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RESEARCH ARTICLE

Formulation and characterization of a floating microsphere of glimepiride by using solvent evaporation technique

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ABSTRACT

The present study is an attempt to formulate microspheres of Glimepiride, an orally administered ant-diabetic drug with a view of improving its oral bioavailability and giving a prolonged release of drug, where here the microspheres with polymers such as Ethyl cellulose and Eudrajit RS 100 and guar gum were successfully prepared by emulsification solvent evaporation method and the particle size analysis revealed that the size of microspheres was increased with increase in the concentration of polymer. The study comprises that floating microsphere of Glimepiride, model drug, may increase the gastric residence time. The floating microspheres are prepared by the emulsification solvent diffusion technique using polymers Ethyl cellulose, Eudragit RS100 and Guar gum, PVA, Dichloromethane in different ratio. The formulated microsphere was evaluated for the percentage yield, percentage encapsulation efficiency, percentage buoyancy and *in-vitro* drug release. Floating microspheres prolong the release of the drug and gastric residence time, release almost 82.35% drug within 24hrs.

KEYWORDS

Glimepiride, Eudragit RS 100, Floating Microsphere, Solvent evaporation techniques

INTRODUCTION

Glimepiride is a drug which is absorbed from the gastrointestinal tract (GIT) and has a short half-life and eliminated quickly from the blood circulation, so it required frequent dosing. To avoid this drawback, the oral sustained-controlled release formulations have been developed in an attempt to release the drug slowly into the GIT and maintain an effective drug concentration in the serum for longer period of time.

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The microspheres are characteristically free flowing powders consisting of proteins or synthetic polymers, which are biodegradable in nature. Solid biodegradable microspheres incorporating a drug dispersed or dissolved throughout particle matrix have the potential for controlled release of drugs where their spherical particles ranging from 1 to 1000 micrometers. Where here the microspheres are prepared from the solvent evaporation method, microspheres are prepared by two particles core material and coating material, where the core material is made up of drug and particulate is of polymers. Microencapsulation for oral use has been employed to sustain the drug release, and to reduce or eliminate gastrointestinal tract irritation.

Multiparticulate delivery systems spread out more uniformly in the gastrointestinal tract. This results in more reproducible drug absorption and reduces local irritation when compared to single-unit dosage forms such as no disintegrating, polymeric matrix tablets.

Microsphere is used to modify and retard drug release; due to its small particle size they are widely distributed throughout the gastrointestinal tract which improves drug absorption and reduces side effects due to localized build-up of irritating drugs against the gastrointestinal mucosa. [1-4]

Floating drug delivery systems (FDDS) or hydro dynamically balanced systems (HBS) are among the several approaches that have been developed to increase the gastric residence time of dosage forms. This Gastro retentive floating drug delivery system (GRFDDS) have a bulk density lower than that of gastric fluids and thus remains buoyant in the stomach without affecting gastric emptying rate for a prolonged period of time. While the system is floating on gastric contents, the drug is released slowly at a desired rate from the system. [5]

The use of oral antidiabetic drugs for the treatment of Type 2 diabetes is increasing rapidly. Glimepiride is an antidiabetic drug belongs to second generation sulphonylurea drug. It lowers the blood glucose level in patients with Type 2 diabetes (non-insulin dependent diabetes mellitus) by stimulating the release of insulin from the pancreatic β-cells. In this way it exerts a long-term effect of reducing the blood glucose levels. In addition, extra pancreatic effects may also play a role in the activity of glimepiride. It has low risk of hypoglycemia because of preservation of physiological suppression of insulin secretion in response to low blood glucose levels1. It is completely (100%) absorbed following oral administration. It has rapid onset of action, 24 h duration of effect with a half-life of 5 h and once a day dosing. [6-7]

Materials and Methods

Glimepiride was obtained as a gift sample from Medley Pharmaceuticals Ltd., Daman Unit, Andheri East, Mumbai, India., Eudragit RS100 were obtained from Natco Pharma; Hyderabad, India and Ethyl cellulose from obtained were from Merck, all other reagents and solvents used were of analytical grade. obtained were from Merck.

PREFORMULATION STUDIES

Preformulation studies mainly focus on those physiochemical properties of the drug that could affect performance and development of an efficacious dosage form such as determining the purity of Active Pharmaceutical Ingredient (API) before formulation any dosage form. Preformulation studies are useful in determining the formulation components and physiochemical properties of new drug substance that will affect the final dosage form and its stability.

Description of Drug

The sample of drug was observed for colour, state and odour.

Drug Excipients Compatibility Study

Before formulating a dosage form it is essential to confirm that drug is not interacting with the polymer under certain experimental studies. Interacting among drug and polymer may affect the efficacy of final dosage form.

Fourier transform infra-red spectrum of pure drug, Eudragit RS 100, Ethyl cellulose, Guar gum and their Physical mixture were recorded. Drug and different excipients were taken in 1:1 ratio. The samples of pure drug and physical mixture of polymer and drug were taken and subjected to FTIR study.

Standard Calibration Curve

A stock solution of glimepiride (10µg/mL) was prepared by dissolving 10 mg of glimepiride with different buffer solution such as 0.1N HCl and phosphate buffer pH 7.4. Further various dilutions were made with these different pH buffer solutions containing concentration 2, 4, 6 & 8 µg/mL of glimepiride and absorbance was measured against blank at λ_{max} 262 nm and a standard calibration curve between concentration and absorbance was plotted as shown in figure. All spectral absorbance

measurements were made on Shimadzu-1700 UV-visible spectrophotometer.

Preparation of Formulations

Formulation of drug-loaded microspheres was carried out by the emulsion solvent diffusion-evaporation method. The polymers ethyl cellulose, Eudragit RS100, Guargum, PVA, Dichloromethane was used in different ratios. Initially a solvent mixture of 10mL of dichloromethane was prepared in the considering their volumes.

An accurately weighed quantity of drug and polymer was co-dissolved at room temperature in a solvent mixture. This solution was introduced into 100 mL of 1% PVA aqueous solution at room temperature and dispersed to form emulsion at stirring rates of 800 rpm using a mechanical stirrer equipped with 4-blade propeller. Agitation provided by stirrer breaks the poured polymer solution to form an oil-in-water (O/W) type emulsion. This emulsion was then stirred for about 45 min at room temperature. After stirring, the solidified microspheres were recovered by filtration and dried.

Evaluation of the Formulated Microsphere

Percent Yield of Microspheres

Microspheres dried at room temperature were then weighed and the yield of microspheres. Preparation was calculated using the following formula.

$$\% \text{ Yield} = \frac{\text{Actual weight of dried microsphere}}{\text{Total weight of drug and excipient}} \times 100$$

Drug Entrapment Efficiency

Encapsulation efficiency of the microspheres was evaluated by deriving percent drug encapsulation. The drug content of drug-loaded microspheres was determined by dispersing 100 mg of microspheres in 50 mL ethanol or the solvent choose according to its solubility followed by agitation with a magnetic stirrer for about 30 min to dissolve the polymer and to extract the drug. After filtration through a 5µm membrane filter, the drug concentration in the ethanol phase was determined by taking the absorbance of this solution spectrophotometrically at 298nm. Eudragit RS100 and ethyl cellulose did not interfere under these conditions. Drug concentration was

Table 1: Formulation of batches of floating microsphere of Glimepiride

Sr. No.	Formulation code	Drug (mg)	Eudragit RS 100 (mg)	Ethyl cellulose (mg)	Guar gum (mg)	PVA (%)	Dichloromethane (mL)	Ratio
1	GMF 1	20	20	20	20	20	20	1:1:1:1:1:1
2	GMF 2	20	20	40	20	20	20	1:1:2:1:1:1
3	GMF 3	20	20	60	20	20	20	1:1:3:1:1:1
4	GMF 4	20	40	20	20	20	20	1:2:1:1:1:1
5	GMF 5	20	40	40	20	20	20	1:2:2:1:1:1
6	GMF 6	20	40	60	20	20	20	1:2:3:1:1:1
7	GMF 7	20	60	20	20	20	20	1:3:1:1:1:1
8	GMF 8	20	60	40	20	20	20	1:3:2:1:1:1
9	GMF 9	20	60	60	20	20	20	1:3:3:1:1:1

then calculated. Thus, the total drug encapsulated in total yielded microspheres from the procedure was calculated. It was expressed in percentage called as "Percent drug entrapment" calculated as.

$$\% \text{ Drug Efficiency} = \frac{\text{Practical amount of drug present in mg}}{\text{Theoretical amount of drug taken in mg}} \times 100$$

Percentage Buoyancy

The floatation studies were carried out to ascertain the floating behavior of various polymers Combinations. Beaker method was initially used to have an idea of the floatation behavior of the proposed dosage form. 50 mg of floating microsphere were placed in each of four 50 mL beakers containing 20 mL of 0.1N HCl containing 0.02% tween 80. The beakers were shaken in a biological shaker at 37◦C ± 0.5◦C at 40 rpm. Floating microspheres were collected at 4,8 and 12 h and dried till constant weight was obtained. The percentage of floating microspheres was calculated by the following equation.

$$\% \, Buoyancy = \frac{Wf}{Wf + Ws} \times 100$$

where Wf and Ws = weights of the floating and settled microspheres, respectively.

Differential scanning colorimetry (DSC)

Differential scanning colorimetry (DSC) a type of thermo analytical process. In this heat require to rise temperature of sample and reference.

Temperature of sample and reference maintain nearly same all over experiment. Sample holds temperature increase linearly as function of time.

These technique used mainly physical change of sample and also determine process is exothermic and endothermic.

When solid sample melt into a liquid require more energy and temperature increase so all over process is endothermic but when liquid change into a solid the temperature decrease to all over process is exothermic.

SEM (Scanning Electron Microscope) Studies

Surface morphology of drug loaded microsphere was inspected using SEM (CIF, IIT BHU, Varanasi). Little quantity of drug loaded microsphere was spread manually on a carbon tape, which is attached to an aluminum stub. Samples were analyzed by SEM with direct data capture of the image on to a computer screen.

Micromeritic properties

Microsphere were characterized for micromeritic backdrop like bend of repose, aggregate density, broke density, carr's basis and hausners ratio.

Bulk density

An exact quantity "M" of microsphere was taken and was placed into a measuring cylinder. Volume "V" occupied by the microspheres was noted without disturbing the cylinder and bulk density was calculated using the following equation;

Bulk density (Pb) = M/V

Tapped Density

The tapping method was used to determine the tapped density in which the cylinder containing known amount (M) of microspheres was subjected to a fixed number of taps (approximately 100) until the bed of microspheres had reached the minimum. The final volume after tapping "Vo" was recorded and the tap density was calculated by the following equation.

Tapped Density (Pp) = M/Vo

Angle of Repose

This property was determined to predict flowability Angle of repose of the microspheres is the maximum angle possible between the surface of the pile of microspheres and the horizontal plane, was obtained by fixed funnel method using the formula

Angle of repose (ϕ) = tan-1[2h/d]

Where, h is height and d is the diameter of the microsphere pile that is on a paper after making the microspheres flow from the glass funnel.

Carr's Index or % Compressibility

A high Carr's index is indicative of the tendency to form bridges can be calculated by using following formula:

Carr index or %compressibility Index or C = [1- V0/V] × 100

Hausner Ratio

Hausner's ratio is measures of the propensity of a powder to be compressed and the flow ability of granule. A higher Hausner ratio indicates greater cohesion between particles.

Hausner Ratio = [100/100+C]

Where C is Carr's Index.

In Vitro Drug Release Studies

The drug release rate from microspheres was determined using USP basket-type dissolution apparatus. A weighed amount of microspheres equivalent to 5 mg drug was filled into a capsule (size 0) and placed in the basket. Dissolution medium used was phosphate buffer 7.4 for first hour and maintained at 37 ± 0.5°C at a rotation speed of 100 rpm. Prefect sink conditions prevailed during the drug release studies.

5 mL of sample was withdrawn at each 1 h interval; later this interval was extended to 2 h. Sample was then passed through a 5 µm membrane filter, and analyzed spectrophotometrically at 300 nm to determine the concentration of drug present in the dissolution medium. The initial volume of dissolution medium was maintained by adding 5 mL of fresh dissolution media after each withdrawal. The dissolution study was continued for next 24 h.

Release kinetics

Release kinetic models, which described the overall release of drug from the dosage forms. Because qualitative and quantitative changes in a formulation may alter drug release and in vivo performance, developing tools that facilitate product development by reducing the necessity of bio-studies is always desirable. In this regard, the use of in vitro drug dissolution data to predict in vivo bio-performance can be considered as the rational development of controlled release formulations. Data obtained from the in vitro release studies were fitted to various model dependent kinetic equations such as zero order, first order, Higuchi model and Korsmeyer- Peppas model.

Higuchi Release Model

To study the Higuchi release kinetics, the release rate data was fitted to the following equation

F = KH.t 1/2

Where, F is the amount of drug release
KH is the release rate constant
t is the release time

When the data was plotted as a cumulative percentage drug release versus square root of time, yields a straight line, indicating that the drug released by diffusion mechanism the slope is equal to k.

Korsmeyer and Peppas Model

The release rate data were fitted to the following equation,

Mt/M8 =KM.tn

Where, Mt/M8 is the fraction of drug release
KM is the release constant
t is the release time

N is the diffusional exponent for the drug release that dependent on the shape of the matrix dosage form. When the data is plotted as log percentage release versus log time, yields as straight line with a slope equal to n and the k can be obtained from y- intercept. For non-fickian release the n values falls between 0.5 and 1.0 while for fickian (case I) diffusion n= 0.5 and zero order release (case II transport) n=1.0.

Zero order release rate kinetics

To study the zero order release kinetics the release rate data are fitted to the following equation

F= K0t

Here, F is the fraction of drug release
K0 is the rate constant
T is the release time
Hen data is plotted a cumulative percentage drug release versus time, if the plot is linear then the data obey zero order release kinetic, with a slope equal to K0.

First order model

This model has also been used to describe absorption and /or elimination of some drug, the release of the drug which followed first order kinetic can be expressed by the equation

$$LogC = logC0-Kt/2.303$$

Where, C0 is the initial concentration of drug
K is the first order rate constant
t is the time
The data obtained are plotted as log cumulative percentage of drug m remaining Vs time. This yields a straight line with a slope of –K/2.303.

RESULT AND DISCUSSION

Table 2: Organoleptic properties

Sr. No.	Properties	Inference
1	Colour	White
2	Odour	Odorless
3	Solubility	Insoluble in water, Soluble in methanol, acetone, dimethyl formamide and methylene chloride

Drug Identification

The accurately weighed quantity of drug was dissolved in sufficient volume of acetone and scan was obtained on UV-VIS spectrophotometer. The wavelength at which maximum absorbance obtained was considered as maximum wavelength (λmax) i.e. 262 nm for the drug.

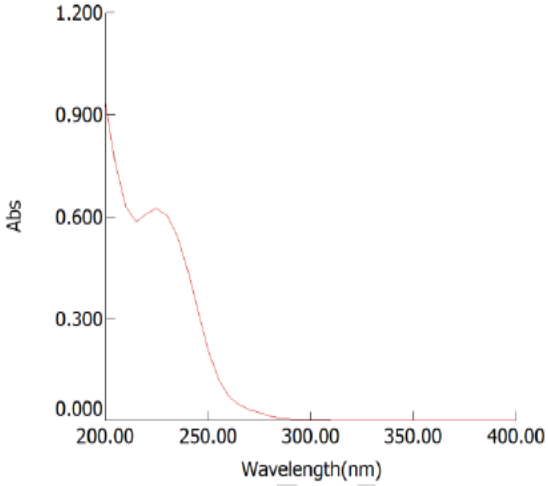


Fig 1: UV Spectra of Glimepiride

Drug- Excipients Compatibility Study

Drug and polymers identified by infra-red spectrum which are compared with its standard IR. The IR spectrum given below shown that the peaks obtained in the test spectrum is similar to that given in standard.

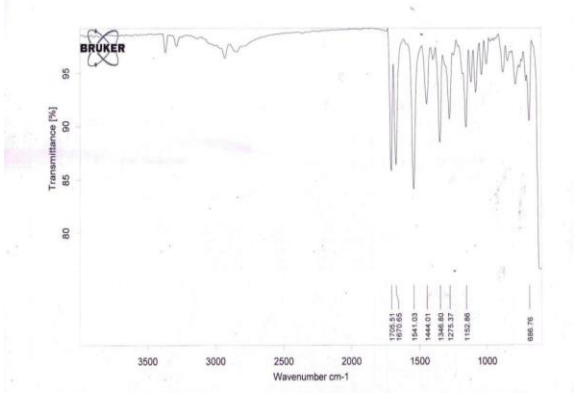


Fig 2: FTIR Spectrum of Glimepiride

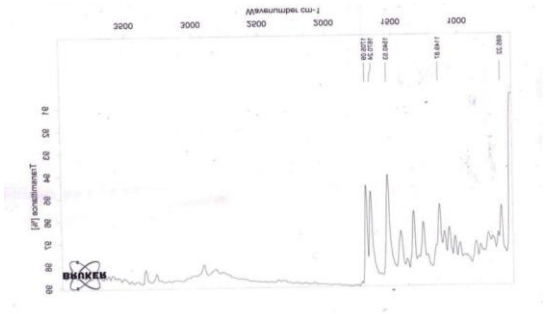


Fig 3: FTIR Spectrum of Glimepiride and Eudragit RS100

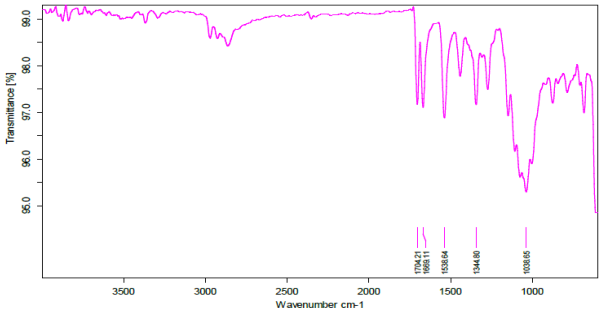


Fig 4: FTIR Spectrum of Glimepiride and ethyl cellulose

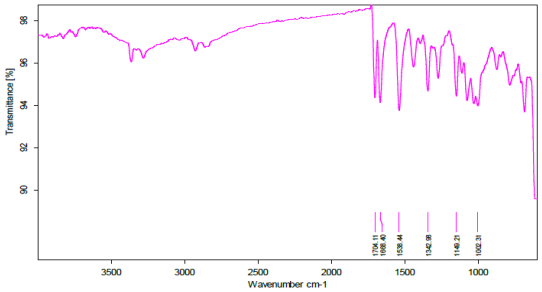


Fig 5: FTIR Spectrum of Glimepiride and guar gum

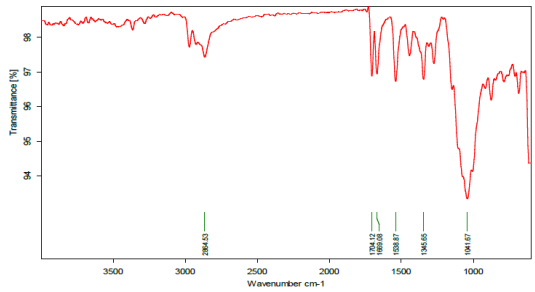


Fig 6: FTIR Spectrum of best formulation

Table 3: Major peak observe in FTIR Spectrum

The IR spectrum of Glimepiride showed characteristic N-H stretch peaks of urea at 3370 and 3289 cm^{-1}, peaks at 1707 and 1673 cm^{-1}corresponding to the carbonyl group, and peaks at 1348 and 1144 cm^{-1} related to the sulfonamide group, peaks at 2850 and 2960.42 cm^{-1} corresponding to the CH aromatic group, and peaks at 3000 and 2915 cm^{-1} corresponding to the CH aliphatic groups.

Sr. No.	Groups	Reported peak	Observed peak
1	NH stretching	3300	3289
2	CH Aromatic stretching	2850	2960.42
3	CH Aliphatic stretching	3000	2915.38
4	C=O stretching	1707	1673
5	Sulphonamide	1348	1144

Preparation of standard calibration curve: Obtained absorbances are shown in the tables 4 and standard calibration curves of glimepiride in a methanol solvent of a phosphate buffer pH 7.4 are shown in figures

Table 4: Standard curve of Repaglinide

S. No.	Concentration (µg/mL)	Absorbance
1.	0	0
2.	20	0.148
3.	40	0.363
4.	60	0.564
5.	80	0.803
6.	100	1.044

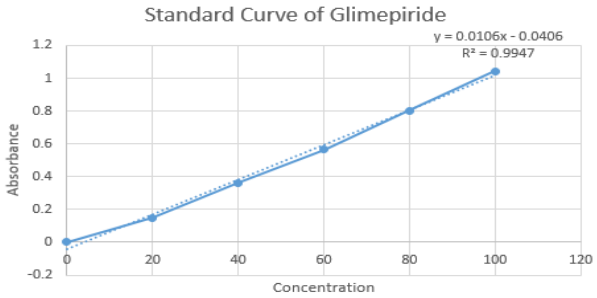


Fig 7: Standard curve of Glimepiride

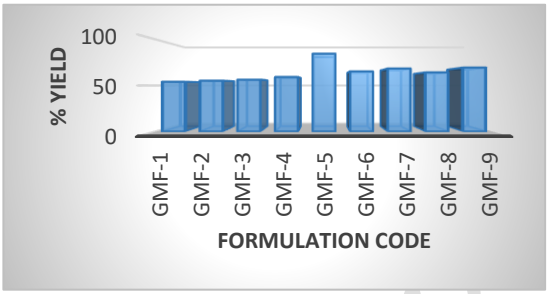


Fig 8: Percentage yield of floating microsphere of Glimepiride

EVALUATION

Percentage Yield

Percentage yield of different formulation was determined by weighing the granules after drying. The percentage yield of different formulation was in range of 54-84.32% as shown in Table 5. The maximum percentage yield was found in GMF5 to shown to figures.

Table 5: Percentage yield of floating microsphere of Glimepiride

Sr. No.	Formulation code	% Yield
1.	GMF1	54
2.	GMF2	55.23
3.	GMF3	56.32
4.	GMF4	59.18
5.	GMF5	84.32
6.	GMF6	65.23
7.	GMF7	68.32
8.	GMF8	64.12
9.	GMF9	69.32

% Entrapment Efficiency of floating Microsphere

The entrapment efficiency was found to be abruptly increasing when both polymers were used together. Entrapment efficiencies of batches GMF1-GMF9 ranged from 36.24% to 87.24%. Maximum encapsulation efficiency was observed of the batch GMF5, where ratio of 2:2:1 of the ethyl cellulose and Eudragit RS100 and Guargum was used. Table no.6 and Fig. 8 represent the entrapment efficiency.

Table 6: % Entrapment Efficiency of floating microsphere of Glimepiride

Sr. No.	Formulation code	% Drug Entrapment efficiency
1.	GMF-1	36.24
2.	GMF -2	38.32
3.	GMF -3	50.12
4.	GMF -4	62.32
5.	GMF -5	87.24
6.	GMF -6	64.66
7.	GMF -7	70.11
8.	GMF -8	68.62
9.	GMF -9	74.35

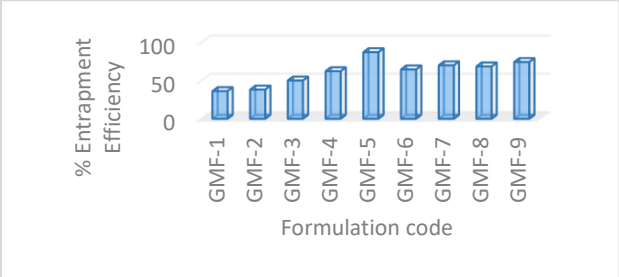


Fig 9: Percentage entrapment efficiency of floating microsphere of Glimepiride

Percentage Buoyancy

The percentage Buoyancy was found to be abruptly increasing when both polymers were used together. Percentage Buoyancy of batches GMF1-GMF9 ranged from 58.13% to 85.42%. Maximum percentage Buoyancy was observed of the batch F5, where ratio of 2:2:1 of the ethyl cellulose and Eudragit RS100 and Guargum was used. Table no.7 and Fig. 13 represent the floating behavior.

Table 7: Percentage buoyancy of floating microsphere of Glimepiride

Sr. No.	Formulation code	% buoyancy
1.	GMF1	63.32
2.	GMF 2	59.12
3.	GMF 3	68.43
4.	GMF 4	72.12
5.	GMF 5	85.42
6.	GMF 6	78.12
7.	GMF 7	74.12
8.	GMF 8	69.22
9.	GMF 9	58.13

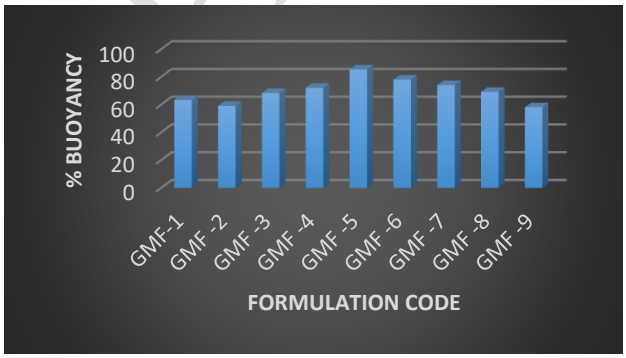


Fig 10: Percentage buoyancy of floating microsphere of Glimepiride

The Differential Scanning Calorimetry (DSC)

The differential scanning calorimetry (DSC) thermograms of pure Glimepiride, Eudragit, Guar gum was found to be 221, 210, 80 °C respectively in figure A,B,C. It was found that the DSC thermogram of GM showed a single endothermic peak at 221°C.

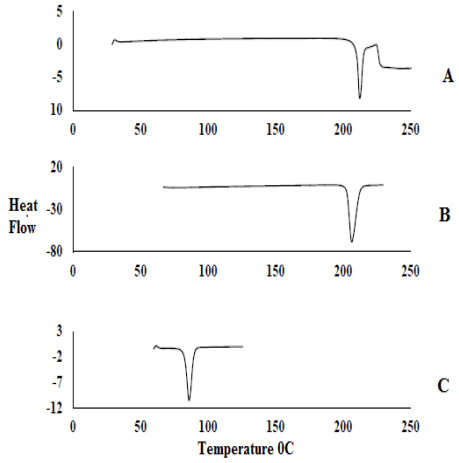


Fig 11: DSC of (A) Glimepiride (B) Eudragit Rs100 (C) Ethyl cellulose

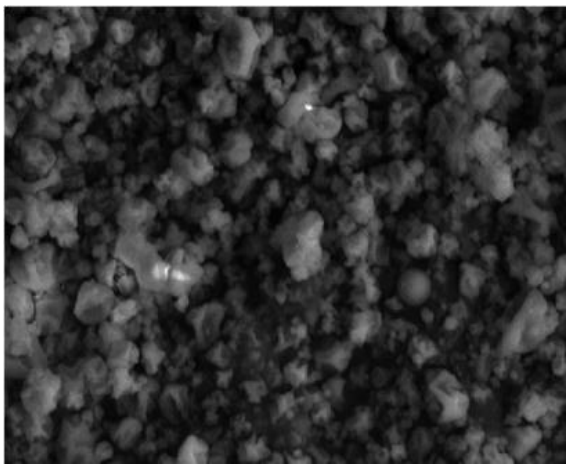
Scanning Electron Microscopy

Surface morphology of drug loaded microsphere was inspected using SEM (CIF, IIT BHU, Varanasi). Little quantity of drug loaded microsphere was spread manually on a carbon tape, which is attached to an aluminum stub. Samples were analyzed by SEM with direct data capture of the image on to a computer screen.

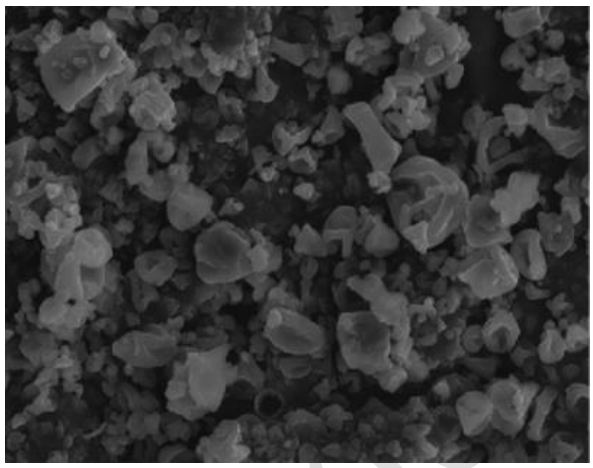
Micromeritic properties

Results of micromeritic properties such as bulk density, tapped density, hausner's ratio, angle of repose and carr's index were within standard limits.

Value of bulk density, tapped density, carr's index, Hausner's ratio and angle of repose of optimized were found to be 0.38±0.017 gm/cm^3, 0.45±0.022 gm/cm^3, 19.33±1.47, 1.16±0.02 and 25.11±1.80 respectively indicating good flow property.



(A)



(B)

Fig 12: SEM of (A) Glimepiride (B) Optimized Batch (GMF 5)

Table 8: Micrometric properties of floating Microspheres of Glimepiride

Sr. No.	Formulation code	Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	Hauseners ratio	Carr's index	Angle of repose
1.	GMF-1	0.27±0.011	0.33±0.016	1.16±0.04	12.15±0.10	27.72±1.78
2.	GMF -2	0.33±0.018	0.34±0.017	1.15±0.03	15.14±0.15	29.45±1.56
3.	GMF -3	0.36±0.012	0.40±0.015	1.22±0.05	17.48±0.01	32.58±2.58
4.	GMF -4	0.40±0.01	0.43±0.014	1.17±0.03	18.66±0.33	24.45±1.43
5.	GMF -5	0.38±0.017	0.45±0.022	1.16±0.02	19.33±1.47	25.11±1.80
6.	GMF -6	0.43±0.016	0.38±0.027	1.19±0.01	21.67±0.88	28.80±1.72
7.	GMF -7	0.46±0.018	0.50±0.016	1.13±0.02	18.46±0.35	27.56±1.67
8.	GMF -8	0.52±0.012	0.52±0.014	1.19±0.01	15.48±0.89	24.79±1.43
9.	GMF -9	0.54±0.018	0.58±0.019	1.20±0.02	13±0.38	26.54±1.59

Table 9: Percentage drug release

Cumulative % release at different time interval									
Time (hrs)	**GMF1**	**GMF2**	**GMF3**	**GMF4**	**GMF5**	**GMF6**	**GMF7**	**GMF8**	**GMF9**
0	0	0	0	0	0	0	0	0	0
1	25.68	28.42	32.0	25.32	34.32	28.32	25.12	24.32	27.32
2	25.69	34.72	33.08	32.35	36.32	29.32	28.25	25.21	28.32
4	27.68	41.68	34.86	34.32	37.35	34.35	32.13	28.31	32.12
5	31.69	44.89	38.89	36.36	42.12	38.39	34.24	32.12	33.21
6	36.04	49.12	42.32	39.32	43.42	42.32	38.38	34.04	34.15
7	38.40	50.13	43.36	42.12	52.32	46.32	42.12	38.54	42.32
8	40.64	52.99	44.48	43.56	58.68	52.12	46.38	39.35	45.31
10	41.08	57.98	49.6	47.48	62.64	53.32	50.12	44.25	52.13
12	43.82	61.37	54.32	54.32	68.98	54.25	52.38	52.12	54.31
14	46.34	64.29	58.45	69.35	74.38	55.36	56.28	54.12	59.35
24	50.51	67.68	62.35	70.12	82.35	58.24	60.31	64.32	68.31

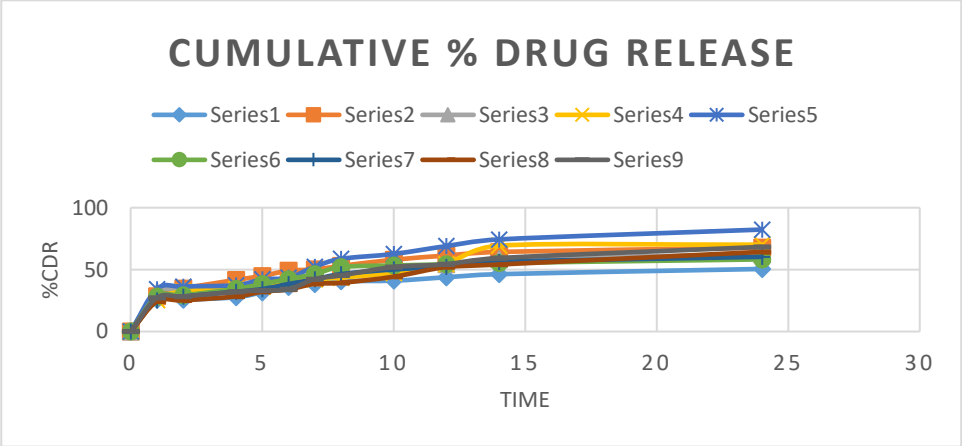


Fig 13: Comparison of drug release of different batches

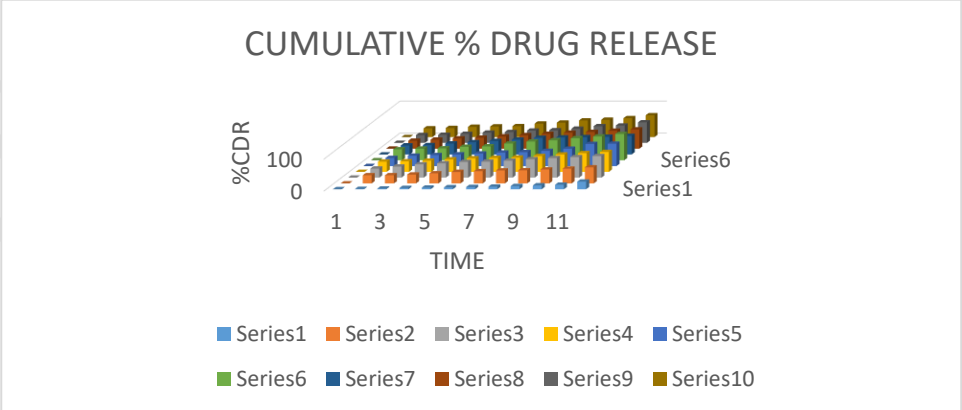


Fig 14: Comparison of drug release of different batches

Table 10: Percentage drug release of optimized Batch (GMF 5)

Cumulative % drug release of optimized batch at different time interval	
Time (hrs)	**GMF5**
0	0
1	34.32
2	36.32
4	37.35
5	42.12
6	43.42
7	52.32
8	58.68
10	62.64
12	68.98
14	74.38
24	82.35

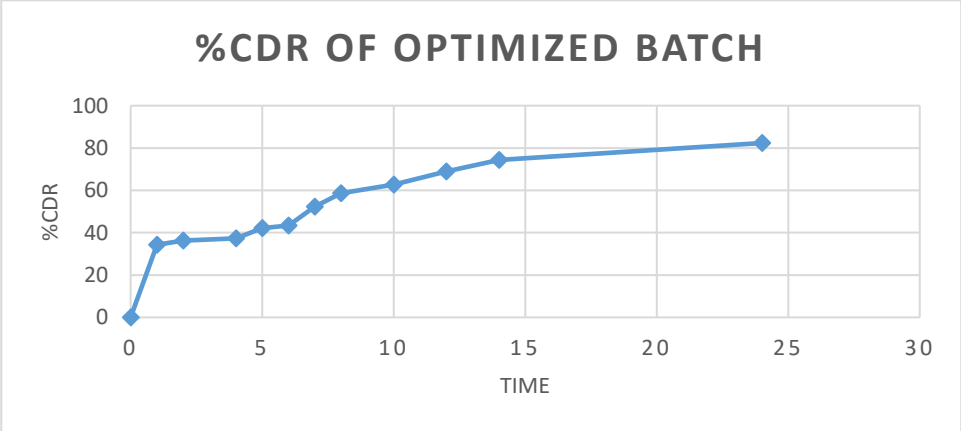


Fig 15: Drug release of optimized batch (GMF 5)

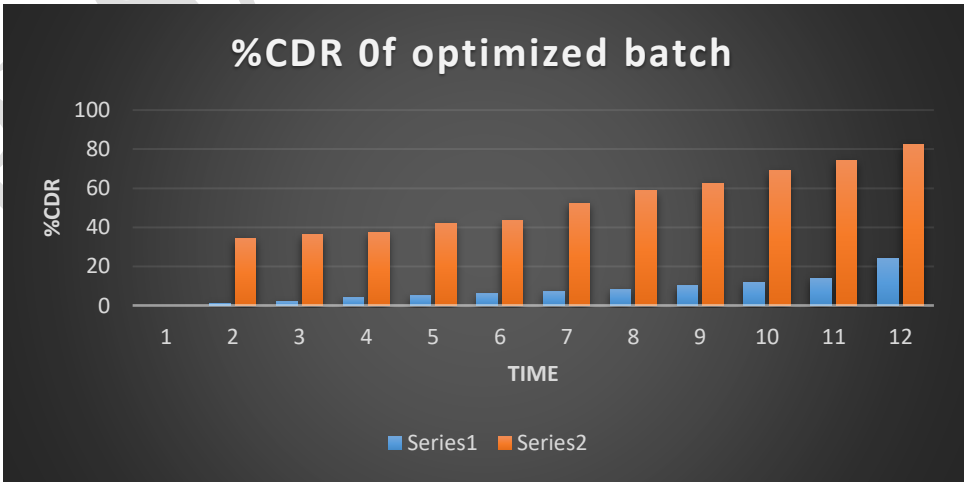


Fig 16: Drug release of optimized batch (GMF 5)

In Vitro Drug Release Studies

In-vitro drug release study were done for determining %drug release of drug from formulation and gives an idea about the effective formulation development. *In-vitro* drug release was done by open end tube at one end it was tied by dialysis membrane.

The required amount of sample was taken in open end tube and the dialysis membrane was activated by soaking it for 24 hours in phosphate buffer 7.4. The aliquots was withdrawn and change with fresh phosphate buffer. absorbance of the prepared dilution were taken at 240nm. The % drug release of optimized batch is 82.35.

Drug Release Kinetics

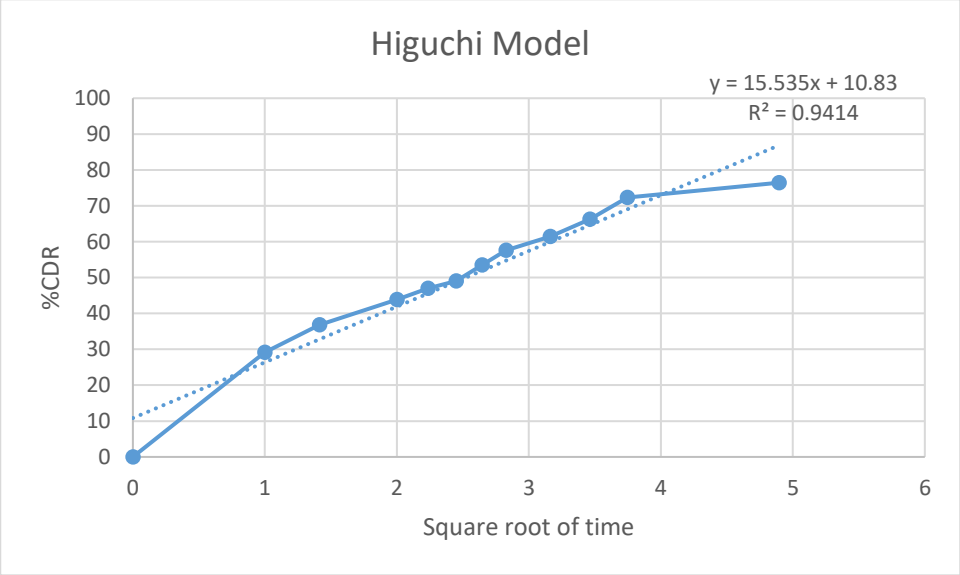


Fig 17: Higuchi Model Release kinetics of optimized batch (GMF 5)

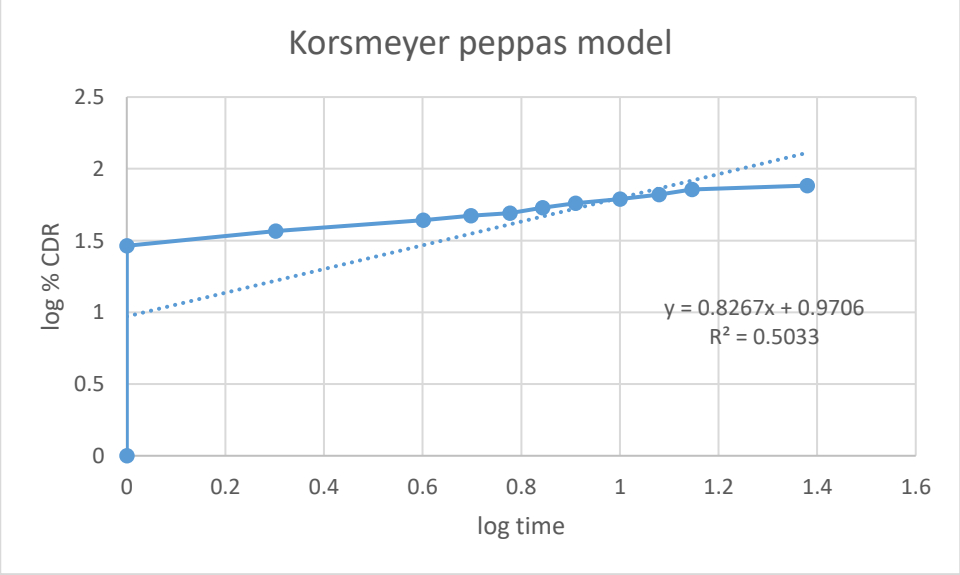


Fig 18: Korsmeyer Model Release kinetics of optimized batch (GMF 5)

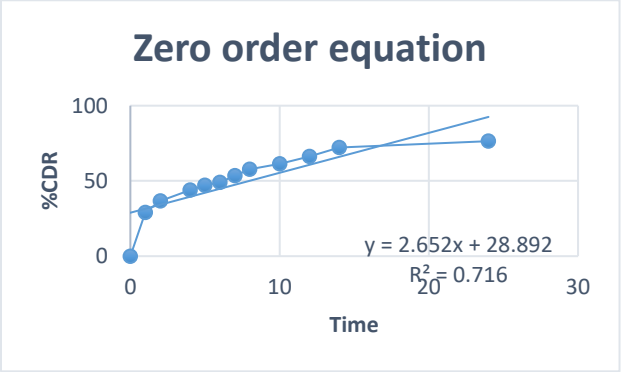


Fig 19: Zero order Model Release kinetics of optimized batch (GMF 5)

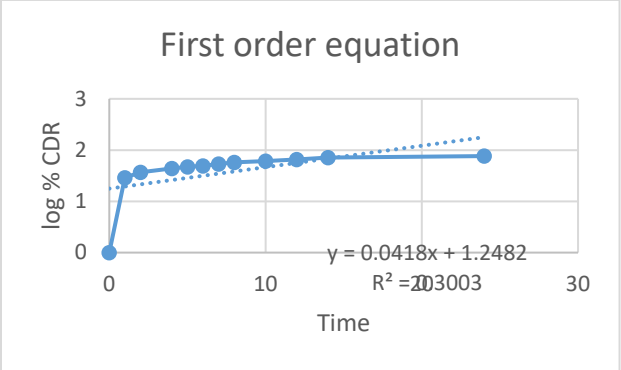


Fig 20: First order Model Release kinetics of optimized batch (GMF 5)

CONCLUSION

The present study has been a satisfactory attempt to formulate microspheres of Glimepiride, an orally administered antidiabetic drug with a view of improving its oral bioavailability and giving a prolonged release of drug. FT-IR spectra of physical mixture showed no significant shifting of the peaks therefore it reveals that the drug is compatible with the polymer used. Microspheres with polymers such as Ethyl cellulose and Eudragit RS 100 and guar gum were successfully prepared by emulsification solvent evaporation method. The percentage yield obtained in all the formulations was good and in the range of 54-84.32%. The particle size analysis revealed that the size of microspheres was increased with increase in the concentration of polymer.

It may be concluded that this sustained release formulation would be a promising drug delivery system to sustain the drug release for about 24 h enhancing the patient compliance. In the formulation, the combination of cost-effective and biocompatible polymers Eudragit RS100, Ethyl cellulose and Guargum had been successfully used and there is scope of scale up of the batches to the commercial level. The best formulation from the 9 batches, found to be efficient with good recovery yield, percent drug entrapment and drug release was F5, prepared using 1:2:2:1:1:1 ratio of polymer.

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