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FORMULATION, DEVELOPMENT AND IN VITRO EVALUATION OF SUSTAINED RELEASE MATRIX TABLETS OF VILDAGLIPTIN

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Abstract:

The main aim of present work was to formulate and evaluate sustain release matrix tablets of Vildagliptin is an oral anti-hyperglycemic agent (anti-diabetic drug) of the dipeptidyl peptidase-4 (DPP-4) inhibitor class of drugs. Sustain release formulation are those which delivers the drug locally or systemically at a predetermined rate for a fixed period of time. The matrix tablet was prepared by direct compression method using by various concentration of Sodium CMC, Acacia and Tragacanth various release retardant polymer. The powder mixtures were subjected to various pre-compression parameters such as angle of repose, bulk density, tapped density and Carr's index shows satisfactory result and the compressed tablets are evaluated for post-compression parameters such as weight variation, thickness, hardness, friability, drug content, in-vitro dissolution studies. In-vitro dissolution studies were carried out for 12 hours using 0.1 N HCL for first 2 hours and pH 6.8 phosphate buffer for 12 hours and the result showed that formulations V3 showed good dissolution profile to control the drug release respectively. Formulation containing higher concentration of Sodium CMC polymer sustained the drug release for the period of 12 hours. The kinetics studies the optimized formulation followed Zero order release kinetics.

Keywords: *Vildagliptin, Sodium CMC, Acacia, Tragacanth, Direct compression and Sustained release matrix tablets.*

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INTRODUCTION:

Administration of drugs, which is due in part to the ease of administration and to the fact that gastrointestinal physiology offers more flexibility in dosage form design than most other routes. The terms Sustained release, prolonged release, modified release, extended release or depot formulations are used to identify drug delivery systems that are designed to achieve or extend therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. The advantages of administering a single dose of a drug that is released over an extended period of time, instead of numerous doses, have been obvious to the Pharmaceutical industry for some time. The desire to maintain a near constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use. Because of increased complication and expense involved in marketing of new drug entities, has focused greater attention on development of sustained or controlled release drug delivery systems . Matrix system is widely used for the purpose of sustained release. It is the release system which prolongs and controls the release of the drug that is dissolved or dispersed. In fact, a matrix is defined as a well-mixed composite of one or more drugs with gelling agent i.e. hydrophilic polymers. The goal of an extended release dosage form is to maintain therapeutic drug level in plasma for extended period of time.[1]

Now a day's conventional dosage forms of drugs are rapidly being replaced by the new and the novel drug delivery systems. Amongst, these the controlled release/sustained release dosage forms have become extremely popular in modern therapeutics. Matrix system is the release system which prolongs and controls the release of the drug, which is dissolved or dispersed. A matrix is defined as a well-mixed composite of one or more drugs with gelling agent i.e. hydrophilic polymers. Introduction of matrix tablet as sustained release (SR) has given a new breakthrough for novel drug delivery system in the field of Pharmaceutical technology. Sustained release constitutes any dosage form that provides medication over an extended time or denotes that the system is able to provide some actual therapeutic control whether this is of a temporal nature, spatial nature or both. Sustained release system generally do not attain zero order type release and usually try to mimic zero order release by providing drug in a slow first order. Repeat action tablet are an alternative method of sustained release in which multiple doses of drug are an alternative method of sustained release, in which, multiple doses are contained within a dosage form and each dose is released at a periodic interval.[2]

The goal in designing sustained or sustained delivery systems is to reduce the frequency of the dosing or to increase effectiveness of the drug by localization at the site of action, reducing the dose required or providing uniform drug delivery. So, sustained release (SR) dosage form is a dosage form that release one or more drugs continuously in a predetermined pattern for a fixed period of time, either systemically or to a specified target organ. The goal of an SR dosage form is to maintain therapeutic blood or tissue levels of the drug for an extended period. This is usually accomplished by attempting to obtained zero-order release from the dosage form. Zero-order release constitutes drug release from the dosage form that is independent of the amount of drug in the delivery system (i.e., a constant release rate). SR systems generally do not attain this type of release and usually try to mimic zero-order release by providing the drug in a slow first-order fashion (i.e., concentration dependent).[3]

Approaches of oral sustained/controlled release formulations:

To achieve the rapid action, Bolourtchian et al developed sublingual tablets of captopril which was effective and safe method of lowering arterial blood pressure in patient with hypertensive emergencies. More rapid attainment of plasma concentration and more rapid onset of pharmacological effect have been observed after sublingual administration of captopril than oral route . Various pharmaceutical approaches have been made to design long acting devices to administer once a day formulation as controlled and sustained release systems to deliver the drug. The different methodologies applied and their limitations are described as follows.

Matrix tablets:

Various methods are available to formulate water soluble drugs into sustained release dosage forms by retarding the dissolution rate. One of the methods used to control the drug release and there by prolonging therapeutic activity is to use of hydrophilic or lipophilic polymers.

Coated tablets:

It is a classical technique to control the drug release. The drug has cross the barriers before it reaches the physiological fluids. The type and composition of the barriers is the release determining step. Barriers are mainly composed of hydrophilic or hydrophobic polymers and that is due to the compatibility of these

substances beside their in vivo safety even when used in large amounts.

Floating tablets:
These systems were used to prolong the gastric residence time of drug delivery systems. They remain buoyant in the stomach for prolonged period of time without affecting the gastric emptying rate of other contents. A floating dosage form is useful for those drugs that act locally in the proximal gastro intestinal tract (GIT), are unstable in lower parts of GIT, or are poorly absorbed in the intestine.

Slow release granules and Sustained release oily matrix:
Stulzer et al developed the captopril granules of controlled release with different polymers as ethyl cellulose, ethyl/methyl cellulose and immediate release with polyvinyl pyrrolidone by fluid bed drier technique. The dissolution profile of granules coated with ethyl cellulose showed a median time release of 4hrs whereas for granules coated with ethyl/methyl cellulose was 3.5hrs. The blockage of angiotensin I-induced hypertensive effect lasted 8 hr in granules coated with PVP and of more than 12 hr in the granules coated with ethyl cellulose and ethyl/methylcellulose.

Sustained release microparticles:
Microparticles are small solid particulate carriers containing dispersed drug particles either in solution or crystalline form. They are made from natural and synthetic polymers. Dandagi et al worked on microparticles of Captopril using bovine serum albumin as a drug carrier prepared by emulsification-heat stabilization technique. The in vitro study of captopril loaded microparticles showed release of drug up to 24hrs. The invivo result showed preferential drug targeting towards liver, lungs, spleen and kidneys.

Mucoadhesive microcapsules:
The adhesive properties of certain types of polymer could be used to increase the residence time of orally administered drugs. A fuller understanding of the molecular processes underpinning such Mucoadhesive phenomena will help in the optimal design of the delivery systems.[4]

Rational for developing of SRDDS
I. Formulation of SRDDS minimizes dosing frequency and sustained release provides availability of a drug at action site throughout the treatment to improve clinical efficiency of a drug molecule.
II. To reduce cost of treatment by reducing number of dosage requirement.
III. To minimize toxicity due to overdose which is often in conventional dosage from.
IV. To enhance the activity duration of a drug possessing short half-life.

Principle of SRDDS
The conventional dosage forms release their active ingredients into an absorption pool immediately. This is illustrated in the following simple kinetic scheme. The absorption pool represents a solution of the drug at the site of absorption, Kr, Ka and Ke - first order rate-constant for drug release, absorption and overall elimination respectively. Immediate drug release from a conventional dosage form implies that Kr>>>>Ka. For non-immediate release dosage forms, Kr<<<Ka i.e. the release of drug from the dosage form is the rate limiting step. The drug release from the dosage form should follows zero-order kinetics, as shown by the following equation:
Kr° = Rate In = Rate Out = Ke.Cd.Vd----------1
Where,
Kr°: Zero-order rate constant for drug release-Amount/time
Ke: First-order rate constant for overall drug elimination-time
Cd: Desired drug level in the body – Amount/volume
Vd: Volume space in which the drug is distributed in litter

Challenges for SRRDS

Dose dumping
This can greatly increase the concentration of a drug in the body and there by produce adverse effects or even druginduced toxicity. Dose dumping means the relatively large quantity of medication in a sustained release formulation is slowly released. If the dose dumping can leads to fatalities in case of potent drug, which have a narrow therapeutic, index e.g. Phenobarbital.

Limited choice of selecting desired dose in the unit
In case of conventional dosage forms, the dose adjustments are much simple e.g. tablet can be divided into two portions. In case of sustained release dosage forms, this can appear to be much more complicated. Sustained release property may get lost, if dosage form is fractured.
Poor *in-vitro – in-vivo* correlation
In sustained release dosage form, the rate of drug release is slowly reduced to achieve drug release possibly over a large region of gastrointestinal tract. Hence it is so called as 'Absorption window' becomes important and give rise to unsatisfactory

drug absorption in-vivo despite excellent in-vitro release characteristics.

Patient variation

The time period required for absorption of drug released from the dosage form may vary among individuals. The coadministration of other drugs, presence or absence of food and residence time in gastrointestinal tract is different among patients. This also gives rise to variation in clinical response among the patient.[5]

METHODOLOGY:

Analytical method development:

Determination of λ max:

100mg of pure drug was dissolved in 10ml methanol (primary stock solution - 1000 µg/ml). From this primary stock solution 1 ml was pipette out into 100 ml volumetric flask and made it up to 100ml with the media (Secondary stock solution – 100µg/ml). From secondary stock solution again 1ml was taken it in to another volumetric flask and made it up to 10 ml with media (working solution - 10µg/ml). The working solution was taken for determining the wavelength.

Determination of Calibration Curve:

100mg of pure drug was dissolved in 10ml methanol (primary stock solution - 1000 µg/ml). From this primary stock solution 10 ml was pipette out into 100 ml volumetric flask and made it up to 10ml with the media (Secondary stock solution – 100µg/ml). From secondary stock solution required concentrations were prepared (shown in Table 8.1 and 8.2) and those concentrations absorbance were found out at required wavelength.

Preformulation parameters

The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Indian Pharmacopoeia.

Formulation development of Tablets:

All the formulations were compress by direct compression. The compositions of different formulations are given in Table 7.4.The tablets were prepared as per the procedure given below and aim is to prolong the release of Vildagliptin. Total weight of the tablet was considered as 300mg.

Procedure:

1) Vildagliptin and all other ingredients were individually passed through sieve no ≠ 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.
3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method.

Table 7.3: Ingredients and Uses

Ingredients	Uses
Vildagliptin	API
Sodium CMC	Binding agent
Acacia	Tablet Binder
Tragacanth	Primarily used in film-coating, binder in tablets
PVP K 30	Binding agent
MCC	Diluent
Magnesium stearate	Lubricant
Talc	Anticaking agent

Table 7.4: Formulation composition for tablets

INGREDIENTS (mg)	FORMULATION CODE								
	V1	V2	V3	V4	V5	V6	V7	V8	V9
Vildagliptin	50	50	50	50	50	50	50	50	50
Sodium CMC	50	100	150	-	-	-	-	-	-
Acacia	-	-	-	50	100	150	-	-	-
Tragacanth	-	-	-	-	-	-	50	100	150
PVP K 30	8	8	8	8	8	8	8	8	8
MCC	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Magnesium stearate	4	4	4	4	4	4	4	4	4
Talc	3	3	3	3	3	3	3	3	3
Total weight	300	300	300	300	300	300	300	300	300

RESULTS AND DISCUSSION:

The present study was aimed to developing sustained release tablets of Vildagliptin using various polymers. All the formulations were evaluated for physicochemical properties and *in vitro* drug release study.

Analytical Method

Graphs of Vildagliptin were taken in 0.1N HCL and in pH 6.8 phosphate buffer at 210 nm and 213 nm respectively.

Table 8.1: Observations for graph of Vildagliptin in 0.1N HCL

Concentration (µg/ml)	Absorbance
0	0
5	0.209
10	0.412
15	0.598
20	0.782
25	0.979

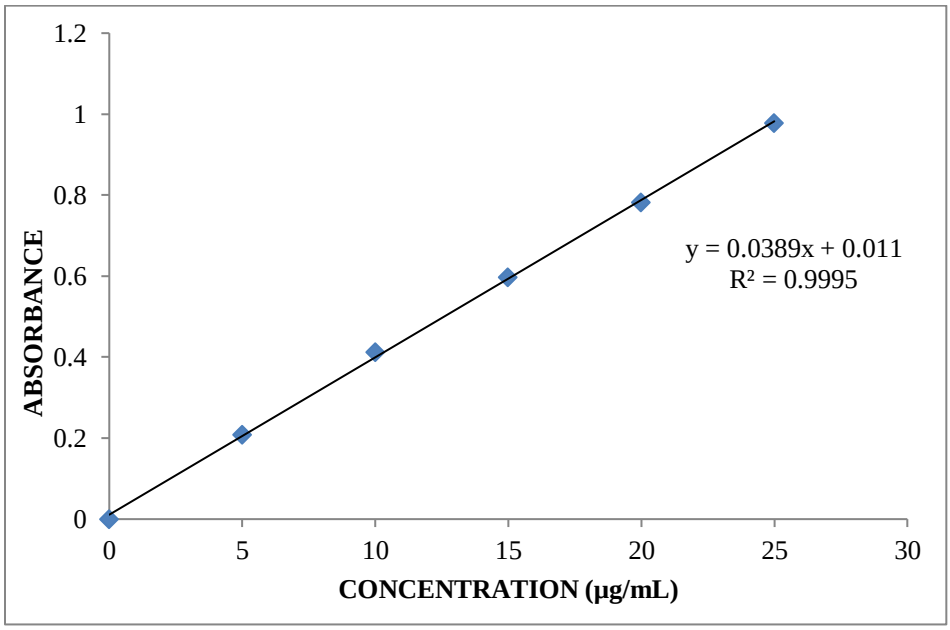

Fig 8.1: Standard curve of Vildagliptin

Table 8.2: Standard graph values of Vildagliptin at 213 nm in pH 6.8 phosphate buffer

Concentration (µg/ml)	Absorbance
0	0
5	0.169
10	0.305
15	0.451
20	0.589
25	0.738

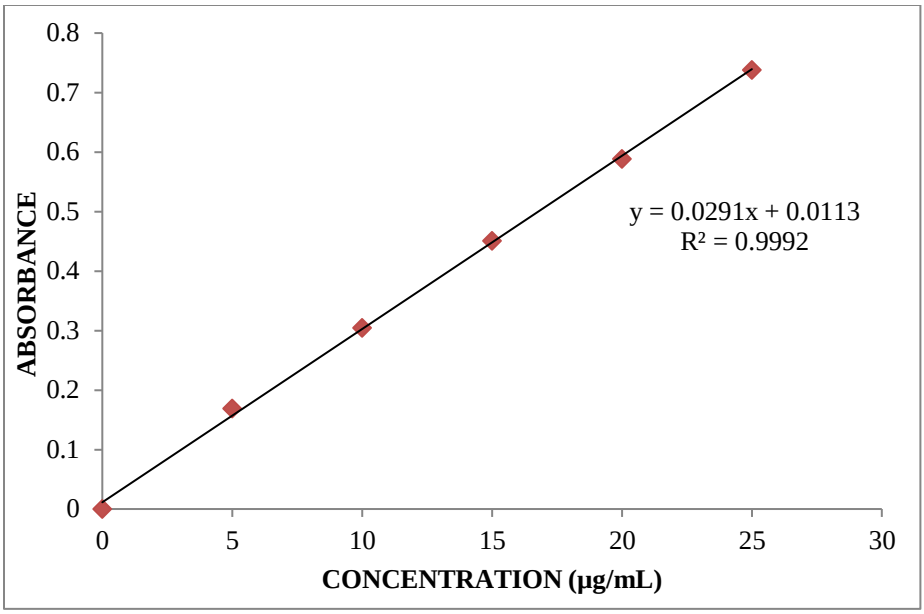

Fig 8.2: Standard curve of Vildagliptin

Preformulation parameters of powder blend

Table 8.3: Pre-formulation parameters of Core blend

Formulation Code	Angle of repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio
V1	29 ± 1.632	0.565±0.015	0.695± 0.011	12.952±1.912	1.139 ±0.023
V2	24 ± 2.654	0.581±0.013	0.639± 0.016	12.185±2.139	1.148 ±0.027
V3	29 ± 1.265	0.621±0.015	0.734± 0.025	11.654±2.364	1.165 ±0.034
V4	26 ± 1.324	0.668±0.031	0.754± 0.010	11.362±2.985	1.129 ±0.038
V5	28 ± 1.852	0.598±0.014	0.680± 0.018	12.078±1.916	1.137 ±0.024
V6	25 ± 1.589	0.669±0.024	0.757± 0.025	11.599±1.213	1.131 ±0.015
V7	23 ± 2.654	0.609±0.016	0.702± 0.011	12.738±1.958	1.146 ±0.025
V8	24 ± 1.564	0.590±0.010	0.672± 0.006	12.107±2.119	1.138 ±0.027
V9	22 ± 3.023	0.598±0.007	0.782± 0.006	12.995±1.105	1.149 ±0.014

All the values represent n=3

Tablet powder blend was subjected to various pre-formulation parameters. The angle of repose values indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range showing that the powder has good flow properties. The tapped density of all the formulations powders has good flow properties. The compressibility index of all the formulations was found to be 11.36 to 11.36 which show that the powder has good flow properties. All the formulations has shown the hausner ratio 1.129 to 1.165 indicating the powder has good flow properties.

Quality control parameters for tablets:

Tablet quality control tests such as weight variation, hardness, friability, thickness, and drug release studies in different media were performed on the compression tablet.

Table 8.4: Quality control parameters for tablets

Formulation codes	Average Weight (mg)	Hardness (kg/cm^2)	Friability (%loss)	Thickness (mm)	Drug content (%)
V1	298.62	4.1	0.68	4.36	98.45
V2	297.40	4.9	0.52	4.95	99.62
V3	299.23	5.3	0.31	4.12	97.15
V4	295.82	4.3	0.59	4.28	99.50
V5	300.01	5.0	0.48	4.99	98.35
V6	298.78	5.5	0.28	4.65	98.92
V7	300.03	4.2	0.49	4.17	97.40
V8	298.42	4.9	0.36	4.30	95.15
V9	299.38	5.2	0.25	4.83	98.79

Weight variation test:
Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet. The average weight of the tablet is approximately in range of 295.82 to 300.03 mg, so the permissible limit is ±7.5% (>300 mg). The results of the test showed that, the tablet weights were within the limit.

Hardness test:
Hardness of the five tablets of each batch was checked by using Pfizer hardness tester and the data's were shown in Table 8.4. The results showed that the hardness of the tablets is in range of 4.1 to 5.5 kg/cm^2, which was within IP limits.

Thickness:
Thickness of five tablets of each batch was checked by using Micrometer and data shown in Table-8.4. The result showed that thickness of the tablet is raging from 4.12 to 4.99 mm.

Friability:
Tablets of each batch were evaluated for percentage friability and the data were shown in the Table-8.4. The average friability of all the formulations was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets.

Drug content:
Drug content studies were performed for the prepared formulations. From the drug content studies it was concluded that all the formulations were showing the % drug content values within 95.15- 99.62 %.
All the parameters such as weight variation, friability, hardness, thickness and drug content were found to be within limits.

***In vitro* drug release studies**

Table 8.5: Dissolution data of Vildagliptin tablets V1-V9

TIME (HR)	% Drug release								
	V1	V2	V3	V4	V5	V6	V7	V8	V9
0	0	0	0	0	0	0	0	0	0
0.5	19.35	16.11	10.70	17.24	12.30	08.29	15.93	09.59	06.82
1	28.97	21.32	16.91	24.51	18.74	14.65	26.51	12.14	10.17
2	35.28	26.96	20.25	30.36	25.63	20.87	35.62	18.76	18.36
3	42.14	31.50	28.66	36.50	31.89	27.21	42.10	26.18	21.94
4	56.86	37.05	31.52	42.19	38.80	33.96	50.79	31.97	28.64
5	63.90	42.97	46.71	48.38	42.17	38.72	58.54	37.15	31.29
6	70.21	50.14	51.83	59.12	47.05	45.55	64.50	42.71	37.15
7	77.63	58.20	58.11	65.54	56.60	49.83	73.61	50.48	42.94
8	83.72	65.16	64.73	71.99	62.79	56.96	78.24	57.12	49.30
9	97.50	73.83	69.97	76.80	70.58	60.72	85.05	61.90	54.42
10		88.95	73.50	84.65	77.42	65.18	98.18	68.47	60.63
11		98.68	82.14	91.47	82.97	71.91		72.83	68.71
12			98.32	95.23	87.65	76.14		86.24	73.59

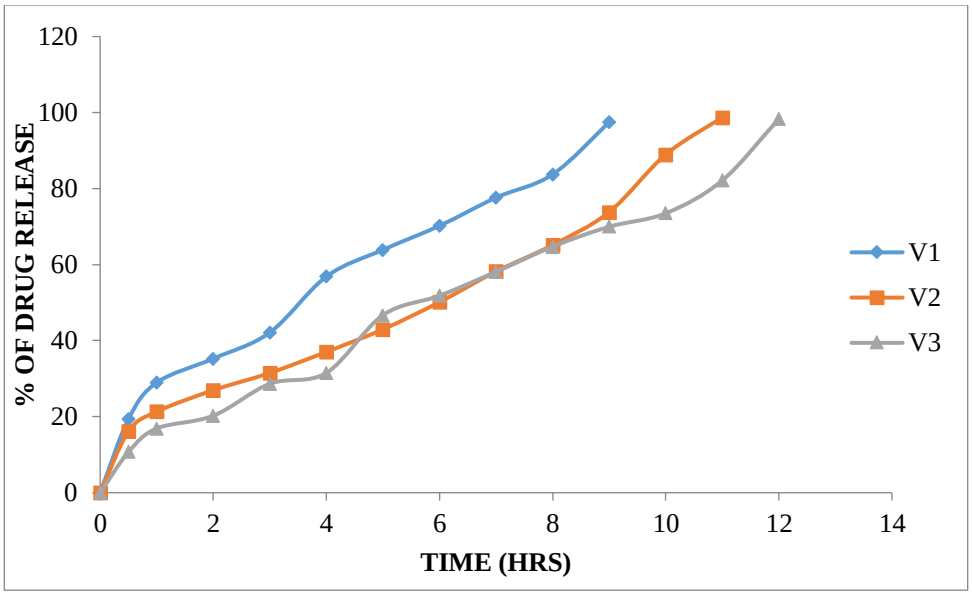

Fig 8.3: Dissolution profile of Vildagliptin (V1, V2 and V3 formulations)

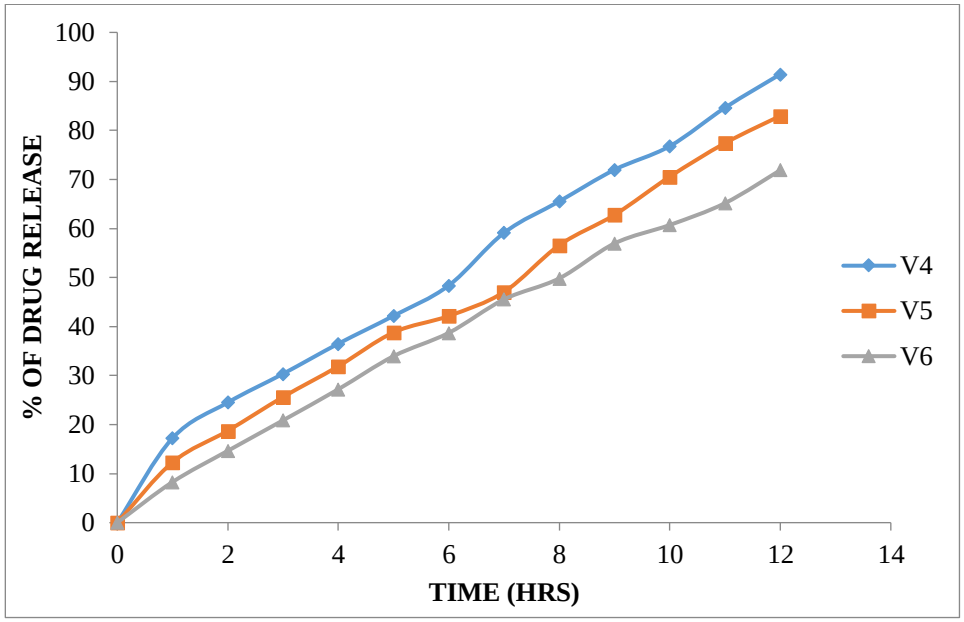

Fig 8.4: Dissolution profile of Vildagliptin (V4, V5 and V6 formulations)

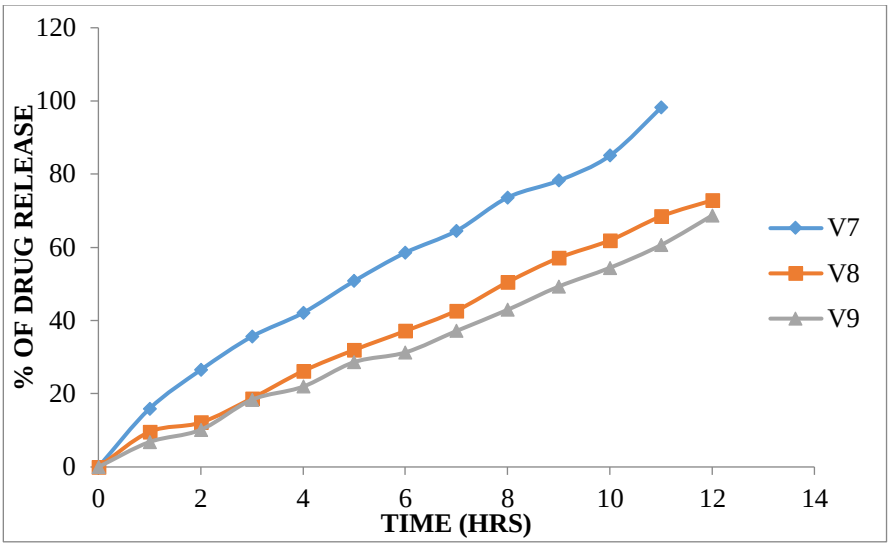

Fig 8.5: Dissolution profile of Vildagliptin (V7, V8 and V9 formulations)

The formulations V1, V2 and V3 are formulated with different concentrations of Sodium CMC with 50, 100, 150 mg respectively. And the release of the drug was faster in low concentration of the polymer. In all these V3 formulations 98.32% of the drug release was within 12 hours. The desired V1 and V2 value was not achieved.

The formulations V4, V5 and V6 are formulated with different concentrations of Acacia with 50, 100, 150 mg respectively. And the release was highly sustaining as the concentration of the polymer is decreasing. In all these formulations the release was more than 95.23% at the end of the 12hour.

The Formulations containing Tragacanth (V7 to V9) have shown initial burst release and extended the release for 10h. As the drug polymer ratio increased to 100mg (V8), the release rate was extended up 12h but drug release was decreased (86.24% at 12h).

The formulations containing Sodium CMC (V3) have shown better release profiles. There was no burst release observed and release was extended up to 12 hours. As the Sodium CMC concentration increases the drug release was increased. Formulation V3 was found to be optimum.
Finally Concluded that V3 formulation was considered as optimized formulation.

Table 8.6: Release kinetics:

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG(%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE / t)	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
10.7	0.5	0.707	1.029	-0.301	1.951	21.400	0.0935	-0.971	89.3	4.642	4.470	0.172
16.91	1	1.000	1.228	0.000	1.920	16.910	0.0591	-0.772	83.09	4.642	4.364	0.278
20.25	2	1.414	1.306	0.301	1.902	10.125	0.0494	-0.694	79.75	4.642	4.304	0.337
28.66	3	1.732	1.457	0.477	1.853	9.553	0.0349	-0.543	71.34	4.642	4.147	0.494
31.52	4	2.000	1.499	0.602	1.836	7.880	0.0317	-0.501	68.48	4.642	4.091	0.550
46.71	5	2.236	1.669	0.699	1.727	9.342	0.0214	-0.331	53.29	4.642	3.763	0.878
51.83	6	2.449	1.715	0.778	1.683	8.638	0.0193	-0.285	48.17	4.642	3.639	1.003
58.11	7	2.646	1.764	0.845	1.622	8.301	0.0172	-0.236	41.89	4.642	3.473	1.169
64.73	8	2.828	1.811	0.903	1.547	8.091	0.0154	-0.189	35.27	4.642	3.279	1.362
69.97	9	3.000	1.845	0.954	1.478	7.774	0.0143	-0.155	30.03	4.642	3.108	1.533
73.5	10	3.162	1.866	1.000	1.423	7.350	0.0136	-0.134	26.5	4.642	2.981	1.660
82.14	11	3.317	1.915	1.041	1.252	7.467	0.0122	-0.085	17.86	4.642	2.614	2.028
98.32	12	3.464	1.993	1.079	0.225	8.193	0.0102	-0.007	1.68	4.642	1.189	3.453

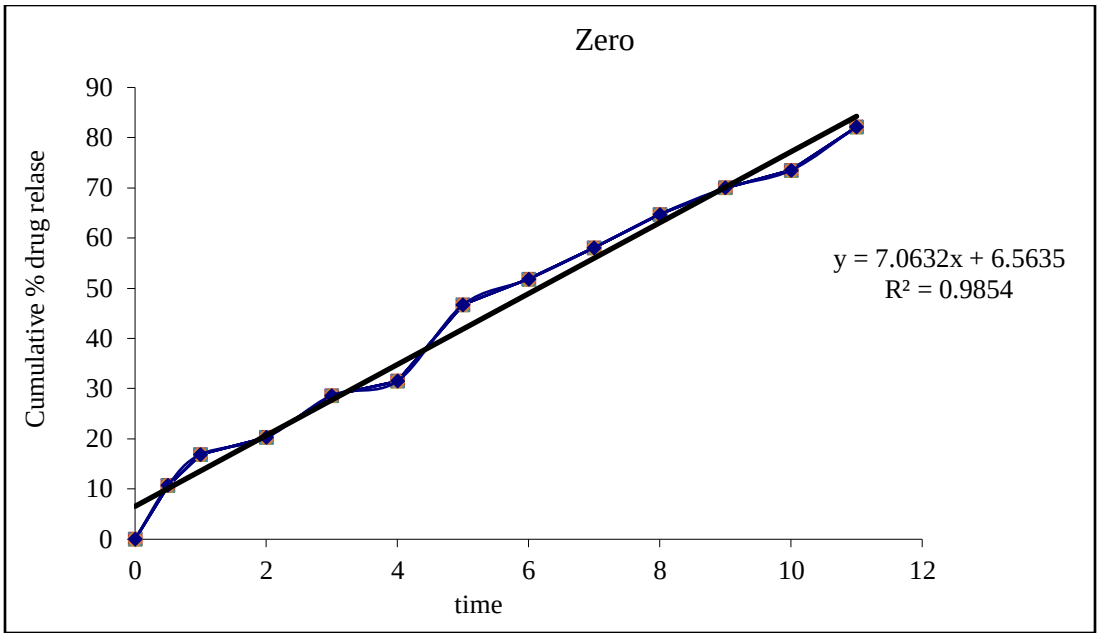

Figure 10.6: Zero order release kinetics graph

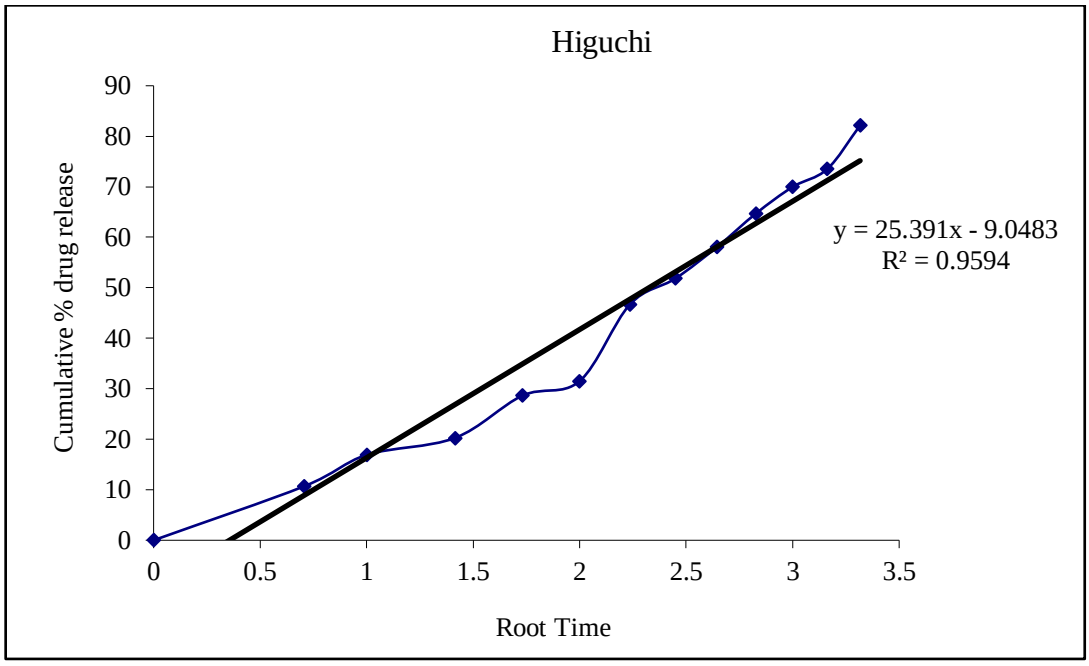

Figure 8.7: Higuchi release kinetics graph

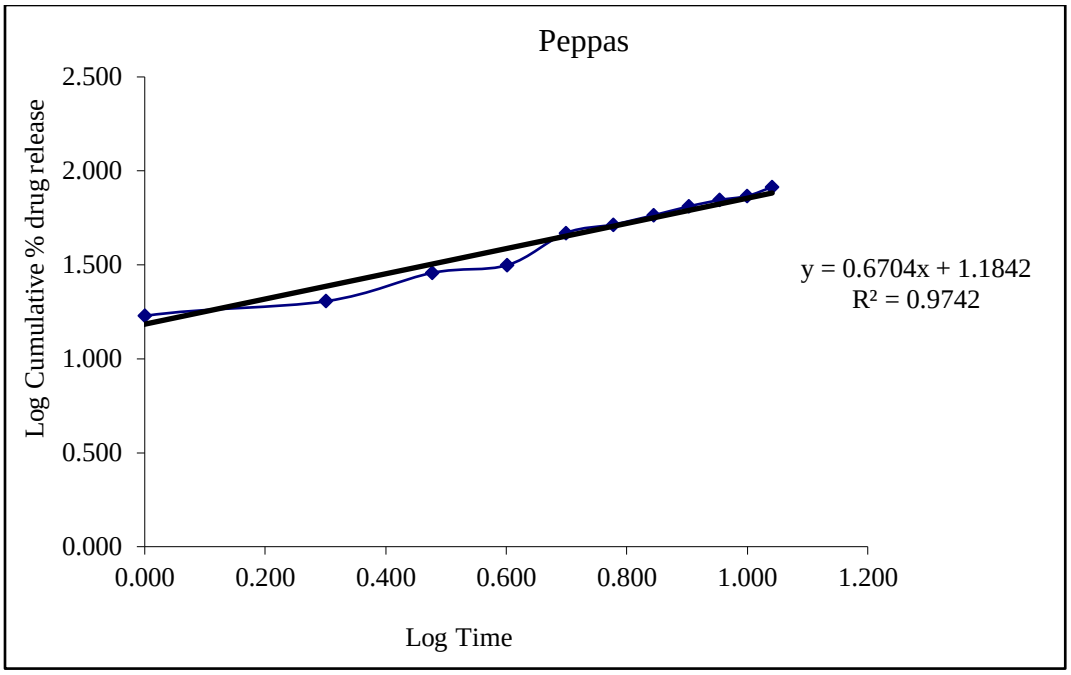

Figure 8.8: Peppas release kinetics graph

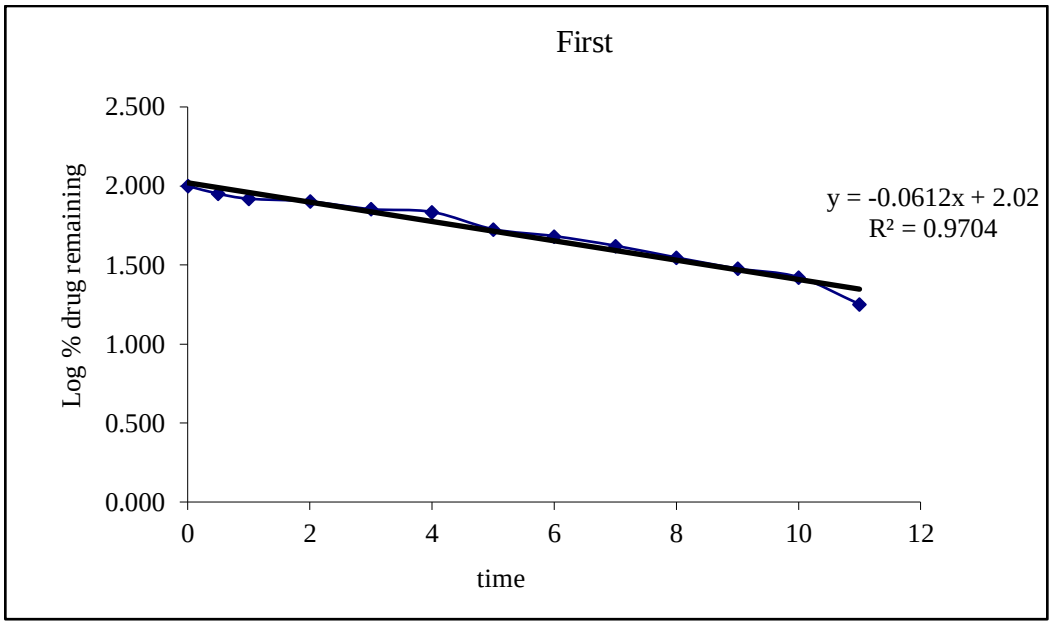

Figure 8.9: First order release kinetics graph

From the above graphs it was evident that the formulation V3 was followed Zero order release mechanism.

Table 8.7: kinetics Correlation coefficient values

Release Kinetics	Correlation coefficient values
Zero order release kinetics	$R^2 = 0.985$
Higuchi release kinetics	$R^2 = 0.959$
Peppas release kinetics	$R^2 = 0.974$
First order release kinetics	$R^2 = 0.970$

Drug – Excipient compatibility studies

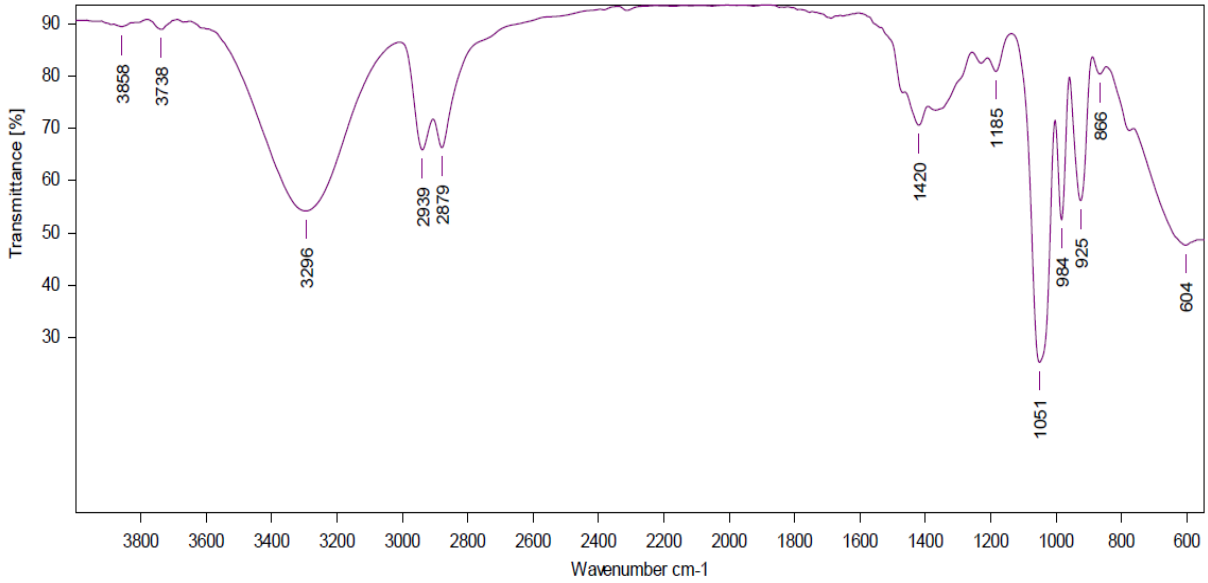

Figure 8.10: FT-TR Spectrum of Vildagliptin pure drug

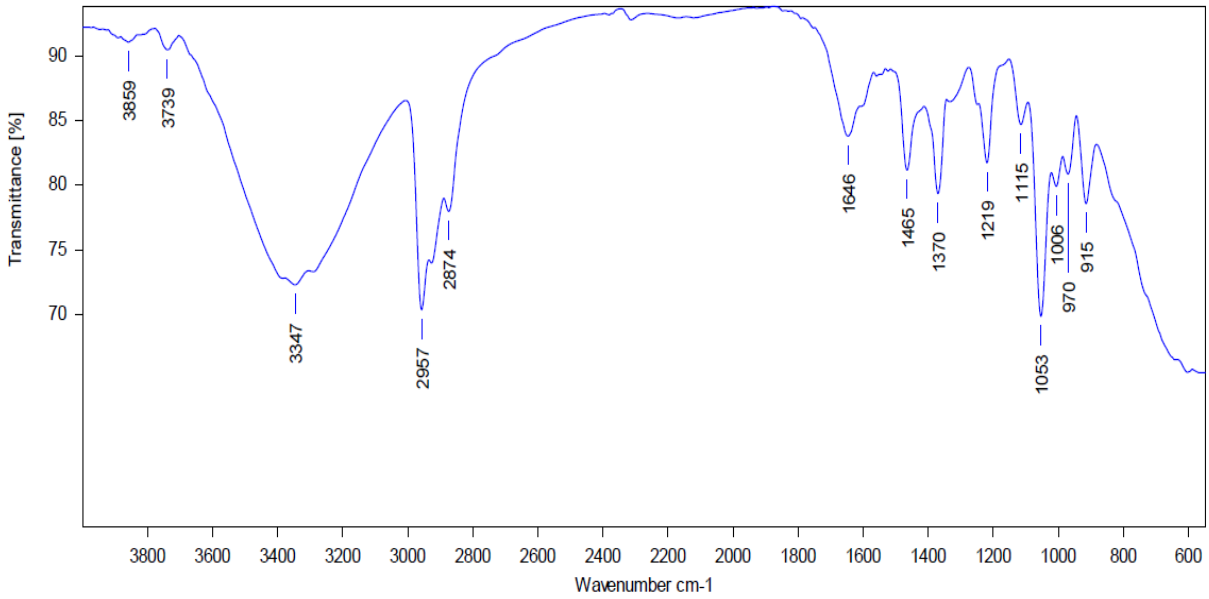

Figure 8.11: FT-IR Spectrum of Optimised Formulation

From the above studies it was found that there was no shifting in the major peaks which indicated that there were no significant interactions occurred between the Vildagliptin and excipients used in the preparation of different Vildagliptin Sustained release formulations. Therefore the drug and excipients are compatible to form stable

Formulations under study. The FTIR spectra of Vildagliptin and physical mixture used for optimized formulation were obtained and these are depicted in above figures. From the FTIR data it was evident that the drug and excipients does not have any interactions. Hence they were compatible.

CONCLUSION:

In this study an effort was made to study sustained release Vildagliptin tablets which can provide sustained drug release for up to 12hrs. Vildagliptin sustained release tablets were formulated and evaluated. Vildagliptin sustained release tablets were prepared with different concentrations of Sodium CMC, Acacia and Tragacanth and were optimized by conducting various trials.

Vildagliptin sustained release tablets are prepared by direct compression method with different polymers. The pre-formulation studies like angle of repose, bulk density, tapped density Hausner's ratio and Carr's index of all formulations were found to be within the standard limits. FTIR studies revealed that there was no chemical interaction between drug and other excipients. The powder mixtures were compressed into tablet and evaluated for post-compression parameters like weight variation, thickness, hardness, friability and drug content. All the formulation batches showed acceptable results. The *in-vitro* drug release was studied with USP Type-II dissolution apparatus in both simulated gastric fluid and intestine fluid for a period of 12 hours.

The optimization procedure aided in the preparation of Vildagliptin sustained release tablets with drug release up to 12hrs. The *in vitro* dissolution studies revealed that the formulated Vildagliptin sustained release the desired concentration of the drug.

Results showed that formulations containing higher concentration of Sodium CMC i.e. V3 (98.32%). The *in-vitro* drug release follows Zero order release kinetics mechanism.

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