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Research Article

FORMULATION AND EVALUATION CARBAMAZEPINE BILAYER TABLET

[1]G.Kumari, [2]Dr.G.Adinarayana, [2]V. J. Krishna Reddy, [2]Chintapalli Kesari, [3]Dr.K.Atchuta Kumar.

[1]M.Pharmacy, Department of Pharmaceutics, Srinivasarao College of pharmacy, affiliated to Andhra University, Visakhapatnam, Andhra Pradesh, India.
[2]M.Pharmacy, Department of Pharmaceutics, Faculty in Pharmaceutics, Srinivasarao College of Pharmacy, affiliated to Andhra University, Visakhapatnam, and Andhra Pradesh, India.
[3]Department of Pharmacognosy, Principal, Srinivasarao College of Pharmacy, affiliated to Andhra University, Visakhapatnam, and Andhra Pradesh, India.

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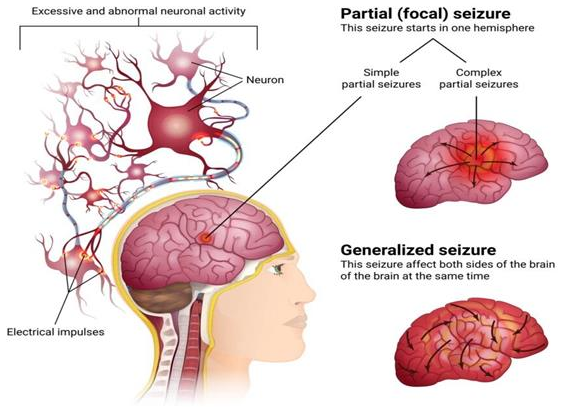
ABSTRACT:

Gastro-retentive medication delivery methods are extensively utilized to extend the retention of dose forms in the stomach. The floating bilayer tablet formulation provides sustained drug release and extended stomach retention, in addition to the benefits of a liquid oral dose form. This study aimed to formulate and assess floating bilayer tablets of Carbamazepine utilizing various polymers, including Lycoat and Crospovidone as superdisintegrants, and Xanthan Gum and Carbopol 934P as extended-release polymers, alongside additional substances such as Magnesium stearate, Sodium bicarbonate, citric acid, Talc, PVP K30, MCC, and Lactose. The fabricated bilayered tablets were assessed for hardness, weight fluctuation, thickness, friability, drug content homogeneity, and in vitro dissolution experiments. F6(IR) and F12(SR) were identified as the optimum formulations based on many assessment factors. The aforementioned buoyancy measurements indicate that F12 exhibits a greater total floating time compared to the other formulations. Formulations F6 (IR) and F12 (SR) exhibited the highest drug release within the specified timeframe. All formulations underwent drug release kinetics tests, including zero order, first order, Higuchi matrix, and Peppas model equations. The sustained release (SR) formulations exhibited zero order release with a super case II transport mechanism.

Keywords: Carbamazepine, Lycoat, Carbopol 934P, FTIR, Bilayered Tablets.

INTRODUCTION

A "seizure" is a sudden disruption of neurological function resulting from the excessive, hypersynchronous firing of neurons in the brain. The term "epileptic seizure" differentiates a seizure resulting from aberrant neural activity from a nonepileptic occurrence, such as a psychogenic seizure. “Epilepsy” refers to the disorder characterized by recurring, spontaneous seizures. Epilepsy has several etiologies, each indicative of underlying cerebral dysfunction[1]. A seizure induced by a reversible insult (e.g., fever, hypoglycemia) does not meet the criteria for epilepsy, as it is a transient secondary syndrome rather than a chronic disorder.



Address for Correspondence: G.Kumari, M.Pharmacy, Department of Pharmaceutics, Srinivasarao College of pharmacy, affiliated to Andhra University, Visakhapatnam, Andhra Pradesh, India, Mail ID: gantakumari1302@gmail.com.

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Figure No.1 Understanding the Different Types of Epileptic Seizures

"Epilepsy syndrome" denotes a collection of clinical features that frequently co-occur, characterized by analogous seizure types, age of start, EEG findings, precipitating causes, genetic predispositions, natural history, prognosis, and responsiveness to antiepileptic medicines (AEDs).

The ambiguous phrase "seizure disorder" need to be eschewed. Epilepsy is among the most prevalent neurological disorders, with an incidence of around 50 new cases annually per 100,000 individuals.[2]

Approximately 1% of the population is afflicted with epilepsy, and roughly one-third of these people experience refractory epilepsy, characterized by seizures that remain uncontrolled despite the use of two or more suitably selected antiepileptic drugs or alternative treatments. About 75% of epilepsy manifests in childhood, indicating the increased vulnerability of the developing brain to seizures.

Carbamazepine is approved by the FDA for the treatment of epilepsy, trigeminal neuralgia, and acute manic and mixed episodes in bipolar I disorder[3,4] Indications for epilepsy pertain primarily to partial seizures with complicated symptomatology (psychomotor, temporal lobe), generalized tonic seizures (grand mal), and mixed seizure patterns. Carbamazepine is contraindicated for absence seizures.[5] Carbamazepine is FDA-approved as a primary therapy for trigeminal neuralgia, often known as tic douloureux. A systematic study demonstrates the effectiveness of carbamazepine extended-release in treating bipolar I mania in individuals experiencing acute manic or mixed episodes.[6]

Carbamazepine is utilized off-label for treatment-resistant schizophrenia. Well-designed trials have demonstrated benefit in patients with schizophrenia exhibiting EEG abnormalities, those experiencing violent episodes, and individuals with schizoaffective disorder.

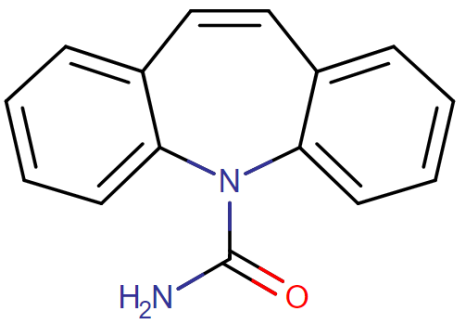

Figure No.2 Structure of carbamazepine

It ameliorates both positive and negative symptoms in individuals with schizophrenia. This medicine is also utilized off-label for the treatment of restless leg syndrome and for mitigating agitation and violence in dementia sufferers.[7,8]

This medicine is also commonly used off-label for the treatment of neuropathic pain and fibromyalgia.[9]Carbamazepine has demonstrated therapeutic usefulness in the treatment of individuals with mild to severe alcohol withdrawal syndrome. This indication lacks FDA clearance and has not demonstrated efficacy in preventing alcohol withdrawal seizures relative to benzodiazepines.[10]

Carbamazepine is furthermore utilized off-label for the maintenance treatment of bipolar illness. In a comparative study of carbamazepine, lithium, and valproic acid, individuals administered carbamazepine exhibited a heightened chance of recurrence, but not to a statistically significant degree.[11,12].

The advancement of sustained or controlled drug delivery systems has gained steam over the past decade, driven by a significant emphasis on the commercialization of novel therapeutic molecules, as the integration of these new compounds has expanded to address various illnesses necessitating diverse dosing regimes. The bilayer tablet enhances patient compliance and is advantageous for either the sequential release of two medications in combination or the sustained and immediate release of the same drug, with one serving as an initial dosage and the other as a maintenance dose. This research seeks to elucidate the importance of bilayer tablets in drug delivery systems and to address the obstacles encountered in their manufacture. This article also examines several strategies for its manufacture and the application of bilayer tablets for different disorders.

Currently, several nations, both developing and developed, are beginning to contemplate the use of combination therapy for the management of various diseases and conditions necessitating prolonged treatment, such as diabetes, cardiovascular diseases, and hypertension. Over 90% of contemporary formulations are intended for oral consumption. This indicates the global popularity of this formulation type, leading most researchers to prioritize it. The primary aim of controlled medication administration is to decrease the frequency of dosing. These data suggest the proposal of a bilayer tablet. One of its layers is designed to facilitate the rapid release of the medication, with the objective of achieving a high serum concentration in a short duration. The second layer is a controlled-release hydrophilic matrix designed to sustain an effective plasma concentration for an extended duration. The pharmacokinetic advantage arises from the fast release of the drug from the first layer, leading to a rapid increase in blood concentration. Nonetheless, the blood concentration stabilizes following the release of the drug from the secondary sustaining layer. The aim of selecting controlled or sustained

delivery systems is to decrease the frequency of dosing or enhance the drug's effectiveness.[13].

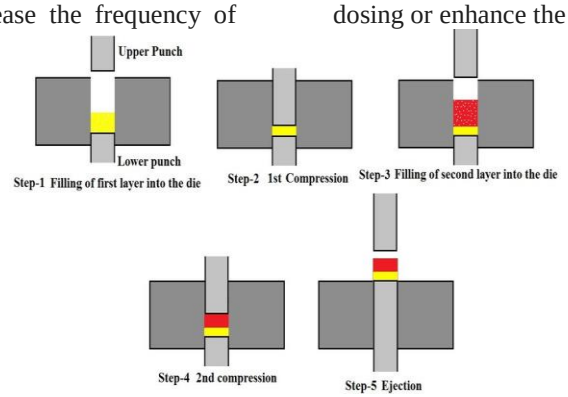

Figure No.3 Step by step approach of bilayer tablet manufacturing.

MATERIALS & METHODS USED: Carbamazepine API was procured from Vasudha Pharma Chem Limited, Hyderabad and Lycoat, Crospovidone, Carbopol 934P were procured from Narmada Chemicals, Hyd, Magnesium Stearate, MCC, Poly vinyl pyrrolidone K 30 were procured from SD Fine chemicals, Lactose were procured from Agastan Bio Cheme Pvt Ltd, Sodium bicarbonate, Citric acid were procured from BMR Chemicals, Hyderabad.

Preparation of Bilayer tablets:

The floating Bilayer tablets of Carbamazepine was prepared by using Direct Compression Method.

a) Preparation of Immediate release layer:

The Immediate release layer contains uniform mixture of Carbamazepine, Crospovidone, LYCOAT and lactose were weighed followed by shifting through 40# sieve and mixed well for 10min. finally prepared powder lubricated with magnesium stearate and Talc the well mixed powder were used as upper layer**.**

b) Preparation of Sustained release layer:

Carbamazepine, Carbopol 934P & Xanthan Gum, variable amount using of MCC, PVP K30, Sodium bicarbonate, citric acid, Magnesium stearate and Talc was mixed properly in a mortar with weighed number of polymers and excipients, the well-mixed powder was compressed by direct compression technique and used as sustained release layer**.**

c) Preparation of Bilayer tablet:

Bilayer tablets were prepared by combining of fast release layer and various formulations of sustained release layer. After the compression, upper punch was lifted and the blend of powder for immediate release layer was poured into the die, containing initially compressed matrix tablet on manesty 12 stationary double rotary compression machine using flat punches, with the hardness of 6-8 kg/cm^2.

FORMULATION DESIGN

Table No.1 Formulation of Immediate release layer (Carbamazepine)

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Carbamazepine	50	50	50	50	50	50
Crospovidone	5	10	15	-	-	-
Lycoat	--	--	--	5	10	15
Lactose	43	38	33	43	38	33
Mg stearate	1	1	1	1	1	1
Talc	1	1	1	1	1	1
Total	100	100	100	100	100	100

Table No.2 Formulation of Multilayer tablets of Carbamazepine

Ingredients (mg)	F7	F8	F9	F10	F11	F12
Immediate release layer	100	100	100	100	100	100
Carbamazepine	150	150	150	150	150	150
Xanthan Gum	25	50	75	--	--	--
Carbopol 934P	--	--	--	25	50	75
Sodium bicarbonate	25	25	25	25	25	25
Citric acid	5	5	5	5	5	5
PVP K30	10	10	10	10	10	10
MCC	81	56	31	81	56	31
Talc	2	2	2	2	2	2
Magnesium Stearate	2	2	2	2	2	2
Total	400	400	400	400	400	400

RESULTS AND DISCUSSIONS

Preformulation Studies

Determination of melting point

The melting point of Carbamazepine was found to be 192.0 °C, which was determined by capillary method.

Solubility Studies

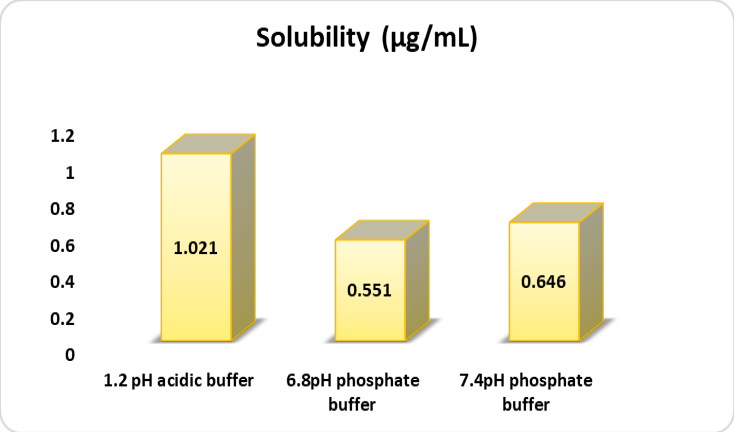

Figure No.4 Solubility studies of Carbamazepine

Discussion: From the solubility studies it was observed that the Carbamazepine have higher solubility in 0.1 N HCL (1.2 pH acidic buffer) pH buffer than the other buffers.

UV spectrum of Carbamazepine

Determination of Carbamazepine λ-max was done in 0.1 N HCL buffer medium for accurate quantitative assessment of drug dissolution rate.

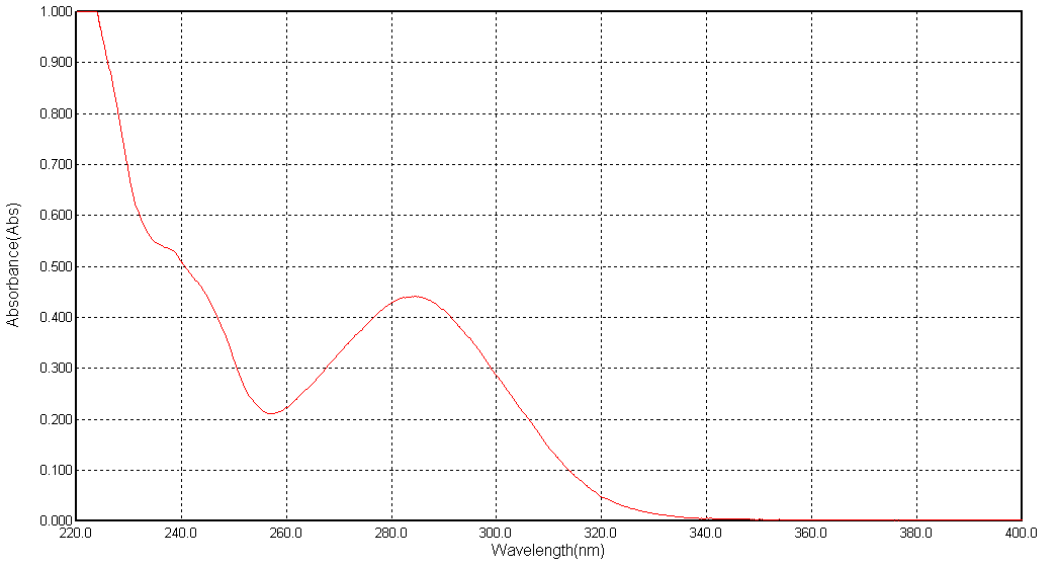

Figure No.5 UV spectra of Carbamazepine at 285.0 nm

Discussion: The λ-max of Carbamazepine of 100% solution i.e 20ppm (µg/ml) by using Single Beam Spectrophotometer (YIS-294) was found to be at 285.0 nm by using 0.1 N HCL Buffer

Calibration curve of pure Drug:

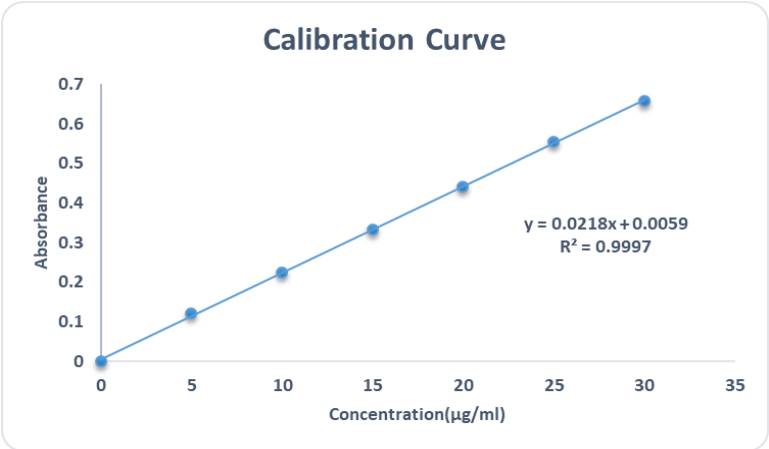

Figure No.6 Calibration curve graph

Discussion: The linearity was found to be in the range of 5-30µg/ml buffer. The regression value was closer to 1 indicating the method obeyed Beer-lamberts' law.

FT-IR SPECTROSCOPY STUDY.

In the present study FT-IR data of drug and excipient was compared with standard spectrum of pure drug. The characteristic peaks associated with specific functional groups and bonds of the molecule and their presence/absence in the polymer carrier formulation were noted. The IR spectra showed that there is no significant evidence for interaction between the drug and the excipients.

Pure Drug:

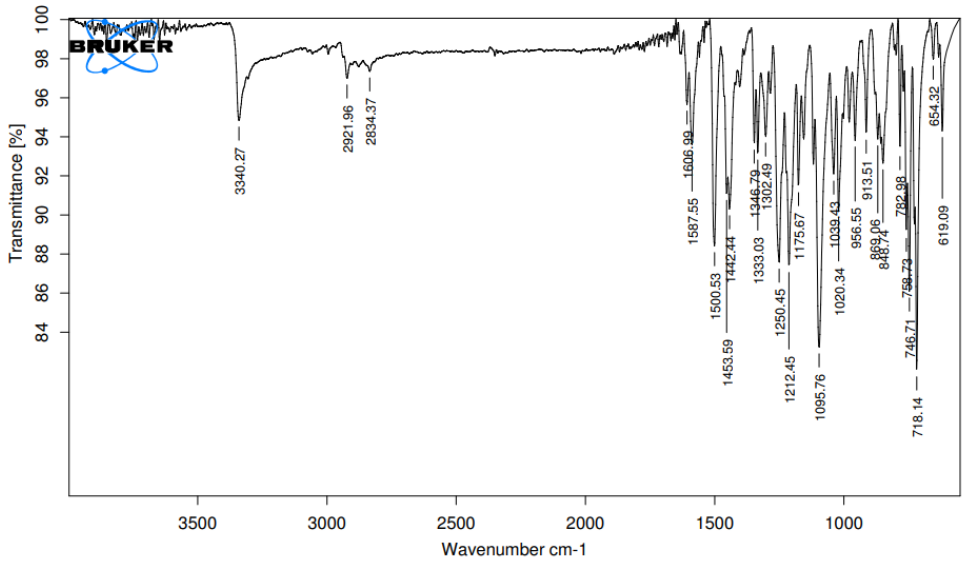

Figure No.7 IR spectra of Carbamazepine pure

Optimized Formulation:

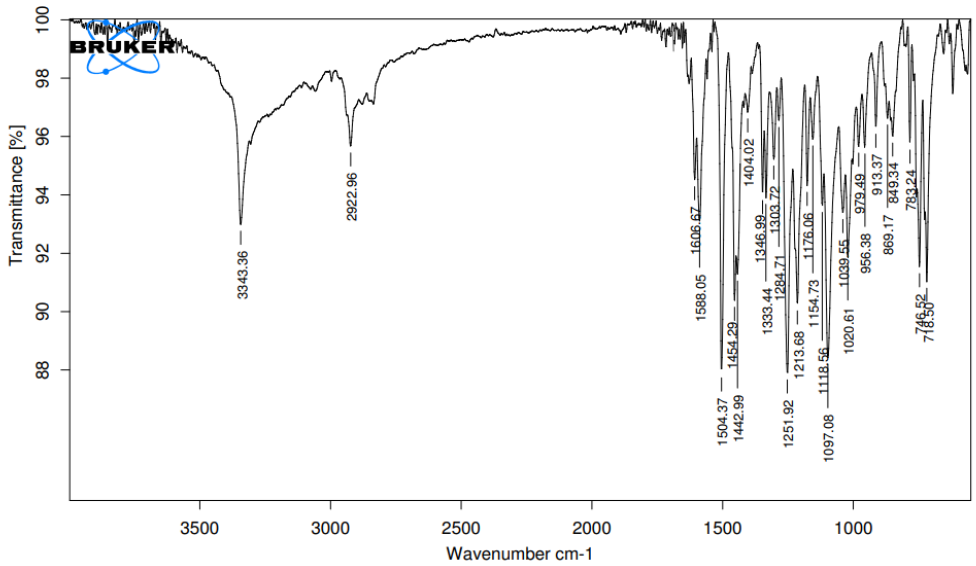

Figure No.8 IR spectra of Carbamazepine + Excipients

Discussion:

The FTIR spectrum of pure Carbamazepine, prepared Bilayer Tablets of Carbamazepine by Direct Compression Techniques are shown in Figure respectively. The units are represented as cm^{-1}. Form the drug excipient compatibility studies we observe that there are no interactions between the pure drug (Carbamazepine) and optimized formulation (Carbamazepine + excipients) which indicates there are no physical changes.

Characterization of blend (immediate release)

Table No.3 Pre Compression parameters (Immediate release)

Code	Angle of Repose	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index. (%)	Hausner's ratio
F1	28.45 ±0.42	0.425 ±0.015	0.548 ±0.052	15.26 ±1.03	1.17 ±0.08
F2	27.48 ±0.36	0.434 ±0.037	0.557 ±0.016	13.82 ±1.02	1.15 ±0.06
F3	29.21 ±0.28	0.458 ±0.061	0.566 ±0.045	12.18 ±1.12	1.13 ±0.02
F4	27.45 ±0.12	0.437 ±0.025	0.554 ±0.018	12.45 ±1.07	1.15 ±0.07
F5	25.67 ±0.47	0.459 ±0.008	0.567 ±0.025	11.41 ±1.10	1.12 ±0.05
F6	29.44 ±0.38	0.461 ±0.012	0.579 ±0.017	10.41 ±1.17	1.10 ±0.03

Discussion: The angle of repose of different formulations (F1-F6) was found to be in the range of 25.67±0.47 to 29.44±0.38 which indicates that material had excellent flow property. So, it was confirmed that the flow property of blends was free flowing. The bulk density of blend was found between 0.425±0.015 to 0.461±0.012. Tapped density was found between 0.548±0.052 to 0.579±0.017. These values indicate that the blends had good flow property. Carr's index for all the formulations was found to be between 10.41±1.17 to 15.26±1.03 and Hausner's ratio from 1.10±0.03 to 1.17±0.08 which reveals that the blends have good flow character.

Characterization of Immediare Release Tablets

Table No.4 Post Compression parameters

Formulation code	Mean Hardness Kg/cm^2	Thickness	Diameter (mm)	Average weight (mg)	Friability % w/w	Disintegration test (sec)	Mean drug content %
F1	4.2±0.04	3.75±0.07	8.42±0.04	102.04 ±1.10	0.45 ±0.05	21	94.37 ±1.48
F2	4.4±0.03	3.68±0.06	8.37±0.05	101.08 ±1.42	0.75 ±0.02	18	95.05 ±1.04
F3	4.6±0.07	3.84±0.05	8.68±0.07	98.46 ±1.15	0.82 ±0.05	15	97.16 ±1.37
F4	4.5±0.02	3.67±0.04	8.58±0.06	99.18 ±1.12	0.61 ±0.04	17	95.28 ±1.41
F5	4.7±0.06	3.86±0.03	8.74±0.08	101.34 ±1.74	0.74 ±0.03	14	97.05 ±1.18
F6	4.8±0.04	3.97±0.02	8.89±0.05	100.03 ±1.07	0.42 ±0.07	11	98.23 ±1.05

Discussion: Hardness of the tablet was acceptable and uniform from batch-to-batch variation, which was found to be 4.2±0.04-4.8±0.04 kg/cm2. Thickness of the tablet was acceptable and uniform from batch-to-batch variation, which was found to be 3.67±0.04-3.97±0.02. Diameter of the tablet was acceptable and uniform from batch-to-batch variation, which was found to be 8.37±0.05-8.89±0.05mm. All the formulations passed the weight variation test as the % weight variation was within the pharmacopoeial limits. Friability values were found to be less than 1% in all the formulations F1 – F6 and considered to be satisfactory ensuring that all the formulations are mechanically stable. The % drug content for all the formulations were close to 100 and varied between 94.37±1.48-98.23±1.05%.

Characterization of blend of Floating SR tablets:

Table No.5 Pre-Compression parameters

Formulation code	Angle of Repose	Bulk Density	Tapped Density	Carr's Index	Hausner's Ratio
F7	27.12 ±1.07	0.527 ±0.005	0.634 ±0.002	17.17 ±0.24	1.17 ±0.05
F8	25.42 ±1.26	0.535 ±0.003	0.657 ±0.005	16.28 ±0.15	1.15 ±0.06
F9	24.17 ±1.06	0.549 ±0.004	0.675 ±0.003	14.37 ±0.15	1.14 ±0.07
F10	26.42 ±1.06	0.537 ±0.007	0.645 ±0.004	15.25 ±0.32	1.13 ±0.06
F11	24.07 ±1.03	0.548 ±0.006	0.667 ±0.001	13.42 ±0.52	1.12 ±0.03
F12	23.10 ±1.16	0.557 ±0.008	0.685 ±0.005	12.18 ±0.26	1.10 ±0.06

Discussion:

The angle of repose of different formulations was ≤ 27.12±1.07 which indicates that material had good flow property. So, it was confirmed that the flow property of bends was free flowing. The bulk density of blend was found between 0.527±0.005g/cm3 to 0.557±0.008g/cm3.Tapped density was found between 0.634±0.002g/cm3 0.634±0.002g/cm^3. These values indicate that the blends had good flow property. Carr's index for all the formulations was found to be between 11.85±0.16-15.61±0.16 and Hausner's ratio from 1.10±0.06-1.17±0.05which 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

Table No.6 Characterization of Bilayer tablets

Formulation	Average Weight (mg)	Thickness (mm)	Diameter (mm)	Hardness	Friability (%)	Drug content (%)
F7	401.47 ±1.15	5.78 ±0.35	13.65 ±0.14	7.6 ±0.3	0.52 ±0.12	98.78 ±1.20
F8	402.65 ±1.37	5.69 ±0.19	13.75 ±0.27	7.9 ±0.1	0.65 ±0.15	97.47 ±1.08
F9	402.24 ±1.43	5.86 ±0.16	13.26 ±0.35	8.4 ±0.1	0.47 ±0.14	98.34 ±1.05
F10	400.15 ±1.29	5.67 ±0.25	13.19 ±0.67	7.8 ±0.2	0.68 ±0.13	96.45 ±1.12
F11	402.45 ±1.18	5.86 ±0.37	13.43 ±0.45	8.2 ±0.1	0.65 ±0.12	98.28 ±1.54
F12	403.15 ±1.25	5.97 ±0.12	13.26 ±0.28	8.6 ±0.2	0.43 ±0.15	99.47 ±1.14

Discussion: Hardness of the tablet was acceptable and uniform from batch-to-batch variation, which was found to be 7.6±0.3- 8.6±0.2kg/cm2. All the formulations passed the weight variation test as the % weight variation was within the pharmacopoeial limits. Friability values were found to be less than 1% in all the formulations F7 – F12 were considered to be satisfactory ensuring that all the formulations are mechanically stable. The % drug content for all the formulations were close to 100 and varied between 97.47±1.08% to 99.47±1.14%.

Effervescent floating systems:

Table No.7 In vitro floating buoyancy studies

Formulation Code	Floating Lag Time (secs)	Total Floating Time (hrs)
F7	143	>09
F8	139	>11
F9	135	>11
F10	132	>10
F11	128	>11
F12	126	>12

Discussion: From the above floating buoyancy studies shows that F12 shows higher Total floating time and formulations and less Floating lag time when compared to the remaining Formulations

In vitro dissolution studies:

Table No.8 Percent Drug Release of Carbamazepine (IR) Tablets for all formulations (F1-F6)

Time (min)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
5	24.45 ±1.68%	31.26 ±1.65%	37.17 ±1.68%	30.45 ±1.18%	38.67 ±1.36%	47.58 ±1.46%
10	31.19 ±1.45%	45.02 ±1.42%	51.24 ±1.45%	38.34 ±1.78%	53.82 ±1.42%	55.45 ±1.28%
15	43.12 ±1.68%	59.32 ±1.38%	63.38 ±1.12%	47.86 ±1.59%	61.91 ±1.62%	64.45 ±1.34%
20	55.67 ±1.43%	65.05 ±1.51%	71.34 ±1.28%	58.58 ±1.15%	75.73 ±1.43%	78.47 ±1.25%
30	61.25 ±1.25%	73.89 ±1.46%	78.45 ±1.15%	69.34 ±1.28%	81.19 ±1.84%	89.65 ±1.47%
40	78.84 ±1.65%	81.12 ±1.85%	85.37 ±1.45%	81.46 ±1.25%	88.23 ±1.16%	93.25 ±1.48%
50	85.19 ±1.54%	90.79 ±1.64%	92.52 ±1.18%	88.38 ±1.45%	93.42 ±1.24%	96.17 ±1.35%
60	97.42 ±1.28%	98.10 ±1.45%	98.25 ±1.16%	98.74 ±1.25%	98.92 ±1.35%	99.45 ±1.28%

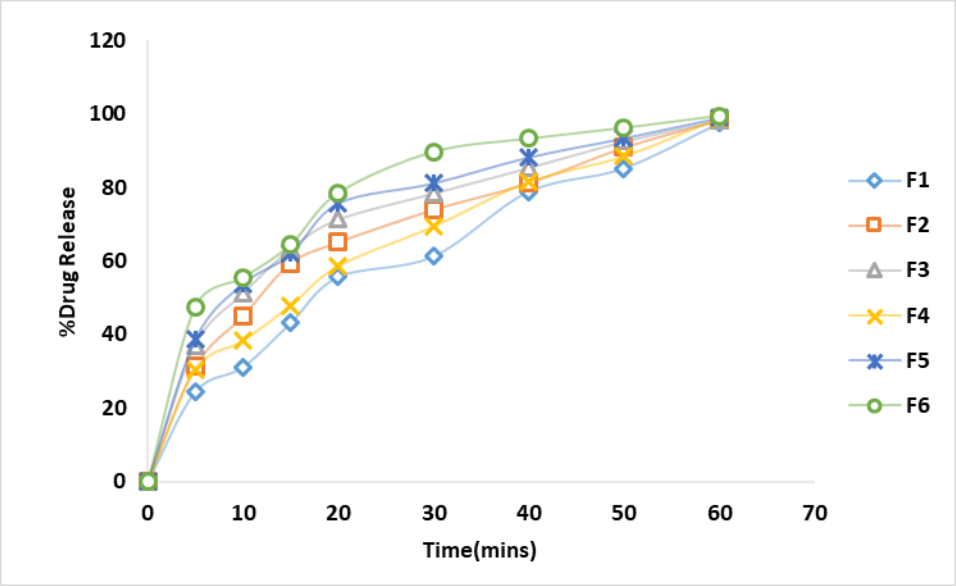

Figure No.9 Percent Drug Release versus Time Plots of Carbamazepine Tablets F1-F6

Discussion: Above dissolution studies indicate that all the formulations F6 formulation containing higher concentration of Lycoat as the disintegrant had showed faster drug release in 60mins. So F6 formulation is considered as Optimized formulation.

In vitro studies for Bilayer tablets:

Table No.9 Dissolution profile for Bilayer tablets of all formulations (F7-F12)

Time (hours)	F7	F8	F9	F10	F11	F12
I.R. Layer						
F6	0	0	0	0	0	**0**
60	**99.45±1.28**	**99.45±1.28**	**99.45±1.28**	**99.45±0.28**	**99.45±1.28**	**99.45±1.28**
S.R. Layer						
1	30.25±1.56	35.47±1.56	28.47±1.21	25.49±1.48	30.08±1.20	**20.10±1.75**
2	42.45±1.47	47.25±1.48	37.45±1.37	36.16±1.84	38.25±1.45	**28.25±1.18**
3	55.18±1.45	54.78±1.25	45.45±1.15	45.24±1.63	55.37±1.45	**34.45±1.18**
4	67.24±1.37	61.33±1.18	54.26±1.37	57.46±1.58	67.18±1.25	**41.12±1.47**
5	78.45±1.25	67.52±1.37	65.45±1.45	65.53±1.74	71.35±1.47	**49.56±1.37**
6	86.67±1.25	72.45±1.10	76.26±1.44	73.18±1.26	78.45±1.37	**57.24±1.46**
7	91.47±1.45	83.28±1.35	85.10±1.16	79.38±1.69	83.58±1.45	**65.35±1.15**
8	94.45±1.58	89.41±1.27	89.08±1.17	85.41±1.54	89.18±1.37	**72.24±1.18**
9	98.45±1.24	94.59±1.40	92.37±1.15	94.54±1.62	92.27±1.45	**82.24±1.41**
10		98.24±1.45	94.17±1.54	98.72±1.29	95.28±1.67	**89.43±1.61**
11			98.78±1.15		98.45±1.37	**95.19±1.25**
12						**99.57±1.21**

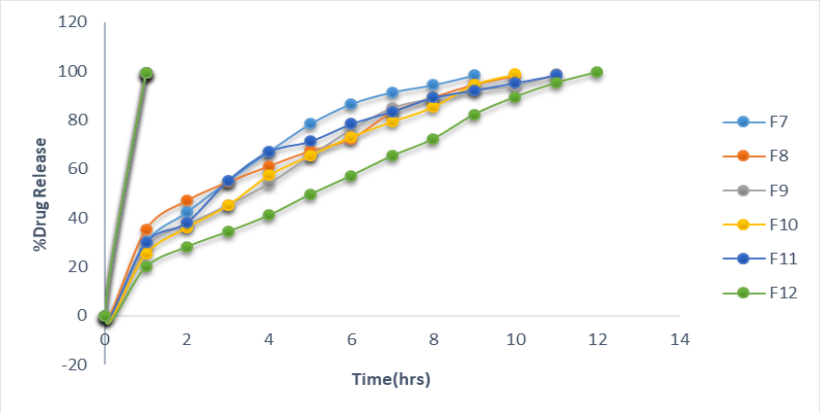

Figure No.10 In-vitro drug release profile of Bilayer tablets of Formulation F7-F12

Discussion: By comparing the in vitro dissolution studies of two polymers like Xanthan Gum and Carbopol 934P, it was observed that the controlled drug delivery was obtained with the higher concentration of Carbopol 934P in F12 formulation than the remaining formulation. So, the drug release kinetics were performed for the formulation F12 formulation, as it maintains constant drug release in a sustained manner with optimum swelling in nature.

DRUG RELEASE KINETICS OF CARBAMAZEPINE BILAYER TABLETS (F12)

Zero order release kinetics

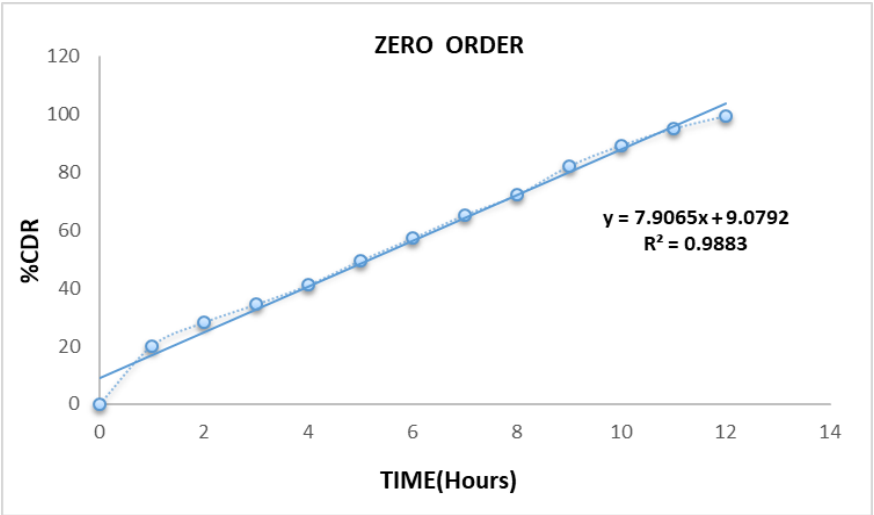

Figure No.11 Zero order release profile of bilayer tablets of Carbamazepine best formulation F12

First order release kinetics:

Figure No.12 First order release profile of bilayer tablets of Carbamazepine best formulation F12

Higuchi Release Kinetics:

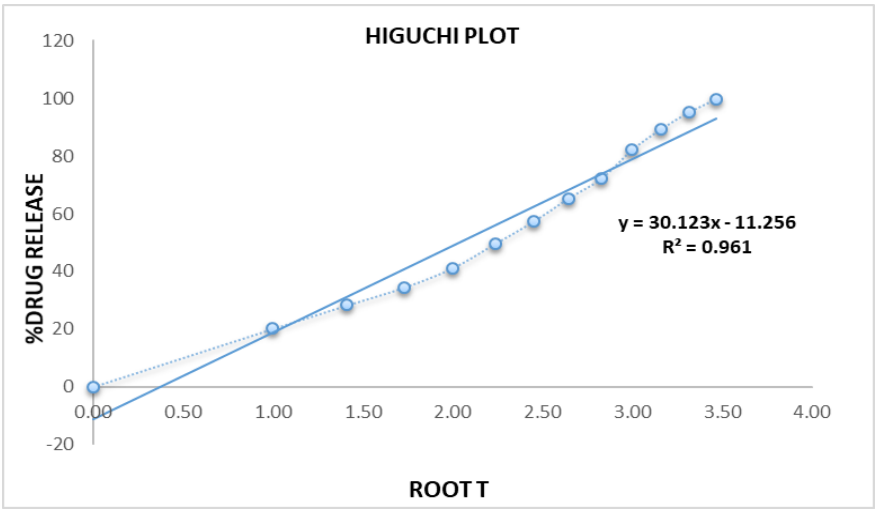

Figure No.13. Higuchi release kinetics profile of bilayer tablets of Carbamazepine best formulation F12

Peppas Release Kinetics:

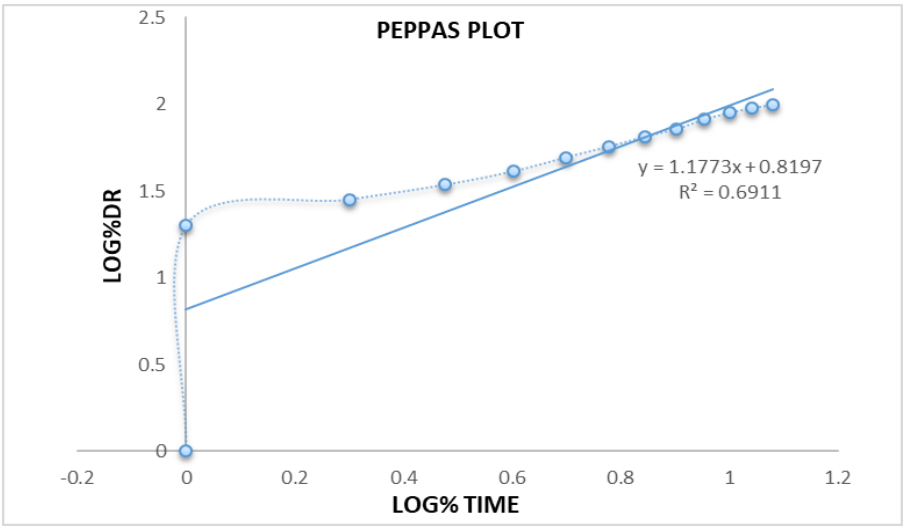

Figure No.14 Peppas release kinetics profile of bilayer tablets of Carbamazepine best formulation F12

Evaluation of drug release kinetics:

Release kinetic study: The kinetic release data was computed from the release data obtained from the *in-vitro* dissolution study of the best formulation F12 and fitted to the mathematical models; Zero order equation, First order, Higuchi release and Korsmeyer- Peppas models.

Different Drug Release Kinetics Model Bilayer tablets best formulation F12

Table No.10 Regression coefficients fit to different drug release kinetics models for best formulation F12

Formulation code Best	Zero order	First order	Higuchi	Peppas	
	r2	r2	r2	r2	n value
F12	0.988	0.736	0.961	0.691	1.177

Discussion: The in vitro dissolution data for best formulation F12 were fitted in different kinetic models i.e, zero order, first order, Higuchi and korsemeyer- peppas equation. Optimized formulation shows R^2 value 0.980. Hence it follows zero order release with Super case II transport Mechanism.

SUMMARY:
Carbamazepine, also known as Tegretol, is an anticonvulsant drug and analgesic drug used to control seizures and to treat pain resulting from trigeminal neuralgia. It was initially approved by the FDA in 1965. Aside from the above uses, this drug is also given to control the symptoms of bipolar 1. Interestingly, carbamazepine was the first anticonvulsant used to treat individuals with bipolar disorder. The aim of present investigation is to increase the gastric residence time by preparing gastro retentive Bi-layered tablet thereby improving bioavailability. Maintaining constant blood levels of the drug in the bloodstream increases the therapeutic effectiveness of the drug. The present work aims to develop a stable and optimized bilayer dosage form containing immediate release and Extended-release. For the formulation of Bi-layered tablets polymers such as Lycoat, Crospovidone as super disintegrants and Xanthan Gum, Carbopol 934P as extended release polymers with some other polymers like Magnesium stearate, Sodium bicarbonate, citric acid, Talc, PVP K30, MCC and Lactose. Fourier transform Infrared spectroscopy confirmed the absence of any drug/polymers/excipient's interactions. The tablets were compressed using 12 stationary double rotary compression machine's. The prepared floating Bi-layered tablets were evaluated for hardness, Weight variation, thickness, friability, drug content uniformity, and in-vitro dissolution studies. Based on various evaluation parameters formulation F6 (IR) & F12 (SR) was selected as optimized formulation. From the above floating buoyancy studies shows that F12 shows higher Total floating time than other formulations. It was observed that Formulations F6 (IR) & F12 (SR) gave maximum drug release within time. F12 formulation was subjected for drug release kinetics studies viz. Zero order, first order, Higuchi matrix, Peppas model equations and the formulations of sustained release(SR) formulations followed zero order release with Super case II transport Mechanism. Thus, conclusion can be made that stable dosage form can be developed for Carbamazepine as Immediate release & Extended release by Bi-layered Tablets.

CONCLUSSION:
The study involves pre-formulation studies, formulation, evaluation and stability studies of prepared matrix tablets. The physical evaluation of API along with excipients has shown compatibility supporting the choice of excipients. FTIR studies reveal no incompatibility between drug, polymer and various excipients used in the formulations. CRDDS of a model drug were formulated and evaluated with different polymers. Formulations with higher concentration of Carbopol 934P polymers has successfully releases the model drug release up to 12hours and they were formulated by using direct compression. Immediate release tablets of a model drug were formulated and evaluated with different polymers. Formulations with Lycoat polymers has successfully released the model drug release within time and they were formulated by using direct compression.The dissolution profiles and kinetic studies (zero-order, first-order, Higuchi's equation and Korsmeyer-peppas equation) indicate that the release of Carbamazepine follows zero order release and with Super case II transport Mechanism.

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