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FORMULATION AND EVALUATION OF SITAGLIPTIN ORAL DISINTEGRATION TABLETS USING SYNTHETIC SUPERDISINTEGRANTS

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ABSTRACT

Research work is formulate the oral disintegrate tablets of Sitagliptin by using Synthetic Superdisintegrants. To formulate oral disintegrating tablets of Sitagliptin using different ratios of synthetic super disintegrates by direct compression technique. The aim of the present study was to develop and optimize oral disintegrating tablets of drug (Sitagliptin) using synthetic superdisintegrants to give quick onset of action by rapidly disintegrating in a few seconds without the need of water with better patient compliance. In such cases, bioavailability of drug is significantly greater and adverse event is reduced than those observed from conventional tablet dosage form. By performing compatibility studies by IR spectrophotometry, no interaction was confirmed. The first 9 formulations of Sitagliptin were formulated with different Concentrations (3, 6, 8%) of Three super disintegrants namely, croscarmellose sodium, sodium starch glycollate and crospovidone. Microcrystaline cellulose was used as directly compressible vehicle. Aerosil used as glidant to improve the flow property of the formulation. Magnesium stearate is used as lubricant respectively. The FG1, FG2 formulations are formulated using fenugreek seed mucilage as a natural superdisintegrant in different concentrations (3 & 6%). The overall results indicated that formulation with croscarmallose sodium (8%) i.e. CCS3 formulation had a higher edge compared to other formulations containing superdisintegrants.

KEYWORDS: Microcrystaline cellulose, oral disintegrating tablets, World Health Organization.

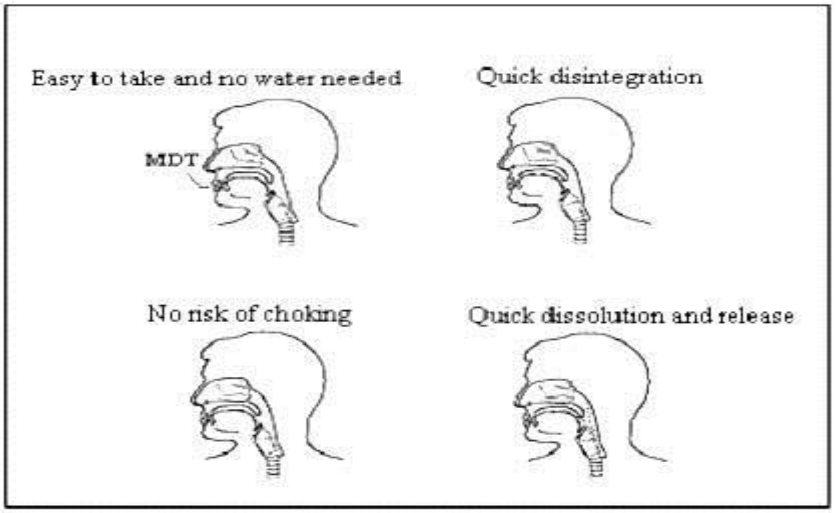
INTRODUCTION

Orally Disintegrating Tablets

The concept of Fast dissolving Drug Delivery System emerged from the desire to provide patient with more conventional means of taking their medication. It is difficult for many patients to swallow tablets and hard gelatin capsules. Hence they do not comply with prescription, which results in high incidence of non-compliance and ineffective therapy.[3] In some cases such as motion sickness, sudden episodes of allergic attacks or coughing and unavailability of water, swallowing conventional tablets may be difficult. Particularly the difficulty is experienced by pediatric and geriatric patients. Such problems can be resolved by means of Fast Dissolving Tablet. When put on tongue, this tablet disintegrates instantaneously, releasing the drug, which dissolves or disperses in the saliva. The center for drug Evaluation and Research states an ODT to be: "A solid dosage form containing medicinal substances, which disintegrate rapidly, usually within a matter of seconds, when placed upon the tongue. These tablets are distinguished from conventional, sublingual tablets, lozenges and buccal tablets which require more than a minute to dissolve in the mouth. In the literature these are also called orally disintegrating, Orodisperse, Mouth dissolving, quick dissolving, Fast-melt and rapidly disintegrating tablets and freeze- dried wafers.

Mechanism of ODT drugs

Generally, ODTs are formulated to disperse rapidly in the mouth, enabling medication to be swallowed without water, thereby increasing convenience and compliance across a broad range of indications and patient types, including the young, elderly, and active patients. "However, ODTs may also be used to deliver drugs to the oral cavity, for local action or, in some cases, absorption across the oral mucosa, thereby avoiding first-pass hepatic metabolism and potentially increasing the rate and extent of uptake, and reducing undesirable metabolites," The potential for such pregastric absorption rests largely in the physicochemical characteristics of the drug molecule.



Diabetes Mellitus

Diabetes mellitus is a syndrome that is caused by a relative or an absolute lack of insulin. It is a chronic disease characterized by symptomatic increase in blood glucose concentration (hyperglycemia) as well as lipid and protein metabolism alterations. Chronically, these metabolic abnormalities, particularly hyperglycemia, contribute to complications development such as nephropathy, neuropathy, retinopathy and cardiovascular complications. This syndrome was first recognized centuries ago by the initial observations of two Indian physicians - Chakrata and Susruta (600 B.C) - who differentiated two forms of the disease. Type-1 diabetes which results from the destruction of the auto immune pancreatic beta-cells and causes an absolute deficiency of insulin is also known as insulin–dependent diabetes. Type-1 diabetes is treated by insulin, diet and exercise (Franz et al. 2004). Diabetes type-2 is a non-insulin-dependent diabetes mellitus. It results when the pancreas retains some beta-cell function, but the variable insulin secretion is insufficient to maintain glucose homeostasis. Factors that influence the development of type 2 diabetes include genetic factors, environmental factors, obesity, physical activity, birth weight and diabetic pregnancy. Diabetes type-2 is treated by diet, exercise and oral anti-diabetic agents; insulin is used when the oral anti-diabetic agents fail to maintain glycemic control. Metformin is the only currently available biguanide. Indeed, it is one of the most widely used oral anti-diabetic drugs, which is the first drug of choice in obese patients whose diet control fails to control diabetes. It's also used in patients on sulfonylurea with inadequate control of diabetes metformin is reviewed as an agent that improves the sensitivity of the liver and muscle to insulin.

Type-2 diabetes

Type-2 diabetes is heterogeneous disorder that is characterized by pancreatic beta-cell dysfunction, resistance to insulin action, increased hepatic production of glucose and obesity. Its prevalence increased dramatically with age. The majority of diabetics are with type-2 diabetes. Metformin: the only currently available form of biguanides group of oral antidiabetic agents. Diabetes mellitus has a high prevalence worldwide in both developed and developing countries. It affects all races, but some much more than others. Its prevalence and incidence has increased in many populations, especially those in the developing countries. According to the WHO (World Health Organization), the epidemiology of diabetes is extremely related to the lifestyle and economic changes. Type-2 diabetes has a distinctive epidemiology, with much of the variation in frequency accounted for by known risk factors, which are: Genetic factors, environmental factors, obesity, physical activity, diet, birth weight, and diabetic pregnancy. The worldwide prevalence of diabetes has grown to alarming levels and it is estimated that at least 170 million will be affected by diabetes by 2030; the increase is particularly evident in the developing countries. Type 2 diabetes is the most common type and its prevalence varies enormously from population to population and throughout the world. WHO estimates that by 2025 about 200-300 million people worldwide will have developed type-2 diabetes and according to statistics from the Center of Disease Control (CDC). This means an increase of about 6 million patients every year.

Aim of the Work

The aim of the present research work is formulate the oral disintegrate tablets of Sitagliptin by using Synthetic Superdisintegrants.

Objective of the Work

The objectives of the research work undertaken are as follows:

1. To formulate oral disintegrating tablets of Sitagliptin using different ratios of synthetic super disintegrates by direct compression technique.
2. To evaluate the drug content and to perform in-vitro drug release study.
3. To study the physical characteristics of the individual drug by FTIR spectroscopy and the optimized formulations by FTIR spectroscopy.
4. To evaluate various characteristics of the resulting tablets.
5. Stability studies were carried out for the optimized formulations for 3 months.

METHDOLOGY

Materials and Suppliers

List of materials used in formulations

S. No.	Name of ingredient	Trade Name	Manufacturer	Pharmaceutical Grade
1.	Sitagliptin	----------	BMR Chemicals, Hyd	Pharmaceutical Grade
2.	MCC (PH-102)	Cyclogel	Kawarlal Exicipients limited, Chennai	Pharmaceutical Grade
3.	Lactose anhydrous	Supertab-21	Kawarlal Exicipients limited, Chennai	Pharmaceutical Grade
4.	Crospovidone NF	Polyplasdone XL	SD Fine, Mumbai	Pharmaceutical Grade
5.	Sodium starch Glycolate	-	SD Fine, Mumbai	Pharmaceutical Grade
6.	Magnesium stearate	-	Kawarlal Exicipients limited, Chennai	Pharmaceutical Grade
7.	Cros Carmellose Sodium	-	Kawarlal Exicipients limited, Chennai	Pharmaceutical Grade
8.	Sodium Sacharin	-	Kawarlal Exicipients limited, Chennai	Pharmaceutical Grade
9.	Orange Flavour	-	Merck specialties Pvt. Ltd, Mumbai	Pharmaceutical Grade
10.	Aerosil	-	SD Fine, Mumbai	Pharmaceutical Grade

Equipment

S. No	Equipment	Model	Manufacturer
1	Analytical balance	AD50B	Adair Dutt Instrument Pvt. Ltd.
2	p^H meter	-	Elico
3	Friability tester	-	Electro lab
4	Hardness tester	-	Ketan
5	Disintegration Tester	USP	Electro lab
6	Dissolution apparatus	Disso 2000	Electro lab
7	UV-Visible spectrophotometer	-	Analytical
8	FTIR	-	Bruker
9	Compression machine (sixteen stationary rotary)	-	Cadmach
10	Bulk Density Tester	-	Cintex

Estimation of Sitagliptin Phosphate

An UV Spectrophotometric method based on the measurement of absorbance at 266nm in pH 6.8 Phosphate buffer was used in the estimation of Sitagliptin.

Preparation of standard solution

Sitagliptin (100 mg) was dissolved in about 10ml of pH 6.8 buffer and the volume was finally made up to 100ml using pH 6.8 Phosphate buffer in a 100 ml volumetric flask.

Procedure

Calibration curve for the estimation of Sitagliptin was constructed using pH 6.8 Phosphate buffer. The standard solution of Sitagliptin was subsequently diluted with pH 6.8 Phosphate buffer to obtain a series of dilutions containing 2, 4, 6, 8, 10, 12, 16 20 µg of Sitagliptin per ml of solution. The absorbance of the above dilutions was measured on a spectrophotometer at 205 nm using p^H 6.8 phosphate buffer as blank. The concentration of Sitagliptin used and the corresponding absorbance is given in table 7.2. The absorbances were plotted against concentration as shown in the fig 7.1. This calibration curve was used in the estimation of Sitagliptin in the present study.

Method of manufacture of Oral Disintegrating tablets of Sitagliptin

Preparation of Mixed blends of drug and excipients: All the ingredients were weighed accordingly specified in the formulation (table 6.3) and mixed well except magnesium stearate. Then the blend was passed through sieve no 60 which was used for the evaluation of flow properties.

Formulation of oral disintegrating tablets of Sitagliptin

Ingredients (mg per tablet)	CCS1	CCS2	CCS3	SSG1	SSG2	SSG3	CP1	CP2	CP3
Sitagliptin	100	100	100	100	100	100	100	100	100
Lactose Anhydrous	90	90	90	90	90	90	90	90	90
MCC PH-102	48.5	44	41	48.5	44	41	48.5	44	41
CrosCarmellose Sodium	4.5	9	12	---	---	---	---	---	---
Sodium Starch Glycollate	---	---	---	4.5	6	12	---	---	---
Crospovidone	---	---	---	---	----	---	4.5	6	12
Feenugreek Seed Mucilage	---	---	---	---	---	---	---	---	---
Sodium Sacharin	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Orange flavour	1	1	1	1	1	1	1	1	1
Aerosil	3	3	3	3	3	3	3	3	3
Magnesium Stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Total Weight	250	250	250	250	250	250	250	250	250

Evaluation of Precompressional and Post Compressional Parameters Of Oro Dispersible Tablets Blend

1. Bulk density; Apparent bulk density was determined by pouring the blend into a graduated cylinder. The bulk volume (V_b) and weight of the powder was determined.

Bulk density = M / V_b

2. Tapped density: The measuring cylinder containing a known mass of powder blend was tapped for a fixed number of times as per USP apparatus-11. The minimum volume occupied by the powder after tapping was measured.

Tapped density = weight/tapped volume

3. Compressibility index; Compressibility index is calculated as follows

Tapped density- Bulk density/ Tapped density*100

The value below 15% indicates a powder with good flow characteristics where as above 25% indicates poor flowability.

4. Haussner's ratio; It is an indirect index of ease of powder flow, it is calculated as follows.

Tapped density/Bulk density

Haussner's ratio <1.25 indicates good flow properties, where as >1.5 indicates poor flowability.

5. Angle of Repose; Angle of repose was determined using funnel method. The blend was poured through funnel that can rise vertically until a maximum cone height (h) was obtained. Radius of the heap(r) was measured and angle of repose was calculated as follows.

$Ø = \tan^{-1} h/r$ $\tan^{-1} h/r$

6. Compression of Tablets

To the mixed blend of powder and excipients finally add magnesium stearate and glyceryl behanate and then mixed for 5 min. The mixed blend was compressed with Nine (09) station tablet punching machine using 7 mm flat punches with break line. Three punches in the Nine station compressor are fixed with die cavity and remaining is fixed with dummy punches. A minimum of 500 tablets for each batch were prepared.

6 Evaluation of Post Compressional Parameters

All the prepared tablets were evaluated for the following parameters as per the I.P guidelines

6.1. Weight variation: Twenty tablets from each formulation were selected randomly and average weight was determined. Individual tablets were then weighed and compared with average weight.

6.2. Hardness test: The force required to break a tablet in a diametric compression was determined by using Pfizer tablet hardness tester.

6.3. Friability: The weight of twenty tablets was noted and placed in the friabilator and then subjected to100 revolutions at 25 rpm. Tablets were dedusted using a soft muslin cloth and reweighed.

Percent friability = [initial weight – final weight / initial weight] × 100

6.4. Wetting time and Water absorption ratio

A piece of paper folded twice was kept in a petri dish (internal diameter 6cms) containing 6ml of purified water. A tablet was put on the paper and time required for complete wetting was measured. The wetted tablet was weighed. Water absorption ratio, R was determined using the following equation.

R = [Wa – Wb / Wb] × 100

Where Wa, Wb are the weights of tablets before and after wetting.

6.5. Invitro dispersion time: Tablet was added to 10ml of distilled water at 37± 0.5˚C, time required for complete dispersion of tablet was measured.

6.6. Drug content uniformity

The drug content uniformity was determined by taking the powder equivalent to 10mg, then it was (n=3) dissolved in P^H6.8 phosphate. Required dilution (10µg/ml) was prepared and absorbance was taken against the blank at 206nm.

6.7. Invitro disintegration time: The disintegration was performed using an I.P 85 disintegration apparatus with distilled water at 37±0.5 ˚C.

6.8. Dissolution studies: Dissolution rate of Sitagliptin from all formulations was performed using LABINDIA DISSO 2000 an eight stage dissolution rate testing apparatus with paddle. The dissolution fluid was 900 ml of P^H6.8 phosphate buffer with a speed of 50 rpm and temperature of 37±0.5˚C were used in each test. 5 ml of sample was withdrawn at different time intervals (2.5, 5, 10, 15 & 20 mins) and fresh medium was replaced to maintain sink conditions. The samples are analyzed by using UV- Visible spectrophotometer at λ_{max} 205 nm. Dissolution studies were performed in triplicate.

6.9. Characterization of Sitagliptin tablets

FTIR studies

The drug- excipients interaction was studied using FTIR. IR spectra for drug and powdered tablets were recorded in a Fourier transform infrared spectrophotometer using KBr pellet technique. This spectrum was scanned over the 3600 to 500 cm^{-1} range.

7. Release Kinetics

The analysis of drug release mechanism from a pharmaceutical dosage form is an important but complicated process and is practically evident in the case of matrix systems. As a model-dependent approach, the dissolution data was fitted to four popular release models such as zero-order, first-order, diffusion and Peppa's- Korsemeyer equations, which have been described in the literature. The order of drug release from matrix systems was described by using zero order kinetics or first orders kinetics. The mechanism of drug release from the matrix systems was studied by using Higuchi equation and Peppa's- Korsemeyer equation. The results are given in Table 16.

7.1. Zero Order Release Kinetics

It defines a linear relationship between the fractions of drug released versus time.

$Q = k_o t$

Where, Q is the fraction of drug released at time t and k_o is the zero order release rate constant.

A plot of the fraction of drug released against time will be linear if the release obeys zero order release kinetics.

7.2. First Order Release Kinetics

Wagner assuming that the exposed surface area of a tablet decreased exponentially with time during dissolution process suggested that drug release from most of the slow release tablets could be described adequately by apparent first-order kinetics. The equation that describes first order kinetics is

In (1-Q) = - K_1t

Where, Q is the fraction of drug released at time t and k_1 is the first order release rate constant.

Thus, a plot of the logarithm of the fraction of drug remained against time will be linear if the release obeys first order release kinetics.

8. Stability Studies

The stability study of the formulations was carried out according to ICH guidelines at 40 ± 2o C/75 ± 5% RH for one month by storing the samples in stability chamber (Lab-care, Mumbai).

RESULTS AND DISCUSSION

A.Organoleptic evaluation

Organoleptic characters like color, odor, and solubility of drug were observed and recorded in Table No. 1. The results are with in standards. The drug is showing solubility in methanol and in water.

Table 1: Organoleptic properties of Sitagliptin

Organoleptic Property	Observation
Colour	White
Odour	Odourless
Solubility	Water and Methanol

B. Analytical evaluation

The λ_{max} of Sitagliptin in pH 6.8 phosphate buffer was scanned and found to have the maximum absorbance at 266 nm. Standard graph of Sitagliptin in pH 6.8 phosphate was plotted by taking concentration ranging from 2 to 10 µg/mL and a good correlation was obtained with R^2 value of 0.999. The absorbance was measured at 266 nm using a UV spectrophotometer (Lab India). Standard calibration curve values were shown in Table.no.2.

Polt a graph between absorbance on y-axis and concentration on x-axis gives a straight line which joins the minimum of three points and the graph was represented in the fig.no.1.

Table 2: Standard curve for Sitagliptin.

Concentration	Absorbance
2	0.206
4	0.398
6	0.656
8	0.842
10	0.986

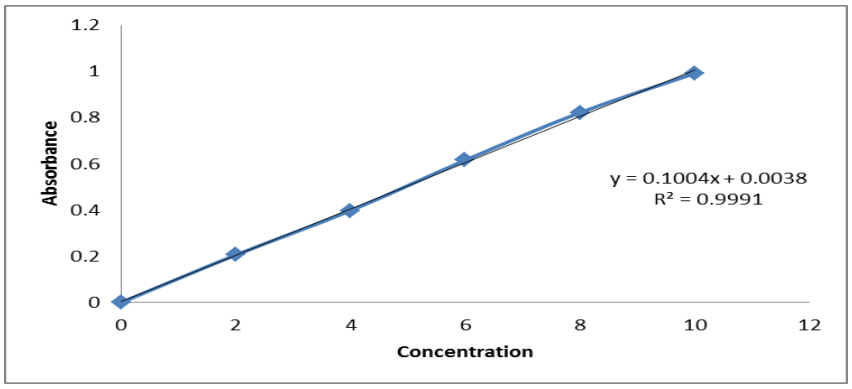


Fig. 1: Calibration Curve of Sitagliptin in 6.8 pH Phosphate Buffer.

Table 3: Quality control tests for the oral disintegrating tablets of Sitagliptin.

Formulations*	Disintegration time * (sec)	Drug content* (%)	Percentage Drug Dissolved After 10 min*.	Invitro Dispertion time* (s)
CCS1	14.25±0.45	102.21±0.73	89.24±0.42	15±0.22
CCS2	13.51±0.71	98.97±0.12	91.21±0.31	13±0.65
CCS3	**10.64±0.61**	**99.58±0.53**	**97.24±0.86**	**11±0.72**
SSG1	54.21±0.14	97.25±0.62	87.24±0.68	61±0.25
SSG2	56.85±0.32	98.21±0.54	91.25±0.45	59±0.36
SSG3	57.21±0.68	98.56±0.41	91.35±0.76	59±0.62
CP1	38.25±0.21	94.95±0.25	84.91±0.13	51±0.98
CP2	37.65±0.24	96.78±0.61	88.24±0.95	50±0.57
CP3	39.78±0.32	98.8±0.32	95.42±0.42	51±0.24

* Data represent mean ±SD (n=3).

Dissolution is carried out in USP apparatus type-2 apparatus at 50rpm in 900ml dissolution media (phosphate buffer pH 6.8) for 10 minutes. At the end of 20 minutes almost total amount of the drug is released (i.e. 96.96±0.54%), from the formulation prepared by the direct compression method with 8% croscarmallose sodium. The results were shown in table.no.7.6 to 7.8 and comparative profiles were shown in fig.No.7.2 to 7.4. The order of

enhancement of dissolution rate with various super disintegrants was found to be croscarmellose sodium > crosspovidone > sodium starch glycollate.

Table 4: Dissolution profile of the oral disintegrating tablets of Sitagliptin with Croscarmellose Sodium.

Formulations	Cumulative % drug dissolved (mins)					
	0	**2.5**	**5**	**10**	**15**	**20**
CCS1	0	37.6±0.26	60.24±0.35	79.25±0.92	91.25±0.24	98.47±0.31
CCS2	0	41.25±0.12	62.25±0.95	81.54±0.7	89.350.89	97.28±0.71
CCS3	**0**	**50.24±0.21**	**71.26±0.31**	**85.45±0.12**	**91.78±0.21**	**99.12±0.11**

* Data represent mean ±SD (n=3)

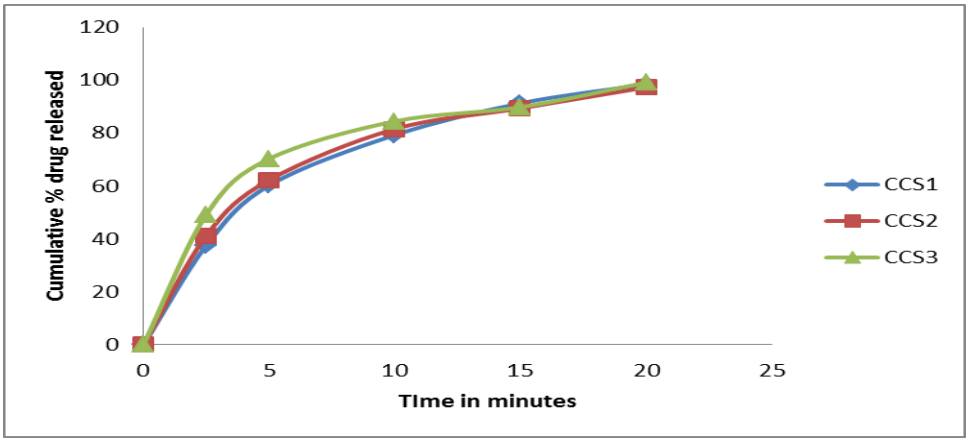


Fig. 2: Comparative dissolution profile of Sitagliptin with croscarmellose sodium.

Table 5: Dissolution profile of the oral disintegrating tablets of Sitagliptin with Sodiumstarchglycollate.

Formulations	Cumulative % drug dissolved (mins)					
	0	**2.5**	**5**	**10**	**15**	**20**
SSG1	0	44.2±3.16	59.21±0.24	78.4±0.12	89.9±0.1	95.24±0.21
SSG2	0	43.21±0.14	60.21±0.1	75.26±0.21	88.7±0.31	96.25±0.14
SSG3	0	43.8±2.3	69.35±0.35	78.98±0.26	91.36±0.32	94.27±0.12

* Data represent mean ±SD (n=3)

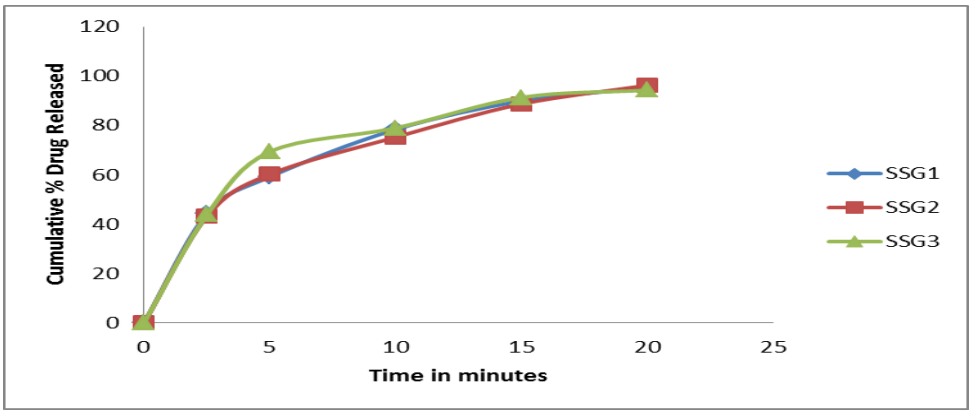


Fig. 3: Comparative dissolution profile of Sitagliptin tablets with sodium starch glycollate.

Table 6: Dissolution profile of the oral disintegrating tablets of Sitagliptin with Crospovidone.

Formulations	Cumulative % drug dissolved (mins)					
	0	2.5	5	10	15	20
CP1	0	39.8±1.26	67.2±0.54	79.28±0.11	90.4±0.12	93.14±0.78
CP2	0	41.6±0.51	68.5±0.32	75.9±0.64	88.6±0.85	95.7±0.74
CP3	0	43.7±2.5	60.35±0.12	75.44±0.46	88.69±1.3	97.25±0.2

* Data represent mean ±SD (n=3)

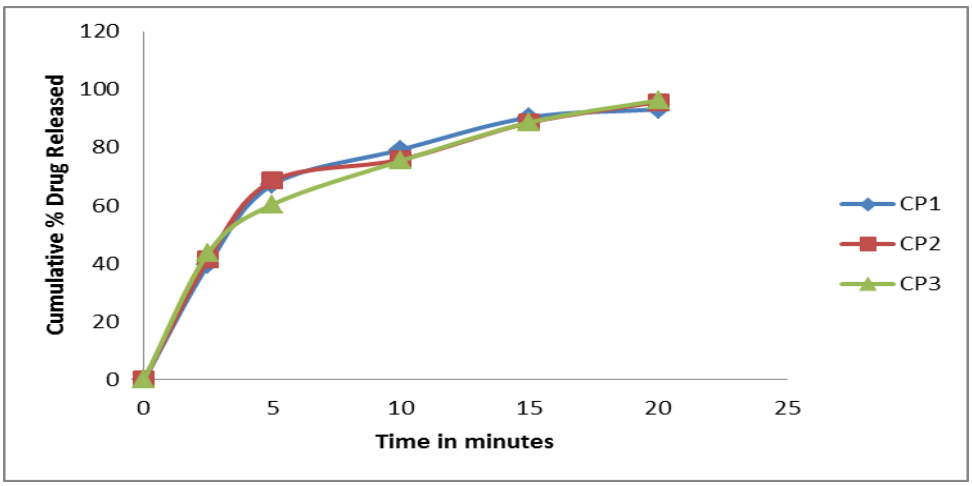


Fig. 4: Comparison of dissolution profiles of Sitagliptin with Crospovidone.

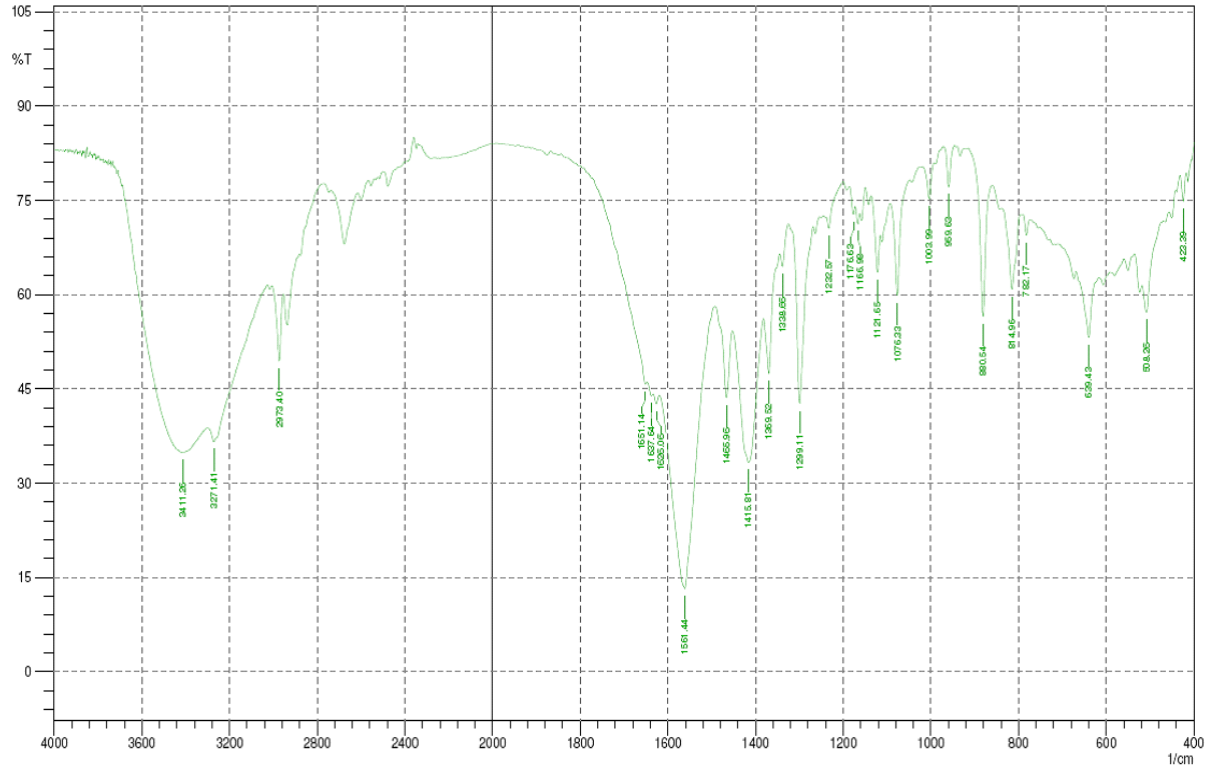


Fig. 5: FT-IR spectra of Sitagliptin.

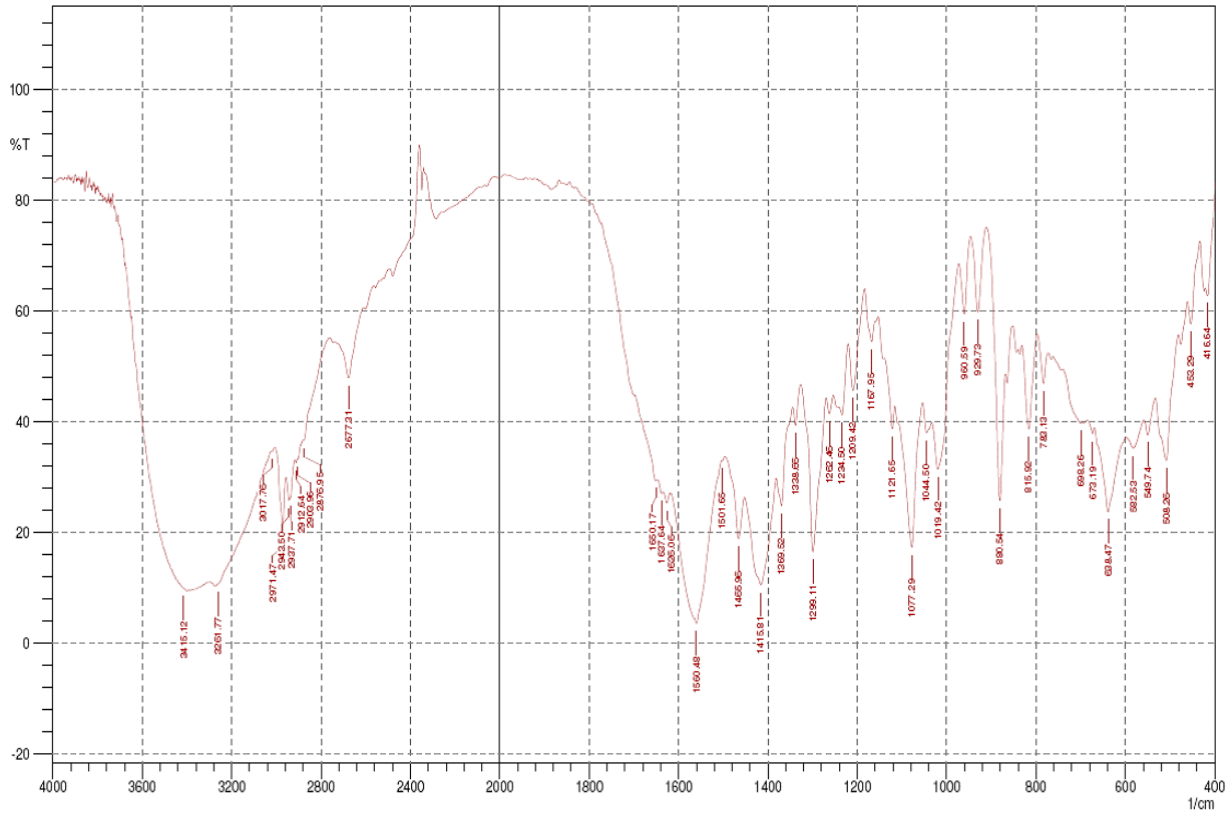


Fig. 6: FT-IR Spectra of Croscarmellose sodium.

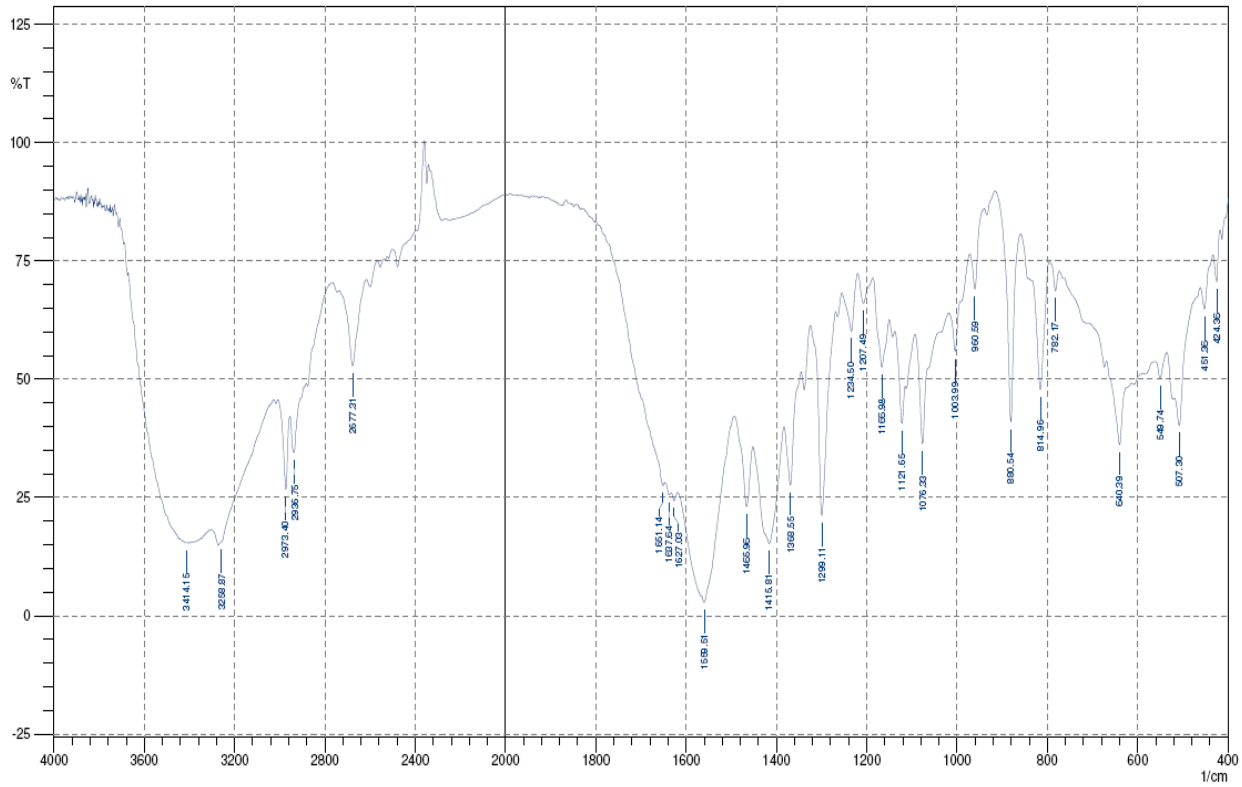


Fig. 7: FT-IR spectra of Sodium starch glycollate.

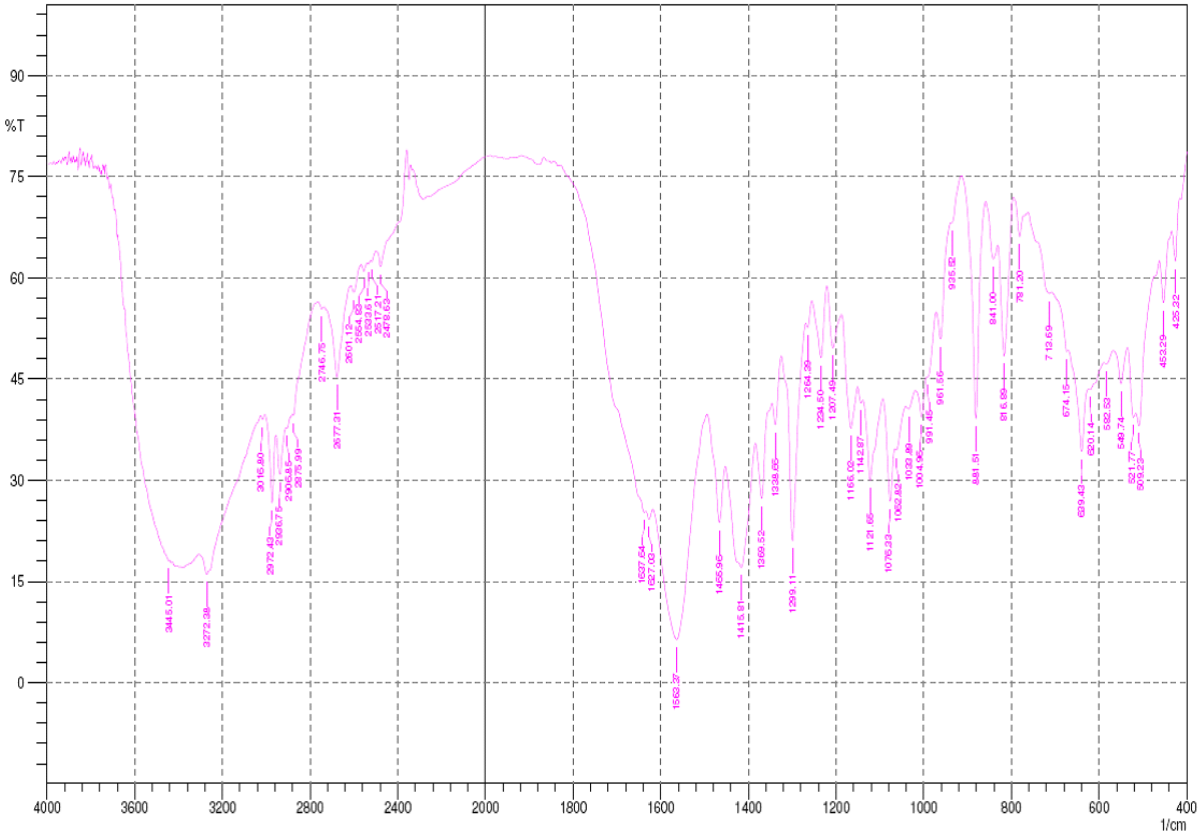


Fig. 8: FT-IR spectra of Sitagliptin+ CCS.

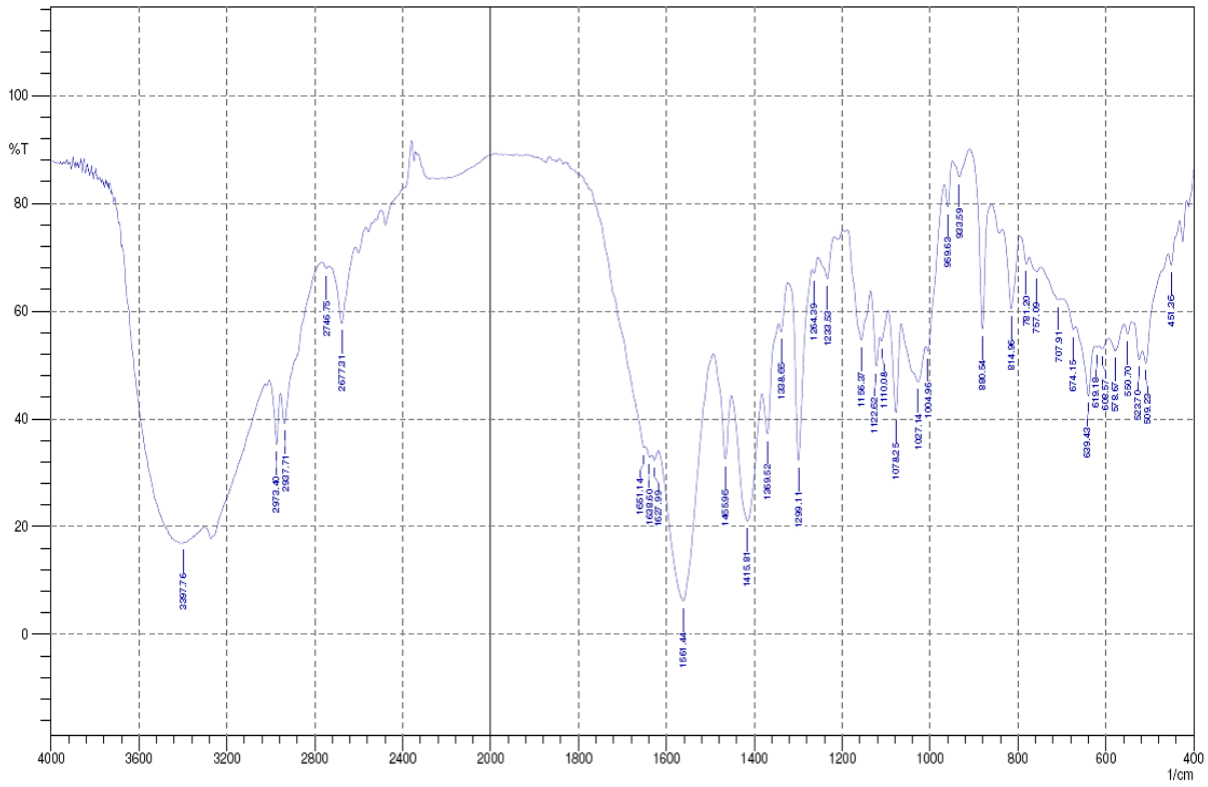


Fig. 9: FT-IR spectra of Sitagliptin+ SSG.

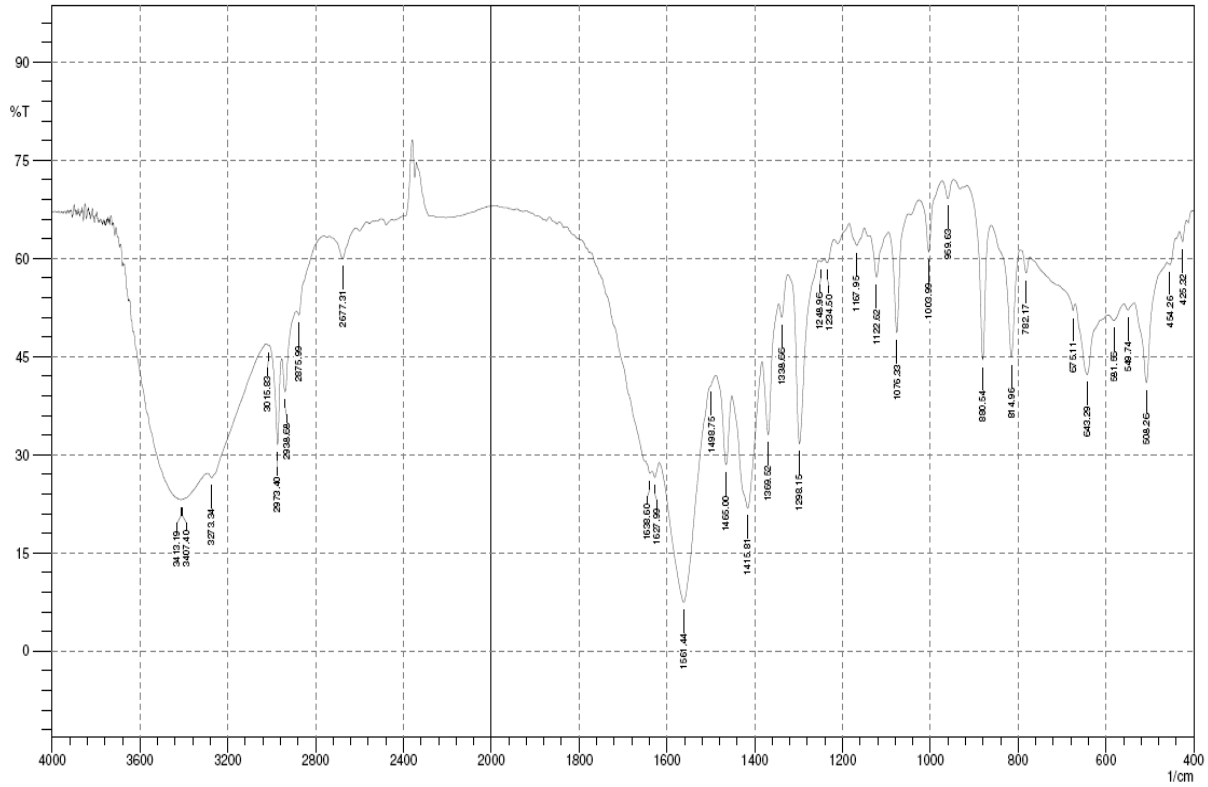


Fig. 10: FT-IR spectra of Sitagliptin+ CP.

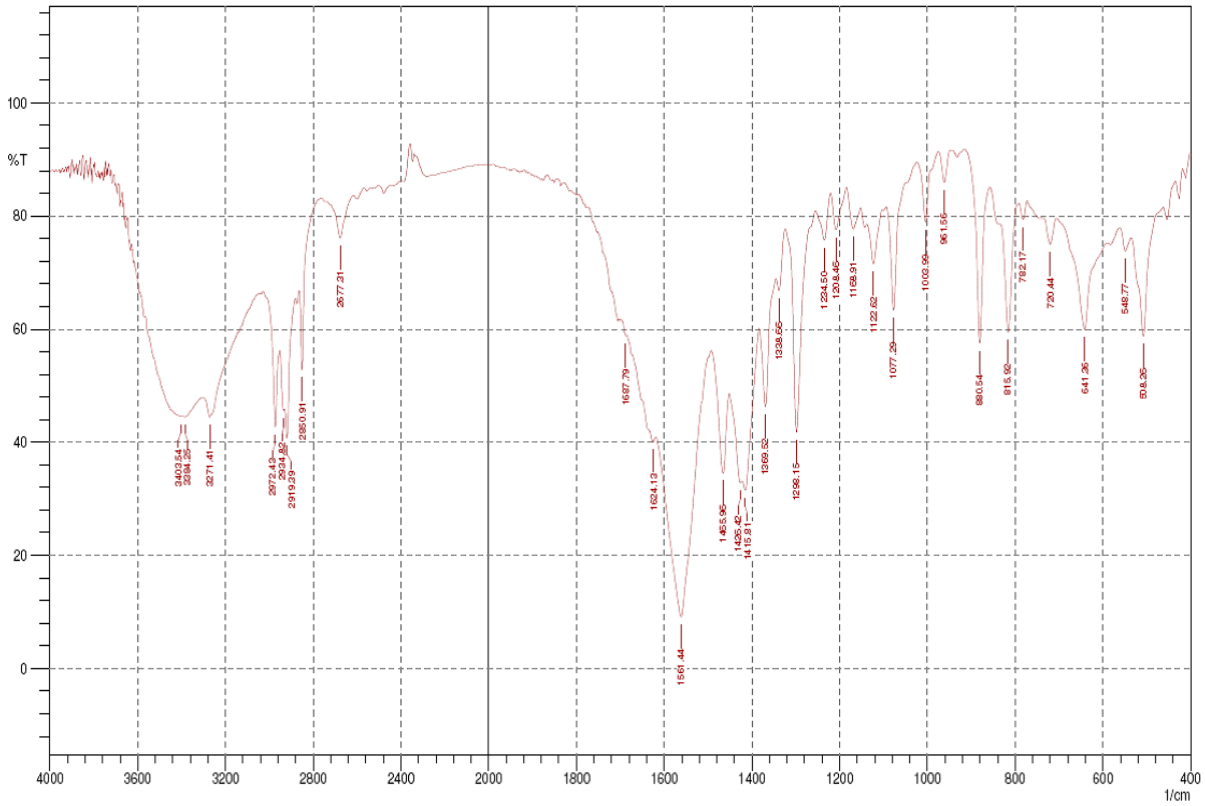


Fig. 11: FT-IR spectra of optimized formulation CCS3.

From IR studies, it was observed that the same characteristic peaks of Sitagliptin were appeared in the formulations containing Sitagliptin apart from excipients peaks. So it was concluded that These peaks were not affected, they were prominently observed in IR-spectra of Sitagliptin along with Natural superdisintegrants and other excipients. The spectral details of the drug and the excipients are shown in (Fig.No.7.5 to 7.11). There was no difference in the position of the absorption bands, hence providing evidence for the absence of any chemical incompatibility between pure drug with the excipients.

Stability analysis

Table 7: Stability Analysis of Optimized Formulations.

Formulation	No of days	25˚C & 60%RH		40˚C &75% RH	
		Wetting time(s)	Disintegration time(s)	Wetting time (s)	Disintegration time (s)
CCS3	0	8.47±0.124	10.68±0.226	8.47±0.225	10.68±0.146
	15	8.45±0.148	10.65±0.446	8.45±0.256	10.61±0.228
	30	8.48±0.346	10.66±0.424	8.46±0.154	10.59±0.446
	45	8.43±0.146	10.64±0.568	8.44±0.654	10.62±0.356
	60	8.44±0.214	10.62±0.146	8.43±0.168	10.64±0.186

Formulation	No of days	25˚C / 60%RH		40˚C / 75% RH	
		Wetting time(s)	Disintegration time (s)	Wetting time (s)	Disintegration time (s)
FG2	0	11.56±0.146	10.02±0.148	11.56±0.983	10.02±0.146
	15	11.54±0.566	9.98±0.167	11.53±0.156	10.0±0.264
	30	11.50±0.354	9.99±0.964	11.51±0.256	9.97±0.446
	45	11.51±0.446	9.98±0.843	11.54±0.140	9.99±0.356
	60	11.49±0.176	9.97±0.116	11.50±0.146	9.98±0.264

Drug content

Formulation	No of days	25˚C / 60%RH	40˚C / 75% RH
CCS3	0	99.08±0.86	99.08±0.86
	15	98.12±0.56	98.75±0.23
	30	98.74±0,24	98.06±0.36
	45	98.38±0.328	97.86±0.28
	60	98.25±0.156	97.54±0.442
FG2	0	98.6±0.24	98.6±0.86
	15	98.24±0.168	98.36±0.52
	30	98.36±0.264	98.12±0.16
	45	98.14±0.188	97.56±0.34
	60	98.08±0.22	97.24±0.28

The stability studies for the optimized formulations CCS3 & FG2 were performed for about 2 months at 40˚C / 75% RH AND 25˚C /60%RH. The samples were analyzed at intervals of 0, 15,30, 45 and 60 days. There were no significant change in the physical appearance of the tablets, disintegration time and wetting time.

CONCLUSION

The above results suggest that the formulated oral disintegrating tablets of Sitagliptin exhibited good physical parameters and rapidly disintegrating without affecting the release profile and is very effective in case of elderly and pediatric patients. The overall results indicated that formulation with croscarmallose sodium (8%) had a higher edge compared to other formulations containing superdisintegrants. They satisfy all the criteria for oral disintegrating tablets. This direct compression process is simple, reproducible and robust to prepare orally disintegrating tablets of sitagliptin.

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