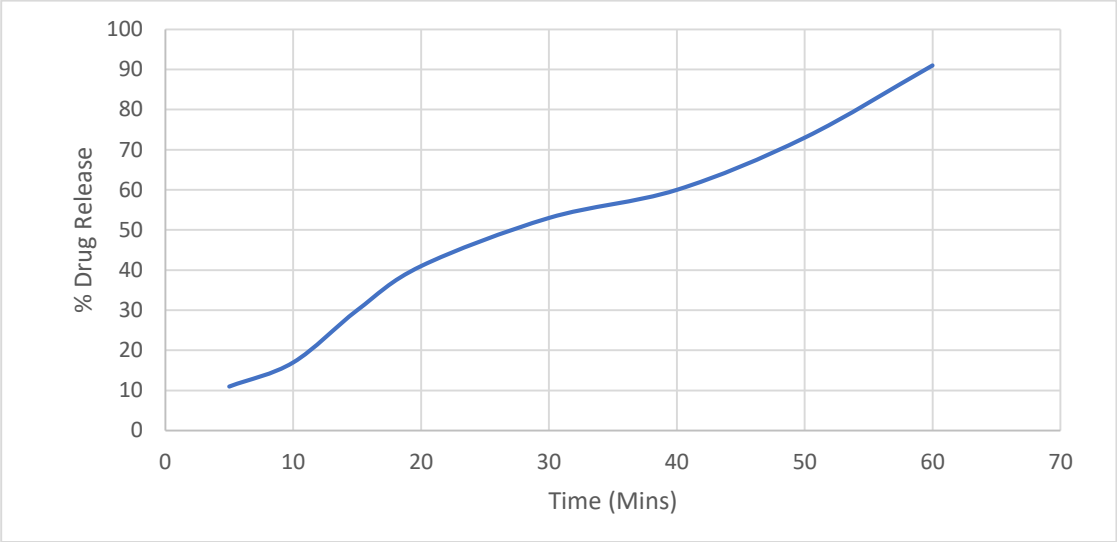
It is directly measured using the hardness tester.

Thickness test: Measuring the thickness of a tablet using an instrument like a vernier caliper is known as a thickness test. Tablet compression and formation machine ensures uniformity of tablets size for packaging and patient acceptability.

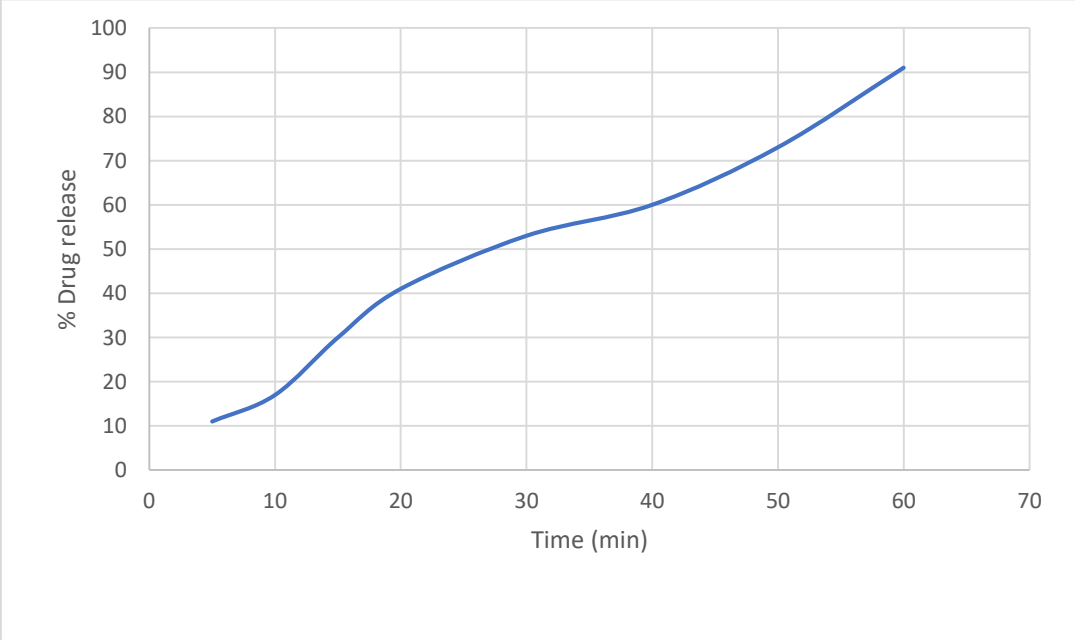
Disintegration time: Disintegration time is time taken for tablet to break in the liquid medium. Standard time is generally 15 minutes for the uncoated tablet. This test is performed using the disintegration test apparatus and ensures that the tablet disintegrate properly after the administration.

Disintegration=Time taken for tablet to completely break in the medium.

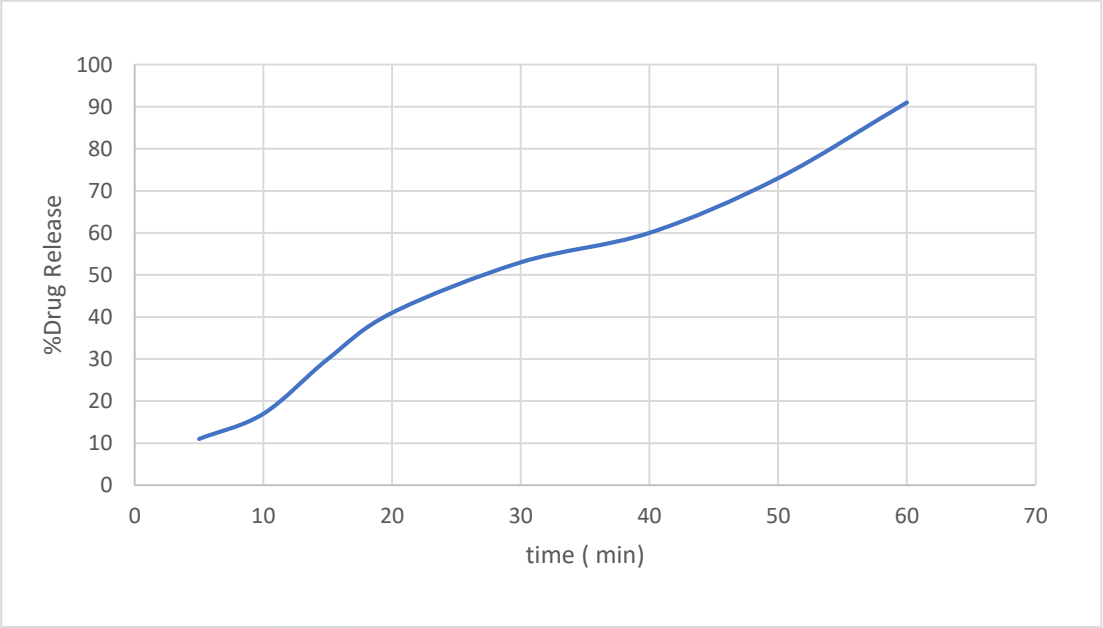
Batch formulation no.1 (Time VS %Drug release)



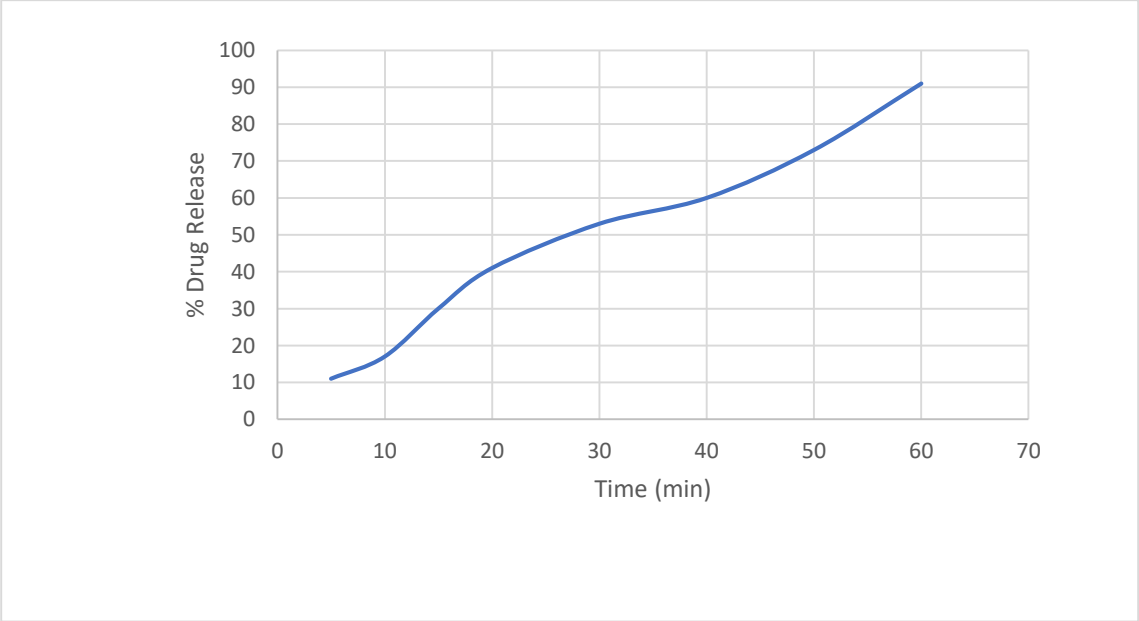
Batch formulation no.2 (Time VS %Drug release)



Batch formulation no.6 (Time VS %Drug release)



Batch formulation no.7 (Time VS %Drug release)



Parameters	Batch F1	Batch F2	Batch F3	Batch F4	Batch F5	Batch F6	Batch F7	Standard
Weight variation	260±4%	260±4%	255±6%	256±7 %	258±6 %	252±+0.8 %	250±0%	250
Friability%	0.72±0.09	0.27±0.13	0.81±0.07	1.6±0.12	0.8±0.09	0.61±0.06	0.93±0.02	1
Hardness test kg/cm^2	4.1±0.3	4.5±0.4	4.6±0.4	4.3±0.3	4.6±0.5	4.5±0.6	4.8±0.2	5.5
Thickness test mm	3.2±0.25	3.4±0.55	3.3±0.51	3.5±0.43	3.8±0.33	3.3±0.30	3.7±0.23	4.5

Disintegration time mins	6±5	12±1	13±2	11±4	9±5	10±2	11±2	13
Moisture content	7±1%	20±2%	4.1±3%	2.7±2%	1.3±4%	2.3±2%	2±2%	5%
pH determination	6.8±1	5.2±0.4	6.1±0.3	6.9±0.4	6.7±1	5±0.2	6±0.5	6.8

Table No.3 Evaluation parameters of tablets

Result and Discussion

The prepared herbal antidiabetic tablets were evaluated for various physiochemical and post compression parameters. The tablets showed the satisfactory results for hardness, friability, weight variation that indicate the good evaluation strength. The dissolution study shows the gradual increase in percent drug release along with time. Thus, the prepared herbal antidiabetic tablet formulation can be considered effective and suitable for sustained drug release, which may enhance patient compliance and therapeutic efficacy.

The Prepared formulations (Batch F1-F7) were evaluated for various pre and post compression parameters. Among all the formulations, the Batch F1, F2, F6 and the F7 have comparatively better performance. These batches show the acceptable hardness and low friability.
In particular these batches have maximum percentage drug release within the specific time which indicate the good dissolution properties. Based on the overall evaluation parameters, **Batch F1, F2, F6 and the F7** were considered as optimized formulations due to its superior performance.

Among the prepared formulations the Batch **F1 and F6** has the superior performance among all. These batches show the better drug release indicating improved formulations properties. Therefore, the **Batch F1 and Batch F6** were selected as the final optimized formulations for further studies. The selected optimized batch are kept for stability studies.

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