International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

Formulation and Evaluation of Sitagliptin Phosphate Enteric Coated Tablets

G. S. Sharma*, T. Rama Rao, LankalaAnusha, OrreLikhitha.
*Associate Professor, Department of Pharmaceutics, CMR College of Pharmacy, Hyderabad.
Students, @Department of Pharmaceutics, CMR College of Pharmacy, Hyderabad.

Submitted: 10-10-2023 Accepted: 20-10-2023

ABSTRACT
The term "enteric" means the small intestine.Coating with a material that permits transit through the stomach to the small intestine before the medication is released.Enteric-coating formulations are used for the drug delaying from releasing which are degraded by gastric enzyme. The present research is designed to achieve control or stopdrug delivery in acidic medium of gastrointestinal tract (GIT) by enteric coating polymers like Eudragit L-100 and Polyvinyl Pyrrolidineand to release in the intestine by using super disintegrants like sodium starch glycolate, croscarmellose sodium and crospovidone, and the other excipients like lactose, magnesium sterate and talc. By using active pharmaceuticalingredientSitagliptinphosphatewhic h is a type-2 anti-hyperglycaemic drug. Tablets are prepared by using wet granulation, compressed into tablet of all the formulations. Pre and post evaluation studies are carried which shows all the formulations are good. Among all the formulation F6 shown best results. FTIR studies are done for pure drug and optimized formulation. Stability studies are carried out over period of 3 months as per ICH guidelines.

KEYWORDS: Sitagliptin, enteric coating polymers, super-disintegrants, evaluation studies, FTIR, drug release kinetics and stability studies.

I. INTRODUCTION

The most popular way to administer medications is oral route. The majority of oral drugs are ingested; however, a limited number are intended to dissolve in the mouth. It is regarded as the most natural, easy, useful, and secure method of administering drugs. It grants greater flexibility in the design of dosage forms, is affordable to manufacture, and is organic[1]. According to current estimates, the worldwide market share for all pharmaceutical formulations designed for human use is owned by oral formulations to an extent of 90%. Orally assigned medicinal products make up around 84% of the top-selling pharmaceuticals and are presently estimated at over $35 billion with a 10% yearly growth rate[2].

An enteric coating is a barrier that manages the position of oral drug in the gastrointestinal system. It defines the word “enteric” specifies small intestine, hence enteric coatings prevent the release of drug before it delivers into the small intestine. The enteric coated excipients persist unionise at lesser pH, and consequently, remain insoluble. But when pH rises in the GIT, the acidic properties are potential to ionisation, and the excipients swells or converts soluble in the intestinal fluid. Polymers used for enteric coatings such as cellulose acetate phthalate, cellulose acetate trimellitate, polyvinyl acetate phthalate, and hydroxypropyl methylcellulose phthalate, fatty acids, waxes, shellac, plastics and plant fibers [3,4].

SitagliptinPhosphate is the most commonly prescribed gliptin to managed diabetes mellitus, alone or with metformin. It is a type-2 Anti-hyperglycaemic drug. It is a BCS Class-1 with high solubility and high permeability. These drug result in control of blood glucose which is confirmed by reduced glycosylated haemoglobin (HbA1c) [5].

II. MATERIALS AND METHODS

Sitagliptin Phosphate sample is gifted by Hetero Pharmaceuticals Hyderabad.Eudragit L-100, polyvinyl pyrrolidinesamples are taken from IndiaMART. Sodium starch glycolate, croscarmellose sodium and crospovidone supplied from KavyaPharma company. Talc and magnesium stearate are from Shiva inorganics Pharmaceuticals. All the chemicals and ingredients were of analytical or Pharmacopoeia grade.

III. PREFORMULATION STUDIES

1. **Organoleptic properties**: such as Colour, odour appearance (under the microscope), melting point, and determination of solubility

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

studies, determination of wavelength, FTIR studies and drug release kinetics.

2. **Solubility studies:**Suitableamounts of drug are taken and dissolved in a given solvent to get a saturated solution. The resultant saturated solution is sonicated and it as kept at a temperature. After it attains the equilibrium, its solubility is checked in UV spectrophotometer at wavelength of 235nm[6].
3. **Determination of wavelengthof Sitagliptin:**Suitable dilutions of sitagliptin were prepared from the standard stock solution. With the help of UVSpectrophotometer, the dilutions of sitagliptin Phosphate were scanned over a range of 200-400 nm. It was detected that the drug showed maximum absorbance at 235 nm which is selected as the wavelength of sitagliptinPhosphate.
4. **Calibration procedure for standard curve:**Different concentrations like 1, 2, 3, 4, 5 and 10 µgm/ml are prepared from the stock solution of100 µg/ml solution aliquots diluted with 6.8 phosphate buffer. For the resultant solutions absorbance is determined by using U.V spectrophotometer at a wavelength range of 235nm**.**
5. **Formulation of the core tablets:** The formulation includes the drug and the polymers like sodium croscarmellose, sodium starch glycolate, lactose, magnesium sterate and talc.They are prepared by wet granulation technique.ThePrepared tablets are coated with enteric coating polymers like eudragit L-100 and polyvinyl pyrrolidine by using spraying coating method.

Table- 1: Formulation of core tablet

S.no	Nameof the drugs	F1	F2	F3
1.	Sitagliptin	100	100	100
2.	Croscarmellose Sodium	50	-	-
3.	Crospovidone	-	50	-
4.	Sodium starch glycolate	-	-	50
5.	Lactose	145	145	145
6.	Magnesium sterate	2.5	2.5	2.5
7.	Talc	2.5	2.5	2.5
	Total	300	300	300

* All units are in mg

IV. EVALUATION STUDIES OFFLOW PROPERTIES [7,8,9]

a. Pore/Bulk density: The true density (ρb) was determined by pouring the pre weighed (M) blend into a graduated cylinder. The bulk volume (Vb) of the blend was measured by this method. Then the true density was calculated by the given below formula.

ρb = M/Vb

b. Tap density: The measured cylinder containing a mass (M) of blend was tapped for a fixed time, and the minimum volume (Vt) occupied in the cylinder was determined. The tapped density was measured by the formula stated below.

Tap density (ρt) = M/Vt

c. Porosity: The porosity of voids and of the drug is defined as the ratio of void volume to the bulk volume of the packaging.

E= (Vb- Vp)/Vb

d. Carr's Index: Based on the apparent bulk density and the tapped density, the percentage compressibility of the bulk drug was measured by using the below formula.

%Compressibility = [(tapped density - bulk density)/ tapped density] X100

e. Hausner's Ratio: The ratio of tapped density to bulk density of the powders is known as Hausner's ratio.

Hausner's Ration= $Db/\ Dt$

Where, Dt = tapped density of the powder; Db = bulk density of the powder.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

Table- 2:Standard values of Compressibility index and Hausner's ratio

Compressibility index [%]	Hausner ratio	Flow characteristics
≤10	1.00-1.11	Excellent
11-15	1.12-1.18	Good
16-20	1.19-1.25	Fair
21-25	1.26—1.34	Passable
26-31	1.35-1.45	Poor
32-37	1.46-1.59	Very poor
>38	>1.60	Very very poor

f. Angle of repose: It was determined by the funnel method. The determination of angle of repose by this method is termed as static angle of repose. Angle of repose is an indirect method of evaluating the powder flow capability because of their relationship with interparticle cohesion.

$\alpha = \tan^{-1}$ (h/r),where 'h' is height of pile and 'r' is radius of pile.

Table- 3: Angle of repose with its flow property

Flow property	Angle of repose(Ɵ)
Excellent	25-30
Good	31-35
Fair	36-40
Passible	41-45
Poor	46-55
Very poor	56-65

g. Void Volume: The volume between the spaces is known as the void volume "V" and is given by the formula,

$V = \rho b - \rho t$

Where, ρb = Bulk volume (volume before tapping); ρt= True volume (volume after tapping)

V. COMPRESSION OF CORE TABLETS

Granules were prepared by using wet granulation method. Drug and other excipients were passed through #85 and add sufficient quantity of binding agent slowly to get dough mass. The mass was sieved through # 16 and dried at 45 ºC for about 1 hour. and then these granules were passed through # 20 and lubricated with magnesium stearate and talc. Mixed blend was compressed into tablets on single punch tablet compression machine to a weight of 300 mg each with thickness of 4.46 ± 0.21 mm and diameter of 7.9 mm using shallow concave plain/ plain punch.

a. **Direct Compression**: The tablets are prepared by compressing the powdered materials directly, without changing the materials physical nature. The main advantages of direct compression are time-saving, the safety of operations and low price.
b. **Dry Granulation:** The dry granulation method is used without the use of a liquid solution to form granules. For goods which are prone to moister and heat, this kind of process is suggested. Forming granules without moisture

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

demands that the powders be compacted and densified.

c. **Wet Granulation:** This is the usually used method for tablet preparation. In this method, the powders are bound by a suitable binder by "adhesion". The binder is added by diluting with a suitable solvent prior to addition to the blended powders to form wet granules which are dried suitably to eject the solvent forming dried granules. Some advantages of wet granulation process are discussed below.

- The granules are uniform in size and shape.
- The granules are free-flowing.
- The granules are strong enough to withstand handling and processing.
- The granules should be compatible with the other ingredients in the formulation.

VI. TABLET COATING PROCESS [10]

In most of the coating methods, when the tablets are being disturbed in a pan, fluid bed, etc. at that time spraying on tablets by coating solution takes place. As the solution is being sprayed, a thin layer is formed that follows directly to each and every tablet. The coating may either be formed by a single use or may be built up in films through the use of multiple spraying rounds. In pharmaceutical industry, rotating coating pans are regularly used. Firstly, uncoated tablets are put into the pan, which is typically slanted at an angle from the horizontal, and later the liquid coating solution is introduced into the pan whereas the tablets are dipping. By passing airborne over the surface of the tumbling tablets, the fluid portion of the coating solution is then disappeared. The coating process is typically a batch operating task consisting of the following stages:

Identification of group and Recipe selection (film or sugar coating) of the tablet is carried out and later loading/ dispensing (exact dosing of all required raw materials) of the tablets are done. Warming and spraying (Both application and rolling are accepted out simultaneously) of the material on the core tablet and drying the tablet. Freezing and discharging of the coated tablets.

Table- 4: Formulation of enteric coating polymer

S.no	Polymer name	C1	C2
1.	Eudragit L-100	300mg	-
2.	Polyvinyl pyrrolidine	-	300mg
3.	Ethyl alcohol	20mg	5mg
4.	Acetone	20mg	15mg
5.	Propylene glycol	15mg	15mg
6.	Sorbitanmonooleate	q. s	q. s

VII. EVALUATION OF COATED TABLETS [11]

The core and enteric coated tablets were evaluated for hardness, thickness, friability, weight variation, in vitro release studies, drug content and disintegration rate.

I. **Hardness:** The tablet crushing strength was determined by using Monsanto tablet hardness tester. A tablet is placed between the anvils and the crushing strength, which causes the tablet to break and was recorded.

II. **Thickness**: The thickness of the tablet was determined by using vernier callipers. Randomly, ten individual tablets from each formulation were used, and the results were averaged.

III. **Friability**: Tablet strength was measured by using Roche friabilator. Twenty tablets were weighed and placed in the friabilator and operated for 100 revolutions in 4 min. The tablets were dedusted and the % weight loss was measured by reweighing the tablets. The tablets that loose less than 1% weight were taken as compliant. The friability was calculated as Friability (%) = [(1- initial weight) /weight retained after 100 rotations] x100

IV. **Weight variation:** In weight variation, 20 tablets were taken randomly and average weight was measured by using an electronic balance. Tablets were weighed individually and compared with average

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

weight. It was taken as per the IP/BP standard and USP standards.

Table-5:Standard values of weight variation

S.no	Average weight of tablet [mg] IP/BP	Limits	USP [mg]
1.	84 or less	±10%	130or less
2.	84-250	±7.5%	130-324
3.	More than 250	±5%	324 or more

V. **Disintegration time**: Disintegration time was calculated using the disintegration apparatus USP in 0.1N HCl for 2 hrs. and then in phosphate buffer pH 6.8 for 1 hour maintaining the temperature at 37 ± 2°C.

VI. **Drug content studies:**10 tablets were weighed individually and powdered. A powder equivalent to 3 mg was taken and 50 mg of drug add 95% water was shaken for 30 minutes. Water was added to produce 100 ml. The liquid equivalent to 0.3mg of drug was pipette out and diluted to 50ml with water. The solution was filtered (through 0.45µm). Drug content was measured at 235nm using UVVisible spectrophotometer.

VII. **In vitro drug release studies:** In vitro drug release study of enteric coated tablets was carried out by using USP six station dissolution rate test apparatus with paddle stirrer. The dissolution rate was studied in 900 ml of 0.1 N HCl (pH 1.2) maintained at a temperature of 37± 1ºC with a speed of 50 rpm for first two hours followed by phosphate buffer (pH 6.8) for further 4hours. Samples of 5 ml were withdrawn for every 15 min, filtered (through 0.45 µm) and replaced with 5 ml of fresh buffer medium. The samples were suitable diluted and estimated in spectrophotometrically at 235 nm by using UV spectrophotometer and cumulative % of drug release was measured.

VIII. **Fourier Transforms Infrared Spectroscopy (FTIR):** The infrared spectrum of Sitagliptin Phosphate and optimized formulation ware recorded by using Bruker alpha model Fourier Transform Infrared Spectroscopy and OPUS Software. The sampling technique used ATR (Attenuated total reflectance). The sample was placed on the sample holder. The surface of the sample levelled. This sample holder was then placed in the analysis chamber and the spectrum was recorded. It is carried out for drug and best formulation F6.

IX. **STABILITY STUDIES** [12,13]: Stability studies on the optimized formulation was carried out to determine the effect of presence of formulation additives on the stability of the drug and also to determine the physical stability of the formulation under accelerated storage conditions. The tablets were stored in an aluminium foil and subjected to elevated temperature and humidity conditions of 40 ± 2^0C/ 75 ± 5 % RH for time period of 3 month. Samples were withdrawn at the end of every week and evaluated for appearance, % drug content, disintegration time and % drug release.

VIII. RESULTS AND DISCUSSIONS

1. **Organolepticproperties:** Organoleptic Property study was conducted as discussed in section **3. a** and the results are discussed in **Table-6** colour white; odour odourless.

Table- 6: Organoleptic Properities of sitagliptin phosphate

Organoleptic Property	Observation
Colour	White
Odour	Odourless

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

2. **Solubility studies:** Solubility studies are conducted as discussed in **section 3.b** andthe results are shown in **Table-7** the results indicate sitagliptin is soluble in water and N, N-dimethyl formamide, slightly soluble in methanol and insoluble in isopropanol.

Table-7: Solubility studies

Solvents	Solubility nature
Water	Soluble
N,N-dimethyl formamide	Soluble
Methanol	Slightly soluble
Isopropanol	Insoluble

3. **Determination of wavelength of sitagliptin:** Thewavelength detection is conducted as discussed in above **section 3. c** andthe results are shown below in **Figure-1** the results indicate that the detection of wavelength of sitagliptin is observed in uv spectroscopy at wavelength 235 nm.

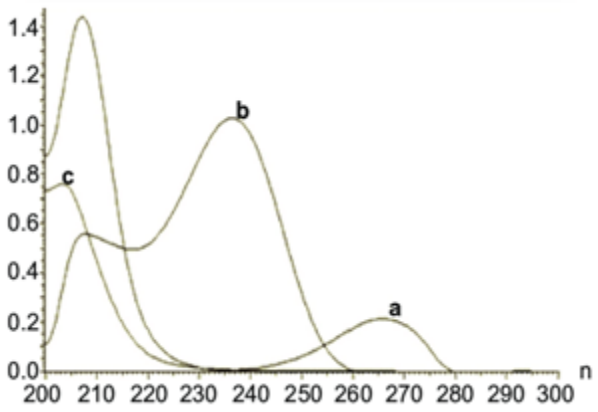

Figure-1: Wave length maxima of Sitagliptin phosphate

4. **Calibration procedure for standard curve:** It wascarried out as above **section 3.d** andare given below.

Table-8:Calibration curve of sitagliptin Phosphate

S.no	Concentration [µg/µL]	Absorbance [nm]
1.	0	0
2.	10	0.19±0.02
3.	20	0.38±0.04
4.	30	0.55±0.02
5.	40	0.73±0.04
6.	50	0.92±0.02

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

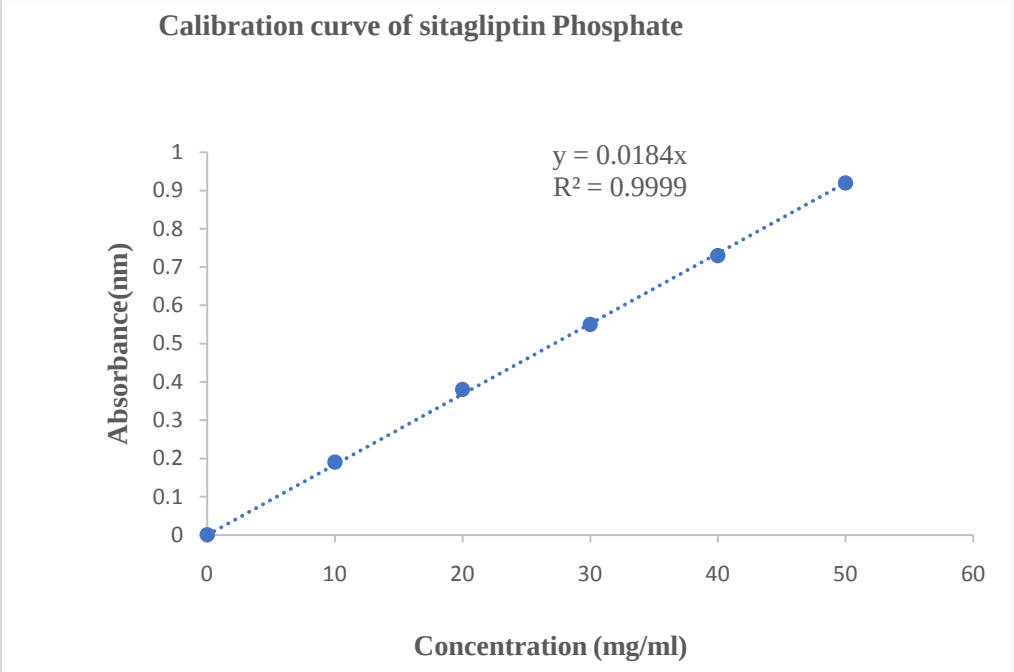

Figure-2:Calibrationcurve of Sitagliptin Phosphateλmax at 235nm

The results shows that the standard graph of sitagliptinstates **goodlinearity** with an **R^2= 0.999,** indicating that it obeys the "Beer- Lamberts" law.

5. **Formulation of the core tablets:** It was conducted as mentioned above in **section3.e** it was carried with different super disintegrants, lubricant and binder to formulate the best formulation.
6. **Evaluation studies of flow properties:** The evaluation studies are conducted as discussed above **section-4** and the results are given in below **Table-9**.

Table-9:Evaluation studies of flow properties

Formulations	Bulk density gm /cm^3	Tapped density gm/cm^3	Carr'sindex [%]	Hausner's ratio [%]	Angle of repose [Ɵ]
F1	0.79±0.12	0.85±0.15	12.0± 0.19	1.20±0.16	28.5±0.14
F2	0.80±0.15	0.86±0.13	13.2±0.20	1.22±0.17	32.8±0.18
F3	0.85±0.16	0.90±0.20	15.4±0.35	1.24±0.22	35.0±0.22
F4	0.74±018	0.89±0.23	9.7±0.38	1.05±0.24	29.3±0.28
F5	0.75±0.14	0.92±0.17	9.8±0.23	1.07±0.18	30.9±0.19
F6	0.72±0.13	0.86±0.19	9.2±0.25	1.03±0.19	27.4±0.21

From the above evaluation studies of flow Properitiesshows that tap density, bulk density, Hausner's ratio, angle of repose and carr's index values are given above **Table-9.** All the 6 formulations are within the ranges and best values are shown by F6 formulation.

7. **Compression of core tablet:**Compression of core tablet is previously discussed in **section 4 B** clearly.
8. **Tablet Coating Process:** The use of coating polymer and method are discussed in above **section- 5** in detail.

9. **EVALUATION OF ENTERIC COATED TABLET**

Evaluation of enteric coating tablets includes hardness,friability, weight variation, thickness, drug content and disintegration studies were clearly explained in **section-6** andits results are discussed below **Table-1**

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

Table-10: Evaluation studies of enteric coating tablet

Parameters	F1	F2	F3	F4	F5	F6
Hardness [kg/cm^{3}]	3.02±0.21	4.09±0.18	4.35±2.8	4.42±0.28	4.15±0.21	4.59±0.28
Friability [%]	1.42±0.8	1.56±0.5	0.58±0.8	0.62±0.8	0.73±0.5	0.71±0.5
Weight variation [%]	470±1.2	400±1.4	420±1.5	342±1.4	387±1.3	321±1.0
Thickness [mm]	4.6±0.3	4.3±0.8	4.5±0.8	4.160.6	4.2±0.4	4.0±0.2
Drug content[min]	0.95 ±0.4	0.99 ±0.4	0.85±0.5	0.98± 0.4	0.88 ±0.5	0.99 ±0.3
Disintegration [HCl]	No change	No change	No change	No change	No change	No change
Disintegration p_{H}-6.8	80min	78min	75min	68min	70min	65min

From the above evaluation studies demonstratesthat all parameters like hardness, friability, weight variation, thickness, drug content and disintegration studies show that all F1-F6 formulation are within the ranges and best results were shown by F6 formulations among other formulation.

1. **In vitro dissolution studies of sitagliptin:** In vitrodissolution studies were clearly explained in above **section -6 g.**Theresults arediscussed below in **Table-11** in detail.

Time [min]	F1	F2	F3	F4	F5	F6
	% of drug release					
15	0	0	0	0	0	0
30	0	0	2.95±0.3	2.65±0.4	5.07±0.3	8.09 ±0.4
45	14.2 ±0.2	12.24±0.2	14.32±0.4	17.37±0.2	10.85±0.5	18.72±0.4
60	25.62±0.3	23.68±0.5	26.85±0.3	28.35±0.4	23.08±0.5	34.92±0.3
75	45.84±0.5	32.67±0.3	43.65±0.5	45.02±0.3	35.85±0.4	58.46±0.1
90	59.81±0.3	44.58±0.5	58.95±0.4	61.24±0.3	49.64±0.3	69.02±0.2
105	68.75±0.6	59.87±0.4	67.84±0.3	74.89±0.6	68.84±0.5	78.81±0.3
120	75.53±0.3	78.36±0.2	81.35±0.4	83.42±0.2	85.49±0.4	87.04±0.4
150	82.96±0.4	84.89±0.5	87.18±0.3	90.60±0.5	91.81±0.5	93.72±0.3
180	89.94±0.2	94.89±0.3	95.98±0.3	96.46±0.3	93.91±0.3	98.72±0.4

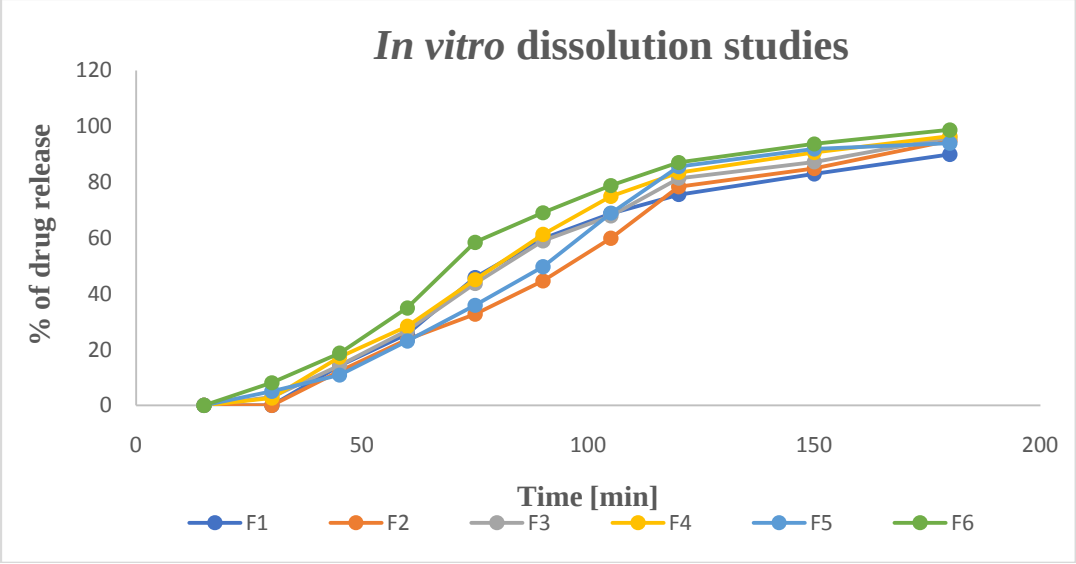

Figure-3:Invitro dissolution studies

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

From the above**Table-11**and **Figure-3** the invitrodissolution studies describes that all F1- F6 formulations shows good results and **F6** formulation shows the %of drug release was **98.72± 0.4%**in**180 min** the and therefore, F6 formulation was considered as optimized formulation.

2. **FTIR STUDIES:**FTIR studies were explained in above **section- 6 h** and results are discussed in below **Figure-4** and **Table-12**

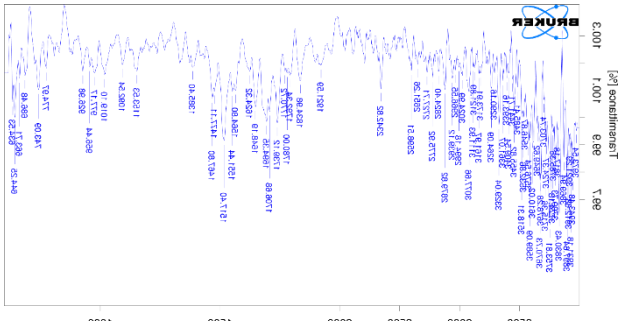

Figure-4: FTIR studies of Sitagliptin phosphate

Table-12: FTIR studies of Sitagliptin phosphate

wavelength	Functional Groups	Types of vibration
3830	O-H	Stretching
2842	O=C=O	Stretching
1517	C-N	Stretching
743	C-H	Bending

From the above FTIR studies describes that different wavelength shows various function group have types of vibration like stretching and bending in above **Figure-4** and **Table-12.**Therefore,is no interaction with function group.

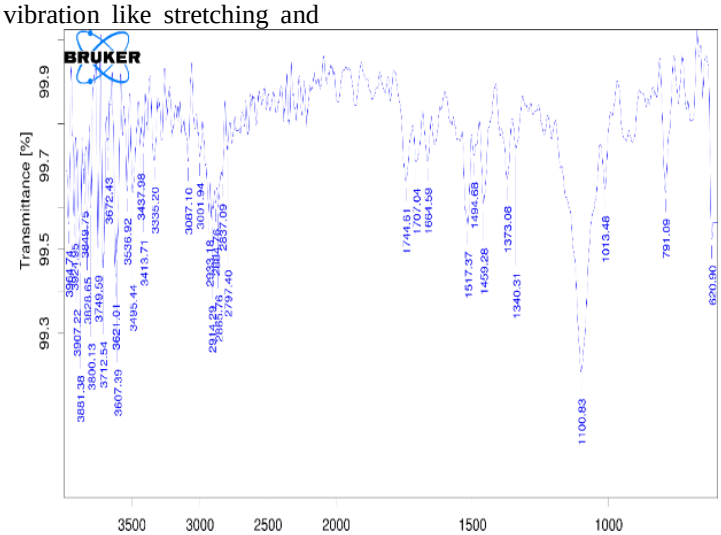

Figure -5: FTIR studies of best formulation[F6]

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

Table-13: FTIR studies of best formulation [F6]

wavelength	Functional Groups	Types of vibration
3800	O-H	Stretching
2837	C-H	Stretching
1517	C-N	Stretching
791	C=C	Bending

From the above of the FTIR spectra of F-6 formulation revealed peaks for C-H stretching, C-N stretching, C=H stretching, and O-H stretching, which are similar to the FTIR spectra of pure drugs. The presence of drug and other compounds was confirmed by the appearance of the above peaks in **Figure 5**and **Table-13.** It has been established that there is no significant shifting or loss of functional peaks between the spectra of pure drug and optimized formulation. Therefore, there is no interaction with functional groups.

3. **Stability studies:**It was conducted to determine the physical stability of the best formulation under accelerated storage conditions as it was mentioned previously in **4.11**. It was done as per ICH guidelines over period of three months with different quality parameters like appearance, hardness, drug contentand dissolution studies.

Quality parameters	1^{ST} month	2^{ND} month	3^{rd} month
Appearance	Round	Round	Round
Hardness	4.51±0.28	4.49±0.28	4.47±0.28
Dissolution [HCl]	No change	No change	No change
Dissolution [KH_2PO_4]	98.69	98.65	98.62
Drug content	0.98 ±0.1	0.98 ±0.3	0.97 ±0.3

Table-14: Stability studies

From the above **Table-14**stability studies states that there was no change in any of the formulation after storage at 25°C ±2°Cor 30,60 and 90 days. The shape, hardness, drug content, and Dissolution were all identical to the initial preparation. However, after 90 days [3months] of storage at 25°C ±2°C, the percentage of drug content in the formulation was less than 97% as per ICH Guidelines and doesn't affect activity of enteric coating tablets.

IX. CONCLUSION

Sitagliptinphosphate is type-2 Anti-hyperglycaemic drug which is formulating into an enteric coating tablet. From the above studies concluded that by using enteric coating polymers like eudragit L-100 and polyvinyl pyrrolidine are inhibiting the releasing of the drug in the acidic medium i.e, in the stomach and rapidly dissolving in the intestine by the addition of super-disintegrants like sodium starch glycolate, croscarmellose sodium and crospovidone and use of excipients like lactose, magnesium sterate and talc into 6 Formulations. Pre and post evaluation studies are conducted to all formulations. Stability studies are carried out as per ICH guidelines for a period of 3months[90days]. The FTIR studies are conducted for pure drug and optimized formulation [F6]. The results show in combination with eudragit L-100 and croscarmellose sodium shows good results among other formulation and in combination with polyvinyl pyrrolidine and sodium starch glycolate[F6] gives best results.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 1237-1247www.ijprajournal.com ISSN: 2249-7781

REFERENCES

[1]. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig; The theory and practice of Industrial Pharmacy;4; Pg. 293-303;
[2]. Herbert A. Liberman, Martin M. Rieger and Gilbert S. Banker; pharmaceutical dosage forms: Tablets; (1)
[3]. Agylirah GA, Banker GS, Boca Raton; Polymers for enteric coating applications.In: Polymers for controlled drug delivery; CRC Press; 1991; 39–66.
[4]. Herbert A. Liberman, Martin M. Rieger and Gilbert S. Banker, pharmaceutical dosage forms: Tablets; (1).
[5]. Davis JA, Singh S, Sethi S, Roy S, Mittra S, Rayasam G; Nature of action of Sitagliptin, the dipeptidyl peptidase-IV inhibitor in diabetic animals; Indian J Pharmacol; 2010; 42(4):229–33.
[6]. Nonaka T, Sekino Y, Iida H; Early effect of single-dose sitagliptin administration on gastric emptying: crossover study using the breath test; J Neuro gastroenterology motility; 2013; 19(2): 227–232.
[7]. Vidyadhara S, Chowdary YA, Murthy TEGK, Rao MV, Reddy KNK; Influence of electrolytes on controlled release of Ambroxol Hydrochloride from methocel matrix tablets; The Pharma Review 2006; June: 101-104.
[8]. Jaimini M, Rana AC, Tanwar YS; Formulation and Evaluation of Famotidine Floating Tablets; Current Drug Delivery 2007; 4: 51-55.
[9]. N. Damodharan, V. Manimaran and B. Sravanthi; Formulation development and evaluation of delayed release doxycycline tablets, International Journal of Pharmacy and Pharmaceutical Sciences, 2(1), 2010.
[10]. Hemchand P, Avinash DR, Tukaram MS, Mahavir B; Recent advances in different aspects of tablet coating; 2017;16.
[11]. PatilAjit, Payghan Santosh and Disouza John; Formulation and Evaluation of Entericcoated tablets of Azithromycin dihydrate; International Journal of Chemtech Research, 3(3), 2011, 1479-1484.
[12]. Ren Y, Jiang L, Yang S, Gao S, Yu H, Hu J, Hu D, Mao W, Peng H, Zhou Y; Design and preparation of a novel colon targeted tablet of hydrocortisone; Braz J Pharm Sci; 2016; 52(2):
[13]. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products; World Health Organization, Technical Report Series; No. 953, 2009.