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Research article

Formulation and Evaluation of Bilayer Matrix Tablet of Vildagliptin and Acarbose

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ABSTRACT

Our investigation aimed to formulate a bilayer matrix tablet that includes vildagliptin as a component for prolonged release and acarbose for immediate release. Treatment with these medications provides a high standard of living for individuals afflicted with type II diabetes mellitus. This medicine offers several key benefits, including its precise targeting of specific actions, exceptional safety, and outstanding effectiveness. Acarbose was immediately formulated with super disintegrants, specifically sodium starch glycolate (SSG) and croscarmellose sodium (CCS). The tablet was then compressed via direct compression. A sustained release layer of vildagliptin was prepared to utilize HPMCK100 as release retarding polymers. The wet granulation technique was employed, and PVP K30 in IPA solution (10%) was used as a granulating agent. The bilayer tablet underwent evaluation for several characteristics, including hardness, friability, weight variation, percentage of medication content, percentage of medication release study, and disintegration time of IR layer. An optimization process was used to refine a formulation, resulting in a formulation that contains 12 mg of CCS and 32 mg of HPMC K100M. Optimized formulation shows 98.3 ± 1.05% immediate release and 34.54 ± 1.54, 69.32 ± 1.60 and 96.75 ± 2.13% drug release at 1, 4 and 8 hours, respectively. Our study revealed that bilayer tablets, including vildagliptin and acarbose, might be a superior alternative to standard dosage forms.

INTRODUCTION

Diabetes mellitus is a disease caused by to deficiency of effective insulin in the body in which there is an altered metabolism of proteins, lipids, and carbohydrates. This leads to hyperglycemia and glycosuria.[1] Diabetes mellitus is a chronic disease that affects any age of the population and is characterized by disturbed insulin release. It is implicated in abnormalities either in the secretion of insulin or in the effects induced by insulin, although other factors may also play a role. Diabetes mellitus is a metabolic condition described by decreased glucose metabolism and increased metabolism of proteins and fats.[2]

The management of these complex complications involves the use of combination therapy with two antidiabetic drugs. By employing a combination of two antidiabetic medications, we can effectively address these multiple challenges. Managing diabetes requires close attention, as it is crucial to maintain glucose levels consistently throughout the day to ensure proper bodily function, especially following meals when glucose levels tend to rise. It is essential to develop sustained-release (SR) formulations that can continuously regulate antidiabetic action to effectively counteract the postprandial increase in glucose levels. This approach will be pivotal in addressing such circumstances. [3-5]

The development of the bi-layer tablet, which incorporates multiple attributes along with a sustained release formulation, represents an innovative approach to the effective administration of medication. By utilizing bilayer tablet technology, it becomes possible to segregate two incompatible substances into distinct layers: an initial dosage that is promptly released and a subsequent

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dosage that is gradually released. Instead of releasing the medication right away after administration, this delayed-release dosage form seeks to release medication at a particular period. [6-8]

Bilayered tablets are comprised of two layers, with 1st layer releasing the drug immediately and 2nd layer providing an extended-release or immediate release. The tablets are produced through the compression of 2 separate feeds into a single die, with one layer placed on top of the other, resulting in clearly defined layers. As a result, they resemble a sandwich, with each layer clearly visible. [9]

Sustained drug delivery's (SDD) primary goals are to boost a medication's effectiveness as well as patient adherence and safety. A tablet helps release two incompatible APIs in two different layers simultaneously. Medications are administered sequentially, with the initial layer providing instant release and the subsequent layer providing a sustained dosage. [10]

Vildagliptin is a novel oral dipeptidyl peptidase-4 (DPP-4) inhibitor medication that is utilized to treat diabetes and hyperglycemia. Vildagliptin prevents GLP-1 and GIP from being inactivated to increase the production of insulin in β-cells and decreases the release of glucagon by the pancreatic islets of Langerhans' α cells. It has been discovered that vildagliptin decreases postprandial and basal glucose levels. It decreases intestinal glucose absorption, lowers hepatic glucose synthesis, and ultimately increases insulin sensitivity. The medication does not go through hepatic metabolism and is primarily excreted unaltered in the urine.

Acarbose does not stimulate insulin secretion, and its antihyperglycemic activity is typically mediated by intestinal α-glucosidase hydrolase enzymes that are coupled to the membrane of pancreatic α-amylase. This inhibition is competitive and reversible. Following intravenous treatment to healthy participants, vildagliptin had total plasma and renal clearances of 41 and 14 L/hour, respectively. The half-life is gone after IV injection in roughly two hours. Following oral administration, the elimination half-life is dose-independent and lasts for around 4 hours.[11-13] Acarbose functions as an oral alpha-glycosidase inhibitor, specifically targeting sucrase. It is administered orally to manage type 2 diabetes mellitus. Research has also explored its potential in addressing reactive hypoglycemia, the dumping syndrome, and certain forms of hyperlipoproteinemia. Due to its increased water solubility and shorter half-life (2 hours), the medication necessitates frequent oral dosing. [14,15]

Our study focuses on formulating and evaluating a bilayer tablet containing vildagliptin and acarbose.

Materials And Methods

Chemicals

Vildagliptin was procured as a complimentary sample from Alpha Lab in Baroda, India, while acarbose was procured from Aristo Pharmaceuticals as a gift sample in Bhopal, India. HPMC K4, HPMC K100M, lactose, and croscarmellose sodium were sourced from Aristo Pharmaceutics. Sodium starch glycolate was received complimentary from Sigma Lab. magnesium stearate, dibasic calcium phosphate, HPMC, Avicel 101 PH, Povidone k-30, Aerosil-200, and Talc were received from Aristo Chemicals in Bhopal, India. The reagents and chemicals utilized were of analytical grade.

Methods

Bilayer tablet of vildagliptin as well as acarbose, was developed through a two-stage process. Initially, the immediate-release layer (IR) of acarbose and the vildagliptin layer for sustained delivery were made independently. Several preliminary trials were carried out to establish the formulation for each layer of the bilayer tablet. Once each layer was optimized, a bilayer tablet was created using the finalized formula. Consequently, the investigational work was split into 3 separate sections.

Immediate-release layer of acarbose

Different immediate-release layers were prepared as per formula shown in Table 1 and compacted through direct compression after the inclusion of various super disintegrants, for example, sodium starch glycolate, croscarmellose sodium (Ac-Di-Sol), and crospovidone, in discrete concentrations. Accurate weighing of all ingredients was done, and they were passed through #40 meshes. The specified quantities of medication, polymer, and diluents were completely blended for a duration of 3 minutes, except magnesium stearate and talc. The glidant and lubricant, talc and magnesium stearate were incorporated into the powder mixture, which was thoroughly mixed for a duration of 3 minutes. The tablet formulations were compressed using a Karnavati rotary tablet compression machine in Mumbai, employing a spherical shape punch.

Sustained-release (SR) layer of vildagliptin

The medication and other additives were precisely measured (as per Table 2) and thoroughly blended using a mortar and pestle. In order to form a moist aggregate, a solution containing PVP K30 in IPA (10%) was introduced into the tablet powder mixture. The wet mixture was then filtered via sieve no #20 to get extruded, which were later dehydrated in a hot air oven at 40°C for 30 minutes. Displaced particles were placed in a polyethylene bag and then combined with talc plus magnesium stearate for a duration of 5 minutes. Colloidal silicon dioxide, which had been passed *via* a 40-mesh screen, was included into the mixture. The resulting dried granules were further compressed to form tablets.

Preformulation Study[16,17]

Identification test by UV-vis spectrophotometer

- *For vildagliptin*

Precisely measured 10 mg of the medication was mixed

Table 1: Ingredients of acarbose fast dissolving tablets

S. No	*Constituents*	*F-1-*	*F-2*	*F-3*	*F-4*	*F-5*	*F-6*
1.	Acarbose	25	25	25	25	25	25
2.	Sodium starch glycolate	4.5	6	7.5	12	12	12
3.	Croscarmellose sodium (Ac-Di-Sol)	2	3	7.5	12	10	10
4.	Lactose	20	65.31	83.5	90	95.33	100
5.	Hydroxypropyl methylcellulose (HPMC) 15 CPS	2.5	2.5	-	-	-	-
6.	Polyvinylpyrrolidone K-30	2	2	-	-	-	-
7.	Magnesium stearate	1	1	1	1	1	1
8.	Talc	1.6	1.6	1.6	1.6	1.6	1.6
9.	Sunset yellow lake	1	1	1	1	1	1
10.	Total weight of acarbose layer	150	150	150	150	150	150

Table 2: Ingredients of vildagliptin sustained release layer

S. No	*Ingredients*	*F-1-*	*F-2*	*F-3*	*F-4*	*F-5*	*F-6*
1.	Vildagliptin	50	50	50	50	50	50
2.	Dicalcium phosphate (DCP)	175	158	150	120	100	100
3.	Sodium carboxymethyl cellulose (SCMC)	25	42	42	65	80	78
4.	Hydroxypropyl methylcellulose (HPMC) K4	25	25	25	25	25	25
5.	Hydroxypropyl methylcellulose (HPMC) K 100	10	10	18	25	30	32
6.	Polyvinylpyrrolidone (K-30)	4	4	4	4	4	4
7.	Talc	4	4	4	4	4	4
8.	Calcium carbonate	4.5	4.5	4.5	4.5	4.5	4.5
10.	Colloidal silicon dioxide	2.5	2.5	2.5	2.5	2.5	2.5
11.	IPA	Qs	Qs	Qs	Qs	Qs	Qs
Total weight of Vildagliptin layer		300	300	300	300	300	300

with 10 mL of water in a 10 mL volumetric flask to achieve a concentration of 1000 µg/mL, creating a stock solution. Next, 1-mL of stock solution was transferred using a pipette and then diluted with distilled water to reach a total volume of 10 mL, resulting in a concentration of 100 µg/mL in the stock solution. Following this, the stock solution was then diluted to create solutions with concentrations of 2, 4, 6, 8 and 10 µg/mL. The drug's spectrum was analyzed in the UV spectrophotometer (SHIMADZU U. V 1800) within the 200 to 400 nm range.

- *For acarbose*

In a 10 mL volumetric flask, 10 mL of 0.1 N HCl was used to dissolve 10 mg of medication that had been accurately weighed. Next, 5 mL of the solution are pipetted out of the aliquot and combined with 50 mL of distilled water. It was diluted appropriately. H. 10, 20, 30, 40 and 50 µg/mL.

Melting point determination[17]

Using the capillary method and the melting point apparatus, melting points of vildagliptin as well as acarbose, were ascertained.

Determination of solubility [17]

The solubility of samples was examined using the shake-flask technique. In summary, 5 mg of the substance was mixed with 5 mL of various solvents, i.e., distilled water, methanol, chloroform, ethanol, and phosphate buffer (6.8), in a glass vial. These solutions were vigorously mixed at 25°C for a duration of 6 hours to reach a state of thermodynamic balance.

Compatibility examination by FTIR spectroscopy[16]

The tablet's powder was combined, and the sample's dried potassium bromide (IR grade) ratio must be 1:100 mg, or 1-mg of sample for every 100 mg of KBr. The mixture is compacted into translucent pellets. At room temperature, the material was scanned from 4000 to 400 cm^{-1} (Alpha ATR Bruker).

Pre-compression Evaluation [16]

Bulk density

The bulk density was assessed by adding a powder mixture in a graduated cylinder and quantifying the combined

weight and volume of powder. The below-mentioned formula was utilized to compute the bulk density:

$$\text{Bulk density (BD)} = W/BV$$

Here, W=Powder weight and BV=Bulk Volume

Tapped density

Tapped density was assessed by tapping the cylinder utilizing tapped density equipment. The cylinder was subjected to 100 taps, following which the volume of tapped material was measured and density was concluded utilizing below mentioned formula:

$$\text{Tapped Density (TD)} = W/TV$$

Here, W = Powder weight and TV=Tapped Volume

Hausner's ratio

Hausner's ratio, which quantifies the ratio of bulk density to tapped density, serves as a crucial measure of the flowability of a powder or powder blend. This ratio is computed utilizing a specific formula:

$$\text{Hausner's ratio} = TD/BD$$

Here, BD = Bulk Density and TD = Tapped Density

Compressibility index

The compressibility index was determined utilizing mentioned formula:

$$\text{Carr's index (\%)} = TD–BD/BD\times100$$

Here, BD = Bulk Density and TD = Tapped Density

Angle of repose

A fixed funnel technique was utilized to determine the angle of repose for the powder blend in each layer of every formulation. The mixture was poured separately *via* funnel till the highest point of the resulting pile touched the tip of the funnel. The angle of repose was subsequently decided to utilize a precise mathematical formula:

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

h = height of pile

r = radius of pile

Post-compression Evaluation [18]

Thickness

The tablet's thickness of was assessed utilizing a vernier caliper. Five tablets were chosen, and their thickness was determined in millimeters.

Hardness

Tablet evaluation involves considering hardness as a crucial parameter. The capability of a tablet to tolerate handling, transportation, and storage is directly related to its hardness. A Monsanto hardness tester was used to assess the tablet's hardness, which is typically expressed in kg/cm^2.

Uniformity weight

The homogeneity of tablet weight was assessed by randomly picking 20 tablets. The weight of each tablet was measured separately and then compared to the average weight.

Friability

The primary factors responsible for the chipping, cracking, or shattering of tablets are friction and shock. A total of ten tablets were taken into the Roche Friabilator apparatus and subjected to repetitive shocks and rolling motion as they fell six inches with each rotation of the device. The pills are weighed after 4 minutes of therapy or 100 revolutions, and the weight is compared to the starting weight. The amount of loss gauges the friability of tablet from abrasion. During the friability test, a weight loss of ≯1% of tablets being tested is deemed generally acceptable; tablets that are shattered or fractured are not selected. The following formula was used to get the %friability:

$$\text{Friability (\%)} = W1 – W2/ W1 \times 100$$

Where W1 = Weight of Tablets (Initial/Before Tumbling) & W2 = Weight of Tablets (After friability or tumbling)

Disintegration test (IR layer)

The apparatus used for the test is described in the Indian Pharmacopeia of 2007. Distilled H_2O is employed as the disintegration medium, and the temperature is kept at 37 ± 2°C. The time required for tablets to crumble completely and leave no appreciable mass behind is estimated in seconds. Three samples were chosen from every batch, and the standard deviation was computed.

Content uniformity

- *For vildagliptin*

To make a powder, 20 tablets were taken and smashed in a mortar. From there, a sample containing an equivalent weight of 50 mg of the medication was extracted and put into a volumetric flask of 100 mL capacity. After adding 30 mL of phosphate buffer 6.8 pH to dissolve the medication and bring the volume up to mark, the mixture was filtered. A UV spectrophotometer (SHIMADZU; U. V1800) was used to test the absorbance of a 1-mL solution that had been diluted with pH 6.8 phosphate buffer from the filtrate.

- *For acarbose*

To create a powder, 20 tablets were taken and smashed in a mortar. From there, a sample containing equivalent weight of 50 mg of medication was extracted and put into a volumetric flask of 100 mL capacity. To dissolve the medication, thirty milliliters of 0.1N HCl (pH = 1.2) was added. Then volume was adjusted utilizing 0.1N HCl (pH=1.2) and filtered. A U. V-spectrophotometer (SHIMADZU; U. V1800) was used to test the absorbance of a 1-mL solution that had been diluted utilizing phosphate buffer (pH 6.8) from filtrate.

In-vitro drug dissolution investigations

- *In-vitro drug release (immediate release tablet) (Acarbose)*

Using a USP II (paddle) equipment (Electrolab TDT-08L)

and 900 cc of dissolving medium kept at 37 ± 1°C for 15 hours at 100 rpm, *in-vitro* release of medication was investigated. pH = 1.2 in a 0.1N HCl solution. About 5 mL of sample were taken out every ten minutes. An identical amount of brand-new dissolving medium was added to the volume removed at each interval. The cumulative percent drug release was computed using UV spectrophotometric analysis of collected samples at 624.5 nm.

- *In-vitro drug release (sustained release tablet) (Vildagliptin)*

Vildagliptine sustained release tablet *in-vitro* dissolving investigation was conducted in a USP type-II dissolution test apparatus (Electrolab TDT-08L) (Paddle type) with 900 cc of pH 6.8 phosphate buffer at 100 rpm and 37 ± 0.5°C. Using a syringe equipped with a pre-filter, 5 mL of samples were taken out at pre-arranged intervals. The volume taken out was replaced with the same quantity of new dissolving media every time. Final samples were examined by determining the percentage release of medication by evaluating absorbance at 253.5 nm utilizing a UV-visible spectrophotometer.

- *In-vitro drug release (bilayer tablet)*

Utilizing a USP Type II (Paddle) dissolution instrument (Electrolab TDT-08L) in sink conditions, the release of bilayer tablets was measured. For 2 hours, the 900 mL 0.1N HCl (pH = 1.2) was kept at 37 ± 0.20°C as a dissolving medium. Phosphate buffer (6.8 pH) was then added in place of the dissolving medium. About 50 rpm was the stirring speed. A portion of the solution was collected at regular intervals and replaced with a new dissolving media. The acarbose and vildagliptin were examined using spectrophotometry at wavelengths of 624.5 and 253.5 nm, respectively, employing the simultaneous equation approach for analysis.

Results And Discussion

Pre-formulation Studies

UV absorption of acarbose at a concentration of 10 µg/mL occurs at a wavelength of 624.5 nm within 200 to 400 nm range, with maximum absorption. In the case of vildagliptin, the absorption occurs at a wavelength of 254.5 nm.
Table 3 includes the results of the melting point, solubility, and compatibility investigations conducted for both medicines.

Pre-compression Evaluation

Study focused on micrometric characteristics, particularly angle of repose, compressibility index, tapped and bulk

Table 3: Preformulation study of acarbose and vildagliptin

S. No.	*Parameter*	*Acarbose*	*Vildagliptin*
1	Identification by UV-vis spectrophotometer (λ_{max})	624.5	254.5 nm
2	Solubility	Very soluble in H_2O and warm H_2O, soluble in acetonitrile and methanol, slightly soluble in chloroform, and insoluble in methylene chloride.	Soluble in H_2O, methanol, ethanol, phosphate buffer, insoluble in ether, sparingly soluble in acetone.
3	Melting point (°C)	168	153
4	Compatibility study	Compatible	Compatible

Table 4: Pre-compression assessment of immediate-release blend of powder (Acarbose)

S. No.	*Parameter*	*A-1*	*A-2*	*A-3*	*A-4*	*A-5*	*A-6*
1	Bulk density (g/mL)	0.50 ± 0.23	0.53 ± 0.12	0.56 ± 0.023	0.59 ± 0.14	0.56 ± 0.11	0.56 ± 0.019
2	Tapped density (g/mL)	0.66 ± 0.19	0.54 ± 0.09	0.621 ± 0.34	0.60 ± 0.611	0.64 ± 0.14	0.613 ± 0.11
3	Angle of repose (º)	29.8 ± 0.17	28.9 ± 0.27	24.15 ± 0.23	31.27 ± 0.14	32.28 ± 0.19	34.61 ± 0.26
4	Compressibility index (%)	4.84	5.93	6.07	5.84	5.24	4.44
5	Hausner's ratio	1.19	1.14	1.16	1.18	1.12	1.077

Table 5: Pre-compression assessment of sustained-release blend of powder (vildagliptin)

S. No.	*Parameter*	*F-1*	*F-2*	*F-3*	*F-4*	*F-5*	*F-6*
1	Bulk density (g/mL)	0.52 ± 1.23	0.53 ± 1.06	0.54 ± 0.14	0.54 ± 1.12	0.53 ± 0.19	0.51 ± 0.36
2	Tapped density (g/mL)	0.61 ± 0.12	0.59 ± 0.27	0.52 ± 0.17	0.59 ± 0.54	0.64 ± 0.14	0.58 ± 0.19
3	Angle of repose (º)	39.28 ± 0.13	38.13 ± 0.72	41.17 ± 0.32	41.24 ± 0.18	49.11 ± 0.29	43.56 ± 0.13
4	Compressibility index (%)	5.92	6.54	6.27	6.07	5.98	6.62
5	Hausner's ratio	1.27	1.43	1.70	1.23	1.15	1.125

Table 6: Post-compression assessment of immediate-release tablets

S. No.	*Parameter*	*A-1*	*A-2*	*A-3*	*A-4*	*A-5*	*A-6*
1	Hardness (kg/cm^2)	3.0 ± 0.89	3.1 ± 1.37	3.2 ± 0.89	3.2 ± 0.47	3.0 ± 0.91	3.1 ± 1.11
2	Friability (%)	0.94	0.88	0.89	0.864	0.88	0.91
3	Uniformity weight (mg)	149 ± 1.02	153 ± 1.11	153 ± 1.23	149 ± 1.47	147 ± 1.09	149 ± 0.02
4	Thickness (mm)	3.0	3.1	3.1	3.0	3.9	2.8
5	Drug content (%)	93.47 ± 1.25	96.10 ± 1.16	96.92 ± 0.87	97.54 ± 1.72	98.10 ± 0.87	98.47 ± 1.11
6	%Drug release in 45 min	92.95	93.24	78.12	91.24	89.32	98.97

Table 7: Post-compression evaluation of sustained-release tablet

S. No.	*Parameter*	*F-1*	*F-2*	*F-3*	*F-4*	*F-5*	*F-6*
1	Hardness (kg/cm^2)	6.2 ± 0.85	6.3 ± 0.57	6.3 ± 1.22	6.3 ± 0.28	6.3 ± 0.29	6.3 ± 0.54
2	Uniformity weight (mg)	299 ± 0.72	299 ± 1.42	293 ± 1.77	301 ± 0.55	287 ± 0.57	299 ± 1.24
3	Friability (%)	0.56	0.88	0.78	0.89	0.83	0.92
4	Thickness (mm)	6.5	6.5	6.2	5.8	6.9	6.3
5	Drug content (%)	98.23 ± 1.34	95.58 ± 1.98	97.28 ± 2.07	97.54 ± 1.33	98.28 ± 0.07	98.47 ± 0.67
6	%Drug release in 8 hours	91.29	96.35	89.33	94.34	94.13	97.37

Table 8: Post-compression assessment of bilayer tablets of A6 and F6 optimized batch

S. No.	*Parameter*	*A-6 F-6*
1	Hardness (kg/cm^2)	6.4
2	Uniformity weight (mg)	449
3	Friability (%)	1.42
4	Thickness (mm)	6.5
5	Medication content (immediate release) (%)	98.30
6	Medication content (Sustained release) (%)	96.75
7	%medication release (immediate release) in 45 minutes (%)	98.75
8	%medication release (Sustained release) in 8 hours (%)	96.74

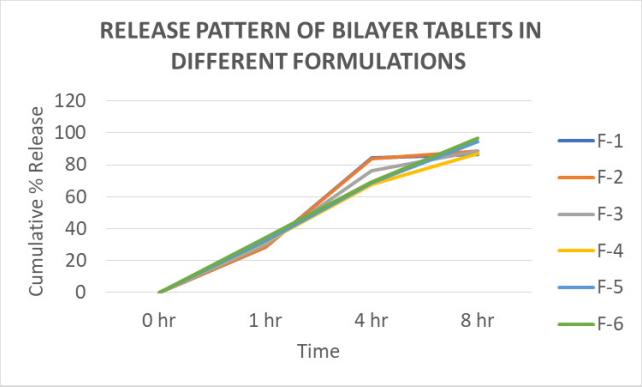

Fig. 1: Release pattern of bilayer tablets in different formulations

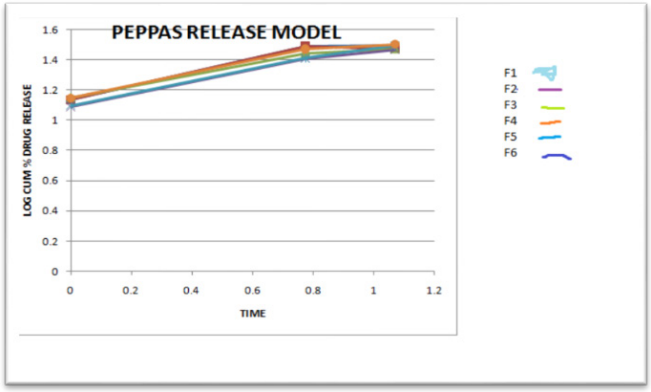

Fig. 2: Plot showing Peppas model of different formulations

Fig. 3: Plot showing first-order release rate of various formulations

density, Hausner's ratio, and of vildagliptin sustained release layer and acarbose instant release layer blend. Tables 4 and 5 show the overall results. The bulk density value denotes well-defined packing properties. The formulation's compressibility index suggests that the powder has good flow characteristics, which were additionally supported by measuring the angle of repose, which falls between 29.8° and 43.6°.

Table 9: *In-vitro* release study of bilayer tablets of different formulations

Immediate release layer-acarbose								
S. No.	*Time*	*Limit%*	*Cumulative percentage medication release*					
1.	45 minutes	NLT 85%	F-1	F-2	F-3	F-4	F-5	F-6
			80.4 ± 1.39	84.2 ± 1.61	86.6 ± 1.65	90.1 ± 1.79	97.3 ± 1.19	98.3 ± 1.05
Sustained release layer- vildagliptin								
1.	1 hour	25–40%	28.35 ± 1.41	28.51 ± 1.46	29.74 ± 1.63	31.66 ± 1.7	32.41 ± 1.39	34.54 ± 1.54
2.	4 hours	60–80%	84.35 ± 1.54	83.67 ± 1.31	76.32 ± 2.18	67.89 ± 1.57	68.76 ± 1.43	69.32 ± 1.60
3	8 hours	NLT 85%	86.37 ± 1.53	88.37 ± 2.08	88.79 ± 2.34	86.95 ± 1.56	94.5 ± 1.63	96.75 ± 2.13

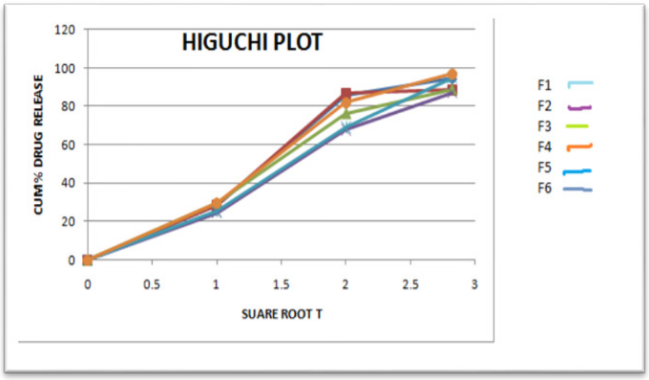

Fig. 4: Plot showing Higuchi plot of different formulations

Post-compression assessment of tablets

Produced tablets were assessed for thickness, hardness, friability, weight variance, consistency of dosage units, and dissolving test results and result were shown in Table 6 for Immediate Release layer of acarbose, Table 7 for sustained release layer of vildagliptin and Table 8 for compressed bilayer tablet. The weight variation test involves measuring the weight each of the 20 tablets separately, figuring out their average weight, and matching those weights with the average. Immediate release and sustained release layers' results were found to be between 149 ± 1.02, 153 ± 1.23, 299 ± 1.24, and 301 ± 0.55 mg, respectively. A Monsanto hardness tester was employed to determine the hardness of tablets in each batch. Kg/cm^2 unit of measurement for hardness was used. Six tablets' hardness was measured; the results showed that for immediate release, the results ranged from 3 ± 0.91 to 3.2 ± 0.89 kg/cm^2 and from 6.2 ± 0.85 to 6 ± 1.223 kg/cm^2.

Table 9 displays the findings of spectrophotometric analysis of vildagliptin and acarbose at 624.5 and 253.5 nm, correspondingly, using the simultaneous equation approach. Release kinetics of several formulations are displayed in Figs 1 to 4.

Conclusion

The manufactured tablets performed satisfactorily in a number of assessment procedures, including those measuring tablet size, friability, hardness, drug content, weight consistency, and *in-vitro* dissolution. For the immediate release layer, A6 was chosen as the optimal formulation based on all the factors, and F6 was chosen for the sustained release layer. Zero-order release was discovered to be the drug release mechanism, reliant on polymer relaxation as well as drug diffusion. For type 2 diabetes mellitus, vildagliptin and acarbose bilayer tablets are helpful.

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