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Research Article

Formulation and Evaluation of Sustained Release Tablet of an Anti-Diabetic Drug Vildagliptin Using Natural Polymer

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ABSTRACT

The goal of the current study was to formulate and evaluate vildagliptin sustained release tablets. It is thought to be a good medicine for the development of sustained release tablets because of its short biological half-life (1.5 h), which will allow it to continue to have a therapeutic effect for longer. Vildagliptin is a novel dipeptidyl peptidase-4 inhibitor family of oral antihyperglycemic medication. Materials and Method: Sustain Release tablets were developed using a direct compression Method using various ratios of natural polymers (Gum). The preparations were examined for their compressibility index, Hausner's ratio, bulk density, and tapped density. statistical analysis The Fourier-transform infrared spectra of vildagliptin and Vildagliptin + polymers mixture, both separately and in combination, demonstrate the drug's compatibility with excipients. Results: The tablets physicochemical characteristics were confirmed to be within acceptable limits. The weight variation, thickness, hardness, friability, drug content, and in vitro release of the produced tablets were all evaluated. In vitro - dissolution studies were carried out using USP paddle apparatus II, at 370C ± 0.50C in 0.1 N HCL (1.2 pH) for 12 hours. the optimized formulation F - 6 Shows the Maximum drug release 99.70 ± 0.5 in 12 hours of dissolution.

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INTRODUCTION

Traditional drug delivery methods have been characterized by fast release and frequent dosing of the drug, which may increase the danger of dosage variation. As a result, a formulation with Sustained release is required to maintain a blood level that is almost constant or uniform. Maintaining a nearly constant or uniform blood level of a medication frequently results in greater patient compliance and increased clinical effectiveness of the medication for its intended usage.(1) Drug delivery systems that are intended to achieve or prolong therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose are known as sustained release, sustained action, prolonged action-controlled release, extended action, timed release, depot, and repository dosage forms. The main goal of sustained release drug delivery systems is to deliver accurate drug concentrations to the site of action in order to produce the desired therapeutic effect or response in the body. Two different distribution system types are typically employed. Conventional drug delivery systems or the immediate release drug delivery systems are the systems which are categorized by the quick and unhindered drug release rate and release kinetics. The other category includes modified-release medication delivery systems.(2)(3)

The most successful way to achieve both local and systemic effects with therapeutic drugs is through oral ingestion, which is the preferred route of delivery. Parenteral, oral, buccal, transdermal, nasal, and pulmonary routes of drug administration can all be used to administer a drug systemically.(4) There isn't a single route that satisfies all the physiological standards for the "ideal" absorption site. However, the oral route is more favorable for drug absorption when taking into account surface area, low metabolic activity, contact time, blood supply, accessibility, lack of variability, and permeability. Oral dosage forms are the ones with the most characteristics of optimum dosage forms when compared to other pharmacological dosage forms.(5)(6)

- The chance of dosage dumping because of dietary, physiological, or formulation factors, or because the patient is chewing or grinding oral formulations, which increases the risk of toxicity.
- Retrieval of drug is difficult in case of toxicity, poisoning or hypersensitivity reactions.
- Reduced potential for dosage adjustment of drugs normally administered.

DRUG:

Vildagliptin is an anti-diabetic medication that belongs to the dipeptidyl peptidase-4 (DPP-4) inhibitor family. Vildagliptin prevents DPP-4 from activating GLP-1 and GIP, allowing GLP-1 and GIP to potentiate insulin production in beta cells and reduce glucagon release in pancreatic islets of Langerhans alpha cells.(7)(8)

DISEASES:

Diabetes mellitus is the most common of the endocrine disorders. It is a chronic condition, characterised by hyperglycemia and due to impaired insulin secretion with or without insulin resistance. Diabetes mellitus may be classified according to an Etiology, by far the most common types being type 1 and type 2 diabetes.(9) More than 2.6 million people in the UK have diabetes, and by the year 2025, this number is estimated to rise to 4 million. Diabetes affects an estimated 77 million individuals (1 in 11 Indians), making India the world's second most afflicted country. According to the International Diabetes Federation, the number of diabetics will reach 134 million by 2045.

CLASSIFICATION (10)(11)

I. Type 1
II. Type 2
III. Gestational diabetes

IV. Other types

a. Type 1:

Type 1 diabetes is a disease characterised by the destruction of the insulin producing pancreatic β-cells, the development of which is either autoimmune T- INTRODUCTION Ali Allana College of Pharmacy, Akkalkuwa 18 cell mediated destruction (type 1A) or idiopathic (type 1B). In over 90% of cases, β-cell destruction is associated with autoimmune disease. Type 1 diabetes usually develops in the young (below the age of 30), although it can develop at any age and is usually associated with a faster onset of symptoms leading to dependency on extrinsic insulin for survival.

b. Type 2:

Type 2 diabetes is mostly seen above the age of 40, with a peak age of onset in developed countries between 60 and 70 years, although it is being increasingly seen in younger people and also in children. The prevalence of type 2 diabetes varies greatly from country-to-country Population, six times more common in populations of South Asian origin compared to those of northern European origin.

Insulin resistance and relative insulin insufficiency are the two main factors that lead to diabetic illnesses. Symptoms typically appear later and are less severe than those of type 1 in general. In particular when patients arrive with diabetes-related problems, such as heart disease, type 2 diabetes may be discovered incidentally. When type 2 diabetes progresses to this point, extrinsic insulin is frequently needed to keep blood glucose levels within normal ranges. Below are some key distinctions between type 1 and type 2 diabetes.

Clinically, it might be difficult to differentiate between type 1 and type 2 diabetes. The degree of metabolic aberration is primarily the major factor in determining the type of treatment, which is something that is crucial to understand.

Gestational Diabetes: Gestational Diabetes develops in pregnant women as the body becomes less sensitive to insulin. Gestational diabetes does not affect all women and normally goes away after the baby is born.

d. Other Types:

Monogenic diabetes and cystic fibrosis-related diabetes are two less prevalent kinds of diabetes.

ADVANTAGES OF SUSTAIN RELEASE SYSTEM:(12)

This type of drug delivery has many benefits over conventional dosage forms, some of which are as follows:

1. Simple to manufacture.
2. Since the medicine is delivered over a longer period of time, the frequency of dose application is decreased.
3. It is essential for patients with chronic illnesses who require plasma medication concentrations that are within the therapeutic range, such as overnight pain control in terminally ill patients.
4. "Dose dumping" and harmful effects brought on by high plasma concentration are diminished.
5. A rise in patient compliance.
6. Better management of therapeutic medication concentration.
7. A rise in the bioavailability of several medications.
8. Increase the stability by protecting the medication from hydrolysis or other derivative modifications in the gastrointestinal tract.
9. Because the number of doses is reduced, cost-effective manufacture is achievable.

DISADVANTAGES OF ORAL SR SYSTEM'S:(13)

Like other formulations, it also possesses several disadvantages, these include:

1. A rise in cost.
2. Toxicology brought on by dosage dumping.

3. The in vitro-in vivo connection is unpredictable and frequently poor.
4. The possibility of adverse effects or toxicity from the drug's rapid release (mechanical failure, mastication, alcohol consumption).
5. Greater possibility of first-pass clearance.
6. The requirement for more patient counselling and education.
7. Lower systemic availability compared to immediate release conventional dosage forms, which may be caused by insufficient release, increased first pass metabolism, increased instability, insufficient residence time for full release, site-specific absorption, pH-dependent stability, etc.
8. The chance of dosage dumping because of dietary, physiological, or formulation factors, or because the patient is chewing or grinding oral formulations, which increases the risk of toxicity.
9. Retrieval of drug is difficult in case of toxicity, poisoning or hypersensitivity reactions.
10. Reduced potential for dosage adjustment of drugs normally administered.

MATERIALS AND METHOD

Vildagliptin sample was a bought from Century Pharmaceutical, private limited Mumbai, Natural gums were bought from Shabir Brothers Treaders, Nandurbar, and other excipients such as talcum powder microcrystalline cellulose, magnesium Sterate were by from Sony enterprises.

STANDARDIZATION OF DRUG

UV Spectrophotometric method for Vildagliptin: - The drug vildagliptin was analyzed by using Shimadzu – UV 1800 spectrophotometer having double beam detector configuration. Calibration curve of vildagliptin was plotted in 0.1N hydrochloric acid at the maximum wavelength of 265 nm.

MICROMETRY STUDY:(14)(15)

- Angle of repose:

The angle of repose is used to measure the flow properties. Frictional forces between the particles cause improper powder flow. The angle of repose is used for quantifying the frictional forces.

Angle of repose is defined as the maximum angle possible between the surface of a powder file and the horizontal plan.

Ø = Tan -1 h/r

Where, h = height of file. R = radius of the base of the pile. Ø = angle of repose.

- Compressibility Index:

The Hausner ratio and compressibility index are measurements of a powder's ability to be compressed, they measure the relative importance of interparticulate interactions. Such interactions are usually less prominent in a free-flowing powder, and the values of the bulk and tapped densities will be closer. There are usually more particle interactions in poorly flowing materials, which results in a larger difference between the bulk and tapped densities. The compressibility index and the Hausner ratio both show these variations.

The compressibility index and Hauser ratio are calculated by measuring the values for bulk density (P bulk) and tapped density (P tapped) as follows:

Compressibility index = P tapped – P bulk/P tapped X 100

Hausner ratio = P tapped / P bulk

- Bulk Density:

The powder sample (mix) under test was screened via sieve #18, and the sample approximately 20gm was accurately weighted and put in a graduated cylinder with a capacity of 100ml. The powder was leveled, and the unsettled volume (V0) was registered.

The bulk density was calculated in g/cm3 by the formula,

Bulk Density = Mass of the Powder / Volume

PREPARATION OF VILDAGLIPTIN SUSTAIN RELEASE TABLETS:

METHOD OF PREPARATION:(16)

Vildagliptin 50 mg sustained release tablet were formulated by using natural gum polymer (F1 – F9), with varying concentration of different formulation ingredients such as Neem gum, Guggul gum, Cassia tora according to tablet. All the ingredient drug and excipients were pass through # 80 meshes. Mix well API, polymer, then adds binders and all required ingredients in mortar pastel and passed through sieve no 80. The tablet was form by direct compression at Rimek mini press 10 station tablet punching machine. The amount required for the formulation is given for following table.(17)(18)

Table 1: Formulation Table of Vildagliptin Sustain Release Tablet

Ingredients	F1	F2	F2	F4	F5	F6	F7	F8	F9
Vildagliptin	50	50	50	50	50	50	50	50	50
Neem Gum	40	80	120	40	80	120	-	-	-
Guggul Gum	-	-	-	120	80	40	40	80	120
Cassia Tora	120	80	40	-	-	-	120	80	40
Mag-Sterate	10	10	10	10	10	10	10	10	10
Talcum Powder	10	10	10	10	10	10	10	10	10
MCC	20	20	20	20	20	20	20	20	20
Total	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**

EVALUATION PARAMETERS OF SUSTAIN RELEASE TABLET (19)

Physiological parameter or post compressional parameters of all formulations

- Weight Variation

From the preparation of tablet twenty tablet were randomly selected from each batch and individually weight. The average weight and the standard deviation of twenty tablets was calculated. The batch passes the test for weight variation test if not more than two of the individual tablet weight deviates from the average weight by more than the percentage shown in a none deviate by more than twice the percentage shown.

$$\%_0\ Deviation = \frac{Tablet\ weight - Average\ weight}{Tablet\ weight}$$

- Dimensions:

The physical dimension of the tablets thickness is essential for consumer acceptance and to maintain tablet to tablet uniformity. For the measurement of the dimension of the tablet instrument called vernier calipers were used. The thickness of the tablet is mostly related to the hardness can be used as initial control parameter.

Randomly six tablets were selected from each batch and their thickness (dimension) was measured by vernier caliper.

- Hardness:

The tablet hardness testing technique is performed to determine the breaking point (mechanical strength) and structural integrity of tablet and finds its changes during storage condition, during shipping, coating, and packaging. This test is also performed to determine proper shape and design. Hardness was measured by using hardness tester instrument known as Pfizer hardness tester. The amount of force required to break the tablet is recorded by the unite is Kg/cm2.

- Friability:

Twenty tablets from each batch were weight and placed in the Roche Friabilator individually batch wise and apparatus was rotated at 25 rpm for every 4 minutes. After revolution the tablets were

dedusted and weight again. The percentage friability was measured using the formula.

%F = {1-(Wt / W)} x 100

- Drug Content:

For the drug content 20 tablets are crush and weight equivalent to 50 mg vildagliptin and dissolved in 0.1N HCl and mark up the volume to 100 ml. From the above prepared solution withdraw 10 ml and dilute to 100 ml with 0.1 N HCL. Read the absorbance at 265 nm in UV spectrophotometer.

- Dissolution Studies:

Perform the test on one tablet from each batch, one tablet in each dissolution vessel containing 900 ml of 0.1 N HCl and 6.8 pH phosphate buffer maintained at 37^0 C ± 0.5^0 C. specific time withdraw the required amount of sample and replace same amount of 0.1 N HCL and 6.8 pH phosphate buffer (maintain sink condition), then absorbance was taken and calculated percentage release.

- Stability Studies:

For the chosen formulation F – 6, stability tests were performed over a 3-month period at 40^0C / 75 % RH. This formulation was chosen because to the sustained – release tablets' ability to reliably release the medication in vitro. The formulation was tested for stability at the typical circumstances for real-time and accelerated stability studies, 40°C and 75% relative humidity. The formulation was testing for aspects like appearance, assay, weight consistency, and in-vitro drug release.

DRUG AND EXCIPIENT COMPATIBILITY STUDY:(20)(21)

- Compatibility Studies by FTIR Spectral analysis:

The objective of drug and excipient evaluation by FTIR spectral analysis was to identify the changes associated with the excipient – drug combination. The appearance and disappearance of absorbance peak, peak strength, emergence of additional peak, is conclusive proof of interaction between drug and excipient. For the FTIR analysis pure drug powder and Drug – Excipient polymer mixture was used.

RESULT AND DISCUSSION:

- Preformulation studies:

UV Spectrophotometric method for vildagliptin

1. Preparation of calibration curve in 0.1N hydrochloric acid

Table 2: Calibration of 0.1 N HCl

S.no.	Concentration (in µg/ml)	Absorbance (in nm)
1.	0	0
2.	1	0.143
3.	2	0.153
4.	3	0.169
5.	4	0.192
6.	5	0.202
7.	6	0.220
8.	7	0.229
9.	8	0.243
10.	9	0.255
11.	10	0.261
R^2	0.98784	

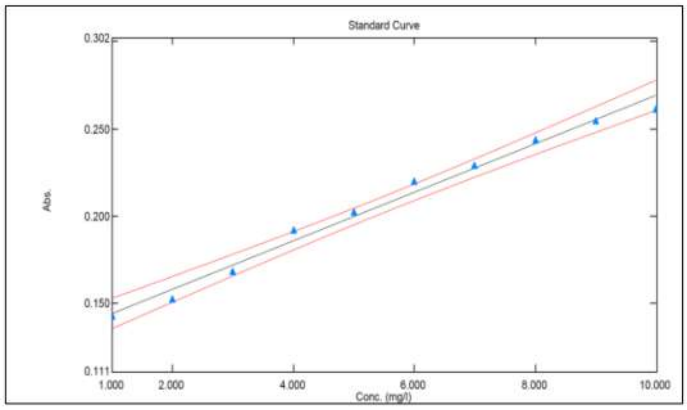

Figure 1: Vildagliptin in 0.1N HCL

2. Preparation of calibration curve in 6.8 pH Buffer Solution.

Table 3: Calibration curve of vildagliptin in 6.8 pH buffer Solution

Sr. No.	Concentration (in µg/ml)	Absorbance (in nm)
1.	0	0
2.	1	0.095
3.	2	0.113
4.	3	0.131
5.	4	0.155
6.	5	0.165
7.	6	0.175
8.	7	0.182
9.	8	0.200
10.	9	0.207
11.	10	0.223
R^2	0.98395	

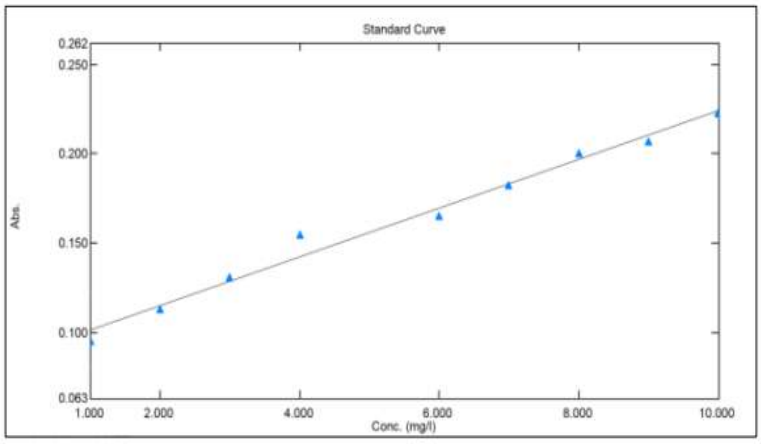

Figure 2: Vildagliptin in 6.8 pH buffer solution

MICROMETRY STUDY:

Micrometrics properties like Angle of repose, bulk density, tapped density Carr's index, hausner's ratio etc. of whole formulation of sustained release tablet of Vildagliptin were performed & found the relevant data, shown in below table.

Table 4: Pre-compression parameters of sustain release tablet

Formulation	Angle of repose	Bulk density(gm/cc)	Tapped Density (gm/cc)	Compressibility Index (%)	Hausner's ratio
F1	$24^{0}5$	0.40	0.44	9.09	1.1
F2	$25^{0}9$	0.39	0.43	9.30	1.1
F3	$28^{0}2$	0.39	0.44	11.36	1.1
F4	$25^{0}6$	0.41	0.44	6.81	1.0
F5	$26^{0}8$	0.38	0.42	9.5	1.1
F6	$28^{0}1$	0.41	0.45	8.8	1.0
F7	$29^{0}5$	0.41	0.44	6.8	1.0
F8	$25^{0}7$	0.40	0.44	9.09	1.1
F9	$29^{0}8$	0.38	0.42	9.5	1.2

EVALUATION PARAMETER

Post compression or physical parameters as (hardness test, weight variation, friability thickness and drug content) of vildagliptin tablet performed and found the relevant data shown in below table.

Table 5: Post compression parameter of sustain release tablet

Formulation	Weight Variation	Thickness	Hardness (Kg/cm^2)	Friability (%)	Drug Content
F1	250.5±0.50	3.48±0.113	9.2±4	0.75	98.23
F2	251.3±1.3	3.42±0.214	9.3±5	0.21	99.68
F3	249.2±0.8	3.61±0.063	9.2±2	0.13	97.34
F4	250.4±0.4	3.63±0.017	9.4±2	0.19	98.73
F5	251.0±1.0	3.62±0.082	9.4±3	0.22	98.61
F6	252.1±2.1	3.52±0.129	9.5±2	0.16	99.70
F7	251.5±1.5	3.50±0.064	9.3±2	0.14	98.94
F8	250.5±0.5	3.45±0.164	9.3±3	0.17	99.00
F9	251.5±1.5	3.42±0.144	9.4±2	0.18	98.65

DISSOLUTION STUDIES:

In vitro, the percentage drug released study of vildagliptin tablet was performed with different polymers concentration at different intervals (1 to 12 hrs) & found the relevant data showing below.

Table 6: In-vitro dissolution studies of sustain release tablet

Time in Hours	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	0.01	8.26	14.52	0.16	2.55	1.65	13.48	0.85	12.78
2	1.58	22.14	21.92	1.20	13.77	8.28	22.85	8.00	26.96
3	9.71	40.48	33.32	1.35	20.13	10.42	29.32	21.38	38.96
4	16.66	57.45	40.01	6.72	34.20	25.35	42.80	39.83	47.49
5	25.00	74.65	66.61	12.38	45.59	32.94	55.11	52.21	57.36
6	34.62	83.97	89.06	20.20	54.47	46.65	73.26	66.34	74.88

7	56.54	99.70	96.57	32.23	65.53	57.88	94.52	75.62	86.16
8	79.85		98.24	53.00	78.57	65.12	96.48	87.54	92.16
9	87.34			65.76	90.14	77.06	97.28	90.04	98.12
10	89.88			79.86	94.48	91.68	98.52	93.25	
11	95.78			84.51	96.60	95.16		94.87	
12	96.74			90.52	97.12	99.68		98.00	

DRUG – EXCIPIENTS COMPATIBILITY STUDIES:

- **FTIR Study:**

Compatibility study of pure drug Vildagliptin with polymer was carried out for the preparation of tablets. IR spectra of pure drug Vildagliptin and that of with polymer (Natural Gums) were obtained, which are listed below. All the characteristic peaks of Vildagliptin were present in spectra thus indicating compatibility between drug and polymers. It also shows that there were no significant changes in the chemical integrity of the drug.

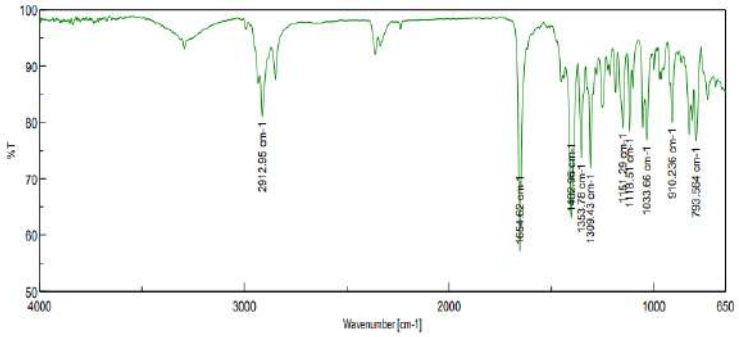

Figure 3: FTIR of Drug Vildagliptin

Sample ID: Vildagliptin
Resolution: 4 cm $^{-1}$
Apodization: Cosine
No. of Scans: 8
Analyst: KBHSST, Malegaon

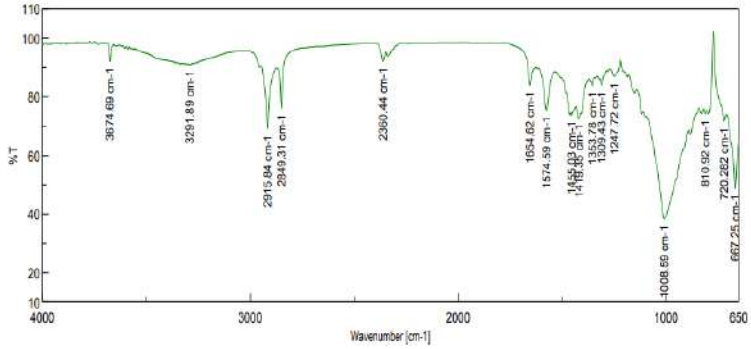

Figure 4: FTIR of Drug + Excipients

Sample ID: Vildagliptin + Excipients
Resolution: 4 cm $^{-1}$
Apodization: Cosine
No. of Scans: 8
Analyst: KBHSST, Malegaon

Table 7: Interpretation of FTIR

Sr. No.	Functional Group	Observed Ranges (cm^{-1})	Standard Ranges (cm^{-1})
1	CH Stretching alkane	2912.95 cm^{-1}	2000 – 3000
2	C=N Stretching	1654.62 cm^{-1}	1600 – 1650
3	CH bending (alkane)	1402.96 cm^{-1} 1353.78 cm^{-1} 1309.43 cm^{-1}	1300 - 1450
4	CN Vibrations	1151.29 cm^{-1} 1118.51 cm^{-1}	1100 - 1250

STABILITY STUDIES:

The stability studies of the prepared tablet were studied for the optimized batch F – 6 for the duration of 3 months at the temperature at 40^0 C ± 2^0 C and 75% ± 5% relative humidity. The table was evaluated by observing various parameter Such as Thickness, Hardness, and drug content drug release studies.

Table 8: Stability Studies of Vildagliptin

Sr. No.	Parameters	Initial	After 3 Months
1.	Thickness	3.52	3.47
2.	Hardness	9.5	9.3
3.	Weight variation	252	250
4.	Drug release	99.70	98.94

SUMMARY AND CONCLUSION:

The goal of the current research project was to create 50mg vildagliptin twice-daily sustained release tablets. The medication release from the dosage form was controlled using varying polymer concentrations (Neem Gum, Guggul Gum, Cassia Tora). The glucose levels management of type II diabetics is effectively improved by this sustained release tablet. For maintaining the drug's release, a sustained release system based on natural polymer (Gums) were used. To achieve the necessary release profile over a 12- hour period, several polymers were used in different ratio. The direct compression method was used to create several batches of sustained release.

All of the formulations underwent testing for stability, kinetics, in vitro dissolution, physical features, and precompression qualities. From the current study, the results listed below have been obtained.

- All of the blended compositions' physical properties were good.
- The produced tablets' assay, weight variation, thickness, and friability results were all within the prescribed ranges.
- For all of the SR formulations, in vitro dissolving tests were carried out.
- In vitro dissolution studies of SR formulations F6 revealed that the drug release profile was adequate when compared to the other 8 formulations.

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