IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

FORMULATION AND IN-VITRO EVALUATION OF FELODIPINE ORODISPERSIBLE TABLETS BY USING VARIOUS SUPER DISINTEGRANTS

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ABSTRACT

In the current study, the anti-hypertensive medication felodipine or dispersible tablets that are employed via direct compression method are modelled and evaluated in vitro using a variety of super disintegrants. Guar gum, sodium starch glycolate, and Croscarmellose sodium were used as super disintegrants in the preparation of the dispersible felodipine tablet. Other excipients included mannitol, talc, magnesium stearate, microcrystalline cellulose, and others. Precompression characteristics of the prepared dispersible tablet, such as bulk and tapped density, angle of repose, cars index, etc., were assessed. The range contains all of the parameters. Studies on post-compression characteristics such as hardness, thickness, disintegration time, dissolution, and stability were also conducted. Out of all the formulations, the F1 formulation was determined to be the most optimised. The F1 formulation had a 15-second disintegration time and a 15-minute drug release percentage of around 100.047%. The stability investigations yield excellent results as well.

KEYWORDS: Orodispersible tablets, Patient compliance, Quick onset, Rapid melt tablets, Antihypertensive activity.

INTRODUCTION

It is necessary to conduct a thorough analysis of the physicochemical principles guiding the formulation of a particular medication in order to establish an acceptable dosage form.[1] Solid dosage forms, such as tablets and capsules, are the most often utilised of all the dosage forms now in use because of their portability, ease of self-administration, and simplicity in production. Lack of access to water can cause motion sickness, difficulty swallowing tablets or hard gelatin capsules, allergic responses, coughing fits from the common cold, and bronchitis. These factors make rapid dissolving tablets, sometimes referred to as disintegrating tablets, important in the oral cavity.[2] In an attempt to provide patients with more conventional ways to take their prescriptions, the Rapid Dissolving Drug Delivery System was created. Dysphagia, or trouble swallowing, affects many individuals of various ages due to physiological alterations associated with, in particular, childhood and ageing. Solid dose forms that can be dissolved, degraded, or suspended by saliva in the mouth may be very beneficial to children, the elderly, and other patients who prefer the ease of easily swallowable dosage forms.[3]

The European Pharmacopoeia defines orodispersible pills as ones that dissolve readily in the mouth before being swallowed.

The US Food and Drug Administration (FDA) described ODT as

“When placed on the tongue, a solid dosage form containing a therapeutic drug or active ingredient dissolves quickly, typically in a couple of seconds.” ODTs typically disintegrate in a period of time between a few seconds and a minute.[4]

It is estimated that 35 percent of the general population, 30 to 40 percent of elderly patients who are institutionalised, and 18 to 22 percent of all residents of long-term care facilities suffer with dysphagia. This condition has been connected to several diseases, including Parkinson's illness, AIDS, thyroid surgery, radiation therapy to the head and neck, and further neurological disorders such as cerebral palsy.[5]

In an effort to maintain therapeutic efficacy while improving drug safety, novel drug delivery systems have recently progressed. The therapeutic effectiveness of rapidly dissolving dose forms stems from their ability to dissolve and release the pharmaceutically active ingredients quickly.[6]

With all of these benefits of oral disintegrating tablets in mind, the current study aims to create Felodipine oral disintegrating tablets with an improved, faster start of action. Additionally, ODT allows for pregastric absorption of medications from the mouth, throat, and oesophagus as saliva flows down, resulting in fast absorption or an increase in bioavailability.

Materials and Methods

Materials

Felodipine was purchased from Alcon Laboratories, Mumbai, India Pvt. Ltd. All other excipients were used are of LR grade. Guar gum, Mannitol, was obtained from Molychem, Mumbai. Crosscarmellose Sodium, Sodium Starch Glycolate, Microcrystalline Cellulose, were obtained from, Loba Chem. Mumbai. Talc, Magnesium Stearate, was obtained from Fine Chem. Mumbai.

Methods

Preformulation studies[7]

Preformulation is defined as the examination of drug compounds' chemical and physical characteristics. Preformulation tests of the API alone and the excipients are carried out prior to formulation in order to provide a stable dosage form.

Physical attributes[8]

Physical attributes can include identifying the colour, smell, and composition of the API. Visual inspection was used to identify the drug's hue, and the smell is decided by simply giving it a brief sniff. Melting point is one of the key characteristics used to identify pure drugs, and melting point apparatus is used to test it.

Solubility Profile[9]

Three tests were conducted to determine the solubility of felodipine in distilled water. A magnetic stirrer was used to shake 10 ml of distilled water, which contained excess medication, in order to conduct the solubility investigation for 48 hours at that temperature (24°C). The mixture was subsequently diluted with the same solvent after being filtered through Whatman's filter paper. A UV-visible spectrophotometer was used to measure the absorbance at 211 nm.

DSC (Differential Scanning Calorimetry)

Using a Differential Scanning Calorimeter (Shimadzu Corporation, Japan TA60WS), differential scanning calorimetric (DSC) analysis was carried out. DSC testing involves heating a tiny amount of material at a set pace. How much energy is needed to heat At the same temperature, the sample and an innocuous reference material are compared. As an endotherm, the sample is designated as such if it uses more energy than the reference. Melting temperature was indicated by the apex of an endotherm.[10]

FTIR study

An FTIR research was used to examine how well Felodipine interacted with other substances. Via the potassium bromide pellet method, an FTIR was used to obtain the infrared spectra of felodipine, felodipine plus various excipients. After the drug mixture was physically manufactured in a 1:1 ratio, sieve number 30 was used. Samples of the medication and excipient were put into vials, sealed, and labelled. After combining the dry sample with potassium bromide in a 1:99 ratio, the mixture was triturated and the pellets were compressed using a sample holder. The pellets that were produced were scanned between 400 and 4000 cm^{-2} in frequency. Using the functional group's standard absorbance range, the spectral analysis was performed.[11]

Calibration curve of Felodipine

The calibration curve of felodipine was drawn by measuring the absorbance of different concentrations (5-25 ppm) in phosphate buffer pH 6.8 at 362nm. The UV- visible spectrophotometric analysis was carried out using Shimadzu UV-1800 spectrophotometer and UV probe software was used for analysis. Phosphate buffer of pH 6.8 is used as a solvent for blank as well as sample preparation and analysed at 362 nm.[12]

Formulation of Felodipine ODT

Using the direct compression approach and the formula found in Table No.1, the ODT was created. Making tablets is made simplest with the direct compression approach. Due to the availability of better excipients, particularly tablet disintegrants, the direct compression approach has been used more recently. Excipients such as, mannitol, micro-crystalline cellulose, sodium starch glycolate, guar gum, and croscarmellose sodium were used to make nine batches, each of which was collected after being passed through mesh number 40. In a mortar and pestle, all of these ingredients were carefully triturated to produce a homogenous mixture.[13] Lastly, add the talc and lubricant, then keep going for five minutes. Eight station tablet compression machines with a 7 mm punch size were used to compress the medication and excipient mixture. Prior to tablet compression, precompression parameters such as bulk density, tap density, compressibility index, angle of repose, and Hausners ratio were applied to the mixture blend of all constituents.[14]

Formulation table

Table no. 1 Formulation table of felodipine orodispersible tablets

Sr. No.	Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Felodipine	5	5	5	5	5	5	5	5	5
2.	Guar gum	9	3	3	6	3	9	3	3	9
3.	Crosscarmellose sodium	7.5	7.5	7.5	4.125	0.75	0.75	7.5	0.75	7.5
4.	Sodium starch glycolate	12	12	12	7.5	12	3	3	3	3
5.	Microcrystalline cellulose (Avicel pH 102)	93.5	99.5	100.25	104.5	106.25	108.5	108.5	115.25	102.5
6.	Mannitol	20	20	20	20	20	20	20	20	20
7.	Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
8.	Magnesium stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	Total Weight	150 mg	150 mg	150 Mg	150 Mg	150 Mg	150 mg	150 Mg	150 Mg	150 Mg

Evaluation of Felodipine Orodispersible Tablets

A) Precompression Parameters

a) Bulk Density

It was the ratio of mass of powder to its bulk volume. Weighed quantity of granules was taken in a graduated cylinder and the weight of the mass was determined. It was calculated by using formula given below;

Bulk Density = M/V0

Where, M = Mass of powder, V0 = Bulk volume of the powder.

b) Tapped Density

The measuring cylinder containing known mass of powder was tapped for 100 times and the volume occupied was measured. It was calculated by dividing mass of powder to its tapped volume.

Tapped Density = M/Vt.

Where, M = Mass of powder, Vt. = Tapped volume of the powder.

c) Compressibility Index

Compressibility Index was calculated by using the formula given below;

Carr's index = Tapped density – Bulk density / Tapped density × 100

d) Hausner's ratio

The ratio of tapped density to bulk density was the Hausner's ratio.

Hausner's ratio = Tapped density / Bulk density

e) Angle of Repose (Ɵ)

It was the maximum angle formed between the surface of the pile and horizontal plane. It is calculated by the equation;

$\Theta = \tan^{-1}(h/r)$

Where, Ɵ = Angle of Repose

h = Height of pile

r = Radius of the base of the conical pile

B) Post Compression Parameters

a) General Appearance

The control of general appearance of a tablet was characterised by parameters such as tablets size, shape, colour, presence or absence of an odour, taste, surface texture, physical flaws and consistency, and legibility of any identifying markings.

b) Weight Variation

Weight variation is used to determined % deviations in weight between different batches. The USP weight variation test was run by weighing 20 tablets individually, calculating the average weight, and comparing the individual tablet weights to the average. The tablets meet the USP test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

c) Hardness

To perform this test, a tablet was placed between two anvils; force is applied to the anvils and the crushing strength that just causes the tablet six tablets from every batch have been taken for determining the hardness using a Pfizer hardness tester.

d) Thickness and diameter

Thickness and diameter were determined by using vernier calliper. Placing 5-10 tablets in a holding tray.

e) Friability

Roche friability tester was used to calculate % friability. A preweighed tablet sample was placed in the friabilator, which was then operated for 100 revolutions at a speed of 25 rpm. The tablets are then dusted and reweighted. % Friability was then calculated by using formula given below;

% Friability = Initial weight – Final Weight / Initial weight × 100

f) Disintegration Time

To check disintegration time, one tablet is placed in each tube of (Electrolab, Mumbai, India, ED 2AL, USP Type 2) disintegration test apparatus and the basket rack is positioned in a 1 L beaker containing phosphate buffer pH 6.8, maintained at 37±2℃, such that the tablets remain 2.5 cm below the surface of the liquid on their upward movement and descend not closer than 2.5 cm from the bottom of the beaker. A standard motor-driven device was used to move the basket assembly containing tablets up and down through the distance of 5 to 6 cm. Finally, 'DT'the time required for the tablets for complete disintegration with no residue remains in the tube was recorded.

g) In-vitro drug release studies

Phosphate buffer of pH 6.8 was utilised as the dissolving medium at 37°C±0.5°C and apparatus (USP Type II Dissolution Electro lab, Mumbai, India. TDL-08L) at 50 rpm. The apparatus was started after placing six tablets in each of dissolving tanks containing phosphate buffer pH 6.8. After first 5, 10, 15, 20, 25, 30, and 35 minutes sample aliquots were collected and filtered. The filtrates were appropriately diluted with phosphate buffer and their absorbance was measured by using UV spectrophotometer at 237 nm.

h) Wetting time and Water absorption ratio

A small piece of tissue paper that has previously been folded twice is placed in a tiny Petri dish that has 6 ml of water. Tablet is placed on that tissue paper. The time required for the tablet for complete wetting was recorded, called it as its wetting time. Next, the wet tablet is weighed once more. The water absorption ratio, R, is determined using the following formula.

$R = 100 (Wa-Wb)/Wb$

Where Wa = Weight of tablet after wetting

Wb = Weight of tablet before wetting.

i) In-vitro dispersion time

In-vitro dispersion time was measured by dropping a tablet in a beaker containing 50ml of phosphate buffer pH 6.8. Three tablets from each formulation were randomly selected and in-vitro dispersion time was performed. The time required for the tablet to for complete dispersion was recorded.

j) Accelerated Stability Studies

Stability testing aims at to provide a stable product that retains its efficacy and safety throughout its self-life during storage. According to ICH criteria for expedited research, the orally disintegrating tablets are packaged appropriately and kept at room temperature for three months. The physicochemical characteristics of tablets are further investigated.

Results and Discussion

Preformulation Studies

Physical characteristics

The physical characteristics of felodipine were found to be, its colour was light yellow, and it is odourless and crystalline in nature.

1. Colour: Light yellow

2. Odor: Odourless

3. Nature: Crystalline powder

Melting Point

The melting point of felodipine was found in the standard range (141-145℃) which was 144℃.

pH

The pH of felodipine was found to be 6.81 which were similar to its standard value i.e. 6.8.

Calibration Curves of Felodipine

Calibration curve of Felodipine in Methanol (362nm, R^2=.09993)

A linear relationship between the concentration and absorbance of felodipine in methanol was established over the examined concentration range (2-10µg/ml). Calibration data was given in table 2.

Table No.2 Calibration curve of Felodipine in Methanol

Sr.No.	Conc.(µg/ml)	Absorbance
1	0	0
2	2	0.1409
3	4	0.2862
4	6	0.4291
5	8	0.5699
6	10	0.7125

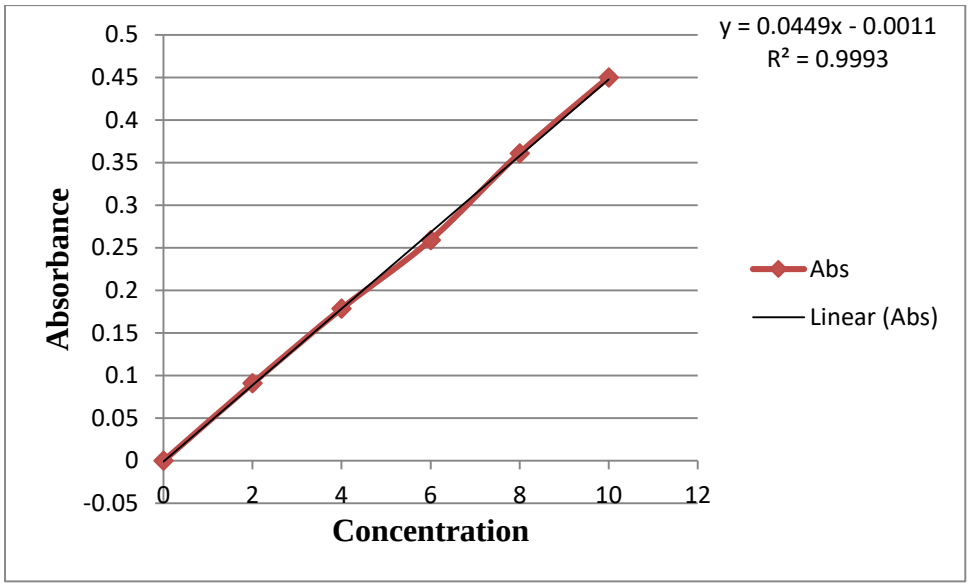

Fig.No. 1 Calibration curve of Felodipine in Methanol

Drug-excipients compatibility study by FTIR

FTIR spectrum was obtained in the region of 4000-650cm^{-1}. The IR spectrum of the pure drug felodipine used in the present study shows characteristic absorption bands in the following IR region. IR spectrum of pure felodipine showed a sharp band at 3388.32 (N-H stretching), 3053.73 (Aromatic C-H stretching), 2980.45 (C=O stretching), 1652 (C=N stretching), 1418 (CH_3 stretching), and 1473 (C=C stretching) C=C 1460 1473.

API(Felodipine)

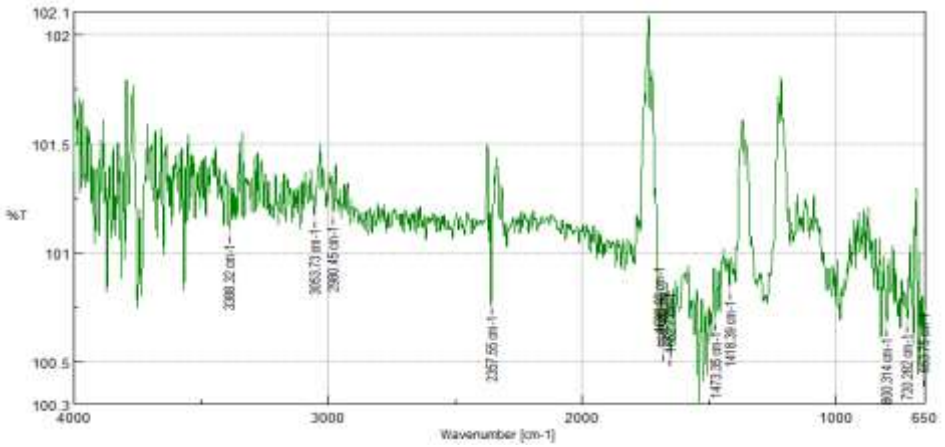

Fig.No.2 FTIR of pure Felodipine

Table No.3 FTIR Spectrum of pure Felodipine

Sr.No.	Functional Group	Reported wave number (cm^{-1})	Observed wave number (cm^{-1})
1.	N-H	3200-3600	3388.32
2.	Aromatic(C-H)	3050-3100	3053.73
3.	C=O	2750-2850	2980.45
4.	C=N	1640-1690	1652
5.	CH_3	1375-1450	1418
6.	C=C	1460	1476

Precompresssion Parameters

Table number 4 shows various precompression parameters of powder blend.

Table No.4 Precompressional Parameters

Formulation	Bulk Density ($gm./cm^2$)	Tapped Density ($gm./cm^2$)	Carr's Index (%)	Hausners Ratio	Angle of Repose (Ɵ)
F1	0.41	0.50	18.00	1.21	29.27
F2	0.49	0.58	15.51	1.18	30.21
F3	0.41	0.49	16.32	1.19	34.56
F4	0.58	0.69	15.94	1.18	30.32
F5	0.52	0.63	17.46	1.21	36.89
F6	0.37	0.45	17.77	1.21	37.33
F7	0.56	0.65	13.84	1.16	35.20
F8	0.33	0.41	19.51	1.24	37.61
F9	0.47	0.55	14.54	1.17	31.69

Bulk density and Tapped density

Bulk density of the tablet formulation ranges from 0.33 to 0.58**.** On the other hand tapped density is in the range of 0.41 to 0.69 respectively. The values that are obtained are within acceptable range. The values of bulk and tapped densities are used for calculating % compressibility index.

Compressibility Index and Hausners ratio

% Compressibility Index covers the range of 15.51 to 19.521. Hausners ratio is in between 1.17 to 1.24. Results shows that the flow properties of all the formulation was good and as well as powder bears good compressibility

Angle of repose

Angle of repose ranged between 29.27 to 37.61°. Angle of repose of all formulations is less than 38**,.**° Angle of repose indicates that the tablet blends have sufficient flowability.

Post Compression Parameters

Table No. 5 Post compressional Parameters (Hardness, Friability, Thickness, Diameter and Weight variation)

Formulation	Hardness(kg/cm$^{2)}$ n=6	Friability (%) n=10	Thickness(mm) n=4	Diameter(mm) n=4	Weight Variation (%) n=20
F1	2.8	0.29	3.40	7	1.49
F2	2.9	0.31	3.51	7	2.63
F3	3.1	0.33	3.56	7	4.61
F4	3.4	0.36	3.43	7	2.94
F5	3.3	0.37	3.45	7	5.79
F6	3.7	0.41	3.55	7	3.89
F7	3.5	0.39	3.47	7	5.37
F8	4.0	0.43	3.52	7	4.47
F9	3.2	0.45	3.49	7	2.96

Hardness and Friability

Table number 6 shows hardness of the tablet determine by employing Pfizer hardness tester. It ranges from 2.8 to 4.0 kg/cm^2. % Friability is determined by using Electro lab Friabilator as per IP. Table number shows % friability values. It ranges from 0.29 to 0.45%. Table number 6 shows % Friability within prescribed limits. Results indicate that the tablets having sufficient mechanical strength.

Thickness and Diameter

Thickness and Diameter is determined by using vernier caliper. Thickness usually depends on the size of punch (7mm) and the weight of the tablet (150mg). It ranges from 3.40 to 3.56 mm. Diameter is found to be 7mm.

Weight Variation

The data of weight variation is almost uniform and within limits. It ranged between 1.49 to 5.79 %. All the tablet formulations have passed the weight variation test as the percent deviations is within pharmacopeial limits i.e.7.5%.

Post compressional Parameters

It includes Drug content, wetting time and water absorption ratio of tablet formulations.

Table No. 6 Post compressional Parameters (Drug content, and Water absorption ratio)

Formulation Code	Drug Content (%)	Wetting time (sec)	Water Absorption Ratio (%)
F1	99.63	25	3.26
F2	94.2	31	4.13
F3	96.4	36	3.86
F4	91.7	44	6.13
F5	93.9	47	5.20
F6	91.2	51	5.53
F7	98.7	49	7.53
F8	97.00	62	6.46
F9	92.5	40	6.73

Drug Content

Drug content is mainly used to calculate the amount of pure drug present in each tablet. It ranged from 91.7 to 99.63%. F1 formulation shows highest value of drug content which is 99.63% respectively. Table number 7 shows % drug contents.

Water absorption ratio and Wetting Time

It includes ratios from 3.26 to 7.53 % of water absorption. Table 30 showing information of water absorption ratio. From the results it is found that the wetting time of formulations are not more than 62 sec. It falls in between 25 to 62 seconds. F1 formulation shows wetting time of about 25 seconds. Table number 8 shows data of wetting time.

Disintegration Time and In-vitro Dispersion Time

Table No. 7 In-vitro Dispersion Time (F1-F9)

Formulation Code	In-vitro Dispersion Time (sec)	Disintegration Time (Sec)
F1	18	15
F2	21	19
F3	26	22
F4	24	29
F5	35	33
F6	39	40
F7	37	38
F8	41	45
F9	30	25

In this a tablet was added to 10 ml of phosphate buffer solution of pH 6.8 at 37±0.5 ℃. Then time required for a tablet to form complete dispersion was measured. Table No. 33 shows Disintegration Time of tablet formulations. Disintegration Time of tablets is ranges from 15 to 45 sec. DT of all formulations is listed below; Out of all the formulations F1 formulations containing guar gum (6%), croscarmellose sodium (5%), and sodium starch glycolate (8%) respectively, shows a rapid DT which is only 15 sec.

In-vitro drug release studies

Table No.8 Cumulative % drug release of Orodispersible Tablet of Felodipine (F1-F4)

Time(sec)	F1	F2	F3	F4
0	0	0	0	0
5	88.40	88.42	88.40	77.00
10	94.38	94.45	94.35	84.86
15	100.047	96.43	95.03	91.59
20	-	99.18	99.09	95.77
25	-	-	-	97.27
30	-	-	-	98.77
35	-	-	-	-

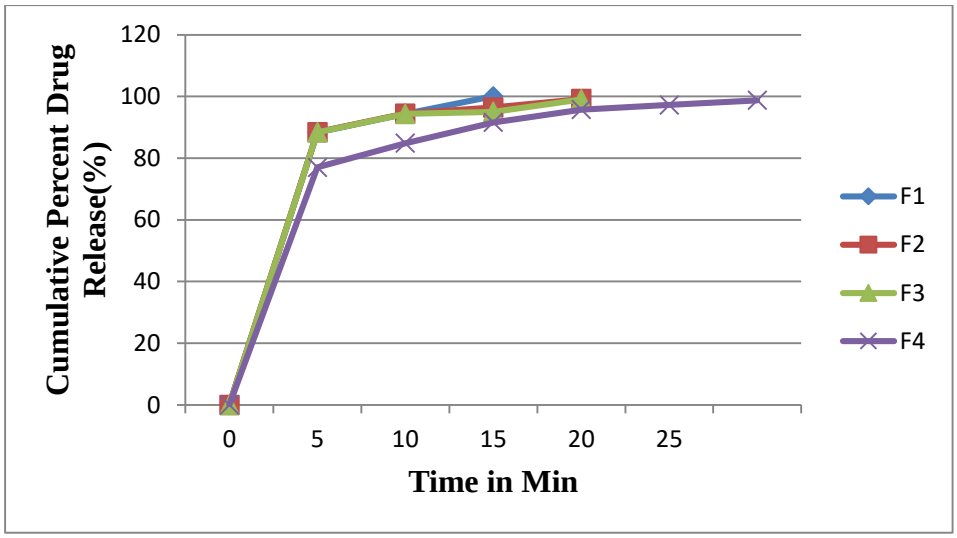

Fig.No. 3 Dissolution Profile of F1 to F4 Tablet Formulations

In-vitro drug release studies were carried out by using USP Dissolution test apparatus at 50 Rpm. Dissolution profiles of tablet formulations from F1 to F4 were shown in table number. F1 formulation contains highest concentration of disintegrtats i.e. guar gum (6%), Crosscramellose sodium (5%), and sodium starch glycolate (8%) respectively. F1 formulation shows highest drug release of about 100.047%.

Dissolution profiles of formulations from F5 to F9 were shown in table number 35

Table No. 9 Cumulative % drug release of Orodispersible Tablet of Felodipine (F5-F6)

Time(sec)	F5	F6	F7	F8	F9
0	0	0	0	0	0
5	75.61	70.74	47.11	44.33	77.69
10	81.87	82.53	53.42	52.02	85.56
15	90.87	89.32	60.32	58.91	95.09
20	94.18	92.93	68.71	63.12	96.58
25	95.17	95.81	79.72	76.88	98.99
30	97.54	97.23	88.50	85.64	-
35	-	-	-	-	-

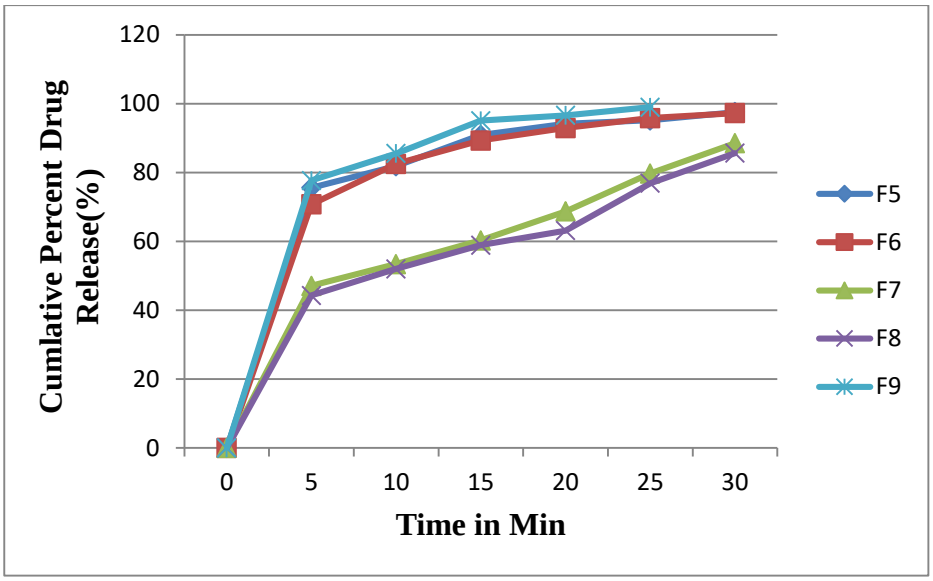

Fig.No.4 Dissolution Profile of F5 to F6 Tablet Formulations

The dissolution profile of tablet formulation is shown in above tables 35 which indicate different drug release patterns of formulations. The % drug release may be varying from about 85.64 to 100.047%. Among F5-F9 formulations F9 shows higher drug release of 98.99 as it contains guar gum (6%), Crosscarmellose sodium (5%), and sodium starch gycolate (2%) respectively.

Accelerated stability studies

Table 12 represents parameters of tablets after stability studies. Accelerated stability studies were performed at room temperature for about three months. After three months disintegration time and drug content of tablet formulations were investigated. The outcomes showed no significant changes in appearance, disintegration and drug content of the tablets. There were not many variations in appearance, disintegration and drug content of the tablets.

Table no.10 Tablet parameters after stability studies

Formulations	**Disintegration time (sec)**	Drug content (%)
F1	16	99.61
F2	20	94.2
F3	23	96.3
F4	31	91.7
F5	35	93.8
F6	41	91.0
F7	39	98.5
F8	47	97
F9	27	92.4

Summary and conclusion

ODT's were prepared by using direct compression method. Overall, nine formulations were designed and formulated in the form of tablets and are subjected various evaluation parameters. Tablets are evaluated for Hardness, Friability, Weight variation, Drug content, Disintegration, and In-vitro drug release.

The outcomes are divided in different sections as given below;

- From IR and various physical examinations, it was seen that there is no significant Drug-Excipient interaction. Melting point of Felodipine was found to be 144℃. The pH is calculated by pH meter and it is 6.8.
- DSC studies reveled that there were no significant changes (due to temperature) on the stability of both the drug as well as Formulations.
- The Bulk density and Tapped density for all formulations was found to be 0.33 to 0.58 gm./cm^2 to 0.41 to 0.69 gm./cm^2 respectively.
- Carr's index for all formulations was between 15.51 to 19.52%. Hausners ratio and Angle of repose was between 1.17 to 1.24% and 29.27 to 37.61° respectively.
- Tablet hardness was observed between 2.8 to 4.0 kg/cm^2. On the other hand, % Friability was between 0.29 to 0.45%.
- Thickness of the tablets was found to at 3.40 to 3.56 mm. While Diameter is at 7 mm. Weight variations bears the values from 1.49 to 5.79%.
- The % drug content of all formulations ranges from about 91.7 to 99.63%. However wetting time of all formulations falls between 25 to 62 sec. The water absorption ratio was found at from 3.26 to 7.53% respectively.
- Disintegration time ranges from 15 to 45 seconds. While cumulative % drug release data of all formulations showed drug release from 85.54 to 100.047%.
- All nine formulations showed satisfactory results for tablet density, disintegration, and drug content.
- Results of in-vitro drug release showed that formulations F1, F2, and F3 are satisfactory.
- From all above observations it can be concluded that the F1 Formulation shows faster disintegration at 15 sec and maximum drug release of 100.047% at minimum time interval (15min).

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