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Formulation and evaluation of orodispersible tablet to enhance dissolution rate of carbamazepine by using solid dispersion technique

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Abstract
A solid dispersion approach has been attempted to create fast-dissolving carbamazepine tablets, employing varying amounts of crosscarmellose sodium as the super disintegrating agent. This medication's poor absorption upon oral administration and extremely low solubility in biological fluids is its main issues. The produced tablets were assessed for drug content, hardness, friability, disintegration time, wetting time, and *in vitro* dissolution investigations. The mannitol solid dispersion formulations exhibited a disintegration time ranging from 12.83 to 16.79 seconds and a drug release duration ranging from 8 to 10 minutes. Nevertheless, the formulations made with PEG-6000 solid dispersion failed to dissolve within the allotted window of time for tablets that dissolve quickly. Within 8 minutes, SM4 demonstrated 99.50% drug release out of all formulations. DSC and FTIR studies were used to characterize the produced tablets. DSC and FTIR investigations did not confirm any chemical interaction between the medication and excipients. The formulations were determined to be stable in the stability investigation, which was carried out in accordance with ICH criteria. The findings showed that rapidly dissolving carbamazepine tablets, which is a poorly soluble medication, improved bioavailability, enhanced dissolution, effective therapy, and ultimately better patient compliance.

Keywords: Carbamazepine, orodispersible tablet, mouth dissolving tablet, superdisintegrants

Introduction

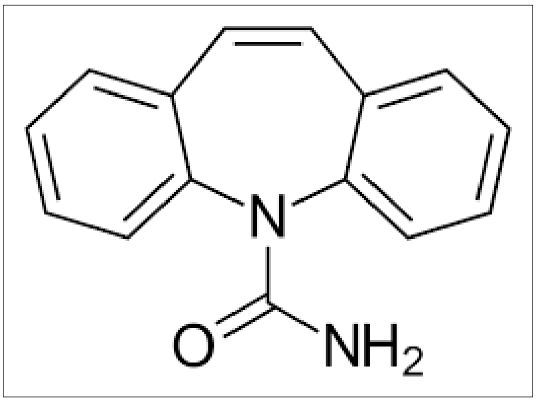
Even though oral pills are the most often used dosage form, patients frequently have trouble swallowing traditional tablets when there isn't any water available. Elderly and pediatric patients may find it difficult to swallow tablets, even if they are taken with water (Furtado, S., Deveswaran, R *et al.*, 2008) [36]. Orodispersible tablets (ORDs), commonly referred to as "mouth dissolving tablets," have the benefit of both traditional tablet and liquid forms, making it easier to absorb the medication in liquid dosing form. Saliva aids in the quick breakdown of ORDs in the mouth, creating a dispersion that is readily ingested without the need for water (Singh, J. and Singh, R. 2009) [37].

Other benefits of ODTs that have been studied include their capacity to improve the dissolution profiles of medications that are poorly soluble in water, thereby increasing the bioavailability of those medications. In addition, hospitalized or bedridden patients with a range of illnesses, including stroke, thyroid disorders, Parkinson's disease, and other neurological conditions including multiple sclerosis and cerebral palsy, are included in the target patient categories (Khalid, K.A., Ahmed, A.H.,2010) [38].

The tablet's ability to dissolve quickly can be attributed to the water seeping into the tablet matrix, which causes the tablet to disintegrate quickly. Therefore, optimizing the tablet matrix's porous structure, adding the proper disintegrating agent, and utilizing highly water-soluble excipients in the formulation are the fundamental methods for creating ODTs.4 ODTs can be prepared using a variety of techniques, including as tablet molding, spray drying, sublimation, Lyophilization, solid dispersion, and the addition of disintegrants, among others (Ghosh, T., Ghosh, A. and Prasad, D. 2011) [39].

Carbamazepine: Anticonvulsant carbamazepine is used to treat several forms of seizures as well as pain from trigeminal neuralgia. Drugs classified as class II drugs under the Biopharmaceutical Classification System (BCS) include carbamazepine, an antiepileptic with low solubility in biological pH fluids (Zahar T, Mohammad Z, *et al.*, 2013) [40]. Improving solubility is crucial for the transport of drugs into fluid media. Innovative technologies like beta-cyclodextrine complexation, solid dispersion, and micronization have been created. The most popular method for improving solubility through faster dissolution and increased bioavailability is solid dispersion. The addition of surfactants to a binary system in the ternary system, an advanced solid dispersion approach, improves the solubility of drugs that are poorly soluble in water (Vasconcelos T, Sarmento 2007) [41]. Several synthetic surface active agents, mostly non-ionic surfactants, are included in the ternary phase at concentrations ranging from 0.5% to 20%w/w; nevertheless, the dissolution rate increases by two or three times as compared to pure weakly soluble drug.

Structure of Carbamazepine



Molecular Formula: C15H12N2O
Chemical Name: 2 - 5H-dibenzo [b, f] azepine-5-carboxamide
State: solid
Melting point: 190.20 °C
Molecular weight: Average: 236.269 g/mol

Mechanism of action

The exact mechanism of action of carbamazepine is unclear and hotly contested.5,22 One popular theory is that carbamazepine reduces seizure activity by preventing sodium channel activation. Studies on animals have shown that carbamazepine works by reducing polysynaptic nerve response and preventing post-titanic potentiation. Carbamazepine has been demonstrated to lessen infraorbital nerve stimulation-induced discomfort in cats and rats. In other investigations, carbamazepine administration was followed by a reduction in the action potential in the lingual mandibular reflex and nucleus ventralis of the thalamus in the brain. By blocking action potentials-which often result in stimulatory effects on nerves-by binding to voltage-dependent sodium channels, carbamazepine produces the aforementioned effects. Carbamazepine is believed to boost dopamine turnover in bipolar illness.

Absorption

Carbamazepine has a bioavailability of 75-85% of a dosage taken orally.3 In a pharmacokinetic investigation, the Cmax of carbamazepine was found to be 1.9 0.3 mcg/mL following a single 200 mg oral extended-release dose. 19 plus 7 hours made up the Tmax. The peak levels of carbamazepine were found to be 11.0 2.5 mcg/mL following repeated doses of 800 mg every 12 hours. The maximum time was shortened to 5.9 1.8 hours. Over a dose range of 200-800 mg, extended-release carbamazepine showed linear pharmacokinetics.

Route of elimination

Following an oral dose of radio labeled carbamazepine, 72% of the dose was found in the patient's urine and the remaining dose was discovered in their feces. Most excreted carbamazepine is found as hydroxylated and conjugated metabolites, with very little of the original drug.

Half life

After taking one dose of carbamazepine extended-release formulations, the average elimination half-life was 35 to 40 hours. After many dosages of carbamazepine, the half-life varied between 12 and 17 hours.

Clearance

The apparent oral clearance of carbamazepine in a pharmacokinetic investigation was 25 5 mL/min after a single dose and 80 30 mL/min after repeated doses.

Material and method

Materials

The following drugs, excipients/polymers and chemicals were used for the formulation and evaluation of microspheres by solvent evaporation method.

Preformulation study

The first step in the logical development of dosage forms for a pharmacological substance is preformulation testing. It can be characterized as an analysis of the physical and chemical characteristics of a drug substance both on its own and in combination with excipients. Pre-formulation testing's main goal is to produce data that the formulator can use to create stable, bioavailable dosage forms that can be manufactured.
The following preformulation studies are carried out:

- Description
- Solubility
- Melting point
- Finding the absorption maxima
- Standard curve
- Infra red spectroscopy studies (compatibility studies)

Description

A dry Petridis is used to collect approximately 1g of material, which is then checked for compliance with the specification.

Melting Point

Capillary tube, which is sealed at one end, is charged with sufficient amount of dry powder to form a column in the bottom of the tube 2.5mm to 3.5mm when packed down as closely as possible by moderate tapping on a solid surface. The apparatus is operated according to the standard operating procedure. The block is heated until the temperature is about 30°c below the expected melting point.
The capillary tube is inserted into the heating block, and the heating is continued at a rate of temperature increased of about 1°c to 2°c per minute until melting is complete. The temperature at which the detector signal first leaves its

initial value is defined as the beginning of melting, and the temperature at which the detector signal reaches its final value is defined as the end of melting, or the melting point. Two temperature fall within the limits of melting range.

Solubility Studies

Solubility is the spontaneous formation of a homogenous molecular dispersion by two or more substances. By gradually adding solvent, a semi-quantitative assessment of the solubility was made amount to a test tube with a predetermined amount of solute, or the opposite. The system was violently agitated and visually inspected for any undeclared solute particles after each addition. The ratio of turns between the solute and solvent was used to express solubility.

The approximate solubility's of substances are indicated by the descriptive terms in the accompanying table. The results are shown in table.

Table 1: Type of solubility

Descriptive term	Parts of solvent required for 1 part of solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Sparingly soluble	From 10 to 30
Slightly Soluble	From 30 to 100
Very slightly soluble	From 100 to 1000
Practically insoluble of Insoluble	Greater than or equal to 10,000

Identification of the drug

Finding the absorption maxima (λ max):

The maxima of absorption were discovered for medication identification. Ultraviolet On the chromophoric portion of the molecules, detailed information has been gleaned using visible Spectrophotometery. When exposed to light in the visible/ultraviolet portion of the spectrum, organic molecules in solutions absorb light of a certain wavelength depending on the type of electronic transition involved in the absorption.

The drug content of the various batches of microspheres was analyzed. Microsphere samples that were precisely weighed were mechanically pulverized. A sufficient amount of phosphate buffer with a pH of 7.2 was used to dissolve the powdered microspheres before filtering. A UV spectrophotometer set at 232 nm was used to determine the filtrate's UV absorbance.

Infrared absorption spectrophotometer

The infrared absorption spectrophotometer was used to determine the identity of Carbamazepine. For the purpose of eliminating moisture, the sample was cooked in a hot air oven. Potassium bromide was added to the sample and mixed in a mortar and pestle. To obtain the spectra, the prepared sample was placed in the FT-IR and scanned at a range of 400 to 4000 cm-1. The acquired spectra were contrasted with the Carbamazepine reference standard IR spectrum.

Drug-Excipients Compatibility studies by FT-IR

After performing independent Fourier infrared spectroscopy (FT-IR) analyses on the pure drug and physical admixtures (Polymers, excipients), the drug and physical admixtures were combined, and FT-IR was used to determine that there was no interaction between the drug, polymers, and excipients. The results are displayed in the table and figure below.

X-Ray Diffraction (XRD)

According to XRD, the angles of flexure, annelation, and torsion in the three-dimensional structure of CBZ are 53°, 30°, and 3°, respectively. The tricyclic psychoactive substances are characterized by or typical of the centers between the benzene rings, which are measured at 4.85

The polymorph employed in commercial pharmaceutical formulations is the form, sometimes known as form III, among the four polymorphic forms of CBZ that have been isolated.

Formulation of Orodispersible Tablets of carbamazepine

The best superdisintegrants, such as sodium starch glycolate, crospovidone, and cross carmellose sodium, are included in the formulation of ODTs. The superdisintegrants were filtered out prior to tablet formulation and added to the formulation together with other excipients for compression using the solid dispersion method. The tablet disintegrates into smaller pieces when it comes into contact with liquid because the superdisintegrants hydrates, swells, and changes the volume of the tablet, among other positive features.

In this study, the formulation development of orodispersible tablets of carbamazepine was attempted using the direct compression method with the aid of superdisintegrants. For the creation of the formulation, the superdisintegrants sodium starch glycolate, crospovidone, and cross carmellose sodium were used. The market offers tablets of carbamazepine in dosages of 5 mg and 10 mg. 10 mg is the dose chosen for the current investigation.

The type and concentration of superdisintegrants played a major role in the development of the orodispersible tablet formulation in the current investigation. To create tablets with desirable physical characteristics, a variety of superdisintegrants in varying concentrations (2.6%, 4%, and 5.3%) were utilized. Microcrystalline cellulose and mannitol, which act as immediately compressible diluents, talc and magnesium stearate, which act as lubricants, aerosil, which promotes flow, aspartame, which acts as a sweetener, and pineapple flavoring which improves the palatability are some of the ingredients. And varied concentrations of Sodium Starch Glycolate (Carboxtmethyl Starch), Crospovidone (Polyplasdone XL), and Cross Carmellose Sodium (Ac- Di-Sol) were used. For example, 2.6%, 4%, and 5.3%.

Table 2: Compositions of different batches of orodispersible tablet of carbamazepine

Formulation ingredients (mg)	F 1	F 2	F 3	F 4	F 5
Carbamazepine	200	200	200	200	200
Sodium starch glycolate	4	6	8	-	-
Crospovidone	-	-	-	6	8
Cross carmellose sodium	4	6	6	-	-
Microcrystalline cellulose	56	56	56	56	56

Aspartame	6	6	6	6	6
Magnesium Stearate	1.5	1.5	1.5	1.5	1.5
Talc	1	1	1	1	1
Aerosil	0.5	0.5	0.5	0.5	0.5
Pineapple flavor	1	1	1	1	1
Mannitol	76	74	70	76	76
Total	350	350	350	350	350

Evaluation of the Prepared Granules

Bulk density

Bulk density was determined by the following formula (Murtaza G., Ahmad A et.al, 2009) [42].

Bulk density= Sample weight/Sample volume

Tapped density

The tapping method, which involved subjecting a cylinder containing a specified quantity (M) of microspheres to a fixed number of taps (about 100) until the bed of microspheres had reached the minimum, was used to calculate the tapped density. The final volume after tapping "Vo" was measured, and the density of the taps was determined using the equation below.

Tapped density= Mass/Volume

Compressibility index (CI), Haussner's ratio and Angle of repose

Carr's index (% compressibility index), Hausner ratio and Angle of repose were determined to predict flow ability and these can be determined by following equations.

$$\text{cI}= \frac{(\text{Tapped density} - \text{Bulk density})}{\text{Tapped density}} \times 100$$

Haussner's ratio = Tapped density/Bulk density

Angle of Repose: The angle of repose was measured by passing the prepared granules through a sintered glass funnel of internal diameter 27 mm on the horizontal surface. The height (h) of the heap formed was measured with a cathetometer, and the radius (r) of the cone base was also determined. The angle of repose (Φ) was calculated from Eq.

Tan ϴ = h/r

Evaluation of the Prepared Orodispersible of carbamazepine tablet

Weight Variation

The weight variation test was performed as per I.P. Twenty tablets were randomly selected from each batch and individually weighed. And then average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The tablets passes the test for weight variation test if no more than two tablets are outside the percentage limit and if no tablet differs by more than two times the percentage limit. Weight variation specification as per I.P. is shown in Table

Table 3: Tablet weight tolerance percentage limits.

Average weight of Tablet	Percentage Deviation
80 mg or less	± 10%
More than 80 mg but less than 250 mg	± 7.5%
250 mg or more	± 5%

Thickness

The vernier caliper from the Electrical lab model was used to measure the thickness of the tablets. Each batch has five pills drawn at random. It was estimated using average values and given in millimeters.

Hardness: Five pills from each formulation were taken to ascertain the hardness, which was then evaluated using a Monsanto hardness meter. Kg/cm3 units of hardness were used to measure it.

Friability

To evaluate the impact of shocks and abrasion, tablets underwent the friability test. The percentage of friability of the tablets was measured using the Roche friabilator. In a plastic chamber that rotates at 25 revolutions per minute and drops a tablet from a height of 6 inches with each revolution, this gadget treats the tablet to the combined effects of abrasion and shock. Tablets that had been pre-weighted were put in the friabilator and given 100 revolutions. The tablets were then taken out, cleaned with a soft muslin towel, and reweighed. The weight loss cannot be greater than 1.0% of body weight. The following formula was used to calculate the % friability.

$$\%F = \frac{\text{W initial } \pm \text{W final}}{\text{W } initial} \times 1000$$

In-vitro Dispersion Time

By dropping a tablet into a petridish containing 10ml of phosphate buffer pH 6.8 solution at 37 0.50c, the in-vitro dispersion time was calculated. Three tablets from each batch were chosen at random, tested, and the amount of time needed for a tablet to completely dissolve was recorded. The seconds represent the in-vitro dispersion time.

Disintegration Time

Using disintegration test equipment, the in-vitro disintegration time of a tablet was calculated. The apparatus was run using distilled water at a temperature of 370°C 20°C with one pill and one disc inserted to each of its six tubes. Then, it took only a few seconds for the tablet to completely dissolve, leaving no discernible mass inside the device.

Drug Content

The method described in IP, 2007 was used to determine the amount of medication in the tablets. Metoclopramide HCl has been said to be detectable at 273 and 305 nm. Because consecutive extraction was done using chloroform, whose maximum absorption was noted at 305 nm as specified in pharmacopoeia, drug content uniformity was carried out at 305 nm.

In- Vitro Drug release study

Using USP apparatus type II at 50 rpm, in-vitro dissolution tests for orodispersible tablets of carbamazepine were performed. Phosphate buffer (900 ml) with a pH of 6.8 was the dissolving media, which was kept at 37 0.5 °C. At various times, aliquots of the dissolution medium (10 ml) were removed, and the amount of carbamazepine was determined by measuring the absorbance at 273 nm. At the 0min, 1min, 2min, and 3min intervals, 10ml aliquots were removed to be continued at the next interval and filtered using Whatman filter paper and a visible spectrophotometer was used for analysis at 232 nm.

Stability Studies: According to the FDA's definition of stability from 1987, stability is "the ability of the drug product to remain within specifications established to ensure its identity, strength, quality, and purity."

Pharmaceutical product stability tests were carried out in accordance with ICH recommendations. These Exaggerated storage conditions are used in investigations to speed up the pace of chemical or physical degradation of the medicinal ingredient or product. There are essentially two kinds of stability investigations.

1. Short -term stability studies
2. Long - term stability studies

Table 4: Stability

Type	Temperature (0 c)	Relative humidity	Minimum time period at submission (month)
Short -term	40±2	75±5	6
Long - term	25±2	60±5	12

Result and Discussion

Melting point: The melting point of carbamazepine was found to be 180 °C to 200 °C

Solubility

Table 5: Solubility profile of losartan potassium

S. No.	Solvent	Solubility
01	Distilled water	Insoluble
02	Alcohol	Freely Soluble
03	Ether	Partially soluble
04	Ethyl acetate	Sparingly soluble
05	propylene glycol	soluble

Identification of λ max and preparation of calibration curve

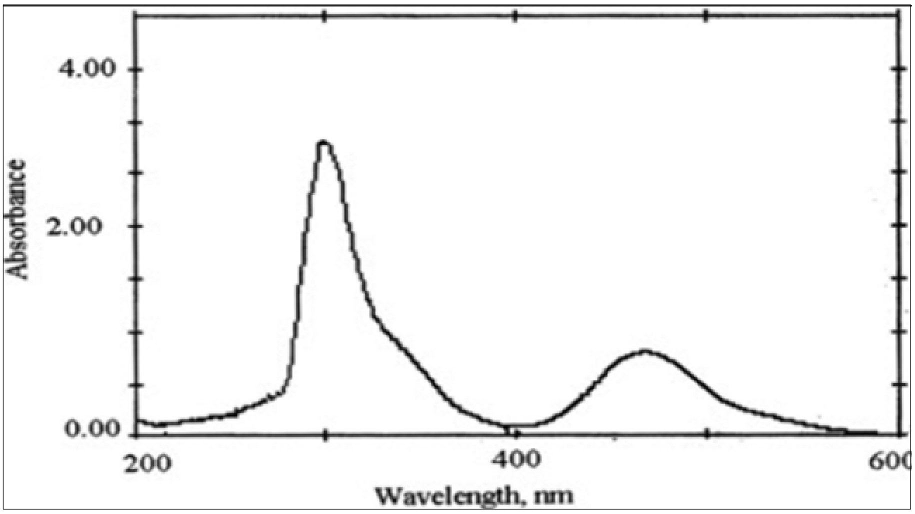


Fig 1: Identification of λ max

Table 6: Absorbance for Calibration curve of Carbamazepine

S.no.	Concentration	Absorbance
1	0	0
2	2	0.785
3	4	0.1456
4	6	0.2138
5	8	0.2789
6	10	0.3395

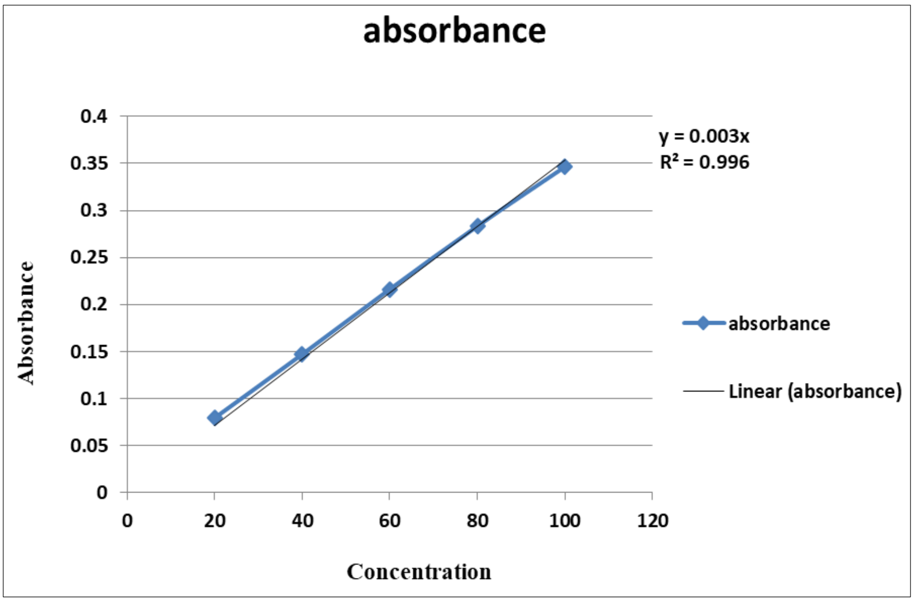


Fig 2: absorbance vs concentration

IR of Carbamazepine: Figure depicts the infrared absorption spectrum of CBZ's unique absorption bands, and Table provides a summary of the description of the bands.

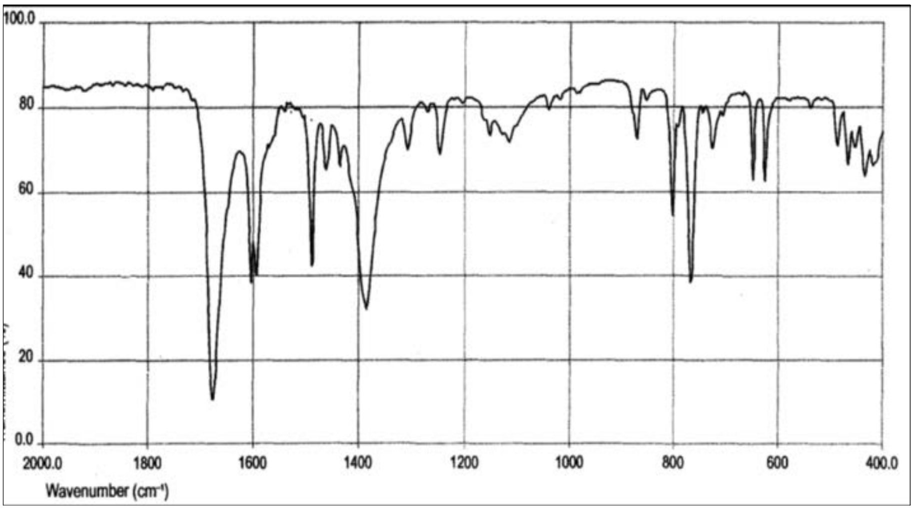


Fig 3: IR Absorption spectrum of carbamazepine

Table 7: IR Spectrum Frequency of carbamazepine

S.No.	Frequency	Assignments
1	3470	NH2
2	1680	C = O
3	1600	Aromatic C = C

When measured in potassium bromide, the characteristic main peaks for CBZ are at 1678, 1388, and 1594 cm-1.

Evaluation of prepared granules

Table 8: Data for Bulk Density and Tapped Density

Formulation code	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Hausner's ratio	Compressibility index
F 1	0.5384±0.191	0.5833±0.272	1.0833	7.6923
F 2	0.5599±0.0.281	0.6087±0.293	1.0869	8.000
F 3	0.6087±0.281	0.6363±0.321	1.0454	4.3478
F 4	0.5384±0.191	0.6363±0.321	1.0400	3.8461
F 5	0.5599±0.221	0.6087±0.293	1.0869	8.000

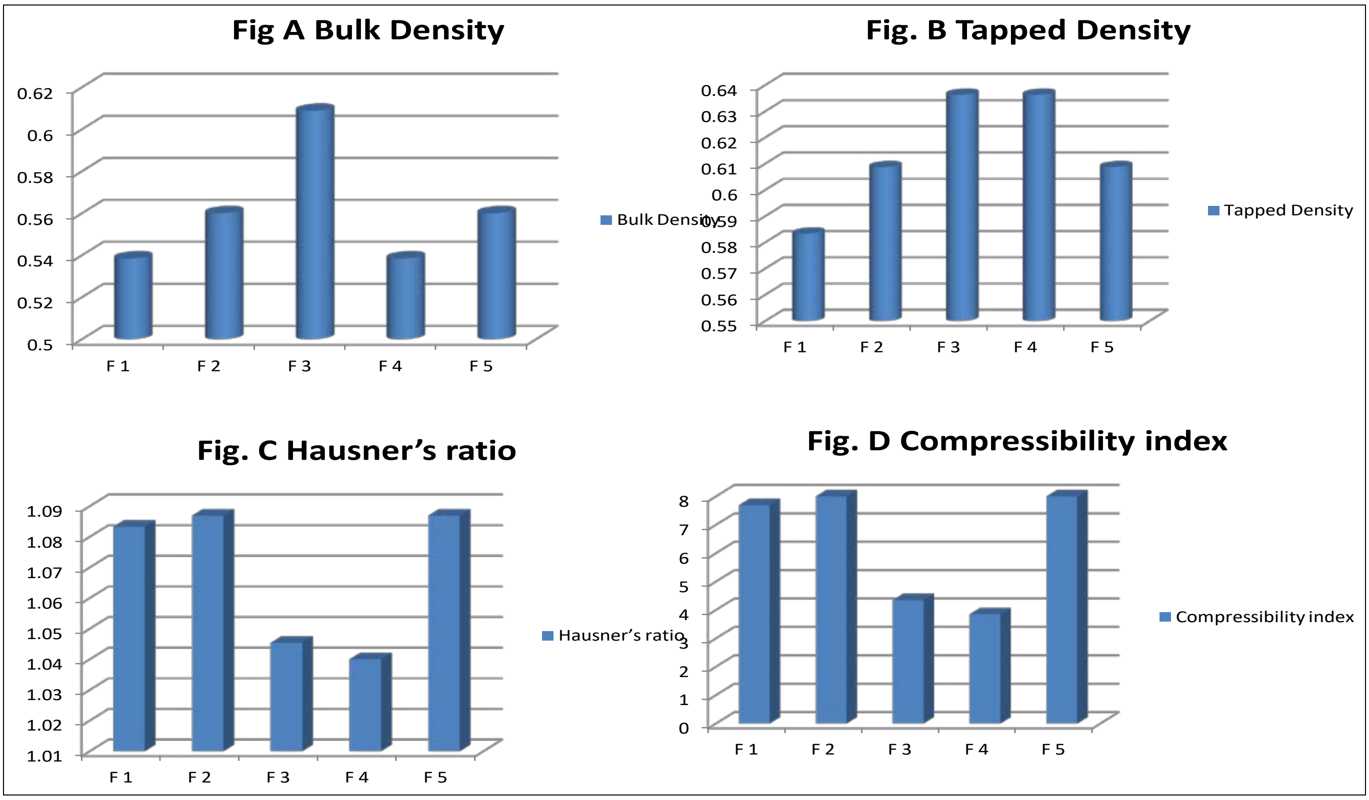


Fig 4: A,B,C and D Show Bulk density, Tapped density, hausner's Ratio and Compressibility Index

Evaluation of the Prepared Orodispersible of carbamazepine tablet

Weight Variation

Utilizing direct compression, tablets were created. Due to the material's freedom of flow, homogeneous die filling allowed for the production of tablets with a consistent weight. According to pharmacopoeia criteria, the tablets were obtained within a range with permitted weight fluctuations. 7.5% or less. The outcomes are shown in Table No.4

Thickness

Vernier calipers were used to assess the tablets. Because to uniform die fill, tablets were discovered to have an identical 2.5 uniform thickness.

Hardness

A hardness tester was used to assess tablets. The range of the tablets' hardness was 1.90 to 2.20. The outcomes are displayed in table no.4

Friability

Utilizing the Roche Friabilator, tablets were assessed for friability, which was found to be within an acceptable range of 0.48 to 0.81 (less than 1%). The outcomes are displayed in table no.4

In-vitro dispersion time

By dropping a tablet into a petridish containing 10ml of phosphate buffer pH 6.8 solution at 37 0.50c, the in-vitro dispersion time was calculated. For all batches, the dispersion time was determined to be between 35 and 42 seconds. The F 5 batch demonstrated the rapid dispersion. The findings are shown in Table no 5

Disintegration time: In the disintegration test apparatus (I.P), the disintegration time of tablets was assessed. For all of the batches, the disintegration time was determined to be in the range of 26 to 36. The batch F 5 disintegration was the quickest. The outcomes are displayed in table no.5

Drug Content

Table No. in the presentation provides the results for content uniformity. The findings indicated that the drug content was within acceptable bounds. According to IP, the test limit for carbamazepine tablets is 90-110%. The assays of the tablets were performed using the procedure described in IP, and the data table is as follows:

In- Vitro drug release study

The release profile was clarified by the comparative examination of each formulation using *in vitro* kinetic parameters. The following table details the in-vitro drug release of orodispersible tablets of carbamazepine for all formulations.

Table 9: Weight, thickness, hardness, friability, variation.

Batch code	Weight (mg) ± S.D Weight variation (7.5%)	Thickness (mm)	Hardness (kg/cm2)	Friability (%)
F 1	150.85 ±0.6	2.571	1.98	0.650
F 2	149.25±0.4	2.552	1.98	0.771
F 3	150.75±0.2	2.558	2.08	0.589
F 4	148.20±0.3	2.573	1.95	0.718
F 5	150.30 ±0.8	2.568	1.98	0.819

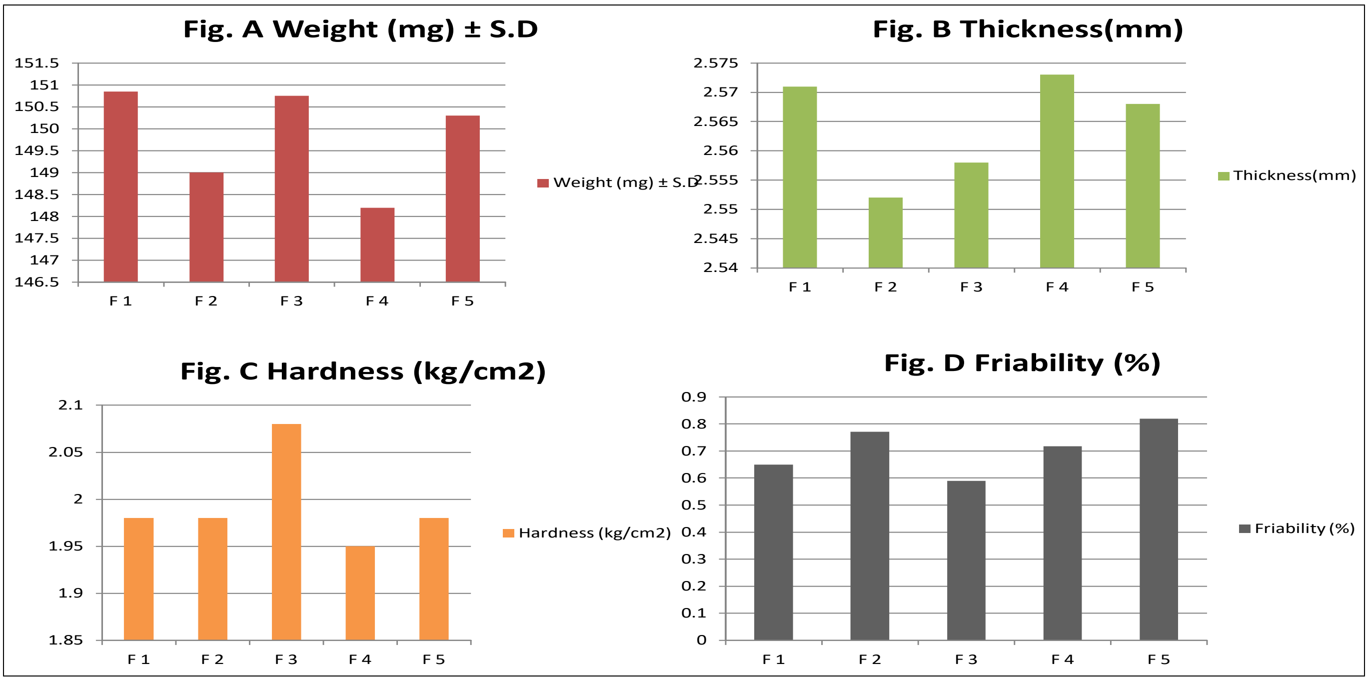


Fig 5: A,B,C and D Show Weight variation, Thickness, hardness, and Friability test

Table 10: Dispersion time, Disintegration time, Drug Content

Batch Code	Dispersion time (sec)	Disintegration Time	Drug content
F 1	39	31	98.96
F 2	37	34	99.02
F 3	40	32	100.30
F 4	36	33	99.16
F 5	35	30	97.91

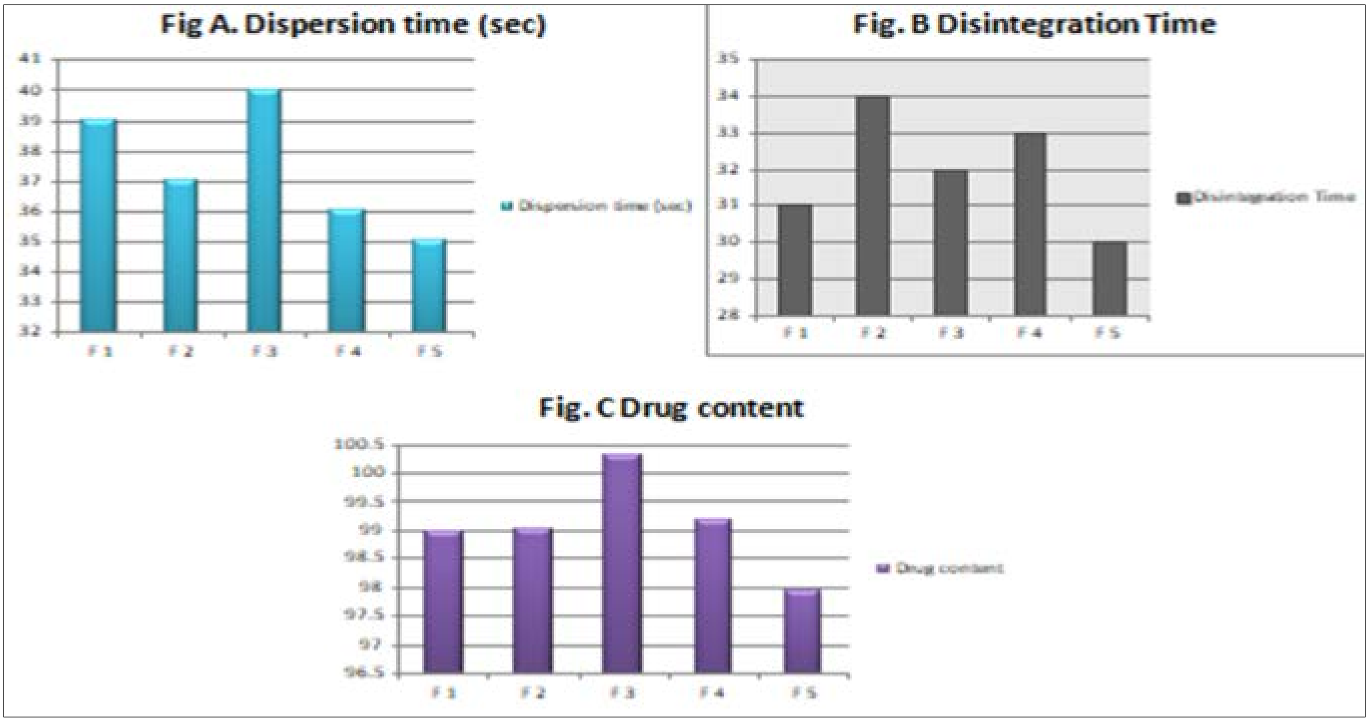


Fig 6: A,B,C and D show Dispersion time, Disintigration time, and drug content

In- Vitro drug release study

The release profile was clarified by the comparative examination of each formulation using *in vitro* kinetic parameters. The following table details the in-vitro drug release of orodispersible tablets of carbamazepine for all formulations.

Table 11: Drug Release study

Time in Min.	F 1	F 2	F 3	F 4	F 5
0	0	0	0	0	0
1	21.46	22.48	28.92	30.68	34.04
2	25.46	28.85	30.06	36.92	41.16
3	35.93	37.95	40.56	42.08	49.52
4	41.41	43.24	49.00	51.88	57.04
5	49.42	51.84	57.84	59.72	63.64
6	57.34	60.53	66.64	70.28	82.08
7	64.94	68.84	74.04	81.64	98.27

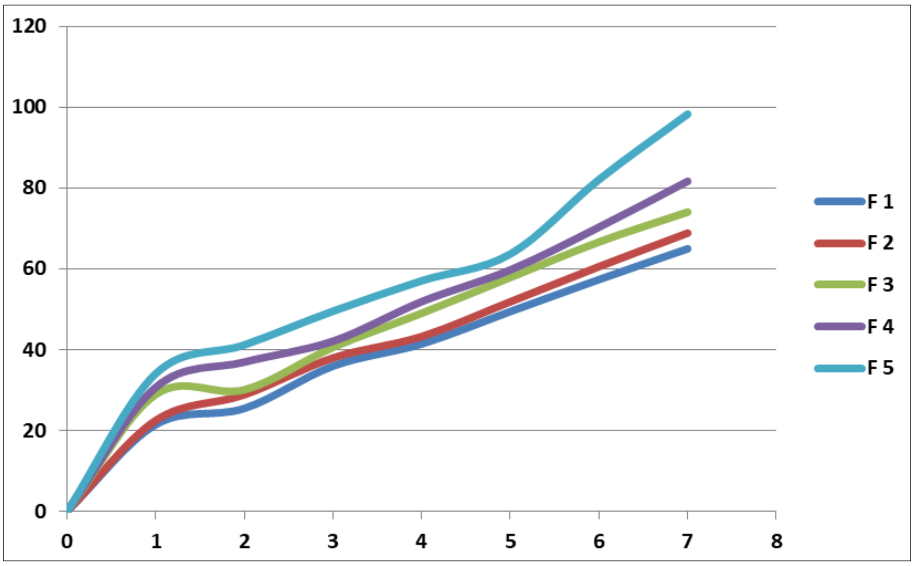


Fig 7: Drug release study

Conclusion

The following conclusion may be taken from the current investigation on carbamazepine orodispersible tablet employing direct compression method.

The total weight of F5 150.30 ±0.8mg carbamazepine, 5.3% crosscarmellose sodium, 33.3% microcrystalline cellulose, 4% aspartame, 1% magnesium Stearate, 0.6% talc, 0.3% Aerosil, 0.6% pineapple flavor, and 48% mannitol were all present in mg.

The Preformulation study provides the following details regarding batch optimization. 280.50° Angle of Repose Bulk density = 0.

5599, 0.608 for tapped density Haussner's ratio is 1.086 and Compressibility Index is 8.00 suitable to flow.

Tablets' post-parameter evaluation Hardness is 198, Friability is 0.819, and Thickness is 2,568. Variation in weight: 150.11 29 seconds for dispersion, and 26 seconds for disintegration 98.93% consistency of the content studies on *in vitro* drug release-in 3 minutes.

When crosscarmellose sodium concentration rises, there is a rapid increase in observed dissolution and disintegration. The data indicate that disintegration takes place in three minutes and takes 26 seconds to disintegrate. The best batch in terms of disintegration time and in-vitro drug release is crosscarmellose sodium. 99.60% in 3 minutes in phosphate buffer pH 6.8 was the best in-vitro release achieved with batch F5's modified formulation. The medication was released after the matrix diffusion mechanism.

Our goal was to create an inexpensive orodispersible tablet that would swiftly disperse in the oral cavity and provide a fast release action for its antiemetic efficacy.

The investigation's fast-disintegrating tablets may make it easier to administer carbamazepine during emesis in a tasty form without water. Faster medication release and disintegration are provided by formulation F5. Thus, it can be said that the F5 formulation, which is an alternative to traditional tablets and is stable and effective for immediate action, is such.

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