IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Preparation, Evaluation And Optimization Of Vildagliptin Floating Beads For Control Release Action.

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Abstract: Diabetes Mellitus (DM) is a prevalent endocrine disorder, affecting 6% of the global population. It is characterized by insufficient insulin production or resistance, leading to elevated blood glucose levels, with serious complications affecting the eyes, kidneys, heart, and nerves. The condition, which dates back to ancient Egypt, is primarily classified into Type 1 and Type 2 diabetes. Type 1 involves the immune system attacking insulin-producing cells, while Type 2 is marked by insulin resistance. Current statistics indicate a rapid increase in Type 2 DM, particularly in developing countries, with projections of 552 million cases by 2030. The development of Floating Drug Delivery Systems (FDDS) represents a significant advancement in oral controlled-release pharmaceuticals, particularly for drugs like Vildagliptin, a DPP-4 inhibitor used to manage Type 2 diabetes. FDDS offers enhanced therapeutic efficacy by ensuring prolonged gastric retention and targeted release in the upper gastrointestinal tract. This system mitigates the fluctuations in drug concentration and improves bioavailability, patient compliance, and clinical outcomes. Vildagliptin, through FDDS, demonstrates improved control over glycemic levels by enhancing insulin secretion and suppressing glucagon release. Floating beads containing Vildagliptin not only maintain stable plasma concentrations but also reduce dosing frequency, leading to better management of diabetes with minimal side effects. The research aims to optimize the formulation of Vildagliptin floating beads to ensure safety, efficacy, and cost-effectiveness in treating Type 2 diabetes

Key words: Diabetes Mellitus, Floating drug delivery system, Control released system, Vildagliptin, floating beads.

1. Introduction:

Diabetes mellitus (DM) is the most widespread endocrine disorder prevalent throughout the world affecting 6 % population world over (100 million) with DM. There is either insufficient insulin production, or the inability of the body to use insulin properly, leading to a high blood glucose level. Insulin resistance leads to the vessels of the blood being destroyed and it may destroy the eyes, kidneys, heart and nerves [1].Symptoms include weight loss and increased urination, and the earliest record of this condition was made by the Egyptians, who described it nearly 5,000 years ago. The Greek physician Aertaeus referred to it as diabetes and introduced the term mellitus from the Latin word for honey. The term "diabetes" is the Ancient Greek word for "siphon" and "mellitus" is its Latin word meaning "honeyed" or "sweet," which refers to blood being sweet with "honey", in diabetes mellitus. Share on...Every ten seconds one person dies from diabetes, a disease that leads to extended ill-health and premature death, costing the lives of 3.4 million people per year -- more than double the number of deaths from HIV-AIDS. [2].

There are quite a number of diseases that cause hyperglycemia continuing over a long period of time, known as Diabetes Mellitus.These diseases can be put into different categories because of the various ways they develop. [3]. Type I diabetes happens when the immune system attacks insulin-producing ß cells within islets of Langerhans leading to their inflammation or destruction which then brings this type about; while type II usually develops due to presence of insulin resistance all over the body tissues as well as having insufficient amount pancreas secreted hormone called insulin [4].

in 2011,There were 366 million people living with diabetes mellitus (DM) and it is predicted that the figure will shoot to 552 million by 2030. A statistic shows an increase in the cases of type 2 DM globally, 80% of which is found in developing countries. In 2011 DM claimed 4.6 million deaths [5]. According to the WHO global report, in 2030 alone there will be about 439 million people with type 2 DM. Community rates of type 2 DM also differ by geographic region because of the different risk factors that are ubiquitous in the environment and life styles [6].This disease can be controlled by following some dietary and exercising regimes and through insulin therapy and medical treatments by biguanides; sulfonylureas; alpha- glucoside inhibitors; meglitinidies; thiazolidinediones; and dipeptidyl peptidase inhibitors (DPP-IV).

Delivering drugs into the systemic circulation by mouth is both easiest and most frequently opted for oral administration. Recently, the pharmaceutical field has shown a new interest towards an oral controlled-release drug delivery system because it has some advantages such as nice therapeutic profile, easy dosing, improving patients' compliance rates and formulation flexibility. Drugs that are well absorbed through the gastrointestinal tract (GIT) and have a short half-life are quickly excreted. [10].Gastro-retentive measure shapes capacity truly well for expanded and unsurprising medication conveyance in the gastrointestinal tract (GIT) [11]. For upper GIT drugs having constrained assimilation window or that are poor in colon steadiness, these structures are advantageous. Besides, they ensure that medication produces its effects locally in the stomach and continues to lie close to the absorbing membrane thus augmenting its efficacy. [12]. Floating systems are drug delivery systems that have been designed to be of low density in such a way that they may float on top of what is in the stomach and still remain at the top without having any impact on the rate at which the stomachs contents are emptied over a long time this type of system is easy for while floating the drug is released at the wanted rate thus attaining the desired concentration [13].

Vildagliptin, a drug for high levels of blood sugar, dissolves easily in water and leave in the body for a short time. It is a kind of medicine called a dipeptidyl peptidase-4 inhibitor that is used to control type 2 diabetes. When it inhibits DPP-4, this medicine stops incretin hormones like glucagon-like peptide-1 and glucose-dependent insulinotropic polypeptide from being broken down, which means that they stay active longer after food is eaten. In a glucose-dependent fashion, this approach makes insulin more effective, lowers levels of glucagon produced by the body and elevates how well our beta cells function [7]. It is an oral preparation active within humans in a bid to regulate glycemia among those suffering from type two diabetes through boosting pancreatic islet functions of alpha and beta cells- leading to impairment of unneeded glucagon's release which in turn raises secretion of insulin by patients with this particular type of the disease. This results not just into suppressed inappropriate glucagon secretion but also reinforcements on insulin presence for individuals who suffer from type II diabetes (T2DM). On its own or in combination with other oral hypoglycemics like TZDs, sulfonylureas, or insulin mnimizes chances of weight gain and induces only minimal cases of hypoglycemia without affecting HbA1c levels in patients [8]. When you take Vildagliptin orally, it quickly gets into the bloodstream. The body breaks down about 70% of this drug by cutting it down; while 85% is gotten rid off through the kidneys as urine; but 23% remains unchanged in urine during elimination processes of liver metabolism. Food does not affect how vitegliptin is broken down into its components; or become absorbed into blood streams after being ingested orally at all.[9]. The Present study aims in formulating a controlled released drug delivery of vildagliptin.

One of the reasons that make it necessary to administer vildagliptin via floating beads is that we want to make sure the treatment becomes effective in treating diabetes type II via improving patient's compliance. By inhibiting enzyme DPP-4 vildagliptin acts better in treating type 2 diabetes because it increases insulin secretion and decreases glucagon release as well. On the other hand, the traditional route of administering

vildagliptin by mouth has been facing some difficulties including varying levels of the drug in the blood stream and the tummy troubles that come along with it. This has necessitated the introduction of a new approach; floating beads which are able to release this substance over a longer period at very slow rate inside the stomach ensuring its effectiveness. Maintaining vildagliptin in the stomach allows it to remain in the gastric region longer, thus improving those plasma concentrations leading to steadier therapeutic effect. Furthermore, dosing can be made less frequent by the beads such that it is easier for patients to follow through with their medication prescriptions. These beads are created with an outer polymer shell that allows them to float without sinking while being filled with vildagliptin; a drug intended for the treatment of diabetes mellitus. This mechanism permits a slow release of the medication thus making it more effective against diabetes without posing health risks arising from drastic concentration changes.

2. MATERIALS AND METHODS:

2.1. Materials:

Vildagliptin was purchased from Aarti Pharmaceuticals (Mumbai), Sodium Alginate was purchased from Loba Chemie Pvt. Ltd (Mumbai), HPMC K4M was purchased Loba Chemie Pvt. Ltd.(Mumbai), Sodium Bicarbonate was purchased Loba Chemie Pvt. Ltd (Mumbai), Calcium Chloride was purchased Loba Chemie Pvt. Ltd.,(Mumbai) and Olive Oil was purchased Pallav Chemicals & Solvents Pvt. Ltd, (Mumbai)

2.2.Method Of Preparation:

2.2.1.Emulsion Gelation Method:

The process involves dissolving the polymer in distilled water and stirring magnetically until it is uniformly dissolved. Without further ado, the oil is poured in followed by the drug amount. The mixture which comprises of oil, drug and polymer in same proportions goes to a 5% calcium chloride solution through a 21 G syringe needle before it is left at room temperature. After some period of time the solution is filtered while the beads are rinsed twice with distilled water and later dried in a room temperature for 12 hours.

2.2.2.Procedure for preparation of vildagliptin loaded floating beads:

Drug (50 mg) was dissolved in the distilled water.Placed on the magnetic stirrer with heating and switch on instrument.Instrment was set at 700 rpm to mix the mixture homogeneously.To this Sodium alginate (9%) was slowly added and wait until it mixed homogeneously.After it mixed well we add HPMC K4M (containing three different concentration 2%,4%,6%) along with olive oil (10%). Then we add Sodium Bicarbonate with 3 different concentrations (4%, 6% adn 8%).This mixture is extruded, using 29 guage syring needle, in 100 ml gently agitated calcium chloride solution concentration 5% w/v solution dropwise.The resulting beads were allowed to stand in solution for 60 min before being separated from the solution.Then separate the beads from the solution by using filter paper and wash twice with 500 ml distilled water.It allowed to dry at room temperature.

Table No. 1. Batches made on the basis of different concentrations.

Formulation	Drug	Sodium Alginate %	HPMC K4M %	Sodium Bicarbonate %	Olive Oil %	Distilled Water	Floating Behaviour [floating time(hour)]	In-Vitro Drug Release
V1	50 mg	10	2	2	10	Q.S.	8	72.26 ± 1.40
V2	50 mg	10	2	4	10	Q.S.	6	63.49 ±2.43
V3	**50 mg**	**10**	**2**	**6**	**10**	**Q.S.**	**12**	**84.33 ± 1.81**
V4	50 mg	10	3	2	10	Q.S.	5	71.87 ± 2.42

V5	**50 mg**	**10**	**3**	**4**	**10**	**Q.S.**	**17**	**86.01 ± 1.56**
V6	50 mg	10	3	6	10	Q.S.	9	79.67 ± 1.82
V7	50 mg	10	4	2	10	Q.S.	5	63.58 ± 1.56
V8	50 mg	10	4	4	10	Q.S.	8	74.73 ± 0.89
V9	**50 mg**	**10**	**4**	**6**	**10**	**Q.S.**	**14**	**81.51 ± 1.93**

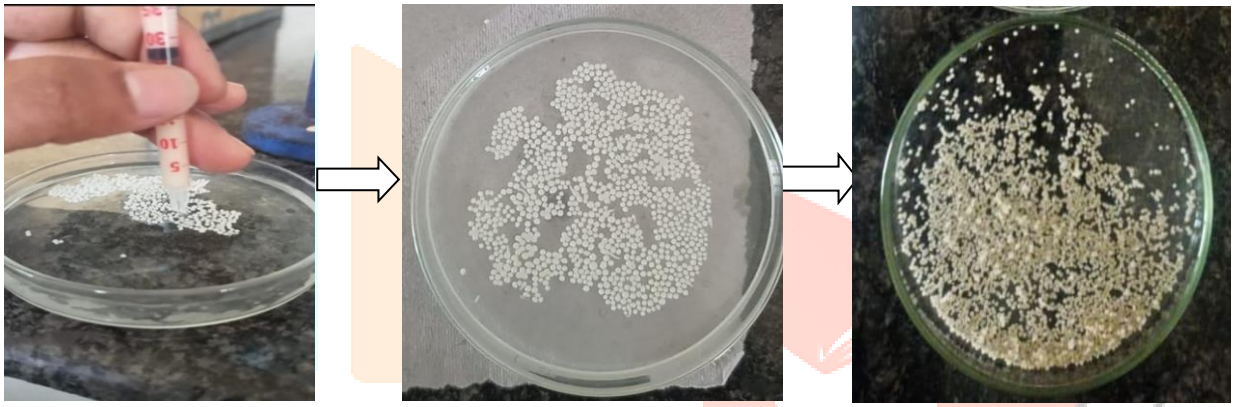

Figure No. 1. Performed Formulation Procedure

2.2.3. Optimization of batch:

The formulations prepared containing various concentrations of polymers as listed in the table. Particular test were done which are required to indicate an good drug release. The test which were performed were Floating behavior of the drug and the in-vitro drug release, from these test it was concluded that batch no V5 has shown a magnificent results among all the formulations and was selected as an optimized batch.

3. EXPERIMENTAL WORK

3.1. Preformulation study:

Preformulation investigation is associated with checking the physical and chemical properties of drug molecules before the stage of mixing, representing a significant first step in the design of new pharmaceutical formulations.The main objective of the preformulation studies are as follows:

- To establish the physicochemical parameter of new drug activity.
- To establish its compatibility with common excipients.

3.1.1. Melting point determination:

A drug and its crystalline state can be identified by its melting point which is very important. The open capillary tube method was used to determine its melting point for Vildagliptin.

Prepare a capillary tube by sealing one end over a flame for 2-3 minutes while rotating it. Then, fill the open end with finely powdered Vildagliptin by dipping it and tapping it gently on a surface to achieve a length of approximately 3-4 mm. Secure the capillary to a thermometer using a rubber band, and immerse the thermometer in a Thiele's tube filled with paraffin oil. Monitor the temperature closely and record it as soon as the substance begins to melt.

3.1.2. Fourier Transform Infrared Analysis:

The Fourier transform infrared spectroscopy (FTIR) technique was employed in examining the Vildagliptin sample using a Bruker Alpha II spectrophotometer. This technique operated within a wave number range from 4000 to 400 cm^-1. In its solid state, the drug was mounted on the sample holder and examined. Polymers samples were also obtained for comparison.

3.2. Spectroscopic Analysis:

3.2.1.Determination of λ_{max} by UV-Spectroscopy in distilled water:

In order to determine the λmax of Vildagliptin, 10 mg of this medicine was dissolved into some distilled water before being diluted using more water in order to make a total of 100 ml (μ= 100 μg/ml). At 400 – 200nm, we scanned through an empty cell containing only H2O which served as our reference material using a UV-Visible spectrophotometer (UV-Vis 1900i Spectrophotometer). It was from this spectrum that we got our maximum absorption wavelength (λmax).

3.2.2.Preparation of Calibration Curve of Vildagliptin:

A spectrophotometric technique was employed in the study to measure the concentration of Vildagliptin, utilizing UV absorption within the 200 to 400 nm range.

3.3. Calibration Curve of Vildagliptin in distilled water:

3.3.1.Preparation Of Vildagliptin stock and working solution:

To prepare the calibration curve, 10 mg of vildagliptin was dissolved in distilled water and the solution was made up to 100 ml, resulting in a concentration of 100 μg/ml. From this stock solution, aliquots of 0.1 ml, 0.2 ml, 0.3 ml, 0.4 ml, and 0.5 ml were taken and each was diluted with distilled water to the same final volume to create a series of standard solutions for the calibration curve.

Absorbance was recorded at 213 nm using UV-Vis Spectrophotometer (Concentration Vs Absorbance). A straight line equation (Y= mx + C) was generated to facilitate the calculation of amount of drug.

Absorbance = slope * concentration + intercept.

3.4.Evaluation of Floating Beads:

3.4.1.Physical appearance:

The organoleptic characteristics like physical appearance colour and odour was checked.

3.4.2.Determination of practical yield:

Solid excipients and the drug were accurately weighed prior to preparation. After formulation and drying, the floating alginate beads were weighed. The production yield was then calculated using the formula:

$$\text{Practical yield} = \frac{\text{Amont of prodct obtained}}{\text{Total weight of solid used in preparation (Drug+Excipient)}} \times 100 \quad \ldots(\text{equation no .1})$$

3.4.3.Average particle size:

The size of particles directly impacts characteristics of materials and is a key parameter in the measurement of particle size everywhere. A diffraction technique (Horiba SZ-100, Horiba Ltd., Japan) was used to determine the particle size of vildagliptin-loaded floating beads. The sample which was dispersed in distilled water whereby measurements were conducted was at an angle of 90° and the average particle size was calculated.

3.4.4.Scanning Electron Microscope:

The external and cross-sectional morphology of beads was characterized by scanning electron microscope (SEM).

3.4.5.Floating Behavior:

As part of the dissolution studies, both the duration of buoyancy and the buoyancy lag time are measured at once. Buoyancy lag time is the amount of time taken for formulated floating beads to rise to the top third of the dissolution vessel after they have been introduced to the medium.The duration of buoyancy is the period during which the formulation consistently floats on the surface of the medium.

3.4.6.In-Vitro Drug Release:

The USP-I apparatus was employed for conducting the dissolution study using Rotating Basket Method. The amount of rotation remained at 50 rpm for the whole duration. Distilled water (900 ml) was used as the dissolution medium containing 37.0°C – 0.5°C as its temperature control. We picked samples at certain time

gaps, replacing them with a new dissolution medium so as to maintain consistency, while their analysis was done by spectrophotometry at a wavelength of 213nm.

Table No. 2. Parameters for dissolution profile.

Sr. No.	Parameter	Specifications
1.	Dissolution media	Distilled Water
2.	Dissolution media volume	900 ml
3.	Temperature	37°C ± 0.5°C
4.	Rotation Speed	50 rpm
5.	Sample Volume withdrawn	5ml
6.	Time Interval	30 minutes

4. RESULTS AND DISCUSSION:

4.1. Preformulation study:

Following results are obtained in the preformulation study of drug by melting point and spectral analysis.

4.1.1. Melting point:

The documented melting point range for vildagliptin falls between 149°C and 153°C. Utilizing the Thieles tube method, the pure vildagliptin exhibited a melting point of 152°C, affirming the purity of the powdered drug and confirming its identity as vildagliptin.

Table No. 3: Melting Point Of Drug.

Drug	Melting Point	Observed Melting Point
Vildagliptin	149°C - 153°C	152°C

4.1.2. Fourier Transform Infrared analysis:

The FT-IR was conducted to determine the compatibility study between the drug (Vildagliptin) and excipients (sodium alginate, HPMC K4M, Sodium bicarbonate) physical mixture and also best formulation. The molecular vibrations of Vildagliptin identifies functional groups: carbonyl stretching at 1655 cm^{-1}, alcohol stretching between 3200-2700 cm^{-1} with a peak at 2907.48 cm^{-1}, and amine salt N-H stretching observed from 3000-2800 cm^{-1} with a peak at 2841.93 cm^{-1}.

The results revealed that the selected polymers were found to be compatible with the drug.

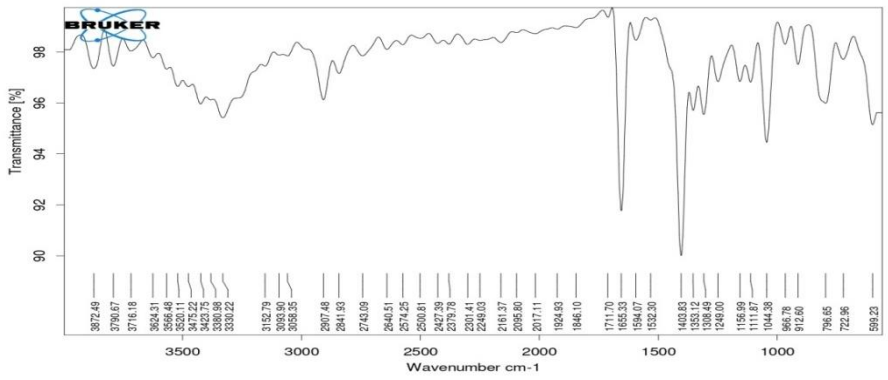

Figure no. 2. FT-IR image of Vildagliptin

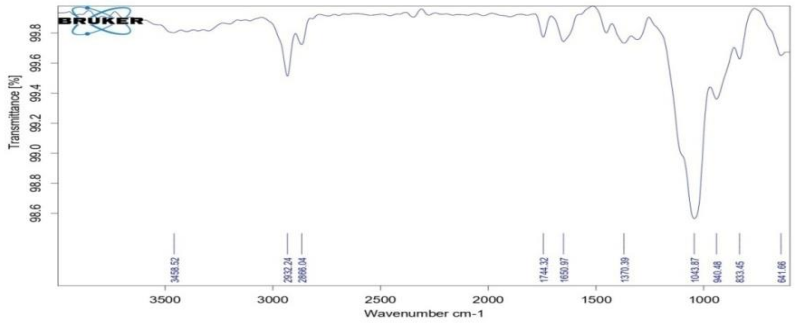

Figure No.3. FTIR spectrum of physical mixture of vildagliptin

4.1.3. SPECTROSCOPIC STUDY:

4.1.3..1. Determination of λ_{max} by UV-Spectroscopy in distilled water:

The absorption spectrum of vildagliptin was acquired from a solution of 100 µg/ml concentration in distilled water, revealing an absorbance peak at 213 nm.

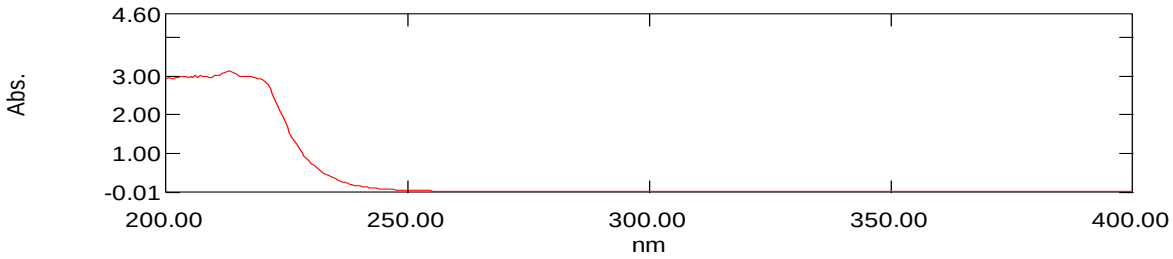

Figure.No.4. UV absorption spectrum of vildagliptin in distilled water.

4.1.3..2. Calibration Curve of vildagliptin in Distilled Water:

The graph of Concentration Vs Absorbance for pure Vildagliptin was found to be in the concentration of range 2-10 µg/ml.

Table No. 4. Calibration Curve Of vildagliptin in Distilled Water.

Concentration (µg/ml)	Absorbance
0	0
2	0.207
4	0.391
6	0.583
8	0.754
10	0.997

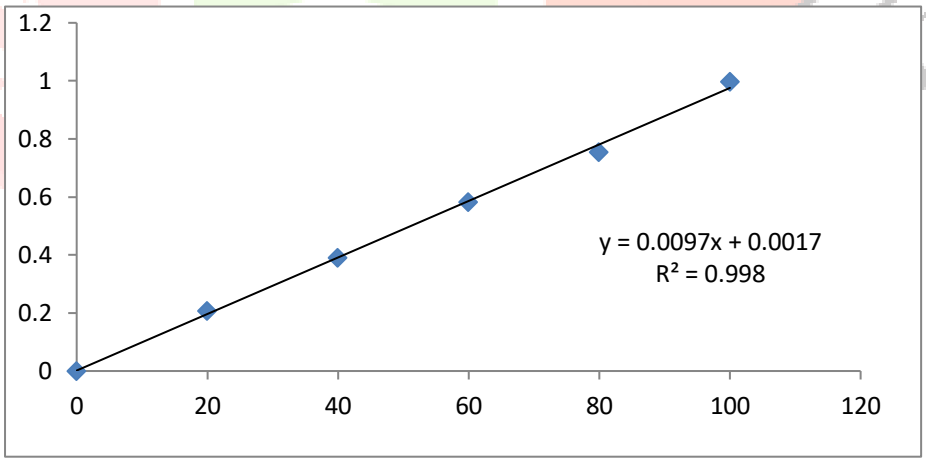

Figure No. 5. Calibration curve of vildagliptin in distilled water

Table No. 5. Various constant for Calibration Curve Of vildagliptin in distilled water

Parameter	Slope	Intercept	R^2
Value for calibration curve in Vildagliptin	0.009	0.001	0.998

4.2.Characterization of Vildagliptin loaded Floating Beads:

4.2.1.Physical Appearance:

The Floating beads of vildagliptin appears to be Disc, spherical and oval shape with a corn silk colour and being odourless.

Table No. 6. Physical Appearance of prepared formulations

Formulations	Shape	Colour	Odour
V1	Disc like	Corn silk colour	Odorless
V2	Spherical	Corn silk colour	Odorless
V3	Spherical	Corn silk colour	Odorless
V4	Oval shape	Corn silk colour	Odorless
V5	Spherical	Corn silk colour	Odorless
V6	Disc like	Corn silk colour	Odorless
V7	Disc like	Corn silk colour	Odorless
V8	Spherical	Corn silk colour	Odorless
V9	Spherical	Corn silk colour	Odorless

4.2.2. Discussion of practical yield:

Practical yield of prepared floating beads were obtained in the range 68% - 84%, as shown in the table no. 7.

Table No. 7. Practical yield of prepared floating beads of vildagliptin

Formulation	% practical Yield
V1	69.98 ± 0.76
V2	82.41 ± 0.92
V3	82.02 ± 1.21
V4	64.45 ± 1.06
V5	77.22 ± 0.93
V6	80.84 ± 0.49
V7	72.68 ± 0.99
V8	79.42 ± 1.07
V9	83.47 ± 0.69

4.2.3. Average Size Determination of Vildagliptin Floating Beads:

Measurement of size distribution is commonly conducted across various industries, playing a crucial role in product assessment. Particle size distribution significantly impacts material properties. The mean average particle size of vildagliptin-loaded floating beads was determined using the Horiba SZ-100 instrument from Horiba Ltd., Japan. The results are depicted in the accompanying figure.

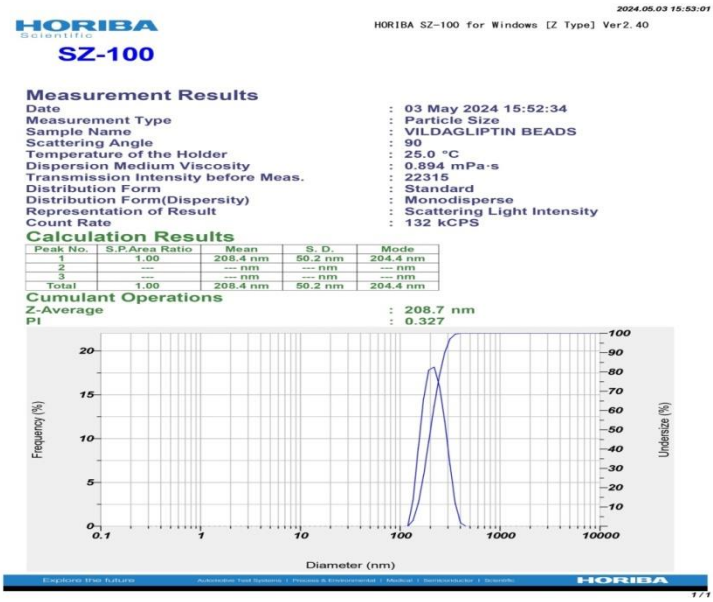

Figure No.6. Particle size distribution report of vildagliptin loaded beads

4.2.4. Floating Behavior:

The beads remained afloat throughout the study period 12 h and the beads continued to float until 18 h.

Table No. 8. Floating behavior of beads formulated by emulsion gelation technique

Formulation	Floating lag time (min)	Floating time (Hr)	Percentage floating
V1	3.04 ± 0.42	8	76.66 ± 3.22
V2	2.33 ± 0.12	6	79.93±3.80
V3	**3.29 ± 0.18**	**12**	**84.81±3.45**
V4	3.14 ± 0.12	5	48.36±2.87
V5	**3.56 ± 0.39**	**17**	**84.18±1.60**
V6	2.05 ± 0.34	9	79.93±3.80
V7	4.59 ± 0.37	5	52.67±2.57
V8	2.26 ± 0.11	8	76.56±1.28
V9	**3.03 ± 0.42**	**14**	**81.05±3.48**

4.2.5. In-Vitro Drug Release

In-Vitro drug release studies of vildagliptin loaded floating beads were carried out by using USP basket apparatus with stirring rate of 50 rpm at 37ºC ± 0.5ºC with distilled water as dissolution medium. The release profile was obtained in the range of 63% - 87%. Among these formulations, formulation batch V3, V5 and V9 shown and better release as compared to other formulations.

Table No. 9. In-Vitro drug release of Batches V1-V9.

Batch Time (min)	V1 (%)	V2 (%)	V3 (%)	V4 (%)	V5 (%)	V6 (%)	V7 (%)	V8 (%)	V9 (%)
0	0	0	0	0	0	0	0	0	0
30	11.34 ± 1.23	16.22 ± 1.04	23.04 ± 1.41	18.23 ± 2.43	25.65 ± 1.84	21.76 ± 1.28	19.20 ± 1.47	21.26 ± 1.92	24.64 ±2.12
60	24.23 ± 1.45	23.45 ± 0.98	33.90 ± 1.19	27.78 ± 1.59	31.26 ± 2.05	29.12 ± 1.30	25.79 ± 1.86	26.49 ± 1.72	32.31 ±1.23
90	30.19 ±1.97	27.79 ± 2.07	45.58 ±3.61	34.96 ± 1.19	40.43 ± 1.37	35.67 ± 1.87	31.82 ± 1.33	32.64 ± 1.91	42.56± 1.45
120	38.45 ± 1.48	34.81 ± 1.21	51.34 ± 2.84	41.88 ± 1.76	54.87 ± 1.27	43.8± 1.54	37.97 ± 1.29	40.43 ± 1.29	49.34 ± 1.38
150	43.76 ± 2.05	39.73 ± 1.48	59.27 ±1.15	49.67 ± 1.46	61.77 ± 2.83	50.47 ± 1.64	42.28 ± 2.28	46.67 ± 1.25	55.78 ± 1.92
180	52.98 ± 1.55	45.67 ±1.57	67.87 ± 2.25	57.81 ± 1.33	72.49 ± 1.05	69.28 ± 1.71	48.32 ± 1.93	60.55 ± 1.15	62.45 ± 2.34
210	64.89 ± 1.79	54.23 ± 1.07	76.61 ± 1.76	63.59 ± 1.78	80.76 ± 2.12	74.72 ± 0.97	56.36 ± 1.37	69.98 ± 1.89	70.34 ± 1.69
240	72.26 ± 1.40	63.49 ±2.43	**84.33 ± 1.81**	71.87 ± 2.42	**86.01 ± 1.56**	79.67 ± 1.82	63.58 ± 1.56	74.73 ± 0.89	**81.51 ± 1.93**

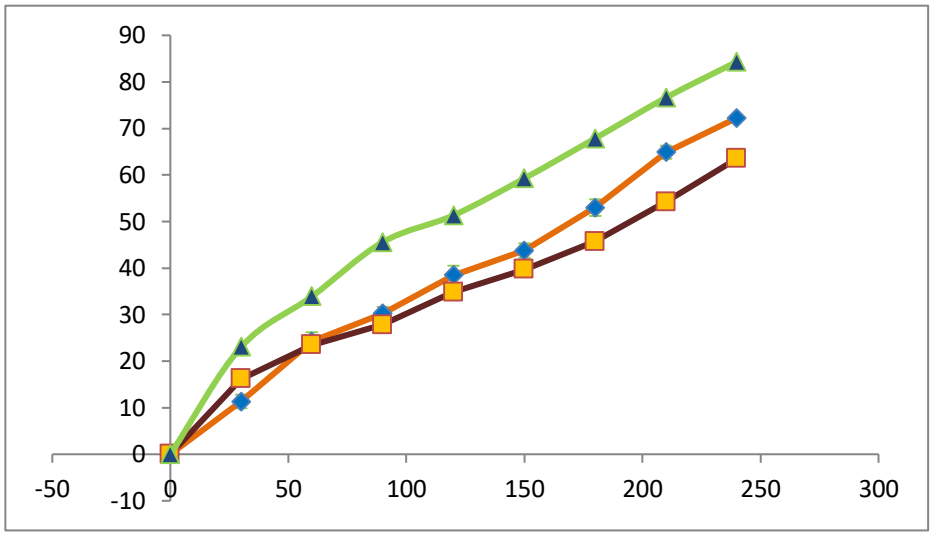

Figure No. 7. Figure depicting In-vitro drug release of Batches V1, V2 and V3.

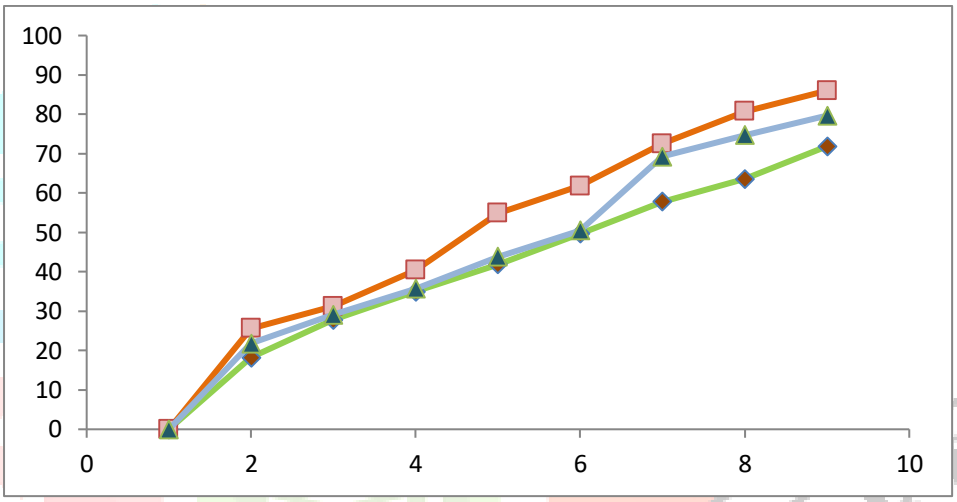

Figure No. 8. Figure depicting in-vitro drug release of batches V4, V5 and V6

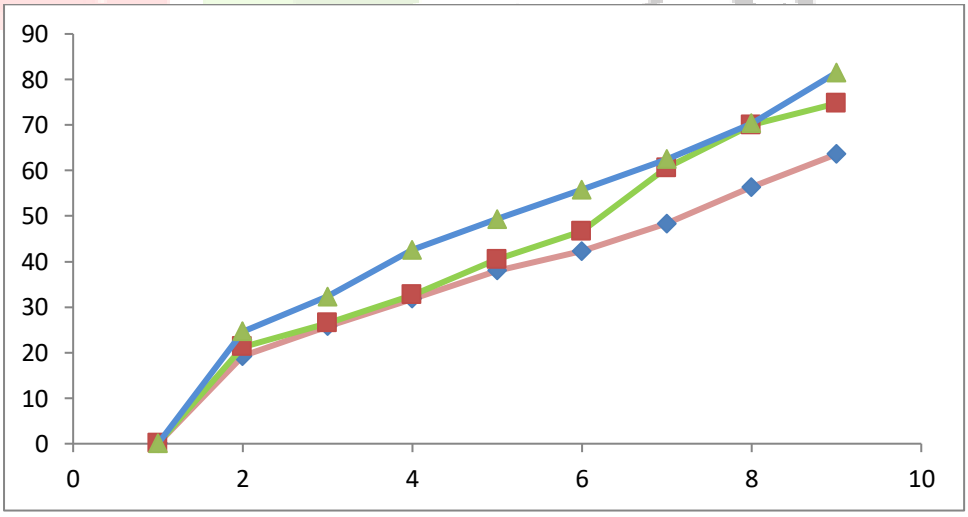

Figure No.9. Figure depicting In-vitro drug release of Batches of V7, V8 and V9.

5. Summary and Conclusion.

The study on vildagliptin-loaded floating beads for diabetes treatment demonstrated significant advancements in controlled drug delivery systems. The practical yield of the prepared beads ranged from 68% to 84%, with optimal yields observed in batches V2, V3, V5, and V9. The particle size distribution, assessed using the Horiba SZ-100 instrument, indicated uniformity crucial for consistent drug release. The floating behavior analysis revealed that the beads remained buoyant for up to 24 hours, ensuring prolonged gastric residence time, which is essential for enhancing drug absorption and efficacy.

In vitro drug release studies showed a release profile between 63% and 87%, with batches V3, V5, and V9 exhibiting superior release characteristics. These findings underscore the potential of these formulations to maintain therapeutic drug levels over an extended period, thereby improving patient compliance and treatment outcomes. The compatibility studies using FT-IR spectroscopy confirmed no significant interactions between vildagliptin and the excipients, ensuring the stability and integrity of the drug within the formulation.

Overall, this research provides a promising outlook for the development of gastro-retentive drug delivery systems using vildagliptin, which could revolutionize the management of type 2 diabetes mellitus by providing a more efficient and patient-friendly therapeutic option. Future studies should focus on in vivo evaluations and long-term stability assessments to further validate these findings and facilitate the transition from experimental to clinical application

6. Acknowledgement:

IwouldliketoexpressmyspecialthanksofgratitudetoourprincipalSir,AshokraoMane Institute of Pharmacy, Ambap. IamreallythankfultothemtoMr. Sardar S. Shelake Sir forthepatienceandsupport in every Methodological aspect of this several other works. Thank you foryour honest advices, your help in overcoming so many obstacles, and above allthankyouforallyourinterest.Secondly I would also like to thanks my friends who helped me a lot in finalizing thisproject within the limited time frame. Last but not the least, my parents are also animportant inspiration for me so with due regards, I express my gratitude to themalso.

7. Conflict of Interest Statement:

The authors declare that they have no conflicts of interest regarding the publication of this review paper. All authors certify that they have no financial or personal relationships with other people or organizations that could inappropriately influence (bias) their work or this manuscript.

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