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Research Article

FORMULATION AND IN VITRO EVALUATION OF CLOBAZAM ORALLY DISINTEGRATING TABLET

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ABSTRACT:
An Orally disintegrating tablet disperses readily in saliva and the drug is available in solution or suspension form for the immediate absorption and resulting in rapid onset of action. In the present research work Clobazam Oral disintegrating tablet were prepared by Direct Compression Technique using varying concentrations of Lycoat, Croscarmellose sodium and Ludiflash as super disintegrants. The formulations prepared were evaluated for precompression & post compression parameters. Form the drug excipient compatibility studies we observe that there are no interactions between the pure drug (Clobazam) and optimized formulation (Clobazam+ excipients) which indicates there are no physical changes. Post compression parameters was found to be within the limits. Among the formulation prepared the tablet containing concentration of Ludiflash shows 99.24±1.42% of the drug release within 60 min & follows first order kinetics. The overall result indicated that the formulation F12 containing Ludiflash is better and fulfilling of the needs of the Orally disintegrating tablet.
Key words: Orally disintegrating tablets, Direct Compression Technique, Clobazam, Ludiflash, FTIR.

INTRODUCTION

Recent advances in new drug delivery systems attempt to increase the safety and efficacy of the medication molecule by developing a dosage form suitable for administration. Orally disintegrating tablets (ODTs) are solid dosage forms that dissolve or disintegrate quickly in the oral cavity, resulting in a solution or suspension that does not require water. These are newer varieties of tablets that dissolve in saliva within a few seconds. Oral disintegration tablets have several benefits over normal pills [1]. Dysphasia is a widespread condition in all age groups, particularly among the elderly and children, due to physiological changes associated with those groups. When it comes to oral solid dose forms, such issues result in a high rate of noncompliance and ineffective therapy. Nowadays, there is a growing interest in developing not just rapid dissolving tablets to make swallowing easier, but also orally decomposing pills that are designed to dissolve quickly in your mouth.

ODTs provide an advantage for the population who have trouble swallowing traditional pills or capsules, bedridden, mentally ill, and recalcitrant people suffering from nausea, motion sickness, abrupt bouts of allergic reaction, or coughing [2]. The key features of this dosage form, in terms of patient compliance, quick onset of action, higher bioavailability, superior stability, and pleasant flavor, enhance the acceptability of bitter tasting medications, making these tablets popular as a dosage form of choice in the present market [3]. The usage of super disintegrants is the fundamental strategy to developing an oral disintegration tablet. Because of the presence of super disintegrants, it dissolves fast, resulting in rapid drug absorption and, consequently, rapid beginning of action. Because absorption occurs straight from the mouth, avoiding first-pass metabolism, the drug's bioavailability rises. Natural disintegrants such as gum karaya, modified starch, agar, and synthetic disintegrants such as microcrystalline cellulose, crospovidone, croscarmellose sodium, sodium starch glycolate, etc. have been used in the formulation of fast dissolving tablets at concentrations of up to 10% by weight relative to the total weight of the dosage form [4]. Throughout modern history, several procedures have been used to manufacture orodispersible tablets, including freeze drying or lyophilization, spray drying, molding, sublimation, mass extrusion, and direct compression [5]. This direct compression approach is preferred over other methods of producing orodispersible tablets because to its inexpensive manufacturing costs, use of standard equipment, and fewer processing stages.

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MATERIALS & METHODS USED: Clobazam API was procured from Metrochem API Private Limited, and Ludiflash, Croscarmellose sodium, Lycoat, Aspartame, Mannitol were procured from Signet Chemical Corp., Mumbai, Talc, Magnesium stearate were procured from S.D. Fine Chem. Ltd., MCC was procured from Aurbindo Pharma Ltd., Hyd.

Solubility

Solubility of Clobazam was determined in pH 1.2, pH 7.4, pH 6.4 and 6.8 phosphate buffers. Solubility studies were performed by taking excess amount of Clobazam in beakers containing the solvents. The mixtures were shaken for 24 hrs at regular intervals. The solutions were filtered by using whattmann's filter paper grade no.41. The filtered solutions are analyzed by spectrophotometrically.

Determination of λmax: -

10 mg of Clobazam was dissolved in 10 ml of 6.8 pH Phosphate Buffer by slight shaking (1000 µg/ml). 1 ml of this solution was taken and made up to 10 ml with 6.8 pH Phosphate Buffer, which gives 100 µg/ml concentration (stock solution). From this Stock solution (100µg/ml) pipette out 1ml to 10ml volumetric flask and makeup with 6.8 pH Phosphate Buffer up to 10ml was prepared in 6.8 pH Phosphate Buffer. This solution was appropriately diluted with 6.8 pH Phosphate Buffer to obtain a concentration of 10µg/ml. The resultant solution was scanned in range of 200-400nm on Single beam spectrophotometer (YIS-294).

Calibration Curve for Clobazam In 6.8 pH Phosphate Buffer

Procedure:

Preparation of Standard Stock Solution: -

10 mg of Clobazam was accurately weighed into 10 ml volumetric flask and dissolved in small quantity of 6.8 pH Phosphate Buffer. The volume was made up to 10 ml with the 6.8 pH Phosphate Buffer to get a concentration of (1000 µg/ml) SS-I. From this, 1 ml was withdrawn and diluted to 10 ml with distilled water to get a concentration of (100 µg/ml) SS-II.

Calibration Curve in 6.8 pH Phosphate Buffer: -

From the standard stock solution (SS-II), 0.2, 0.4, 0.6, 0.8,1 and 1.2 ml were withdrawn and volume was made up to 10 ml with 6.4 phosphate buffer to give a concentration of 2, 4, 6,8 10 and 12µg/ml. Absorbance of these solutions was measured against a blank of 6.8 pH Phosphate Buffer at 232 nm for Clobazam and the absorbance values are summarized in Table Calibration curve was plotted, drug concentrations versus absorbance was given in the Figure.

DRUG-EXCIPIENT COMPATIBILITY STUDIES BY I.R.: -

Excipients are integral components of almost all pharmaceutical dosage forms. The successful formulation of a stable and effective solid dosage form depends on the careful selection of the excipients, which are added to facilitate administration, promote the consistent release and bioavailability of the drug and protect it from degradation.

Schematic representation of compatibility studies

Infra Red spectroscopy is one of the most powerful analytical techniques to identify functional groups of a drug.

Method:- The pure drug and its formulation were subjected to IR studies. In the present study, the potassium bromide disc (pellet) method was employed.

Table.1 formulation table for Clobazam oral disintegrating tablet

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Clobazam	10	10	10	10	10	10	10	10	10	10	10	10
Croscarmellose Sodium	6.25	12.50	18.75	25.00	--	--	--	--	--	--	--	--
Lycoat	--	--	--	--	6.25	12.50	18.75	25.00	--	--	--	--
Ludiflash	--	--	--	--	--	--	--	--	6.25	12.50	18.75	25.00
Mannitol	75.75	69.5	63.25	57	75.75	69.5	63.25	57	75.75	69.5	63.25	57
M.C.C	60	60	60	60	60	60	60	60	60	60	60	60
Aspartame	4	4	4	4	4	4	4	4	4	4	4	4
Magnesium stearate	2	2	2	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2	2	2	2
Total weight(mg)	250	250	250	250	250	250	250	250	250	250	250	250

FORMULATION OF ORAL DISINTEGRATING TABLETS OF CLOBAZAM:

The Clobazam oral disintegrating tablets were prepared using super disintegrants by direct compression method. Clobazam tablet each weighing 250 mg containing 10 mg of Clobazam was formulated as follows, all the ingredients were passed through #60mesh sieve separately. The drug & Mannitol were mixed by adding small portion of each at a time and blending it to get a uniform mixture and kept aside. Then the other ingredients were mixed in geometrical order and passed through coarse sieve (#44 mesh) and the tablets were compressed using hydraulic press. Compression force of the machine was adjusted to obtain the hardness in the range of 3.5-5 kg/cm2 for all batches. The weight of the tablets was kept constant for all formulations F1 to F12 (250 mg).

EVALUATION PARAMETERS

Pre compression Parameters90-93

Method Preparation of Mixed Blend of Drug and Excipients

All the materials were passed through sieve no. 80. Required quantity of each ingredient was taken for each specified formulation (Mentioned in Table) and all the ingredients were subjected to grinding to a required degree of fineness (except magnesium stearate and talc). The powdered blend was evaluated for flow properties as follows.

Angle of repose

Angle of repose is determined by using funnel method. The accurately weighed blend is taken in a funnel. The height of the funnel is adjusted in such a way that the tip of the funnel just touches the apex of the heap of blend. The drug-excipient blend is allowed to flow through the funnel freely on to the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation. Angle of Repose less than 30 ° shows the free flowing of the material.

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

Bulk density

Apparent bulk density is determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight.

The bulk density was calculated by using the below mentioned formula

$$Db = M/Vo$$

Tapped density

It is determined by placing a graduated cylinder, containing a known mass of drug-excipients blend. The cylinder is allowed to fall under its own weight onto a hard surface from the height of 10 cm at 2 second intervals. The tapping is continued until no further change in volume is noted.

The tapped density was calculated using the following formula,

$$DT = M/Vt$$

Compressibility index

The simplest way for measurement of free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility index(I) which is calculated as follows,

$$\text{Carr's Index (I)} = (\text{Tapped Density} - \text{Bulk Density})/(\text{Tapped Density}) \times 100$$

Hausner's Ratio

Hausner,s ratio is an indirect index of ease of powder flow. It is calculated by the following formula

$$\text{Hausner's Ratio} = \text{BulkDensity}/(\text{Tapped Density})$$

EVALUATION OF TABLETS

Post compression parameters

Weight variation test

The weight variation test is carried out in order to ensure uniformity in the weight of tablets in a batch. First the total weight of 20 tablets from each formulation is determined and the average is calculated. The individual weight of the each tablet is also determined to find out the weight variation.

Tablet hardness

The hardness of tablet is an indication of its strength. It is the force required to break a tablet by compression in the radial direction. The force is measured in kg and the hardness of about 3.5-5 kg/cm2 is considered to be satisfactory for uncoated tablets. Hardness of 10 tablets from each formulation is determined by Monsanto Hardness tester. Excessive hardness significantly reduces the disintegration time.

Tablet friability

Friability is the loss of weight of tablet in the container due to removal of fine particles from the surface. Friability test is carried out to access the ability of the tablet to withstand abrasion in packaging, handling and transport. Roche friabilator is employed for finding the friability of the tablets. Weigh the 20 tablets from each batch and place in Roche friabilator that will rotate at 25 rpm for 4 minutes. All the tablets are dedusted and weighed again. The percentage of friability can be calculated using the formula.

$$\% \text{ Friability} = [(W1-W2)100]/W1$$

In-Vitro Disintegration time

Tablet disintegration is an important step in drug absorption. The test for disintegration was carried out in Electrolab USP disintegration test apparatus. It consists of 6 glass tubes which are 3 inches long, open at the top, and held against a 10 mesh screen, at the bottom end of the basket rack assembly. To test the disintegration time of tablets, one tablet was placed in each tube and the basket rack was positioned in a 1 liter beaker containing 6.8 pH Phosphate Buffer solution at 37°C ± 1°C such that the tablet remains 2.5 cm below the surface of the liquid. The time taken for the complete disintegration of the tablets was noted.

Thickness and Diameter

Tablet thickness and diameter can be measured using a simple procedure. Five tablets are taken and their thickness is measured using Vernier calipers. The thickness and diameter is measured by placing tablet between two arms of the Vernier calipers.

Drug content uniformity

The tablets were tested for their drug content uniformity. At random 20 tablets were weighed, powdered & dissolved in 100ml of 6.8 pH Phosphate Buffer. The solution was shaken thoroughly. The undissolved matter was removed by filtration through Whatmann No.41 filter paper. Then the dilute the solution to obtain 10µg solution. The absorbance of the diluted solutions was measured at 232 nm.

In vitro Dissolution Study:

In vitro dissolution of Clobazam Oral disintegrating tablets was studied in USP XXIV dissolution test apparatus. 900ml Phosphate buffer 6.8 pH Phosphate Buffer was used as dissolution medium. The stirrer was adjusted to rotate at 100RPM. The temperature of dissolution medium was maintained at 37±0.5ºC throughout the experiment. One tablet was used in each test. Samples of dissolution medium (5ml) were withdrawn by means of syringe fitted with pre-filter at known intervals of time and analyzed for drug release by measuring the absorbance at 232 nm. The volume withdrawn at each time interval was replaced with fresh quantity of dissolution medium. Cumulative percent Clobazam released was calculated and plotted against time.

Data Analysis (Curve fitting analysis):

To analyze the mechanism of the drug release rate kinetics of the dosage form, the data obtained were plotted as:

Cumulative percentage drug released Vs time (Zero order plot)

Log cumulative percentage drug remaining Vs Time (First order plots)

Zero order model:

The pharmaceutical dosage forms following these profiles release the same amount of drug by unit of time and it is the ideal method of drug release in order to achieve a pharmacological prolonged action. The following relation can, in a simple way, express this model:

$$Qt = Q0 + K0t$$

First order model:

The application of this model to drug dissolution studies was first proposed by Gibaldi and Feldman (1967) and later by Wagner (1969). This model has been also used to describe absorption and/or elimination of some drugs, although it is difficult to conceptualise this mechanism in a theoretical basis .

$$\log Qt = \log Q0 + (K1/2.303)$$

RESULTS & DISCUSSION

Solubility studies:

Solubility of Clobazam was carried out at 250C using 0.1N HCl, 6.8 phosphate buffer, 7.4pH buffer and purified water.

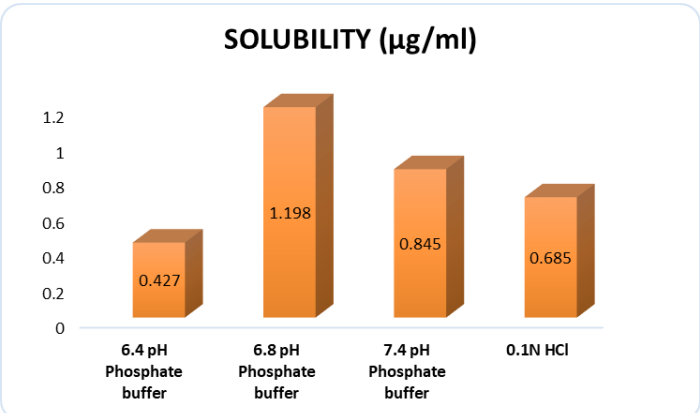

Figure.1 Graphs for the solubility studies of pure Drug

Discussion: From the above conducted solubility studies in various buffers, we can say 6.8 pH phosphate buffer has more solubility when compared to other buffer solutions.

Determination of λ_{max}:-

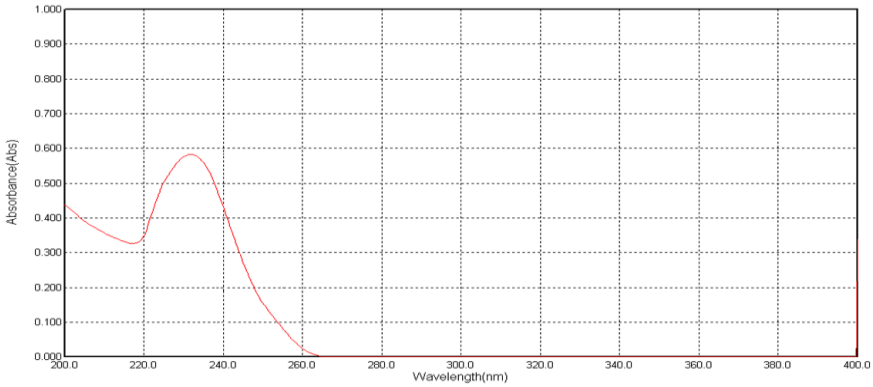

Figure.2 UV Spectrum curve of Clobazam

Discussion: The Absorption maxima of Clobazam drug in the 100% concentration by using 6.8 pH Phosphate buffer was found to be at 232 nm by using Single Beam Spectrophotometer (YIS-294).

Calibration curve of Clobazam in 6.8 pH phosphate Buffer

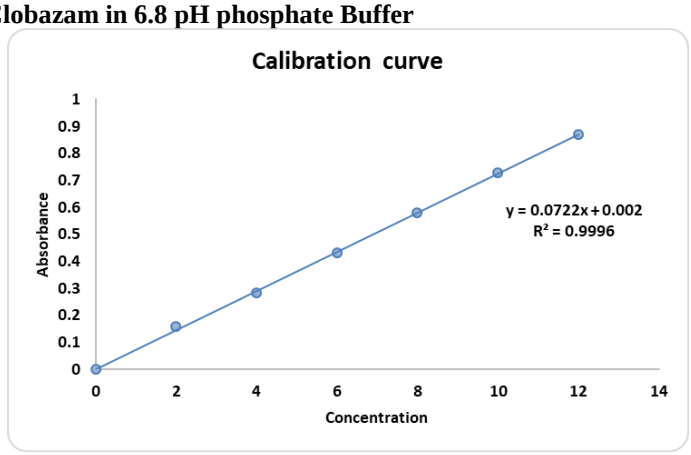

Figure.3 Standard graph of Clobazam

Discussion: The linearity was found to be in the range of 2-12µg/ml in pH 6.8 phosphate buffer. Regression analysis was selected because it minimizes the deviation and correct the variance heterogeneity. The regression line was defined by its slope (m) and its intercept (C) for normal regression analysis was found as 0.0722 and 0.002, with regression coefficient of 0.9996 respectively. The regression value was closer to 1 indicating the method obeyed Beer-lamberts' law.

FTIR STUDIES:

Drug excipient compatibility:

Drug and excipient compatibility was confirmed by comparing spectra of FT-IR analysis of pure drug with that of various excipients used in the formulation.

PURE DRUG:

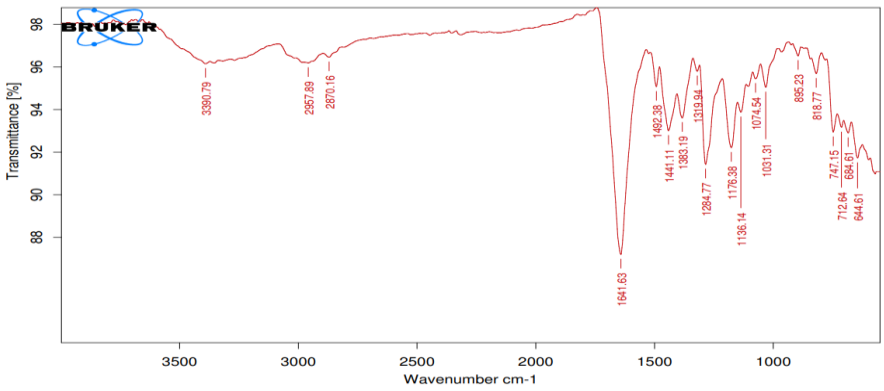

Figure.4 IR spectrum of Clobazam

OPTIMIZED FORMULATION:

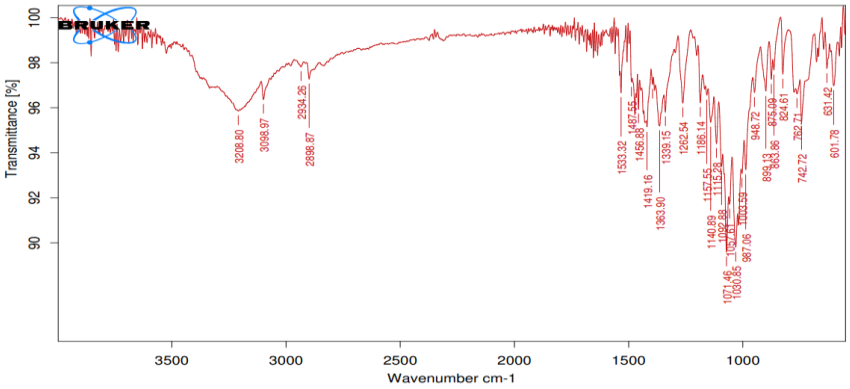

Figure.5 IR spectrum of Optimized formulation

Discussion:

The FTIR spectrum of pure Clobazam, prepared Oral Disintegration Tablets of Clobazam formulation by Direct Compression Techniques are shown in Figure respectively. From the drug excipient compatibility studies we observe that there are no interactions between the pure drug (Clobazam) and optimized formulation (Clobazam + excipients) which indicates there are no physical changes.

Characterization of blend:

Table.2 Pre-Compression parameters:

Formulation Code	Derived properties		Flow properties		
	Bulk density (mean± SD)	Tapped density (mean± SD)	Angle of repose (mean± SD)	Carr's index (mean± SD)	Hausner's ratio (mean± SD)
F1	0.218±0.005	0.327±0.004	28.24±1.42	21.14±1.49	1.19±0.01
F2	0.224±0.006	0.336±0.006	27.46±1.28	19.27±1.54	1.17±0.04
F3	0.222±0.002	0.345±0.003	26.18±1.47	18.45±1.16	1.15±0.02
F4	0.236±0.007	0.359±0.004	25.43±1.26	16.36±1.16	1.16±0.04
F5	0.223±0.006	0.332±0.003	29.27±1.78	18.71±1.15	1.18±0.02
F6	0.235±0.007	0.344±0.004	28.58±1.22	17.16±1.21	1.17±0.05
F7	0.251±0.004	0.359±0.009	27.29±1.48	16.20±1.26	1.15±0.02
F8	0.269±0.006	0.365±0.006	26.45±1.35	15.37±1.42	1.14±0.09
F9	0.231±0.002	0.346±0.007	27.55±1.74	17.45±1.61	1.15±0.05
F10	0.246±0.003	0.357±0.003	26.66±1.28	15.27±1.26	1.13±0.06
F11	0.261±0.004	0.376±0.006	25.85±1.36	13.51±1.42	1.12±0.07
F12	0.279±0.002	0.386±0.005	24.17±1.35	12.42±1.24	1.11±0.02

Discussion:

The angle of repose of different formulations was ≤ 28.58±1.22, which indicates that material had good flow property. So, it was confirmed that the flow property of blends was free flowing. The bulk density of blend was found between 0.218±0.005 g/cm^3 to 0.279±0.002 g/cm^3. Tapped density was found between 0.327±0.004 g/cm^3 to 0.386±0.005 g/cm^3.These values indicate that the blends had good flow property. Carr's index for all the formulations was found to be between 21.14±1.49-12.42±1.24 and Hausner's ratio from 1.11±0.02-1.19±0.01, which reveals that the blends have good flow character.

Characterization of tablets

Post Compression parameters

All the batches of tablet formulations were characterized for official evaluation parameters like Weight variation, Hardness, Friability, Tablet thickness and drug content and results are shown in the table.

Table.3 Characterization Clobazam oral disintegrating tablets

Formulation	Average Weight (mg)	Thickness (mm)	Hardness (kp)	Friability (%)	Disintegrating time(sec)
F1	251.6±1.08	2.9±0.01	5.4±0.01	0.59±0.02	21.41±0.07
F2	250.1±1.12	2.7±0.02	5.0±0.03	0.57±0.06	18.25±0.08
F3	249.5±1.13	2.6±0.01	5.8±0.02	0.63±0.08	17.31±0.06
F4	248.2±1.12	2.5±0.02	5.3±0.01	0.69±0.02	16.48±0.07
F5	252.5±1.08	2.7±0.02	5.6±0.01	0.62±0.08	18.14±0.09
F6	251.3±1.11	2.9±0.01	5.4±0.06	0.67±0.06	17.25±0.07
F7	249.5±1.10	2.7±0.02	5.8±0.05	0.69±0.04	16.16±0.05
F8	251.4±1.07	2.8±0.02	5.7±0.07	0.49±0.08	15.24±0.02
F9	249.6±1.11	2.6±0.01	5.6±0.08	0.74±0.02	16.17±0.06
F10	250.9±1.08	2.9±0.02	5.5±0.06	0.45±0.05	15.16±0.02
F11	251.2±1.11	2.6±0.01	5.6±0.07	0.63±0.09	13.25±0.12
F12	250.1±1.00	2.1±0.02	5.9±0.06	0.45±0.07	10.12±0.15

Discussion: Hardness of the tablet was acceptable and uniform from batch-to-batch variation, which was found to be 5.4±0.01–5.9±0.06 kg/cm^2 and thickness was found to be 3.5±0.03-4.1±0.05 mm. All the formulations passed the weight variation test as the % weight variation was within the pharmacopoeial limits of the tablet weight. Friability values were found to be less than 1% in all the formulations F1–F12 and considered to be satisfactory ensuring that all the formulations are mechanically stable. Disintegration time as per IP, for all the formulations was found to be between 21.41±0.07-10.12±0.15 seconds, which was well within IP limit. Formulations with Ludiflash as super disintegrants shows quicker disintegration among all the formulations. Ludiflash with 25mg as a super disintegrant shows very less disintegration time.

Drug content uniformity of formulations: The prepared formulations were analyzed for drug content and the data is reported in below Table. The drug content was found to be within the limits which show that the drug was uniformly distributed in all the formulations.

Table.4 Drug content uniformity of formulations F1-F12

Formulation	% of drug content
F1	93.47±1.18
F2	94.45±1.26
F3	96.08±1.45
F4	97.12±1.85
F5	95.45±1.29
F6	96.28±1.40
F7	97.43±1.35
F8	98.35±1.19
F9	96.12±1.45
F10	97.45±1.38
F11	98.67±1.45
F12	99.27±1.18

Discussion: % Drug content values of formulation F1 – F12 was found to be in the range of 93.47±1.18%-99.27±1.18%.

Dissolution studies: The prepared tablets were subjected to dissolution studies in order to know the amount drug release. As the concentration of super disintegrant increased, the drug release time decreased.

Table.5 % Cumulative drug release of formulations F1-F6

Time (Min)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
5	23.45±1.45	49.15±1.95	60.17±1.02	79.18±1.36	28.28±1.20	55.42±1.54
10	45.75±1.64	60.48±1.67	69.31±1.65	86.25±1.20	52.15±1.62	67.16±1.20
20	67.86±1.84	76.26±1.57	79.46±1.25	92.41±1.74	65.47±1.27	76.25±1.65
30	76.38±1.57	83.18±1.29	90.82±1.20	98.75±1.62	81.15±1.54	89.41±1.84
45	88.21±1.78	98.48±1.58	98.48±1.36		88.87±1.56	96.84±1.26
60	94.44±1.62				99.48±1.28	

Table.6 % Cumulative drug release of formulations F7-F12

Time (Min)	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0
5	68.47±1.67	77.25±1.48	39.38±1.21	52.24±1.67	67.98±1.25	85.04±1.42
10	73.15±1.25	88.64±1.48	48.85±1.45	59.72±1.55	73.85±1.57	90.39±1.45
20	81.26±1.75	92.15±1.25	56.23±1.61	76.32±1.67	89.25±1.68	95.12±1.47
30	90.78±1.61	98.75±1.25	67.53±1.28	92.48±1.45	98.46±1.21	99.24±1.42
45	98.29±1.74		89.74±1.64	98.42±1.84		
60			95.85±1.94			

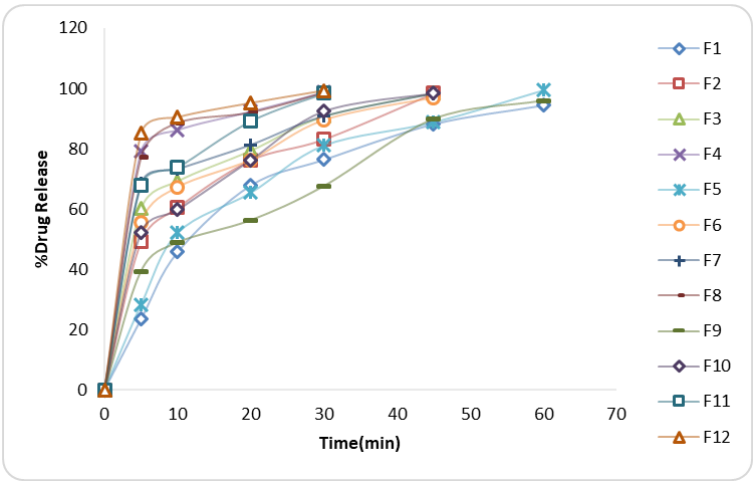

Figure.6 %DR of F1-F12

Discussion:

From the in vitro drug release studies it was observed that the formulations containing Croscarmellose Sodium(F1-F4) as super disintegrant in the concentrations of (6.25mg, 12.50mg, 18.75mg and 25.00mg). The Formulation F1, F2, F3 shows 94.44±1.62% at the end of 60 minutes, 98.48±1.58% at the end of 45 minutes, 98.78±1.36% drug release at the end of 45 minutes and 98.75±1.62% drug release at the end of 30 minutes. Whereas F4 shows 98.75±1.62% drug release at the end of 30 minutes. Whereas the formulations containing Lycoat (F5-F8) as super disintegrant in the concentrations of 6.25mg, 12.50mg, 18.75mg and 25.00mg) shows 99.48±1.28% at the end of 60 minutes, 96.84±1.26% at the end of 45 minutes, 98.29±1.74% drug release at the end of 45 minutes and 98.75±1.25% drug release at the end of 30 minutes. While the formulations containing super disintegrant such as Ludiflash (F9-F12) as super disintegrant in the concentrations of (6.25mg, 12.50mg, 18.75mg and 25.00mg) 95.85±1.94% at the end of 60 minutes, 98.42±1.84% at the end of 45 minutes, 98.46±1.21% drug release at the end of 30 minutes and 99.24±1.42% drug release at the end of 30 minutes. So F12 formulation was considered as the optimized formulation. Further kinetics were measured for F12 formulation.

DRUG RELEASE KINETICS STUDIES:

ZERO ORDER:

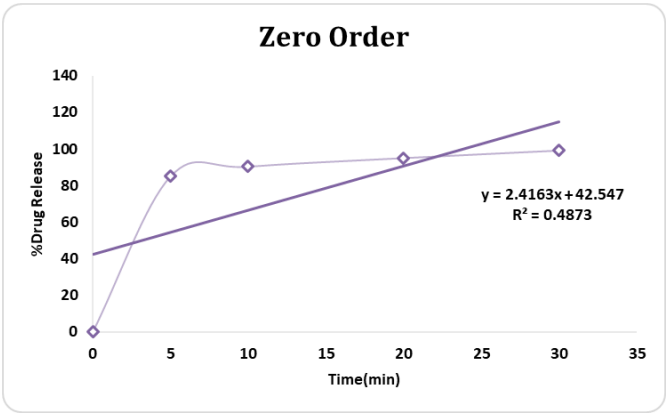

Figure.7 Zero order plot of Clobazam F12 Formulation

FIRST ORDER:

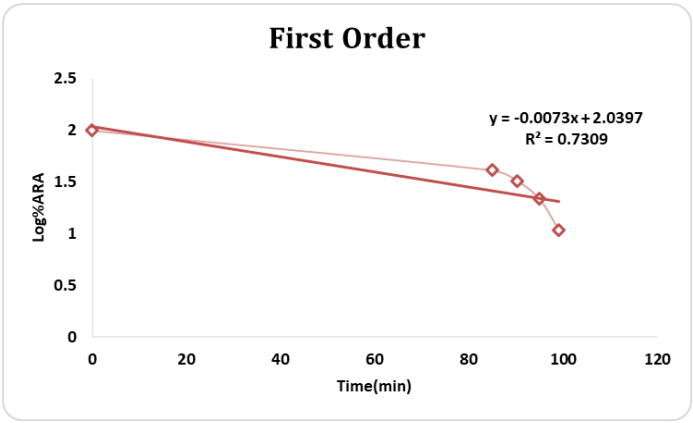

Figure.8 First order plot of Clobazam F12 Formulation (Time Vs Log% ARA)

Discussion:

The drug release from the oral disintegrating tablets was explained by the using mathematical model equations such as zero order, first order methods. Based on the regression values it was concluded that the optimized formulation F12 follows First order drug release.

SUMMARY

The present study is an attempt to select the best possible diluent - disintegrant combination to formulate Oral disintegrating tablets of Clobazam, which disintegrates in matter of seconds in the oral cavity, thereby reducing the time of onset of pharmacological action. Lycoat, Croscarmellose sodium and Ludiflash, were used as disintegrants. In all the formulations, and Magnesium stearate and talc were used as lubricant and glidant respectively. The results of the drug – excipient compatibility studies revealed that there was no chemical interaction between the pure drug and excipients. Direct Compression Technique was employed to formulate the tablets, because of its cost effectiveness and due to reduced number of manufacturing steps. The precompression parameters like bulk density, tapped density, Carr's index and angle of repose were determined. All the formulations showed acceptable flow properties. The post compression parameters like the hardness, thickness, friability and weight variation, disintegration time, disintegration time in oral cavity and Invitro release were carried out and the values were found to be within IP limits. The percentage drug content of all the tablets was found to be between 93.47±1.18%-99.27±1.18% of Clobazam, which was within the acceptable limits. Among all the formulations F12 shows 99.24±1.42% drug release at the end of 60min. F12 contains Ludiflash (25mg), it shows better % drug release when compared to other formulations. So, F12 was considered as the optimized formulation. The drug release kinetics shows that the optimized formulation F12 follows First order drug release.

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