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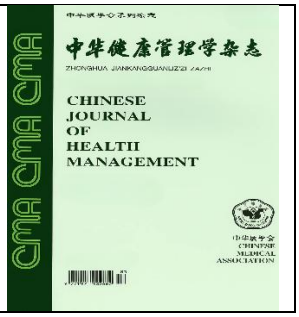
ISSN: 1674-0815 **cjhmonline.com** **DoI-10.564220/1674-0815**	Chinese Journal of Health Management **Chinese Medical Association**	

Formulation and Evaluation of Sustained Release Matrix Tablets of Gemigliptin

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Gemigliptin, Sustained release Matrix tablets, Natural polymers, In-vitro dissolution.

ABSTRACT:

Objective: The objective of the present study was to formulate and evaluate sustained release matrix tablets of Gemigliptin to prolong drug release and improve patient compliance in the treatment of type II diabetes mellitus. **Materials and Methods:** Sustained release matrix tablets of Gemigliptin were prepared by the wet granulation method using natural polymers such as xanthan gum, guar gum as release-retarding agents. The prepared formulations were evaluated for pre-compression parameters, post-compression parameters like thickness, diameter, hardness, friability, weight variation, drug content, swelling index, in-vitro drug release and release kinetics. **Results and Discussion:** All formulations showed acceptable flow properties and complied with pharmacopeia requirements. Formulations containing higher concentration of xanthan gum (30%) and guar gum (30%) showed higher swelling capacity and sustained drug release up to 18 hours. The optimized formulation batch F9 released 97.76% of Gemigliptin at 18 hours and followed zero-order release kinetics. The result of stability study of the batch F9 showed that there were no significant changes in all post formulation parameters after period of one month when stored at 40° ± 2°C and 75 ± 5% RH. **Conclusion:** From the study, it was concluded that sustained release matrix tablets of Gemigliptin using natural polymers can be successfully formulated and may serve as an effective once-daily dosage form for the management of type II diabetes mellitus.

INTRODUCTION:

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycaemia resulting from impaired insulin secretion, insulin action, or both. Type II diabetes mellitus is the most prevalent form and is associated with lifestyle-related factors such as obesity, physical inactivity and unhealthy dietary habits. Long-term uncontrolled diabetes can lead to serious complications including cardiovascular diseases, nephropathy,

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neuropathy and retinopathy. [1-2]

Gemigliptin is a potent and selective dipeptidyl peptidase-4 (DPP-4) inhibitor widely used in the management of type II diabetes mellitus. It enhances endogenous incretin levels, thereby increasing insulin secretion and decreasing glucagon release in a glucose-dependent manner. However, conventional immediate-release dosage forms may result in fluctuations in plasma drug concentration, which can reduce therapeutic effectiveness and patient compliance. [3]

Sustained release drug delivery systems are designed to maintain constant plasma drug concentration for an extended period of time, reduce dosing frequency and improve patient adherence. Matrix tablets prepared using natural polymers are widely investigated due to their biocompatibility, safety, cost-effectiveness and ease of formulation. Hence, the present study was undertaken to formulate and evaluate sustained release matrix tablets of Gemigliptin using natural polymers. [4-5] So the main objective was to formulate sustained release matrix tablets of gemigliptin as a once a daily dosage form.

MATERIALS AND METHOD:

Materials:

Gemigliptin was received as a gift sample from a Parisar pharmaceuticals Pvt. Ltd, Ahmedabad, Gujarat, India. Xanthan gum and guar gum, Polyvinyl pyrrolidone K30 (PVP K30), Microcrystalline, magnesium stearate, talc procured from chemdyes corporation, Rajkot, Gujarat, India.

Method:

Preparation of Sustained Release Matrix Tablets[6-7]

Sustained release matrix tablets containing 50 mg of Gemigliptin were prepared by the wet granulation method. Accurately weighed quantities of drug and polymers were mixed uniformly. Granulation was carried out using 10% w/v PVP K30 solution as a binder. The wet mass was passed through sieve #60 and dried at 45–50°C. The dried granules were passed through sieve #22, lubricated with magnesium stearate and talc, and compressed into tablets using a tablet compression machine (Table 1).

Table 1: Formulation Design of Sustained Release Matrix Tablets of Gemigliptin

Ingredients	Formulation batch								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Gemigliptin(mg)	50	50	50	50	50	50	50	50	50
Xanthan Gum(mg)	25	50	75	25	50	75	25	50	75
Guar Gum(mg)	25	25	25	50	50	50	75	75	75
MCC (mg)	108	83	58	83	58	33	58	33	8
PVP K30(mg)	30	30	30	30	30	30	30	30	30
Talc(mg)	6	6	6	6	6	6	6	6	6
Magnesium Stearate(mg)	6	6	6	6	6	6	6	6	6
Water(ml)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Total(mg)	250	250	250	250	250	250	250	250	250

Determination Of Melting Point Of Gemigliptin [8]

Melting point of Gemigliptin was measured by melting point apparatus. Minimum amount of drug was placed in a thin-walled capillary tube closed at one end. This capillary was then mounted in a melting point apparatus with thermometer and then their temperature range over which Gemigliptin melts is measured. The readings were taken in triplicate.

Identification By Uv-Visible Spectrophotometry [9]

Standard stock solution of Gemigliptin was prepared by dissolving 10 mg of Gemigliptin in 100 ml 0.1 N HCl, which make the stock solution of concentration of 100 µg/ml. For determination of λ_{max}, stock solution was scanned between 200-400 nm against 0.1 N HCl as a blank in the UV-Visible spectrophotometer. Working solution of concentration 10, 20, 30, 40 and 50 ppm were prepared by pipette outing 1, 2, 3, 4 and 5 ml respectively from the stock solution of 100 ppm and diluted up to 10 ml volumetric flask. Absorbance of working solutions was measured in triplicate at λmax at 256 nm against 0.1 N HCl as a blank.

Pre-Compression Parameters [10-14]

Bulk density, tapped density, Hausner's ratio, Compressibility index, Angle of repose, were all measured. Good

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flow qualities were indicated by the powder mixture's minimum Carr's index, Hausner's ratio, and Angle of repose.

Bulk density: Accurately weighed the powder mixture and transferred to measuring cylinder carefully measure the volume of powder without compacting. It is expressed as gm/ml.

$$\textbf{Bulk Density} = \frac{\textbf{Mass of powder (gm)}}{\textbf{Bulk Volume of powder (ml)}}$$

Tapped density: Tapped density was measured by placing graduated cylinder containing formulation blend on mechanical tapping apparatus. Tapped volume was measured until constant tapped volume is not achieved. It is expressed as gm/ml.

$$\textbf{Tapped Density} = \frac{\textbf{Mass of powder (gm)}}{\textbf{Tapped Volume of powder (ml)}}$$

Compressibility index: Compressibility index is a ratio of difference of tapped density and bulk density to tapped density. It is expressed in percentage (%).

$$\textbf{Compressibility Index} = \frac{\textbf{Tapped density} - \textbf{Bulk density}}{\textbf{Tapped density}} \times 100$$

Angle of repose: Angle of repose was determined by funnel method. Powder blend was poured from funnel that can be raised vertically until it reaches maximum cone height (h) was obtained. Radius (r) of the pile was measured. Angle of repose was measured by following formula.

$$\textbf{Tan}\ \theta = \frac{h}{r} \qquad \theta = \tan^{-1}\frac{h}{r}$$

Where, θ = Angle of repose,
h = Height of pile,
r = Radius of pile

Hausner's ratio: Hausner's ratio is a ratio of tapped density to bulk density. Value of 1.25 Hausner's ratio indicates good powder flow and more than 1.25 indicated poor powder flow. Generally, glidant were added to improve the powder flow of the material.

$$\textbf{Hausner's ratio} = \frac{\textbf{Tapped density}}{\textbf{Bulk density}}$$

Post Compression Parameters[10, 15-17]

Thickness and diameter: Tablet thickness and diameter were measured by Digi-matic Vernier calipers. Five tablets were randomly collected and their thickness and diameter were measured by placing between two arms of Vernier calipers.

Weight variation: Twenty tablets were randomly collected and average weight was determined by using an electronic balance (Table 2).

Table 2: Weight variation limit

Average weight of tablet	% Deviation
80 mg or less	±10
More than 80 mg but less than 250 mg	±7.5
250mg or more	±5

Hardness: Tablet hardness has been defined as the force required to break a tablet in a diametric compression test and was measured by using Monsanto type hardness tester.

Friability test: The friability of tablets was measured by Roche type friabilator. Twenty tablets were initially weighed and then tablets were placed in friabilitor at 25 rpm for 4 min then tablets were deducted and weighed again. Loss in weight should not be more than 1%. % friability determined by using following equation.

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$$\% \textbf{ Friability} = \frac{\textbf{Initial weight} - \textbf{Final weight}}{\textbf{Initial weight}} \times \textbf{100}$$

Drug content[18]: Ten tablets were powdered and equivalent to 50 mg of Gemigliptin was weighed and dissolved in 100 ml of 0.1 N HCl. The solution was filtered and 2 ml from filtrate was diluted to 10 ml and absorbance of this solution was analyzed by UV spectrophotometer at 256 nm.

Swelling Index[19-20]: The extent of swelling was determined in terms of percentage weight gained by the tablets. One tablet from each formulation was kept in dissolution apparatus USP type I (basket) containing volume of 900 ml 0.1N HCl. At regular time interval, tablets were withdrawn, soaked on tissue paper and weighed, and then percentage weight gain by the tablet was calculated using the formula.

$$\textbf{Swelling Index} = \frac{(\boldsymbol{Mt} - \boldsymbol{Mo})}{\boldsymbol{Mo}} \textbf{ x 100}$$

Where, Mo = Initial weight of tablet and Mt = Final weight of tablet at time "t"

***In Vitro* Drug release study [21]:** Percentage drug release of Gemigliptin sustained release matrix tablet was determined by USP type II (paddle type) dissolution apparatus. This test performed using 900 ml of 0.1 N HCl at 37° ± 0.5 °C at 50 rpm. 5 ml sample solution was withdrawn from dissolution apparatus at regular time interval and the same quantity of sample was replaced with fresh dissolution media. The sample was filtered through 0.45 µm membrane filter. Absorbance of these samples was analyzed by using UV spectrophotometer at 256 nm.

Stability Study[22]
Stability studies were conducted on the optimized formulation for one month at 40°C ± 2°C and 75% ± 5% RH. Tablets were evaluated, thickness, hardness, %swelling index drug content and drug release profile.

RESULT:

Determination of Melting Point of Gemigliptin:
Melting point determination was carried out to confirm the purity and identity of Gemigliptin using a melting point apparatus. The observed melting point values were found to be 171-179 °C which is nearer to reported melting point range 174-177 °C of Gemigliptin, confirming the identity of the drug (Table 3).

Table 3: Melting point of Gemigliptin

Sr. No.	Reported Melting Point (°C)	Observed Melting point (°C)
1.	174-177 °C	171-175 °C
2.		174-179 °C
3.		173-176 °C

Estimation of Drug by UV Spectrophotometric Method UV spectrophotometric analysis of Gemigliptin was carried out in 0.1 N HCl. The drug showed maximum absorbance (λmax) at 256 nm. Calibration curve was constructed by plotting concentration versus absorbance, which showed good linearity over the concentration range of 10–50 ppm (Table 4 and Figure 1).

Table 4: Absorbance of different concentration of Gemigliptin in 0.1 N HCl

Sr. No.	Concentration (ppm)	Absorbance			Mean Absorbance ± S. D.
		I	II	III	
1.	10	0.589	0.582	0.583	0.584 ± 0.0037
2.	20	0.762	0.768	0.769	0.766 ± 0.0037
3.	30	0.971	0.973	0.973	0.972 ± 0.0011
4.	40	1.181	1.189	1.182	1.184 ± 0.0043
5.	50	1.392	1.396	1.398	1.395 ± 0.0030

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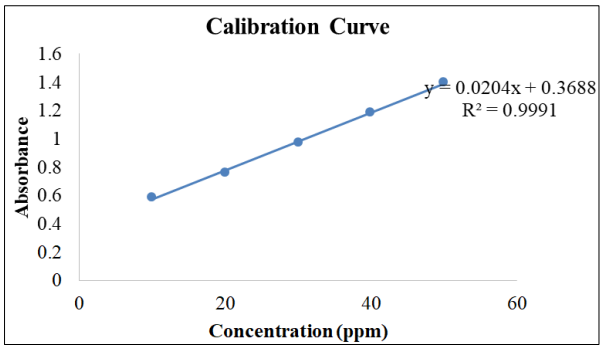

Figure 1: Calibration curve of Gemigliptin in 0.1 N HCl

Pre-Compression Parameters:

All formulation blends were evaluated for bulk density and tapped density. Bulk density was found to be 0.38± 0.01 gm/ml to 0.46± 0.02 gm/ml and tapped density was found to be 0.42± 0.02 gm/ml to 0.57± 0.04 gm/ml. Carr's index of all formulation blend lies within the range of 12.92± 0.88 to 26.67± 1.01 %. From Carr's Index flow of powder was found to be excellent fair to passable. Hausner's ratio of all formulation was found in the range of 1.14± 0.02 to 1.36±0.03. From Hausner's ratio flow of powder was found to be good. Angle of repose of all formulation was in the range of 23.48± 0.71 to 29.34±0.91. From observed Angle of repose, flow of powder was found to be good to excellent (Table 5).

Table 5: Bulk density, Tapped density, Carr's index, Hausner's ratio and Angle of Repose data

Batch	Bulk density (gm/cm^3) ± S.D.	Tapped density (gm/cm^3) ± S.D.	Carr's index ± S.D.	Hausner's ratio ± S.D.	Angle of repose (Ø) ± S.D.
F1	0.39±0.02	0.47±0.03	17.68±1.12	1.21±0.02	27.74±0.84
F2	0.40±0.02	0.54±0.04	26.46±1.34	1.36±0.03	29.34±0.91
F3	0.38±0.01	0.42±0.02	12.92±0.88	1.14±0.02	26.79±0.76
F4	0.40±0.02	0.54±0.03	18.92±1.05	1.36±0.03	28.10±0.83
F5	0.41±0.02	0.47±0.03	13.73±0.94	1.15±0.02	27.50±0.79
F6	0.45±0.02	0.55±0.04	26.67±1.41	1.23±0.03	26.93±0.82
F7	0.46±0.02	0.57±0.04	18.71±1.09	1.23±0.02	23.48±0.71
F8	0.43±0.02	0.52±0.03	17.39±1.01	1.27±0.03	27.06±0.80
F9	0.46±0.02	0.54±0.03	16.41±0.96	1.25±0.02	25.82±0.77

Post-Compression Parameters

Weight variation limits for tablet weight 250 mg was ± 7.5 according to U.S Pharmacopeia. Weight of prepared formulations were in the range of 249.35 ± 4.51 mg to 252.50 ± 3.21 mg. Thus all the formulated Batch comply with the Weight variation limits. Thickness of the formulated Batch was found to be in the range of 3.13 ± 0.06 mm to 3.37 ± 0.59 mm. Diameter of the formulated Batch was found to be in the range of 12.03 ± 0.05 mm to 12.20 ± 0.20 mm. Hardness of sustained release matrix tablets prepared by wet granulation was found in the range of 4.1 ± 0.15 kg/cm^2 to 5.7 ± 0.21 kg/cm^2. Friability of the tablets was found in the range of 0.36 to 0.76 %. According to IP, Limits of Friability is less than 1%. Observes values of friability indicated that tablets were having a good mechanical stability. Drug content of the formulated Batch was found to be in the range of 97.67± 0.82 % to 99.92± 0.88% (Table 6).

Table 6: Weight variation, Thickness, Diameter, Hardness, Friability and Drug Content Data

Batch	Weight variation (mg) ± S.D.	Thickness (mm) ± S.D.	Diameter (mm) ± S.D.	Hardness (kg/cm^2)	Friability ± S.D.	Drug Content ± S.D.
F1	250.35 ± 3.51	3.37 ± 0.15	12.12 ± 0.17	4.4 ± 0.21	0.48	98.33±0.86
F2	251.25 ± 2.52	3.30 ± 0.17	12.17 ± 0.11	4.5 ± 0.25	0.37	97.25±0.79
F3	249.35 ± 4.51	3.27 ± 0.06	12.23 ± 0.20	5.5 ± 0.15	0.36	97.67±0.82
F4	250.10 ± 5.69	3.23 ± 0.06	12.33 ± 0.11	4.5 ± 0.06	0.67	98.83±0.91
F5	250.10 ± 5.69	3.27 ± 0.12	12.07 ± 0.05	4.6 ± 0.12	0.56	99.92±0.88
F6	252.50 ± 3.21	3.40 ± 0.17	12.17 ± 0.20	5.7 ± 0.21	0.38	99.29±0.84
F7	251.80 ± 1.00	3.3 7 ± 0.59	12.20 ± 0.20	4.1 ± 0.15	0.76	98.27±0.90
F8	250.20 ± 1.53	3.37 ± 0.12	12.13 ± 0.11	4.2 ± 0.06	0.72	99.75±0.87

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F9	250.05 ± 1.53	3.13 ± 0.06	12.03 ± 0.05	4.4 ± 0.12	0.56	99.28±0.85

(s.d, n=6)

Swelling Index (%)

The swelling index study was carried out to evaluate the hydration and swelling behaviour of the polymeric matrix tablets. It was observed that the swelling index increased with time due to hydration and weight gain of the tablets. The swelling increased up to a certain limit, after which it gradually decreased due to erosion and dissolution of the outer gel layer into the dissolution medium (Figure 2, 3 and 4).

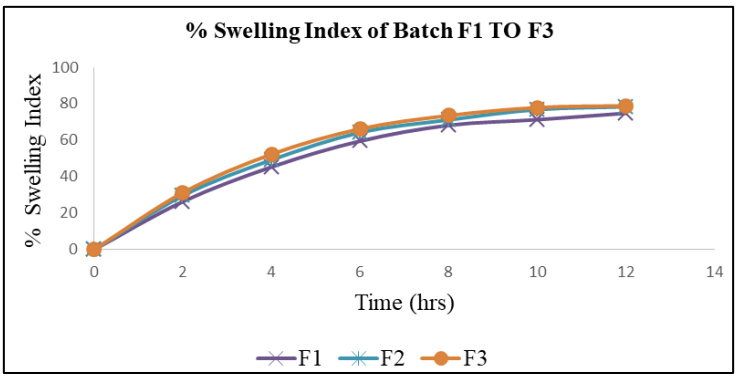

Figure 2: % Swelling Index vs Time of Batch F1-F3

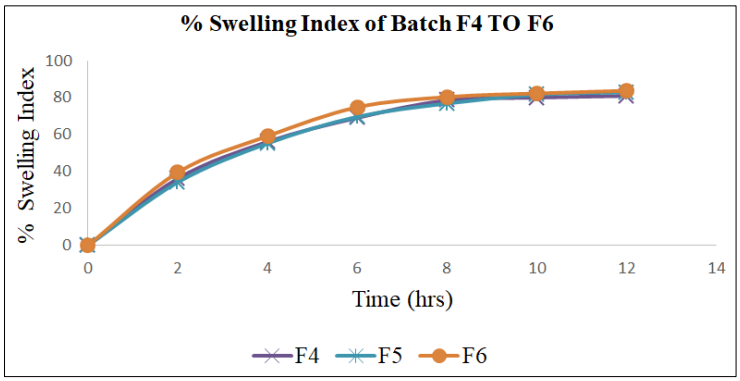

Figure 3: % Swelling Index vs Time of Batch F4-F6

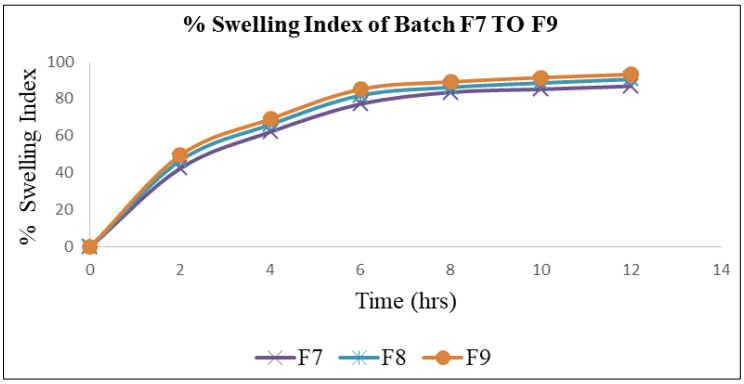

Figure 4: % Swelling Index vs Time of Batch F7-F9

In-Vitro Drug Release Study

In-vitro drug release study was carried out using USP type II (paddle) apparatus in 0.1 N HCl (pH 1.2) at 37 ± 0.5°C and 50 rpm. The results indicated that increase in polymer concentration resulted in a decrease in the drug release rate. Formulations F1–F3 released 99.18%, 99.09% and 97.62% of drug within 12, 14 and 14 hours, respectively. Formulations F4–F6 showed 98.62%, 97.24% and 97.98% drug release at 14, 16 and 16 hours,

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while formulations F7–F9 released 98.19%, 99.49% and 99.76% of drug at 16, 18 and 18 hours, respectively. Among all formulations, batch F9 exhibited the most prolonged and controlled drug release (Figure 5, 6 and 7).

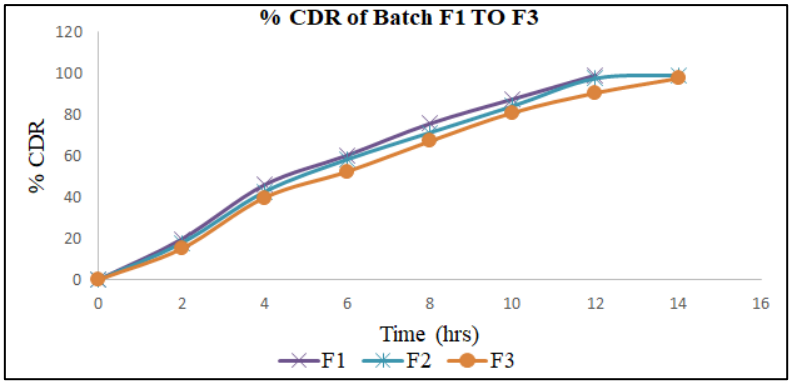

Figure 5: % CDR vs Time of batch F1-F3

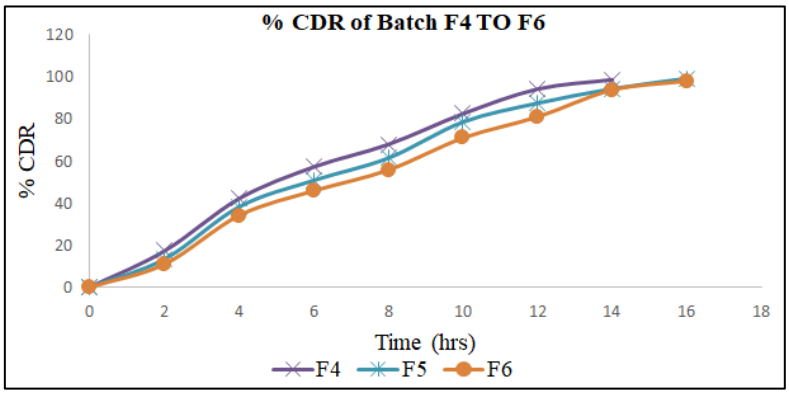

Figure 6: % CDR vs Time of batch F4-F6

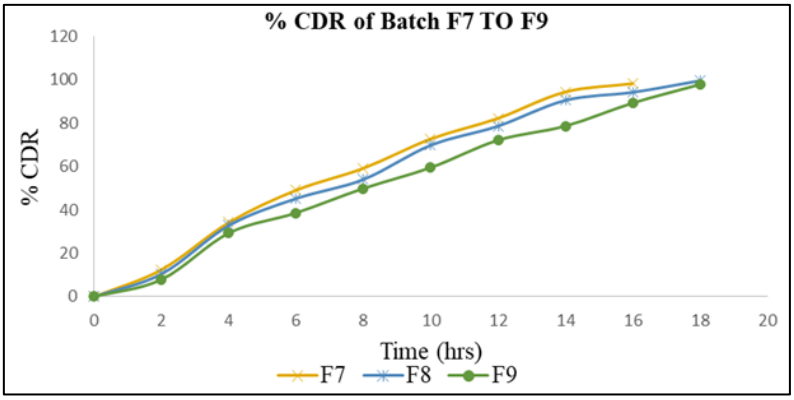

Figure 7: % CDR vs Time of batch F7-F9

Drug release kinetics

Different drug release kinetics model was performed for optimized batch and highest R^2 was found to be 0.9886 for zero order. Thus, from data it was concluded that Zero order release kinetics was followed by formulation (Table 7).

Table 7: Drug Release Kinetics of Optimized Batch

Model	First Order	Zero Order	Higuchi release model	Korsmeyer Peppas release model
R^2	0.7014	0.9886	0.9423	0.9233
Slope	0.0858	5.4702	24.678	1.4401
Intercept	0.7402	3.0604	15.085	0.3211

Stability study

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Stability studies were conducted to evaluate the influence of storage conditions on the physicochemical properties and performance of the optimized formulation. The optimized batch (F9) was subjected to accelerated stability conditions to assess any changes in tablet thickness, hardness, swelling index and drug content. The study was carried out to ensure the integrity and therapeutic effectiveness of the formulation during storage. The stability testing also helps in predicting the shelf life and storage requirements of sustained release matrix tablets.

From the data of % CDR after Stability it has been found that there was minor change in the amount of drug released from the optimized formulation. Stability data showed that all the parameters were in acceptable limits as there was minor change in the results. Thus, the prepared batch F9 was stable over period of 1 month. From the comparison of % CDR values before and after stability testing, it was observed that there was no significant variation in the drug release profile. Stability data revealed that all the parameters were within acceptable limits and only minor changes were observed. Thus, the optimized batch F9 was found to be stable over a period of one month (Table 8, 9 and figure 8).

Table 8: Result of the Stability study

Parameters	**Optimized batch (F9)**	**Optimized batch after 1 month**
Thickness(mm)±s.d	3.13 ± 0.06	3.12 ± 0.06
Hardness (kg/cm^2)±s.d	4.4 ± 0.12	4.2 ± 0.11
% Swelling IndexAfter 12 hours	93.24	92.83
Drug Content (%)	99.28	97.69

Table 9: % Cumulative Drug Release of Stability batch

Time (hrs)	**% CDR of Optimized Batch (F9)**	**% CDR of Optimized batch After 1 Month**
0	0 ±0.00	0 ±0.00
2	7.93±0.42	10.24±0.48
4	29.34±0.96	31.65±1.02
6	38.62±1.05	40.93±1.10
8	49.88±1.18	52.19±1.24
10	59.48±1.22	61.79±1.30
12	72.09±1.36	74.40±1.41
14	78.61±1.42	80.92±1.46
16	89.21±1.55	91.52±1.60
18	97.76±1.63	98.25±1.68

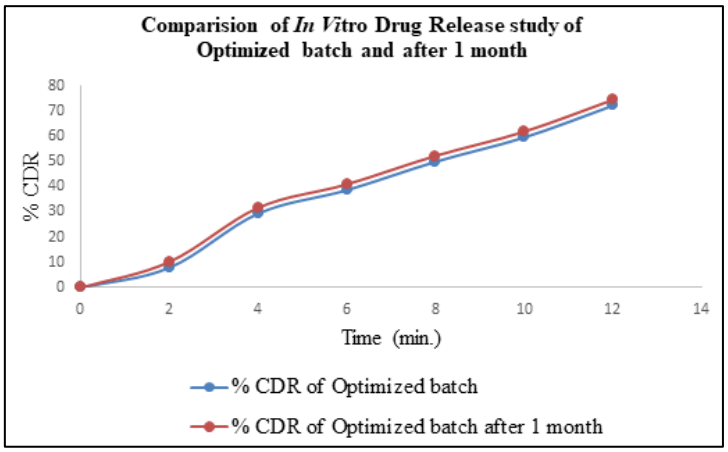

Figure 8: Comparison of % CDR of Optimized batch and Stability batch

CONCLUSION:

The present study was aimed at the formulation and evaluation of sustained release matrix tablets of Gemigliptin using natural polymers to improve patient compliance and therapeutic efficacy. Sustained release tablets were prepared by the wet granulation method using polymers such as xanthan gum, guar gum. All the prepared granules were evaluated for pre-compression parameters such as bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose. The results indicated good flow properties and compressibility of granules, confirming their suitability for tablet compression. Post-compression evaluation of the prepared tablets including weight variation, hardness, friability and drug content showed that all parameters were within acceptable limits as per pharmacopoeia specifications, indicating good mechanical strength and uniform drug

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distribution. Swelling index studies demonstrated that the polymeric matrix showed adequate hydration and gel layer formation, which played an important role in controlling the release of Gemigliptin from the tablets. The optimized formulation (batch F9) exhibited satisfactory tablet properties and sustained drug release up to 18 hours, releasing 97.76% of Gemigliptin at 18 hr. Drug release kinetics revealed that the optimized batch followed zero-order kinetics, indicating controlled and prolonged drug release from the polymeric matrix. Stability studies conducted under accelerated conditions indicated no significant change in the drug release profile after storage, confirming the stability of the optimized formulation. Furthermore, the use of natural polymers such as xanthan gum and guar gum was found to be effective in controlling the drug release and improving the overall performance of the sustained release matrix tablets. Thus, it can be concluded that sustained release matrix tablets of Gemigliptin can be successfully formulated using natural polymers and may serve as a suitable once-daily dosage form for the management of type II diabetes mellitus. Thus, it can be concluded that sustained release matrix tablets of Gemigliptin can be successfully formulated using natural polymers for the management of type II diabetes mellitus.

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CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

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